



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 3.0

**SECTION: Commercial Drug
SUBJECT: Geisinger Health Plan (GHP)
Formulary Exception**

Applicable line of business:

Commercial	X	Medicaid	
Medicare		ACA	X
GHP Kids	X	Self-Insured	X

POLICY:

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee.

The Plan's Department of Pharmacy maintains a process by which a member or healthcare provider can request a formulary exception for specific drugs, drugs used for an off-label purpose, and biologicals and medications not included in the Health Plan's drug formulary. Members and healthcare providers can initiate requests for a formulary exception by contacting Pharmacy Services by phone, fax, or written request.

Formulary exception requests will be evaluated, and a determination of medical necessity made utilizing all the following criteria:

1. Member's eligibility to receive requested services (enrollment in the plan, prescription drug coverage, specific exclusions in member's contract).
2. Utilization of the requested agent for a clinically proven treatment indication or diagnosis.
3. Therapeutic failure, intolerance, or contraindication to use of formulary agents and/or agents designated as therapeutically equivalent.
4. Appropriateness of the nonformulary agent compared with available formulary agents (including but not limited to):
 - A. Safety.
 - B. Efficacy.
 - C. Therapeutic advantage as demonstrated by head to head clinical trials.
 - D. Meets Health Plan criteria for drug or drug class formulary exception.
5. Additional policies that may be referenced as part of a coverage decision include:
 - A. Policy 9.0 Brand
 - B. Policy 296.0 Triptan Quantity Limit Exceptions
 - C. Policy 469.0 Statin Quantity Limit Exceptions
 - D. Policy 487.0 Quantity Limit Exceptions

PURPOSE/OBJECTIVE:

The purpose of the Formulary Exception process is to provide a mechanism whereby an exception can be made for coverage of medications as noted above when a member or healthcare provider initiates such a request for coverage. Medications that are benefit exclusions are not eligible for review through the exception process.

This policy will be maintained in compliance with the standards of NCQA and any other applicable state and federal regulatory entities.

Member confidentiality will be maintained as outlined in the Health Plan Administrative Policy #02, Privacy and Confidentiality.

RESPONSIBILITY

Geisinger Health Plan Pharmacy Department
Geisinger Health Plan Medical Directors
Geisinger Health Plan Advisory Committee

REQUIRED DEFINITIONS:

1. **Attachment** – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. **Exhibit** – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. **Devised** – the date the policy was implemented.
4. **Revised** – the date of every revision to the policy, including typographical and grammatical changes.
5. **Reviewed** – the date documenting the annual review if the policy has no revisions necessary.

ADDITIONAL DEFINITIONS:

1. **Formulary ("Drug Formulary")** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. **FDA** – Food and Drug Administration.
3. **Formulary (Drug Formulary) products** – prescription medications that meet criteria for Formulary inclusion.
4. **Nonformulary products** – those medications which are not included in the Formulary.
5. **Healthcare Provider** - a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
6. **Specialist** – a healthcare provider whose practice is not limited to primary health care services and who has additional post-graduate or specialized training, has board

certification or practices in a licensed specialized area of health care and is actively practicing (i.e., Gynecology, Neurology).

7. **NCQA** – National Committee for Quality Assurance.
8. **GHP** – Geisinger Health Plan or "Plan."
9. **New drugs (medications)** – those medications that have been FDA-approved and available on the market for a period of six months or less.
10. **P&T Committee** – Pharmacy and Therapeutics Committee.
11. **Urgent Care Claim** – care for which a request to extend a course of treatment beyond the initially approved period of time or number of treatments must be decided, and notification made, within not more than 24 hours (provided that the claim is made at least 24 hours prior to the expiration of the initial approval period); or a claim for care that, if subjected to normal timeframes, could seriously jeopardize the life or health of the claimant (or his or her ability to regain maximum function), or subject the claimant to severe pain that cannot be managed adequately.
12. **Pre-Service Claim** – any claim for benefits that, under the terms of the plan, must be approved (either in whole or part) before medical care is obtained.
13. **Post-Service Claim** – any claim for benefits that is not a pre-service claim.
14. **Adverse benefit determination** – a denial, reduction, or termination of benefits or a failure to provide or pay for benefits.
15. **Date received (received, receipt)** – date and time received by Geisinger Health Plan, regardless of which department receives it.
16. **PAHub** – electronic solution that is used by Geisinger Health Plan to track, monitor, and complete all requests for pharmacy medication reviews. This includes an activity log capturing the dates and times of all actions completed for each request.
17. **Written notification date** – date and time the written notification leaves Geisinger Health Plan via mail or fax.
18. **CPHT** – Certified pharmacy technician
19. **LPN** – Licensed practical nurse

PREREQUISITES

Plan Members with a prescription drug rider, including all lines of business, unless a specific limitation or exception exists.

PROCEDURE:

1. A member or their healthcare provider may initiate a request for a formulary exception in accordance with the following:
 - A. Requests should be directed to the Department of Pharmacy Services (as communicated in writing through the member handbook, provider guide, on-line pharmacy service, the formulary and written communication to members and providers).
 - B. Information needed for an exception include, but is not limited to, the following:
 - (1) Caller's name and telephone number;

- (2) Member's medical record number and insurance identification number;
 - (3) Prescribing healthcare provider's name and telephone number;
 - (4) The exception requested;
 - (5) Clinical rationale including medical records, laboratory data, past treatment history and other documentation, as determined by the Plan to be relevant.
2. The prescribing Healthcare Provider will be contacted to review the request and available formulary alternatives. If an exception is still requested, appropriate medical record documentation and treatment information will be requested verbally and in writing. A due date for the required information (15 days from the date of the request) will be included in the verbal and written notifications. When all requested information has been received, this will be attached to the flow sheet for documentation as a pre- or post-service request.
 - A. If the requested information is not received within 15 days, the healthcare provider will be contacted and a second request for information will be made both verbally and in writing. The date by which the information is required will be included in the verbal and oral requests.
 - B. If the required information is not received by the due date, a determination of coverage will be rendered based on the information available.
3. Requests for exception are reviewed and a determination of coverage made within a timeframe in accordance with the following:
 - A. When the request for coverage is related to an Urgent Care Claim, a determination of coverage will be made within 24 hours of receipt of the necessary information.
 - B. When the request for coverage is deemed to be a Pre-Service or Post-Service claim, a determination of coverage will be made within 48 business hours (Commercial members) or 72 hours (Marketplace members) of the receipt of the necessary information.
 - C. All requests for GHP Kids members will be reviewed within 24 hours of receipt of the necessary information.
4. Requests for exception will be reviewed as follows:
 - A. A Certified Pharmacy Technician (CPhT) or License Practical Nurse (LPN), under the supervision of a Health Plan Pharmacist, will perform an initial review of medical record documentation and treatment history to recommend approval or denial of cases where there are explicit utilization management criteria and no clinical judgement is required.
 - (1) If the request for exception is approved, no further action will be required on the part of the Health Plan Pharmacist or the Licensed Physician.
 - (2) If the CPhT or LPN recommends denial upon initial review, the case will be forwarded to a Health Plan Pharmacist for review.
 - B. For all cases where clinical judgement is required, explicit utilization management criteria do not exist, or those which a CPhT or LPN recommends

- denial, a Health Plan Pharmacist will perform an initial review of medical record documentation and treatment history to recommend approval or denial.
- (1) If the request for exception is approved, no further action will be required on the part of the Licensed Physician.
 - (2) If the Health Plan Pharmacist recommends denial upon initial review, the case will be forwarded to a Licensed Physician for review.
- C. A Licensed Physician shall make the final decision in all instances where a Health Plan Pharmacist recommends denial based on medical necessity and appropriateness.
5. Based on the determination of coverage made, one of the following will occur:
- A. If the formulary exception is approved:
 - (1) An electronic override will be entered into the pharmacy claims adjudication system.
 - a. The Member (or Member's authorized representative) and Healthcare Provider will be verbally notified of the determination of coverage within 24 hours of the request if the request is urgent or two business days of the request if the request is not urgent.
 - b. At the time of notification, the Plan will indicate the coverage provided in the amount disclosed by the Plan for the service requested.
 - (2) A written confirmation of the approval will be sent to the provider and Member (or Member's authorized representative) within 24 hours of the request if the request is urgent or two business days of the request if the request is not urgent.
 - B. If the request for a formulary exception is denied, resulting in an adverse benefit determination, the following will occur:
 - (1) The Healthcare Provider and Member (or Member's authorized representative) will be verbally notified of the adverse determination within 24 hours of the request if the request is urgent or two business days of the request if the request is not urgent.
 - (2) This verbal notification will include instructions on how to initiate a Grievance and/or Appeal Process. (For additional information on appeals see Policy 4.0.)
 - (3) The prescribing healthcare provider will be offered the opportunity to discuss the determination of coverage with a Plan Pharmacist or a Plan Medical Director.
 - (4) The Member (or Member's authorized representative) and Healthcare Provider will be sent a written confirmation of the adverse benefit determination within 24 hours of the request if the request is urgent or two business days of the request if the request is not urgent. The written notification shall include the specific reason for the

determination, the basis and clinical rationale utilized in rendering the determination of coverage (if applicable), any internal policy or criterion applied (if applicable) as well as instructions regarding initiation of the Grievance and/or Appeal Process.

6. Documentation of the determination of coverage and the notifications will take place in PAHub.

Continuity of Care – Classes of Clinical Concern

For initial requests, Geisinger Health Plan will not require members to meet prior authorization or step therapy criteria if they are currently taking a medication in one of the following drug classes:

- Immunosuppressants (for prophylaxis of organ transplant rejection)
- Antidepressants
- Antipsychotics
- Anticonvulsants
- Antiretrovirals
- Antineoplastics
- Tumor Necrosis Factor Blockers
- Multiple Sclerosis
- Attention Deficit Hyperactivity Disorder/Attention Deficit Disorder

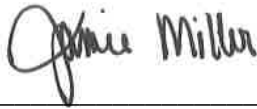
If members are currently receiving one of these medications requests for coverage will be approved as long as there is medical record documentation that the safety and effectiveness of use for the prescribed indication is supported by Food and Drug Administration (FDA) approval or adequate medical and scientific evidence in the medical literature.

Continuity of Care – All Others

Requests for continuity of care for all other medications will be at the discretion of the reviewer and may be considered if being used for a medically acceptable indication and the member is stable on therapy.

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE
STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND
FEDERAL REGULATORY ENTITIES.**

**THIS POLICY WILL BE REVISED AS NECESSARY AND
REVIEWED NO LESS THAN ANNUALLY.**



Signed: _____

Title: Director, Pharmacy Services

Date: April 6, 2022

- Devised: 6/99
- Reviewed: 7/99
- Revised: 7/99
- Reviewed: 11/00
- Revised: 3/01
- Revised: 10/01
- Revised: 11/01
- Revised: 12/01
- Revised: 5/02
- Revised: 6/02
- Revised: 10/02
- Revised: 12/02
- Reviewed: 1/03 – DOH approved
- Reviewed: 1/04
- Revised: 3/04 – updated the name of Policy #02 on pg. 1
- Revised: 3/05 – updated title
- Revised: 3/06 – updated title
- Reviewed: 3/07
- Revised: 4/07 – added signature
- Reviewed: 3/08 – annual review
- Reviewed: 4/09 – annual review
- Revised: 4/09 – clarified 48 business hours
- Reviewed: 3/10 – annual review
- Reviewed: 3/1/11 – annual review
- Revised: 1/30/12 – changed title and signature
- Reviewed: 1/30/13 – annual review
- Reviewed: 1/30/14 – annual review
- Revised: 1/30/15 – annual review, updated signature
- Reviewed: 6/1/15 – annual review
- Revised: 5/1/16 – updated format, logo, & procedure
- Reviewed: 6/1/16 – annual review
- Revised: 6/1/17 – annual review, update standard Marketplace timeline
- Revised: 6/1/18 – annual review, updated hours & sig., added continuity of care language, updated procedure 6
- Revised: 8/24/18 – updated notification, verbal and written, will be within the specified time frame from the request date.
- Revised: 3/13/19 – moved policy from technical/operational to Commercial Clinical policies
- Revised: 3/1/20 – annual review, added GHP Kids
- Revised: 8/6/20 – updated date received definition, added written notification date definition, added activity log to PA Hub definition



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 3.0

**SECTION: Commercial Drug
SUBJECT: Geisinger Health Plan (GHP)
Formulary Exception**

- Revised: 8/10/20 – added CPhT and LPN definitions, added LPN as a reviewer
Revised: 3/1/21 – annual review, updated logo, added CHIP timeline, corrected typo
Revised: 3/1/22 – annual review, clarified can be made by member or healthcare provider in policy section, updated referenced policies
Revised: 4/6/22 – replaced COC for all others with updated language



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 8.0

**SECTION: Commercial Drug
SUBJECT: Ramelteon, Doxepin (generic
Silenor), and Sublingual
Zolpidem**

Applicable line of business:

Commercial	X	Medicaid	
Medicare		ACA	X
GHP Kids	X	Self-Insured	X

POLICY:

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.00T Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for ramelteon, doxepin (generic Silenor), and sublingual zolpidem for GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 487.0 Quantity Limit Exceptions

REQUIRED DEFINITIONS:

1. **Attachment** – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. **Exhibit** – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. **Devised** – the date the policy was implemented.
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5. **Reviewed** – the date documenting the annual review if the policy has no revisions necessary.

ADDITIONAL DEFINITIONS:

1. **Formulary** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. **Non-formulary products** – those medications that are not included in the Formulary.
3. **Healthcare provider** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
4. **NCQA** – National Committee for Quality Assurance.



**POLICY AND PROCEDURE
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POLICY NUMBER: 8.0

**SECTION: Commercial Drug
SUBJECT: Ramelteon, Doxepin (generic
Silenor), and Sublingual
Zolpidem**

5. **Medically Necessary or Medical Necessity** – covered services rendered by a provider that the Health Plan determines are:
- A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
 - B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
 - C. In accordance with current standards of medical practice;
 - D. Not primarily for the convenience of the Member, or the Member's Provider; and
 - E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

PROCEDURE:

A formulary exception for coverage of ramelteon or doxepin (generic Silenor) may be made for members who meet the following criteria:

- The member has medical record documentation of a diagnosis of chronic insomnia, defined as a history of insomnia greater than or equal to two (2) months **AND**
- The member has medical record documentation of failure on, intolerance to, or contraindication to use of formulary agents zolpidem (including controlled-release forms) **AND** eszopiclone **AND** zaleplon

A formulary exception for coverage of Sublingual Zolpidem (generic Intermezzo) may be made for members who meet the following criteria:

- Medical record documentation of therapeutic failure on, intolerance to, or contraindication to two of the following: eszopiclone **OR** zaleplon **OR** zolpidem immediate-release **AND**
- Medical record documentation of therapeutic failure on, intolerance to, or contraindication to zolpidem CR

MEDISPAN AUTHORIZATION LEVEL: GPI-12, generic only

If a formulary exception is approved ramelteon, doxepin (generic Silenor), or sublingual zolpidem will be paid for under the member's prescription drug benefit.



**POLICY AND PROCEDURE
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POLICY NUMBER: 8.0

**SECTION: Commercial Drug
SUBJECT: Ramelteon, Doxepin (generic
Silenor), and Sublingual
Zolpidem**

Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.

FORMULARY ALTERNATIVES:

eszopiclone, estazolam, temazepam, zolpidem, zolpidem CR, zaleplon

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE
STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND
FEDERAL REGULATORY ENTITIES.**

**THIS POLICY WILL BE REVISED AS NECESSARY AND
REVIEWED NO LESS THAN ANNUALLY.**

Signed: _____

Title: Director, Pharmacy Services

Date: March 1, 2022

- Devised: 7/99
- Effective: 7/99
- Revised: 12/99
- Reviewed: 12/99
- Reviewed: 11/00
- Revised: 3/01
- Revised: 2/02
- Reviewed: 4/02
- Revised: 3/03
- Reviewed: 3/04
- Revised: 3/05-updated title
- Revised: 3/06-updated title
- Revised: 4/06-updated criteria for coverage of this class of drugs
- Reviewed: 3/07
- Revised: 4/07 added signature
- Revised: 8/07 corrected typo
- Reviewed: 3/08 – annual review
- Revised: 4/09 – annual review – updated alt (zaleplon)
- Reviewed: 3/10 – annual review
- Revised: 3/1/11 – annual review, updated with generic Ambien & removed old criterion
- Revised: 3/1/12 – annual review, updated signature
- Revised: 3/6/12 – fixed typo, zolpidem CR missing **

HPRX02

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Dev. 7/99

Rev. 3/1/22



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 8.0

**SECTION: Commercial Drug
SUBJECT: Ramelteon, Doxepin (generic
Silenor), and Sublingual
Zolpidem**

Revised: 3/29/12 – added Intermezzo to policy
Revised: 3/1/13 – annual review, updated logo and definitions, fixed typo
Revised: 3/1/14 – annual review, updated formatting, changed ER to CR for zolpidem
Revised: 3/1/15 – annual review, updated signature, update Lunesta to eszopiclone
Revised: 4/13/15 – removed PA from eszopiclone
Revised: 7/22/15 – added Silenor to policy, updated criteria to require failure on eszopiclone
Reviewed: 3/1/16 – annual review
Revised: 3/24/16 – removed copay per 15 requirement, removed QL indicator from FA
Revised: 5/1/16 – updated format, logo, and procedure
Reviewed: 3/1/17 – annual review
Revised: 3/1/18 – annual review, updated signature, updated Intermezzo to sublingual zolpidem
Reviewed: 3/1/19 – annual review
Revised: 11/21/19 – updated Rozerem to generic ramelteon
Revised: 3/1/20 – annual review, added GHP Kids
Revised: 11/18/20 – updated Silenor to generic
Revised: 3/1/21 – annual review, updated logo, added MediSpan approval level
Revised: 3/1/22 – annual review, updated referenced policies & covered LOBs



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 9.0

**SECTION: Commercial Drug
SUBJECT: Brand**

Applicable line of business:

Commercial	X	Medicaid	
Medicare		ACA	X
GHP Kids	X	Self-Insured	X

POLICY:

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for brands that have a generic for GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 487.0 Quantity Limit Exceptions

REQUIRED DEFINITIONS:

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5. **Reviewed** – the date documenting the annual review if the policy has no revisions necessary.

ADDITIONAL DEFINITIONS:

1. **Formulary** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. **Non-formulary products** – those medications that are not included in the Formulary.
3. **Healthcare provider** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
4. **NCQA** – National Committee for Quality Assurance.
5. **Medically Necessary or Medical Necessity** – covered services rendered by a provider that the Health Plan determines are:



**POLICY AND PROCEDURE
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POLICY NUMBER: 9.0

**SECTION: Commercial Drug
SUBJECT: Brand**

- A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
- B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
- C. In accordance with current standards of medical practice;
- D. Not primarily for the convenience of the Member, or the Member's Provider; and
- E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

PROCEDURE:

A formulary exception for coverage of a branded (formulary) medication, for which there is an AB-rated generic, may be made for members who meet the following criteria:

- Medical record documentation of a therapeutic failure on, or intolerance to the generic formulary agent(s) **OR**
- Medical record documentation of a therapeutic failure on, intolerance to, or contraindication to the inactive ingredients of the generic formulary agent(s)

AND

- Medical record documentation of therapeutic failure on, intolerance to, or contraindication to up to three formulary alternatives, if available

If an exception is made, the branded medication will be paid for under the member's prescription drug benefit.

Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.

FORMULARY ALTERNATIVES:

AB-rated generics as listed in the Formulary



**POLICY AND PROCEDURE
PHARMACY
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POLICY NUMBER: 9.0

**SECTION: Commercial Drug
SUBJECT: Brand**

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE
STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND
FEDERAL REGULATORY ENTITIES.**

**THIS POLICY WILL BE REVISED AS NECESSARY AND
REVIEWED NO LESS THAN ANNUALLY.**

Signed: _____

Title: Director, Pharmacy Services

Date: March 1, 2022

Devised: 7/99
Effective: 7/99
Revised: 12/99
Reviewed: 12/99
Reviewed: 12/00
Revised: 3/01
Revised: 2/02
Reviewed: 6/02
Revised: 6/02
Revised: 3/03
Reviewed: 3/04
Revised: 3/05 -updated title
Revised: 3/06-updated title
Reviewed: 3/07
Revised: 4/07 added signature
Reviewed: 3/08 – annual review
Reviewed: 4/09 – annual review
Reviewed: 3/10 – annual review
Revised: 3/1/11 – annual review; clarified introduction
Revised: 3/1/12 – annual review, updated signature
Revised: 3/1/13 – annual review, updated logo and definitions
Revised: 3/1/14 – annual review, updated formatting
Revised: 5/28/14 – updated to require failure on generic & failure on FA, updated signature
Revised: 3/1/15 – annual review
Reviewed: 3/1/16 – annual review
Revised: 5/1/16 – updated format, logo, and procedure
Reviewed: 3/1/17 – annual review
Revised: 3/1/18 – annual review, updated signature
Reviewed: 3/1/19 – annual review
Revised: 3/1/20 – annual review, added GHP Kids
Revised: 3/1/21 – annual review, updated logo
Revised: 3/1/22 – annual review, updated referenced policies & covered LOBs



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 22.0

**SECTION: Commercial Drug
SUBJECT: Linezolid**

Applicable line of business:

Commercial	X	Medicaid	
Medicare		ACA	X
GHP Kids	X	Self-Insured	X

POLICY:

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- Policy 9.0 Brand
- Policy 487.0 Quantity Limit Exceptions

REQUIRED DEFINITIONS:

1. **Attachment** – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. **Exhibit** – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
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ADDITIONAL DEFINITIONS:

1. **Formulary** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. **Non-formulary products** – those medications that are not included in the Formulary.
3. **Healthcare provider** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
4. **NCQA** – National Committee for Quality Assurance.
5. **Medically Necessary or Medical Necessity** – covered services rendered by a provider that the Health Plan determines are:

- A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
 - B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
 - C. In accordance with current standards of medical practice;
 - D. Not primarily for the convenience of the Member, or the Member's Provider; and
 - E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.
6. **VRE** – Vancomycin-resistant *Enterococcus*
 7. **MRSA** – Methicillin resistant *Staphylococcus aureus*
 8. **MSSA** – Methicillin susceptible *Staphylococcus aureus*

PROCEDURE:

A formulary exception for coverage of linezolid may be made for members who meet the following criteria:

- Medical record documentation of Vancomycin-Resistant *Enterococcus* (VRE) *faecium* infection which has been diagnosed and documented with Infectious Disease consultation **OR**
- Medical record documentation of a diagnosis of nosocomial pneumonia caused by *Staphylococcus aureus* (MSSA and MRSA) or *Streptococcus pneumoniae* which has been diagnosed and documented with Infectious Disease consultation **OR**
- Medical record documentation of a diagnosis of complicated skin and structure infections, without concomitant osteomyelitis, caused by *Staphylococcus aureus* (MSSA and MRSA), *Streptococcus pyogenes*, or *Streptococcus agalactiae* which has been diagnosed and documented with Infectious Disease consultation **OR**
- Medical record documentation of a diagnosis of uncomplicated skin and skin structure infections caused by *Staphylococcus aureus* (MSSA only) which has been diagnosed and documented with Infectious Disease consultation **OR**
- Medical record documentation of a diagnosis of community acquired pneumonia caused by *Streptococcus pneumoniae* or *Staphylococcus aureus* (MSSA only) which has been diagnosed and documented with infectious disease consultation

AND

- Medical record documentation of culture and sensitivity showing the member's infection is not susceptible to alternative antibiotic treatments **OR**



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 22.0

**SECTION: Commercial Drug
SUBJECT: Linezolid**

- Medical record documentation of previous intolerance to or contraindication to other antibiotics shown to be susceptible on the culture and sensitivity **OR**
- Medical record documentation that linezolid therapy was started during an inpatient setting

For linezolid oral tablet requests exceeding 56 days of therapy in 180 days:

- Medical record documentation of an infectious disease consultation documenting continued need of linezolid therapy

MEDISPAN AUTHORIZATION LEVEL: GPI-12, generic only

AUTHORIZATION DURATION: 28 days

If a formulary exception is approved linezolid will be paid for under the member's prescription drug benefit.

Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.

FORMULARY ALTERNATIVES:

none

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE
STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND
FEDERAL REGULATORY ENTITIES.**

**THIS POLICY WILL BE REVISED AS NECESSARY AND
REVIEWED NO LESS THAN ANNUALLY.**

Signed: _____

Title: Director, Pharmacy Services

Date: March 1, 2022

Devised: 2/01

Effective: 2/01

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Dev. 2/01

Rev. 3/1/22



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 22.0

**SECTION: Commercial Drug
SUBJECT: Linezolid**

- Revised: 3/01
- Revised: 2/02
- Reviewed: 4/02
- Revised: 6/02
- Revised: 1/03
- Revised: 3/03
- Reviewed: 3/04
- Revised: 3/05- updated title
- Revised: 3/06—updated title
- Reviewed: 3/07
- Revised: 5/07-removed vancomycin failure requirement
- Reviewed: 3/08 – annual review
- Reviewed: 4/09 – annual review
- Reviewed: 3/10 – annual review
- Reviewed: 3/1/11—annual review
- Revised: 3/1/12 – annual review, updated signature
- Revised: 3/1/13 – annual review, updated logo and definitions
- Revised: 3/1/14 – annual review, updated formatting
- Revised: 3/1/15 – annual review, updated signature
- Revised: 3/1/16 – annual review, updated policy title to linezolid based on generic availability
- Revised: 3/25/16 – updated nosocomial pneumonia bullet, complicated skin & structure infections, uncomplicated skin & structure infections, added community acquired pneumonia, added culture & sensitivity requirements
- Revised: 5/1/16 – updated format, logo, and procedure
- Revised: 7/8/16 – corrected 2 typos in CAP criterion, corrected typo in definition
- Revised: 7/27/16 – added language for tablet QL exceptions
- Revised: 3/1/17 – annual review, corrected typo in definitions
- Revised: 3/1/18 – annual review, updated signature
- Reviewed: 3/1/19 – annual review
- Revised: 3/1/20 – annual review, added GHP Kids
- Revised: 3/1/21 – annual review, updated logo, added MediSpan approval level
- Revised: 3/1/22 – annual review, updated referenced policies & covered LOBs



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 27.0

**SECTION: Commercial Drug
SUBJECT: Edarbi and Edarbyclor**

Applicable line of business:

Commercial	X	Medicaid	
Medicare		ACA	X
GHP Kids	X	Self-Insured	X

POLICY:

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for Edarbi and Edarbyclor for GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 487.0 Quantity Limit Exceptions

REQUIRED DEFINITIONS:

1. **Attachment** – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. **Exhibit** – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. **Devised** – the date the policy was implemented.
4. **Revised** – the date of every revision to the policy, including typographical and grammatical changes.
5. **Reviewed** – the date documenting the annual review if the policy has no revisions necessary.

ADDITIONAL DEFINITIONS:

1. **Formulary** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. **Non-formulary products** – those medications that are not included in the Formulary.
3. **Healthcare provider** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
4. **NCQA** – National Committee for Quality Assurance.
5. **Medically Necessary or Medical Necessity** – covered services rendered by a provider that the Health Plan determines are:



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 27.0

**SECTION: Commercial Drug
SUBJECT: Edarbi and Edarbyclor**

- A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
 - B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
 - C. In accordance with current standards of medical practice;
 - D. Not primarily for the convenience of the Member, or the Member's Provider; and
 - E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.
6. **ACE** – angiotensin converting enzyme
 7. **HCT** – hydrochlorothiazide

PROCEDURE:

An exception for coverage of Edarbi or Edarbyclor may be made for individuals who meet the following criteria:

- Medical record documentation of a therapeutic failure on, intolerance to, or contraindication to three (3) preferred formulary angiotensin receptor blockers

MEDISPAN AUTHORIZATION LEVEL: GPI-12

QUANTITY LIMIT: *No QLs need to be entered within the authorization unless the requested quantity exceeds the QL.*

- **QL FOR LETTER ONLY:** one tablet per day

If a formulary exception is approved Edarbi or Edarbyclor will be paid for under the member's prescription drug benefit.

Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.

FORMULARY ALTERNATIVES:

ARB: candesartan, losartan, irbesartan, olmesartan, telmisartan, valsartan

ARB/diuretic combinations: candesartan/hctz, irbesartan/hctz, losartan/hctz, olmesartan/hctz, telmisartan/hctz, valsartan/hctz

ACE inhibitors: benazepril, captopril, enalapril, fosinopril, lisinopril, moexipril, quinapril, trandolapril, ramipril



**POLICY AND PROCEDURE
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**SECTION: Commercial Drug
SUBJECT: Edarbi and Edarbyclor**

ACE inhibitors/diuretic combinations: captopril/hctz, benazepril/hctz, enalapril/hctz, lisinopril/hctz, moexipril/hctz

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE
STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND
FEDERAL REGULATORY ENTITIES.**

**THIS POLICY WILL BE REVISED AS NECESSARY AND
REVIEWED NO LESS THAN ANNUALLY.**

Signed: _____

Title: Director, Pharmacy Services

Date: March 1, 2022

Effective: 5/01
Devised: 3/01
Reviewed: 6/01
Revised: 7/01
Revised: 9/01
Revised: 12/01
Revised: 5/02
Revised: 3/03
Revised: 4/03 Cozaar criteria updated to reflect revised QIC guidelines
Revised: 3/04 – updated formulary alternatives
Revised: 3/05 – updated title
Revised: 3/06 – updated criteria and title
Revised: 3/07 – updated generics
Revised: 4/07 – added signature
Revised: 3/08 – annual review, updated alternatives
Revised: 4/09 – annual review, Cozaar removed
Revised: 7/09 – added other ARB's, updated criteria
Revised: 8/09 – fixed typo
Reviewed: 3/10 – annual review
Revised: 4/10 – updated alternatives
Revised: 3/1/11 – annual review-updated alternative section
Revised: 2/2/12 – added Edarbi to policy
Revised: 3/1/12 – annual review, updated sig, removed Teveten & Teveten HCT
Revised: 3/29/12 – added Edarbyclor to policy
Revised: 3/1/13 – annual review, updated logo and definitions, removed Avapro and Avalide, changed Atacand HCT to candesartan HCT, changed Diovan HCT to

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Dev. 5/01

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**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 27.0

**SECTION: Commercial Drug
SUBJECT: Edarbi and Edarbyclor**

- valsartan HCT, updated title
- Revised: 7/29/13 – removed generic valsartan/hctz & added Diovan HCT, updated criteria for Diovan HCT
- Reviewed: 3/1/14 – annual review
- Revised: 12/1/14 – added failure of irbesartan or irbesartan/hctz, updated alternatives, updated signature
- Revised: 3/1/15 – annual review, updated Micardis to telmisartan, updated Micardis HCT to telmisartan HCT, removed Diovan HCT from policy, updated Atacand to candesartan, updated Diovan to valsartan
- Revised: 9/19/15 – added failure of valsartan, updated Micardis to telmisartan, removed valsartan from policy name, removed Diovan references, updated FA
- Revised: 5/1/16 – updated format, logo, and procedure
- Revised: 3/1/17 – annual review, updated Benicar to generic, updated FA formatting
- Revised: 3/1/18 – annual review, updated signature
- Revised: 3/1/19 – annual review, removed candesartan, candesartan/hctz, olmesartan, olmesartan/hctz, telmisartan, and telmisartan/hctz from policy, updated FA
- Revised: 5/29/19 – updated criteria to failure of 3 preferred ARBs, added QL, corrected typo, deleted note
- Revised: 3/1/20 – annual review, added GHP Kids
- Revised: 3/1/21 – annual review, updated logo, added MediSpan approval level, added QL note
- Revised: 3/1/22 – annual review, updated referenced policies & covered LOBs



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 29.0

**SECTION: Commercial Drug
SUBJECT: Human Growth Hormone**

Applicable line of business:

Commercial	X	Medicaid	
Medicare		ACA	X
GHP Kids	X	Self-Insured	X

POLICY:

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for human growth hormone for GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 487.0 Quantity Limit Exceptions

REQUIRED DEFINITIONS:

1. **Attachment** – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. **Exhibit** – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. **Devised** – the date the policy was implemented.
4. **Revised** – the date of every revision to the policy, including typographical and grammatical changes.
5. **Reviewed** – the date documenting the annual review if the policy has no revisions necessary.

ADDITIONAL DEFINITIONS:

1. **Formulary** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. **Non-formulary products** – those medications that are not included in the Formulary.
3. **Healthcare provider** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
4. **NCQA** – National Committee for Quality Assurance.
5. **Medically Necessary or Medical Necessity** – covered services rendered by a provider that the Health Plan determines are:



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 29.0

**SECTION: Commercial Drug
SUBJECT: Human Growth Hormone**

- A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
- B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
- C. In accordance with current standards of medical practice;
- D. Not primarily for the convenience of the Member, or the Member's Provider; and
- E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

PROCEDURE:

Coverage for human growth hormone is available for members of Geisinger Health Plan who meet the following criteria:

For Norditropin:

- Medical record documentation of use for a Food and Drug Administration (FDA) approved indication

For all other Growth Hormone Agents:

- Medical record documentation of use for a Food and Drug Administration (FDA) approved indication **AND**
- Medical record documentation of therapeutic failure on, intolerance to, or contraindication to Norditropin* (if applicable)

MEDISPAN AUTHORIZATION LEVEL:

- Norditropin GPI-14 (enter all): 3010002000D212, 3010002000D230, 3010002000D240, 3010002000D260
- Genotropin, Humatrope, Nutropin AQ, Saizen, Serostim, Skytrofa, Zomacton: GPI-12
- Omnitrope GPI-12 (enter all): 301000200021, 970510501063

AUTHORIZATION DURATION:

Authorization for Growth Hormone will be for a time period of one year. Continuation of coverage will be provided based on medical record documentation to determine if there is appropriate follow up care with the physician, if any endpoint criteria are met, or if any major change in clinical status has occurred.



**POLICY AND PROCEDURE
PHARMACY
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POLICY NUMBER: 29.0

**SECTION: Commercial Drug
SUBJECT: Human Growth Hormone**

FDA Approved Indications:

Pediatric Growth Hormone Deficiency: Norditropin, Genotropin, Humatrope, Nutropin AQ, Omnitrope, Saizen, Skytrofa, Zomacton

Prader-Willi syndrome: Norditropin, Genotropin, Omnitrope

Small for Gestational Age (SGA): Norditropin, Genotropin, Humatrope, Omnitrope, Zomacton

Turner syndrome: Norditropin, Genotropin, Humatrope, Nutropin AQ, Omnitrope, Zomacton

Idiopathic short stature: Norditropin, Genotropin, Humatrope, Nutropin AQ, Omnitrope, Zomacton

Short stature homeobox-containing gene (SHOX) deficiency: Humatrope, Zomacton

Noonan syndrome: Norditropin

Growth Failure Secondary to Chronic Kidney Disease: Nutropin AQ

Adult Growth Hormone Deficiency: Norditropin, Genotropin, Humatrope, Nutropin AQ, Omnitrope, Saizen, Zomacton

HIV patients with wasting or cachexia: Serostim

Short bowel syndrome: Zorbtive

If an exception is made, human growth hormone will be paid for under the member's prescription drug benefit.

Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.

FORMULARY ALTERNATIVES:

Norditropin*

*prior authorization required



**POLICY AND PROCEDURE
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MANUAL**

POLICY NUMBER: 29.0

**SECTION: Commercial Drug
SUBJECT: Human Growth Hormone**

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE
STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND
FEDERAL REGULATORY ENTITIES.**

**THIS POLICY WILL BE REVISED AS NECESSARY AND
REVIEWED NO LESS THAN ANNUALLY.**

Signed: _____

Title: Director, Pharmacy Services

Date: April 4, 2022

- Devised: 4/97
- Revised: 1/99
- Reviewed: 12/00
- Revised: 3/01
- Revised: 2/02
- Revised: 4/02
- Revised: 3/03
- Revised: 3/04 – removed Vitaline requirement
- Revised: 3/05 – updated title
- Revised: 6/05 – entire policy updated as a result of April P&T
- Revised: 3/06 – updated title
- Reviewed: 3/07
- Revised: 4/07 – added signature
- Reviewed: 3/08 – annual review
- Reviewed: 4/09 – annual review
- Reviewed: 3/10 – annual review
- Revised: 4/10 – revised policy as a result of addition of preferred agents
- Revised: 9/10 – revised policy to include FDA approved indications
- Reviewed: 3/1/11 – annual review
- Revised: 3/1/12 – annual review, updated signature
- Revised: 1/25/13 – updated FDA approved indications
- Revised: 3/1/13 – annual review, updated logo and definitions
- Revised: 3/1/14 – annual review, updated formatting
- Revised: 3/1/15 – annual review, update signature
- Revised: 3/1/16 – annual review, removed Accretropin, Nutropin, & Tev Tropin (no longer available), removed HumatroPen (device) added Zomacton, updated current FDA approved indications
- Revised: 5/1/16 – updated format, logo, and procedure, updated preferred agent from Genotropin to Nutropin, updated FA
- Reviewed: 3/1/17 – annual review
- Revised: 3/1/18 – annual review, updated signature, added PA indicator to FA
- Revised: 4/6/18 – removed Nutropin as a preferred agent, updated FDA indications, updated FA
- Revised: 2/6/19 – updated FDA approved indications for Zomacton

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**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 29.0

**SECTION: Commercial Drug
SUBJECT: Human Growth Hormone**

Reviewed: 3/1/19 – annual review
Revised: 3/1/20 – annual review, added GHP Kids
Revised: 3/1/21 – annual review, updated logo, added MediSpan approval level, removed coinsurance statement
Revised: 3/1/22 – annual review, updated referenced policies & covered LOBs
Revised: 4/4/22 – added Skytrofa



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 30.0

**SECTION: Commercial Drug
SUBJECT: Topical Tretinoin**

Applicable line of business:

Commercial	X	Medicaid	
Medicare		ACA	X
GHP Kids	X	Self-Insured	X

POLICY:

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for agents to treat insomnia for GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 487.0 Quantity Limit Exceptions

REQUIRED DEFINITIONS:

1. **Attachment** – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. **Exhibit** – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. **Devised** – the date the policy was implemented.
4. **Revised** – the date of every revision to the policy, including typographical and grammatical changes.
5. **Reviewed** – the date documenting the annual review if the policy has no revisions necessary.

ADDITIONAL DEFINITIONS:

1. **Formulary** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. **Non-formulary products** – those medications that are not included in the Formulary.
3. **Healthcare provider** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
4. **NCQA** – National Committee for Quality Assurance.
5. **Medically Necessary or Medical Necessity** – covered services rendered by a provider that the Health Plan determines are:



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 30.0

**SECTION: Commercial Drug
SUBJECT: Topical Tretinoin**

- A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
- B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
- C. In accordance with current standards of medical practice;
- D. Not primarily for the convenience of the Member, or the Member's Provider; and
- E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

PROCEDURE:

An exception for coverage of topical tretinoin may be made for members who meet the following criterion:

- Medical record documentation of a diagnosis of acne, acne vulgaris, or adult onset acne

MEDISPAN AUTHORIZATION LEVEL: GPI-10, add ONLY OAL and generic only

NOTE: Authorization not needed for members less than 30 years of age

If an exception is made, topical tretinoin will be paid for under the member's prescription drug benefit.

Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.

FORMULARY ALTERNATIVES:

benzoyl peroxide, clindamycin, erythromycin, erythromycin and clindamycin gel, erythromycin and benzoyl peroxide gel, isotretinoin, sulfacetamide and sulfur lotion, tetracycline



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 30.0

**SECTION: Commercial Drug
SUBJECT: Topical Tretinoin**

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE
STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND
FEDERAL REGULATORY ENTITIES.**

**THIS POLICY WILL BE REVISED AS NECESSARY AND
REVIEWED NO LESS THAN ANNUALLY.**

Signed: _____

Title: Director, Pharmacy Services

Date: March 1, 2022

- Devised: 4/97
- Reviewed: 3/01
- Revised: 3/01
- Revised: 2/02
- Reviewed: 4/02
- Revised: 3/03
- Reviewed: 03/04
- Revised: 09/04 – updated Accutane to generic
- Revised: 03/05 – updated title
- Revised: 3/06 – updated title
- Revised: 3/07 – updated generics
- Revised: 4/07 – added signature
- Reviewed: 3/08 – annual review
- Reviewed: 4/09 – annual review
- Revised: 8/09 – added gel
- Reviewed: 3/10 – annual review, added alt of generic Benzaclin
- Reviewed: 3/1/11—annual review
- Revised: 3/1/12 – annual review, updated sig, added Retin A MicroGel
- Revised: 3/1/13 – annual review, updated logo and definitions
- Revised: 3/1/14 – annual review, updated formatting
- Revised: 3/1/15 – annual review, updated formatting, updated signature
- Reviewed: 3/1/16 – annual review
- Revised: 5/1/16 – updated format, logo, and procedure
- Revised: 3/1/17 – removed Retin A MicroGel
- Revised: 3/1/18 – annual review, updated signature
- Reviewed: 3/1/19 – annual review
- Revised: 3/1/20 – annual review, added GHP Kids
- Revised: 3/1/21 – annual review, updated logo, added MediSpan approval level
- Revised: 3/1/22 – annual review, updated referenced policies & covered LOBs, added OAL



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 32.0

**SECTION: Commercial Drug
SUBJECT: Coverage of Compounded
Prescriptions**

Applicable line of business:

Commercial	X	Medicaid	
Medicare		ACA	X
GHP Kids	X	Self-Insured	X

POLICY:

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for compounded prescriptions for GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 487.0 Quantity Limit Exceptions

REQUIRED DEFINITIONS:

1. **Attachment** – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. **Exhibit** – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. **Devised** – the date the policy was implemented.
4. **Revised** – the date of every revision to the policy, including typographical and grammatical changes.
5. **Reviewed** – the date documenting the annual review if the policy has no revisions necessary.

ADDITIONAL DEFINITIONS:

1. **Formulary** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. **Non-formulary products** – those medications that are not included in the Formulary.
3. **Healthcare provider** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
4. **NCQA** – National Committee for Quality Assurance.
5. **Medically Necessary or Medical Necessity** – covered services rendered by a provider that the Health Plan determines are:



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 32.0

**SECTION: Commercial Drug
SUBJECT: Coverage of Compounded
Prescriptions**

- A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
- B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
- C. In accordance with current standards of medical practice;
- D. Not primarily for the convenience of the Member, or the Member's Provider; and
- E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

PROCEDURE:

Coverage of compounded prescriptions is available if the following criteria are met:

- The compounded medication does not contain any excluded active ingredients **AND**
- The safety and effectiveness of use for the prescribed indication is supported by Food and Drug Administration (FDA) approval or adequate medical and scientific evidence in the medical literature **AND**
- Medical record documentation of therapeutic failure on, contraindication to, or intolerance to formulary alternatives

****If none of the ingredients being compounded requires a prescription to be dispensed, the compounded prescription is excluded from coverage. ****

****Compounds of products that have not received FDA approval or for a diagnosis for which there is no FDA approved treatment indication are excluded from coverage (i.e., natural hormones).****

****Certain compounds will require a prior authorization if a certain cost threshold is met.****

****Claims for compounded prescriptions must be submitted at the point of service through the electronic claims processing system and will be paid based on the calculated ingredient cost.****

If an exception is made, the compounded prescription will be paid for under the member's prescription drug benefit.



POLICY NUMBER: 32.0

**POLICY AND PROCEDURE
PHARMACY
MANUAL**

**SECTION: Commercial Drug
SUBJECT: Coverage of Compounded
Prescriptions**

Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.

FORMULARY ALTERNATIVES:

none

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE
STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND
FEDERAL REGULATORY ENTITIES.**

**THIS POLICY WILL BE REVISED AS NECESSARY AND
REVIEWED NO LESS THAN ANNUALLY.**

Signed: _____

Title: Director, Pharmacy Services

Date: March 1, 2022

- Devised: 3/97
- Reviewed: 3/98
- Reviewed: 3/99
- Reviewed: 12/00
- Revised: 3/01
- Revised: 4/01
- Revised: 2/02
- Revised: 5/02
- Revised: 3/03
- Reviewed: 3/04
- Revised: 8/04 – updated verbiage
- Revised: 3/05 – updated title
- Revised: 3/06 – updated title
- Reviewed: 3/07
- Revised: 4/07 – added signature
- Reviewed: 3/08 – annual review
- Reviewed: 4/09 – annual review
- Reviewed: 3/10 – annual review
- Revised: 3/1/11 – annual review—updated informational section
- Revised: 3/1/12 – annual review and updated signature
- Revised: 9/17/12 – updated criteria for coverage and updated location

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Dev. 3/97
Rev. 3/1/22



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 32.0

**SECTION: Commercial Drug
SUBJECT: Coverage of Compounded
Prescriptions**

Revised: 3/1/13 – annual review, updated logo and definitions, corrected signature title
Revised: 3/1/14 – annual review, updated formatting
Revised: 3/1/15 – annual review, updated signature
Revised: 3/1/16 – annual review, updated payment logic to reflect pay as calculated
Revised: 5/1/16 – updated format, logo, and procedure
Revised: 3/1/17 – annual review
Revised: 3/1/18 – annual review, updated signature
Revised: 3/1/19 – annual review, defined FDA
Revised: 3/1/20 – annual review, added GHP Kids
Revised: 3/1/21 – annual review, updated logo
Revised: 3/1/22 – annual review, updated referenced policies & covered LOBs



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 33.0

**SECTION: Commercial Drug
SUBJECT: Itraconazole**

Applicable line of business:

Commercial	X	Medicaid	
Medicare		ACA	X
GHP Kids	X	Self-Insured	X

POLICY:

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for itraconazole for GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 487.0 Quantity Limit Exceptions

REQUIRED DEFINITIONS:

1. **Attachment** – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. **Exhibit** – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. **Devised** – the date the policy was implemented.
4. **Revised** – the date of every revision to the policy, including typographical and grammatical changes.
5. **Reviewed** – the date documenting the annual review if the policy has no revisions necessary.

ADDITIONAL DEFINITIONS:

1. **Formulary** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. **Non-formulary products** – those medications that are not included in the Formulary.
3. **Healthcare provider** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
4. **NCQA** – National Committee for Quality Assurance.
5. **Medically Necessary or Medical Necessity** – covered services rendered by a provider that the Health Plan determines are:

- A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
- B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
- C. In accordance with current standards of medical practice;
- D. Not primarily for the convenience of the Member, or the Member's Provider; and
- E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

PROCEDURE:

Coverage of itraconazole for the treatment of onychomycosis is not a covered service under the prescription benefit.

Itraconazole coverage is available if **all** of the following criteria are met:

- Medical record documentation of **one or a combination** of the following diagnoses:
 - Dermatomycoses due to tinea corporis, tinea cruris, tinea pedis, or pityriasis versicolor
 - Invasive pulmonary aspergillosis
 - Noninvasive pulmonary aspergillosis
 - Extrapulmonary aspergillosis
 - Oral candidiasis
 - Oral/esophageal candidiasis
 - Chronic pulmonary histoplasmosis
 - Cutaneous sporotrichosis
 - Lymphatic sporotrichosis
 - Paracoccidioidomycosis
 - Chromomycosis
 - Blastomycosis
- Medical record documentation of a positive culture substantiating the diagnosis and/or diagnoses

MEDISPAN AUTHORIZATION LEVEL: GPI-12, generic only

If an exception is made, itraconazole will be paid for under the member's prescription drug benefit.



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 33.0

**SECTION: Commercial Drug
SUBJECT: Itraconazole**

Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.

FORMULARY ALTERNATIVES:

none

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE
STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND
FEDERAL REGULATORY ENTITIES.**

**THIS POLICY WILL BE REVISED AS NECESSARY AND
REVIEWED NO LESS THAN ANNUALLY.**

Signed: _____

Title: Director, Pharmacy Services

Date: March 1, 2022

- Devised: 1/98
- Reviewed: 3/99
- Reviewed: 6/01
- Revised: 7/01
- Revised: 10/01
- Revised: 6/02
- Revised: 3/03
- Reviewed: 3/04
- Revised: 3/05 – updated title
- Revised: 3/06 – updated title
- Revised: 3/07 – updated generic itraconazole
- Revised: 4/07 – added signature
- Revised: 7/07 – updated generic (terbinafine)
- Reviewed: 3/08 – annual review
- Revised: 5/08 – changed “drug rider” to “benefit”
- Reviewed: 4/09 – annual review
- Reviewed: 3/10 – annual review
- Reviewed: 3/1/11 – annual review
- Revised: 3/1/12 – annual review and update signature
- Revised: 3/1/13 – annual review, updated logo and definitions
- Revised: 3/1/14 – annual review
- Revised: 3/1/15 – annual review, removed terbinafine from policy, updated signature

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Dev. 1/98

Rev. 3/1/22



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 33.0

**SECTION: Commercial Drug
SUBJECT: Itraconazole**

Revised: 3/1/16 – annual review, updated bullet formatting
Revised: 5/1/16 – updated format, logo, & procedure, removed terbinafine
Reviewed: 3/1/17 – annual review
Revised: 6/2/17 – added extrapulmonary aspergillosis
Revised: 3/1/18 – annual review, updated signature
Reviewed: 3/1/19 – annual review
Revised: 3/1/20 – annual review, added GHP Kids
Revised: 3/1/21 – annual review, updated logo, added MediSpan approval level
Revised: 3/1/22 – annual review, updated referenced policies & covered LOBs



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 36.0

**SECTION: Commercial Drug
SUBJECT: Dexlansoprazole & Omeprazole/
Sodium Bicarbonate**

Applicable line of business:

Commercial	X	Medicaid	
Medicare		ACA	X
GHP Kids	X	Self-Insured	X

POLICY:

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for dexlansoprazole and omeprazole/sodium bicarbonate for GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 487.0 Quantity Limit Exceptions

REQUIRED DEFINITIONS:

1. **Attachment** – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. **Exhibit** – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. **Devised** – the date the policy was implemented.
4. **Revised** – the date of every revision to the policy, including typographical and grammatical changes.
5. **Reviewed** – the date documenting the annual review if the policy has no revisions necessary.

ADDITIONAL DEFINITIONS:

1. **Formulary** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. **Non-formulary products** – those medications that are not included in the Formulary.
3. **Healthcare provider** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
4. **NCQA** – National Committee for Quality Assurance.
5. **Medically Necessary or Medical Necessity** – covered services rendered by a provider that the Health Plan determines are:



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 36.0

**SECTION: Commercial Drug
SUBJECT: Dexlansoprazole & Omeprazole/
Sodium Bicarbonate**

- A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
- B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
- C. In accordance with current standards of medical practice;
- D. Not primarily for the convenience of the Member, or the Member's Provider; and
- E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

PROCEDURE:

An exception for the coverage of **dexlansoprazole** may be made for members who meet the following criterion:

- Medical record documentation of a contraindication to, intolerance to, or therapeutic failure on the maximal doses of omeprazole, pantoprazole, lansoprazole, rabeprazole, and esomeprazole (in that order)

MEDISPAN AUTHORIZATION LEVEL: GPI-12

QUANTITY LIMIT: *No QLs need to be entered within the authorization unless the requested quantity exceeds the QL.*

- QL FOR LETTER ONLY: 1 capsule per day

An exception for the coverage of **Omeprazole/Sodium Bicarbonate** may be made for members who meet the following criterion:

- Medical record documentation of a contraindication to, intolerance to, or therapeutic failure on the maximal doses of omeprazole, pantoprazole, lansoprazole, rabeprazole, dexlansoprazole*, and esomeprazole (in that order)

MEDISPAN AUTHORIZATION LEVEL: GPI-12, generic only

If an exception is made, Dexilant or omeprazole/sodium bicarbonate will be paid for under the member's prescription drug benefit.

Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.



POLICY NUMBER: 36.0

**POLICY AND PROCEDURE
PHARMACY
MANUAL**

**SECTION: Commercial Drug
SUBJECT: Dexlansoprazole & Omeprazole/
Sodium Bicarbonate**

FORMULARY ALTERNATIVES:

omeprazole, pantoprazole, lansoprazole, rabeprazole, esomeprazole

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE
STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND
FEDERAL REGULATORY ENTITIES.**

**THIS POLICY WILL BE REVISED AS NECESSARY AND
REVIEWED NO LESS THAN ANNUALLY.**

Signed: _____

Title: Director, Pharmacy Services

Date: March 1, 2022

Devised: 10/01
Effective: 10/01
Revised: 2/02
Reviewed: 5/02
Revised: 6/02
Reviewed: 1/03
Revised: 1/03
Revised: 3/03
Reviewed: 3/04
Revised: 3/05 – updated title
Revised: 6/05 – added Zegerid to policy
Revised: 3/06 – updated title
Reviewed: 3/07
Revised: 4/07 – added signature
Revised: 7/07 – added step criteria
Revised: 10/07
Reviewed: 3/08 – annual review
Revised: 6/08 – removed step therapy reference
Revised: 7/08 – changed Protonix to pantoprazole
Reviewed: 4/09 – annual review
Revised: 11/09 – added Kapidex
Revised: 1/10 – updated quantity limit for Kapidex
Reviewed: 3/10 – annual review
Revised: 4/10 – updated name change for Kapidex to Dexilant
Revised: 9/10 – added generic Zegerid (omeprazole/sodium bicarbonate) to policy
Reviewed: 3/1/11 – annual review

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Dev. 10/01
Rev. 3/1/22



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 36.0

**SECTION: Commercial Drug
SUBJECT: Dexlansoprazole & Omeprazole/
Sodium Bicarbonate**

Revised: 3/1/12 – annual review updated signature
Revised: 3/1/13 – annual review, updated logo and definitions, updated title, removed Kapidex
Reviewed: 3/1/14 – annual review
Revised: 12/9/14 – removed Aciphex from policy, added failure of rabeprazole to all drugs included in policy, updated alternatives, updated signature
Revised: 3/1/15 – annual review, removed Aciphex from Policy section 1
Revised: 9/19/15 – updated Nexium to esomeprazole, removed failure of Dexilant from esomeprazole, added failure of esomeprazole to Dexilant, updated FA
Revised: 3/1/16 – updated Nexium to esomeprazole in Zegerid criterion, updated quantity limit formatting
Revised: 5/1/16 – updated format, logo, & procedure
Revised: 3/1/17 – annual review, removed brand name Zegerid
Revised: 3/1/18 – annual review, updated signature
Revised: 10/8/18 – removed PA from esomeprazole
Reviewed: 3/1/19 – annual review
Revised: 3/1/20 – annual review, added GHP Kids
Revised: 3/1/21 – annual review, updated logo, added MediSpan approval level, updated QL language
Revised: 3/1/22 – annual review, updated referenced policies & covered LOBs, updated Dexilant to generic



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 41.0

**SECTION: Commercial Drug
SUBJECT: Enbrel**

Applicable line of business:

Commercial	X	Medicaid	
Medicare		ACA	X
GHP Kids	X	Self-Insured	X

POLICY:

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for Enbrel for GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 487.0 Quantity Limit Exceptions

REQUIRED DEFINITIONS:

1. **Attachment** – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. **Exhibit** – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. **Devised** – the date the policy was implemented.
4. **Revised** – the date of every revision to the policy, including typographical and grammatical changes.
5. **Reviewed** – the date documenting the annual review if the policy has no revisions necessary.

ADDITIONAL DEFINITIONS:

1. **Formulary** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. **Non-formulary products** – those medications that are not included in the Formulary.
3. **Healthcare provider** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
4. **NCQA** – National Committee for Quality Assurance.
5. **Medically Necessary or Medical Necessity** – covered services rendered by a provider that the Health Plan determines are:



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 41.0

**SECTION: Commercial Drug
SUBJECT: Enbrel**

- A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
- B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
- C. In accordance with current standards of medical practice;
- D. Not primarily for the convenience of the Member, or the Member's Provider; and
- E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

PROCEDURE:

New members to the plan already established on therapy may be eligible for continuity of care coverage as long as there is medical record documentation that the safety and effectiveness of use for the prescribed indication is supported by Food and Drug Administration (FDA) approval or adequate medical and scientific evidence in the medical literature.

For treatment of adult rheumatoid arthritis:

An exception for coverage of Enbrel (which is self-administered) may be made for members who meet the following criteria:

- Medical record documentation of a diagnosis of moderate to severe rheumatoid arthritis (made in accordance with the American College of Rheumatology Criteria for the Classification and Diagnosis of Rheumatoid Arthritis) **AND**
- Medical record documentation that Enbrel is prescribed by a rheumatologist **AND**
- Medical record documentation of age greater than or equal to 18 years **AND**
- Medical record documentation of therapeutic failure on, intolerance to, or contraindication to a minimum 3 month trial of Humira*, Rinvoq*, OR Xeljanz* **AND**
- Medical record documentation that Enbrel is not being used concurrently with a tumor necrosis factor (TNF) blocker or other biologic agent

MEDISPAN AUTHORIZATION LEVEL: GPI-10, number of claims authorized = 1, enter for the remainder of the calendar year

QUANTITY LIMIT: *No QLs need to be entered within the authorization unless the requested quantity exceeds the QL.*

- **QL FOR LETTER ONLY:**
 - 50 mg syringe/pen: 4 mL per 28 days
 - 25 mg syringe: 4 mL per 28 days
 - 25 mg vial: 8 vials per 28 days



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 41.0

**SECTION: Commercial Drug
SUBJECT: Enbrel**

RE-AUTHORIZATION CRITERIA: Enbrel is configured as a prior authorization for new starts only. Enbrel will no longer be covered if it is identified that the member is not receiving appropriate follow-up care from the prescribing specialist or if the member has greater than or equal to a 90 day break in therapy.

- Medical record documentation that the member is receiving appropriate follow-up care from the prescribing specialist

FORMULARY ALTERNATIVES:

Humira*, Rinvoq*, Xeljanz*

*prior authorization required



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 41.0

**SECTION: Commercial Drug
SUBJECT: Enbrel**

For treatment of polyarticular juvenile idiopathic arthritis or juvenile rheumatoid arthritis:

An exception for coverage of Enbrel (which is self-administered) may be made for members who meet the following criteria:

- Medical record documentation of age greater than or equal to 2 years **AND**
- Medical record documentation that Enbrel is prescribed by a rheumatologist **AND**
- Medical record documentation of a diagnosis of moderate to severely active polyarticular juvenile idiopathic arthritis or juvenile rheumatoid arthritis **AND**
- Medical record documentation of an inadequate response to a minimum 3 month trial of both NSAID therapy **AND** methotrexate or other DMARD if methotrexate therapy is contraindicated **OR** medical record documentation of a therapeutic failure on or intolerance to prior biologic therapy **AND**
- Medical record documentation that Enbrel is not being used concurrently with a tumor necrosis factor (TNF) blocker or other biologic agent

RE-AUTHORIZATION CRITERIA: Enbrel is configured as a prior authorization for new starts only. Enbrel will no longer be covered if it is identified that the member is not receiving appropriate follow-up care from the prescribing specialist or if the member has greater than or equal to a 90 day break in therapy.

- Medical record documentation that the member is receiving appropriate follow-up care from the prescribing specialist

MEDISPAN AUTHORIZATION LEVEL: GPI-10, number of claims authorized = 1, enter for the remainder of the calendar year

QUANTITY LIMIT: *No QLs need to be entered within the authorization unless the requested quantity exceeds the QL.*

- **QL FOR LETTER ONLY:**
 - 50 mg syringe/pen: 4 mL per 28 days
 - 25 mg syringe: 4 mL per 28 days
 - 25 mg vial: 8 vials per 28 days

FORMULARY ALTERNATIVES:

methotrexate, sulfasalazine



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 41.0

**SECTION: Commercial Drug
SUBJECT: Enbrel**

For the treatment of Psoriatic Arthritis:

An exception for coverage of Enbrel (which is self-administered) may be made for members who meet the following criteria:

- Medical record documentation of a diagnosis of moderately to severely active psoriatic arthritis which must include the following:
 - Documentation of either active psoriatic lesions or a documented history of psoriasis **AND**
- Medical record documentation that Enbrel is prescribed by a rheumatologist or dermatologist **AND**
- Medical record documentation of therapeutic failure on, intolerance to, or contraindication to Cosentyx* **AND** Humira* **AND**
- Medical record documentation that Enbrel is not being used concurrently with a tumor necrosis factor (TNF) blocker or other biologic agent

RE-AUTHORIZATION CRITERIA: Enbrel is configured as a prior authorization for new starts only. Enbrel will no longer be covered if it is identified that the member is not receiving appropriate follow-up care from the prescribing specialist or if the member has greater than or equal to a 90 day break in therapy.

- Medical record documentation that the member is receiving appropriate follow-up care from the prescribing specialist

MEDISPAN AUTHORIZATION LEVEL: GPI-10, number of claims authorized = 1, enter for the remainder of the calendar year

QUANTITY LIMIT: *No QLs need to be entered within the authorization unless the requested quantity exceeds the QL.*

- **QL FOR LETTER ONLY:**
 - 50 mg syringe/pen: 4 mL per 28 days
 - 25 mg syringe: 4 mL per 28 days
 - 25 mg vial: 8 vials per 28 days

FORMULARY ALTERNATIVES:

Cosentyx*, Humira*

*prior authorization required



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 41.0

**SECTION: Commercial Drug
SUBJECT: Enbrel**

For the treatment of ankylosing spondylitis:

An exception for coverage of Enbrel (which is self-administered) may be made for members who meet the following criteria:

- Medical record documentation of a diagnosis of ankylosing spondylitis **AND**
- Medical record documentation that Enbrel is prescribed by a rheumatologist **AND**
- Medical record documentation of age greater than or equal to 18 years **AND**
- Medical record documentation of therapeutic failure on, intolerance to, or contraindication to Cosentyx* **AND** Humira* **AND**
- Medical record documentation that Enbrel is not being used concurrently with a tumor necrosis factor (TNF) blocker or other biologic agent

RE-AUTHORIZATION CRITERIA: Enbrel is configured as a prior authorization for new starts only. Enbrel will no longer be covered if it is identified that the member is not receiving appropriate follow-up care from the prescribing specialist or if the member has greater than or equal to a 90 day break in therapy.

- Medical record documentation that the member is receiving appropriate follow-up care from the prescribing specialist

MEDISPAN AUTHORIZATION LEVEL: GPI-10, number of claims authorized = 1, enter for the remainder of the calendar year

QUANTITY LIMIT: *No QLs need to be entered within the authorization unless the requested quantity exceeds the QL.*

- **QL FOR LETTER ONLY:**
 - 50 mg syringe/pen: 4 mL per 28 days
 - 25 mg syringe: 4 mL per 28 days
 - 25 mg vial: 8 vials per 28 days

FORMULARY ALTERNATIVES:

Cosentyx*, Humira*

*prior authorization required



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 41.0

**SECTION: Commercial Drug
SUBJECT: Enbrel**

For the treatment of moderate to severe Plaque Psoriasis:

An exception for coverage of Enbrel (which is self-administered) may be made for members who meet the following criteria:

- Medical record documentation that Enbrel is prescribed by a dermatologist **AND**
- Medical record documentation of age greater than or equal to 18 years **AND**
- Medical record documentation of a diagnosis of moderate to severe plaque psoriasis characterized by greater than or equal to 5% of body surface area involved or disease involving crucial body areas such as the hands, feet, face, or genitals **AND**
- Medical record documentation of therapeutic failure on, intolerance to, or contraindication to Cosentyx* **AND** Humira* **AND**
- Medical record documentation that Enbrel is not being used concurrently with a tumor necrosis factor (TNF) blocker or other biologic agent

RE-AUTHORIZATION CRITERIA: Enbrel is configured as a prior authorization for new starts only. Enbrel will no longer be covered if it is identified that the member is not receiving appropriate follow-up care from the prescribing specialist or if the member has greater than or equal to a 90 day break in therapy.

- Medical record documentation that the member is receiving appropriate follow-up care from the prescribing specialist

MEDISPAN AUTHORIZATION LEVEL: GPI-10

QUANTITY LIMIT:

- **Initial Request for Enbrel 50 mg syringe/pen, 25 mg syringe**
 - Add PA, OQL, DS, max number of claims authorized 3, max quantity dispense 8, max day supply 28, min day supply 28, with a duration of 3 months
 - **QL FOR LETTER:** Loading dose: 8 mL per 28 days; Maintenance dose: 4 mL per 28 days
- **Initial Request for Enbrel 25 mg vial**
 - Add PA, OQL, DS, max number of claims authorized 3, max quantity dispense 16, max day supply 28, min day supply 28, with a duration of 3 months
 - **QL FOR LETTER:** Loading dose: 16 mL per 28 days; Maintenance dose: 8 mL per 28 days
- **Renewal Requests** – *No QLS need to be entered within the authorization unless the requested quantity exceeds the QL.*
 - **QL FOR LETTER ONLY:**
 - 50 mg syringe/pen: 4 mL per 28 days
 - 25 mg syringe: 4 mL per 28 days



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 41.0

**SECTION: Commercial Drug
SUBJECT: Enbrel**

- 25 mg vial: 8 vials per 28 days

FORMULARY ALTERNATIVES:

Cosentyx*, Humira*

*prior authorization required

For the treatment of pediatric Plaque Psoriasis:

An exception for coverage of Enbrel (which is self-administered) may be made for members who meet the following criteria:

- Medical record documentation that Enbrel is prescribed by a dermatologist **AND**
- Medical record documentation of age greater than or equal to 4 years **AND**
- Medical record documentation of a diagnosis of moderate to severe plaque psoriasis characterized by greater than or equal to 5% of body surface area involved or disease involving crucial body areas such as the hands, feet, face, or genitals **AND**
- Medical record documentation of a therapeutic failure on, intolerance to, or contraindication to two (2) topical corticosteroids **AND**
- Medical record documentation that Enbrel is not being used concurrently with a tumor necrosis factor (TNF) blocker or other biologic agent

RE-AUTHORIZATION CRITERIA: Enbrel is configured as a prior authorization for new starts only. Enbrel will no longer be covered if it is identified that the member is not receiving appropriate follow-up care from the prescribing specialist or if the member has greater than or equal to a 90 day break in therapy.

- Medical record documentation that the member is receiving appropriate follow-up care from the prescribing specialist

MEDISPAN AUTHORIZATION LEVEL: GPI-10, number of claims authorized = 1, enter for the remainder of the calendar year

QUANTITY LIMIT: *No QLs need to be entered within the authorization unless the requested quantity exceeds the QL.*

- **QL FOR LETTER ONLY:**
 - 50 mg syringe/pen: 4 mL per 28 days
 - 25 mg syringe: 4 mL per 28 days
 - 25 mg vial: 8 vials per 28 days

FORMULARY ALTERNATIVES:

Low-potency topical corticosteroids: alclometasone dipropionate 0.5% cream and ointment (Aclovate); fluocinolone acetonide 0.01% soln. (Synalar); hydrocortisone 2.5% cream, ointment, and lotion (Hytone)

Medium-potency topical corticosteroids: betamethasone valerate 0.1% cream (Valisone); fluocinolone acetonide 0.025% cream and ointment (Synalar); fluticasone propionate 0.05% cream, ointment, and lotion (Cutivate); triamcinolone 0.1% cream, ointment and lotion (Kenalog); triamcinolone acetonide 0.025% cream, ointment and lotion (Kenalog); triamcinolone acetonide 0.147 mg/g aerosol (Kenalog Spray)



POLICY NUMBER: 41.0

POLICY AND PROCEDURE
PHARMACY
MANUAL

SECTION: Commercial Drug
SUBJECT: Enbrel

High-potency topical corticosteroids: augmented betamethasone dipropionate 0.05% cream (Diprolene AF); betamethasone valerate 0.1% ointment (Valisone); triamcinolone 0.5% cream (Kenalog); fluocinonide 0.05% cream, ointment and gel (Lidex)

Very high-potency topical corticosteroids: augmented betamethasone dipropionate 0.05% ointment, gel and lotion (Diprolene); clobetasol 0.05% cream, ointment, and scalp lotion (Temovate) diflorasone diacetate 0.05% cream and ointment (ApexiCon/Psorcon)

If an exception is made, Enbrel will be paid for under the member's prescription drug benefit.

Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE
STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND
FEDERAL REGULATORY ENTITIES.**

**THIS POLICY WILL BE REVISED AS NECESSARY AND
REVIEWED NO LESS THAN ANNUALLY.**

Signed: _____

Title: Director, Pharmacy Services

Date: March 1, 2022

Devised: 10/01
Effective: 10/01
Revised: 1/02
Revised: 2/02
Revised: 3/03
Revised: 3/04 – updated criteria to coordinate with Medical Benefit Pharmaceutical Policy 6.0
Revised: 10/04 – updated criteria to include moderate to severe plaque psoriasis.
Revised: 3/05 – updated title
Revised: 6/05 – spelling error corrected.
Revised: 10/05 – updated for generic Arava availability
Revised: 3/06 – updated title
Reviewed: 3/07
Revised: 4/07 – added signature
Reviewed: 3/08 – annual review
Revised: 4/08 – changed psoriasis criteria to 10%



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 41.0

**SECTION: Commercial Drug
SUBJECT: Enbrel**

- Revised: 5/08 – updated criteria
- Reviewed: 4/09 – annual review
- Reviewed: 3/10 – annual review
- Reviewed: 3/1/11 – annual review
- Revised: 3/1/2012 – annual review updated signature
- Revised: 9/17/2012 – updated authorization duration and updated location
- Revised: 3/1/13 – annual review, updated logo & definitions, removed JIA criterion from RA
- Revised: 5/4/13 – updated age restriction for JIA
- Revised: 3/1/14 – annual review, updated formulary alternatives
- Revised: 4/1/14 – removed “and administered” from RA prescriber criteria
- Revised: 9/22/14 – updated clinical criteria for all indications (except PJIA) and alternative criteria for all indications, updated FA, updated signature, modified authorization duration wording for all indications, updated PJIA header.
- Revised: 11/21/14 – from PJIA, removed wording regarding Humira’s age restrictions and removed, “For patients aged 4 years and older”
- Revised: 2/9/15 – updated alternatives criteria for all indications, formulary alternatives, and prescriber criteria for PsA
- Reviewed: 3/1/15 – annual review
- Revised: 9/19/15 – removed joint count criteria from initial and renewal requirements
- Revised: 3/1/16 – annual review, updated policy formatting to improve readability, added approval statement
- Revised: 5/1/16 – updated format, logo, & procedure
- Revised: 3/1/17 – annual review, updated FA
- Revised: 3/27/17 – added pediatric psoriasis indication, peripheral vs. axial PsA, updated FA
- Revised: 3/1/18 – annual review, updated signature, added grandfather language, updated age and prescriber formatting
- Revised: 5/30/18 – added combination with other biologic agents, added QL, updated failure to Cosentyx & Humira (PsA, AS, PP), defined 2 alternatives for pediatric PP, updated FA
- Revised: 10/1/18 – removed failure of MTX & added failure of Humira for RA, updated RA FA
- Reviewed: 3/1/19 – annual review, defined TNF, added QL approval note, added PA required for RA
- Revised: 7/24/19 – added authorization parameters to PP
- Revised: 09/25/19 – updated QL
- Revised: 01/28/20 – updated RA FA and added failure of Rinvoq and Xeljanz
- Revised: 3/1/20 – annual review, added GHP Kids
- Revised: 3/1/21 – annual review, updated logo, added MediSpan approval level, updated QL statement
- Revised: 12/2/21 – added one-time PA to approval crit., removed auth duration & added re-auth crit., updated QL auth entry for PP
- Revised: 3/1/22 – annual review, updated referenced policies & covered LOBs, updated how adult PsO QL is entered



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 45.0

**SECTION: Commercial Drug
SUBJECT: Pulmozyme**

Applicable line of business:

Commercial	X	Medicaid	
Medicare		ACA	X
GHP Kids	X	Self-Insured	X

POLICY:

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for Pulmozyme for GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 487.0 Quantity Limit Exceptions

REQUIRED DEFINITIONS:

1. **Attachment** – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. **Exhibit** – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. **Devised** – the date the policy was implemented.
4. **Revised** – the date of every revision to the policy, including typographical and grammatical changes.
5. **Reviewed** – the date documenting the annual review if the policy has no revisions necessary.

ADDITIONAL DEFINITIONS:

1. **Formulary** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. **Non-formulary products** – those medications that are not included in the Formulary.
3. **Healthcare provider** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
4. **NCQA** – National Committee for Quality Assurance.
5. **Medically Necessary or Medical Necessity** – covered services rendered by a provider that the Health Plan determines are:



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 45.0

**SECTION: Commercial Drug
SUBJECT: Pulmozyme**

- A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
- B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
- C. In accordance with current standards of medical practice;
- D. Not primarily for the convenience of the Member, or the Member's Provider; and
- E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

PROCEDURE:

An exception for coverage of Pulmozyme may be made for members who meet all of the following criteria:

- Medical record documentation of a diagnosis of cystic fibrosis (CF) **AND**
- Medical record documentation that Pulmozyme is prescribed by a pulmonologist

MEDISPAN AUTHORIZATION LEVEL: GPI-12

If an exception is made, Pulmozyme will be paid for under the member's prescription drug benefit.

Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.

FORMULARY ALTERNATIVES:

none

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE
STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND
FEDERAL REGULATORY ENTITIES.**

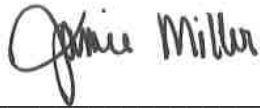
**THIS POLICY WILL BE REVISED AS NECESSARY AND
REVIEWED NO LESS THAN ANNUALLY.**

Geisinger

**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 45.0

**SECTION: Commercial Drug
SUBJECT: Pulmozyme**



Signed: _____

Title: Director, Pharmacy Services

Date: March 1, 2022

Devised: 7/99
Effective: 7/99
Revised: 10/01
Revised: 4/02
Revised: 3/03
Reviewed: 3/04
Revised: 3/05 – updated title
Revised: 3/06 – updated title
Reviewed: 3/07
Revised: 4/07 – added signature
Reviewed: 3/08 – annual review
Reviewed: 4/09 – annual review
Reviewed: 3/10 – annual review
Reviewed: 3/1/11 – annual review
Revised: 3/1/12 – annual review
Revised: 3/1/13 – annual review, updated logo and definitions
Revised: 3/1/14 – annual review, updated formatting
Revised: 3/1/15 – annual review, updated signature
Revised: 3/1/16 – annual review, added formulary alternative section
Revised: 5/1/16 – updated format, logo, & procedure
Reviewed: 3/1/17 – annual review
Revised: 6/2/17 – removed age restriction
Revised: 3/1/18 – annual review, updated signature, updated formatting
Reviewed: 3/1/19 – annual review
Revised: 3/1/20 – annual review, added GHP Kids
Revised: 3/1/21 – annual review, updated logo, added MediSpan approval level
Revised: 3/1/22 – annual review, updated referenced policies & covered LOBs



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 48.0

**SECTION: Commercial Drug
SUBJECT: Inhaled Tobramycin**

Applicable line of business:

Commercial	X	Medicaid	
Medicare		ACA	X
GHP Kids	X	Self-Insured	X

POLICY:

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for agents to treat insomnia for GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 487.0 Quantity Limit Exceptions

REQUIRED DEFINITIONS:

1. **Attachment** – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. **Exhibit** – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. **Devised** – the date the policy was implemented.
4. **Revised** – the date of every revision to the policy, including typographical and grammatical changes.
5. **Reviewed** – the date documenting the annual review if the policy has no revisions necessary.

ADDITIONAL DEFINITIONS:

1. **Formulary** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. **Non-formulary products** – those medications that are not included in the Formulary.
3. **Healthcare provider** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
4. **NCQA** – National Committee for Quality Assurance.
5. **Medically Necessary or Medical Necessity** – covered services rendered by a provider that the Health Plan determines are:



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 48.0

**SECTION: Commercial Drug
SUBJECT: Inhaled Tobramycin**

- A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
- B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
- C. In accordance with current standards of medical practice;
- D. Not primarily for the convenience of the Member, or the Member's Provider; and
- E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

PROCEDURE:

An exception for coverage of inhaled tobramycin may be made for members who meet **all** of the following criteria:

- Medical record documentation of a diagnosis of cystic fibrosis **AND**
- Medical record documentation that tobramycin inhalation solution is prescribed by a pulmonologist

MEDISPAN AUTHORIZATION LEVEL: GPI-12, if request is for tobramycin inhalation solution include generic only.

QUANTITY LIMIT: *No QLs need to be entered within the authorization unless the requested quantity exceeds the QL.*

- **QL FOR LETTER ONLY:**
 - Tobramycin inhalation solution: 280 mL per 56 days
 - Tobi PodHaler: 224 mL per 56 days

If an exception is made, inhaled tobramycin will be paid for under the member's prescription drug benefit.

Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.

FORMULARY ALTERNATIVES:

Bethkis*

*prior authorization required



POLICY NUMBER: 48.0

**POLICY AND PROCEDURE
PHARMACY
MANUAL**

**SECTION: Commercial Drug
SUBJECT: Inhaled Tobramycin**

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE
STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND
FEDERAL REGULATORY ENTITIES.**

**THIS POLICY WILL BE REVISED AS NECESSARY AND
REVIEWED NO LESS THAN ANNUALLY.**

Signed: _____

Title: Director, Pharmacy Services

Date: March 1, 2022

Devised: 7/99
Effective: 7/99
Revised: 10/01
Revised: 2/02
Revised: 4/02
Revised: 3/03
Reviewed: 3/04
Revised: 3/05 – updated title
Revised: 3/06 – updated title
Reviewed: 3/07
Revised: 4/07 – added signature
Reviewed: 3/08 – annual review
Reviewed: 4/09 – annual review
Reviewed: 3/10 – annual review
Reviewed: 3/1/11 – annual review
Revised: 3/1/12 – annual review, updated signature
Revised: 3/1/13 – annual review, updated logo and definitions
Revised: 3/1/14 – annual review, updated title based on generic availability
Revised: 3/1/15 – annual review, updated signature
Revised: 11/20/15 – updated title, added QL, added FA
Reviewed: 3/1/16 – annual review
Revised: 5/1/16 – updated format, logo, & procedure
Revised: 3/1/17 – annual review, updated inhalation solution QL
Revised: 3/1/18 – annual review, updated signature, updated formatting
Revised: 3/1/19 – annual review, added QL approval note
Revised: 6/4/19 – removed CSR QL note, added authorization parameters
Revised: 3/1/20 – annual review, added GHP Kids
Revised: 3/1/21 – annual review, updated logo, added MediSpan approval level, updated QL statement
Revised: 3/1/22 – annual review, updated referenced policies & covered LOBs



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 49.0

**SECTION: Commercial Drug
SUBJECT: Darifenacin ER, Gemtesa,
Oxytrol, Tolterodine ER,
Toviaz, and Trosipium XR**

Applicable line of business:

Commercial	X	Medicaid	
Medicare		ACA	X
GHP Kids	X	Self-Insured	X

POLICY:

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for darifenacin ER, Gemtesa, Oxytrol, tolterodine ER, Toviaz, and trosipium XR for GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 487.0 Quantity Limit Exceptions

REQUIRED DEFINITIONS:

1. **Attachment** – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. **Exhibit** – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. **Devised** – the date the policy was implemented.
4. **Revised** – the date of every revision to the policy, including typographical and grammatical changes.
5. **Reviewed** – the date documenting the annual review if the policy has no revisions necessary.

ADDITIONAL DEFINITIONS:

1. **Formulary** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. **Non-formulary products** – those medications that are not included in the Formulary.
3. **Healthcare provider** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
4. **NCQA** – National Committee for Quality Assurance.
5. **Medically Necessary or Medical Necessity** – covered services rendered by a provider that the Health Plan determines are:



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 49.0

**SECTION: Commercial Drug
SUBJECT: Darifenacin ER, Gemtesa,
Oxytrol, Tolterodine ER,
Toviaz, and Trospium XR**

- A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
- B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
- C. In accordance with current standards of medical practice;
- D. Not primarily for the convenience of the Member, or the Member's Provider; and
- E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

PROCEDURE:

An exception for coverage of darifenacin ER, Gemtesa, Oxytrol, tolterodine ER, Toviaz, or trospium XR may be made for members who meet the following criteria:

- Medical record documentation of therapeutic failure on, intolerance to, or contraindication to use of oxybutynin, oxybutynin XL or tolterodine **AND** solifenacin

MEDISPAN AUTHORIZATION LEVEL: GPI-12, if request is for darifenacin ER, tolterodine ER, or trospium XR include generic only.

If a formulary exception is approved darifenacin ER, Gemtesa, Oxytrol, tolterodine ER, Toviaz, or trospium XR will be paid for under the member's prescription drug benefit.

Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.

FORMULARY ALTERNATIVES:

oxybutynin, oxybutynin XL, solifenacin, tolterodine, Myrbetriq

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE
STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND
FEDERAL REGULATORY ENTITIES.**

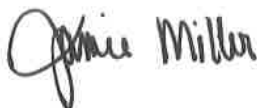
**THIS POLICY WILL BE REVISED AS NECESSARY AND
REVIEWED NO LESS THAN ANNUALLY.**

Geisinger

**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 49.0

**SECTION: Commercial Drug
SUBJECT: Darifenacin ER, Gemtesa,
Oxytrol, Tolterodine ER,
Toviaz, and Trospium XR**



Signed: _____

Title: Director, Pharmacy Services

Date: March 1, 2022

Devised: 7/99
Effective: 7/99
Revised: 10/01
Revised: 2/02
Revised: 3/02
Revised: 3/03
Reviewed: 3/04
Revised: 3/05 – updated title
Revised: 3/06 – updated title
Revised: 3/07 – updated title and generics
Revised: 4/07 – added signature
Revised: 7/07 – added Enablex, Sanctura to title, Vesicare to alternatives
Revised: 8/07 – added Oxytrol
Reviewed: 3/08 – annual review
Reviewed: 4/09 – annual review
Revised: 7/09 – annual review
Reviewed: 3/10 – annual review
Reviewed: 3/1/11 – annual review
Revised: 3/1/12 – annual review, updated signature
Revised: 3/29/12 – added Anturol to policy
Revised: 1/25/13 – added Myrbetriq to policy, removed Detrol from policy, updated title
Revised: 3/1/13 – annual review, updated logo and definitions, updated title and generics
Revised: 3/1/14 – annual review, updated formatting, updated Detrol LA to tolterodine ER
Revised: 3/1/15 – annual review, updated signature
Reviewed: 3/1/16 – annual review
Revised: 5/1/16 – updated format, logo, & procedure
Revised: 3/1/17 – annual review, removed Anturol, updated Enablex to darifenacin
Revised: 3/1/18 – annual review, updated signature, updated formatting
Revised: 10/8/18 – removed Myrbetriq PA, updated FA
Reviewed: 3/1/19 – annual review
Revised: 3/1/20 – annual review, added GHP Kids
Revised: 3/1/21 – annual review, updated logo, added MediSpan approval level, updated Vesicare to gen.
Revised: 7/1/21 – added Gemtesa
Revised: 3/1/22 – annual review, updated referenced policies & covered LOBs



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 50.0

**SECTION: Commercial Drug
SUBJECT: Antihemophilic Agents for
Hemophilia B**

Applicable line of business:

Commercial	X	Medicaid	
Medicare		ACA	X
GHP Kids	X	Self-Insured	X

POLICY:

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for antihemophilic agents for hemophilia B for GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 487.0 Quantity Limit Exceptions

REQUIRED DEFINITIONS:

1. **Attachment** – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. **Exhibit** – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. **Devised** – the date the policy was implemented.
4. **Revised** – the date of every revision to the policy, including typographical and grammatical changes.
5. **Reviewed** – the date documenting the annual review if the policy has no revisions necessary.

ADDITIONAL DEFINITIONS:

1. **Formulary** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. **Non-formulary products** – those medications that are not included in the Formulary.
3. **Healthcare provider** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
4. **NCQA** – National Committee for Quality Assurance.
5. **Medically Necessary or Medical Necessity** – covered services rendered by a provider that the Health Plan determines are:



POLICY NUMBER: 50.0

**POLICY AND PROCEDURE
PHARMACY
MANUAL**

**SECTION: Commercial Drug
SUBJECT: Antihemophilic Agents for
Hemophilia B**

- A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
- B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
- C. In accordance with current standards of medical practice;
- D. Not primarily for the convenience of the Member, or the Member's Provider; and
- E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

PROCEDURE:

An exception for coverage of self-administered antihemophilic agents for hemophilia B may be made for members who meet all of the following criteria:

- Medical record documentation of a diagnosis of hemophilia B (a documented Factor IX deficiency) **AND**
- Medical record documentation that the antihemophilic agent will be for outpatient use **AND**
- Medical record documentation that the antihemophilic agent will be used appropriate for routine prophylaxis, on-demand treatment/control of bleeding episodes, **OR** perioperative management of bleeding

	Routine Prophylaxis	On-Demand/ Perioperative
Alphanine SD		X
Alprolix	X	X
Bebulin		X
BeneFIX		X
Idelvion	X	X
Ixinity		X
Mononine		X
Profilnine		X
Rebinyn		X
Rixubis	X	X

MEDISPAN AUTHORIZATION LEVEL: GPI-12



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 50.0

**SECTION: Commercial Drug
SUBJECT: Antihemophilic Agents for
Hemophilia B**

If an exception is made, the antihemophilic agent for hemophilia B will be paid for under the member's prescription drug benefit.

Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.

FORMULARY ALTERNATIVES:

none

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE
STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND
FEDERAL REGULATORY ENTITIES.**

**THIS POLICY WILL BE REVISED AS NECESSARY AND
REVIEWED NO LESS THAN ANNUALLY.**

Signed: _____

Title: Director, Pharmacy Services

Date: March 1, 2022

Devised: 7/99
Effective: 7/99
Revised: 10/01
Revised: 2/02
Revised: 6/02
Revised: 3/03
Revised: 3/04 – updated to reflect coverage changes
Revised: 3/05 – updated title
Revised: 3/06 – updated title
Reviewed: 3/07
Revised: 4/07 – added signature
Reviewed: 3/08 – annual review
Revised: 4/09 – annual review; removed old renewal language
Reviewed: 3/10 – annual review
Reviewed: 3/1/11 – annual review
Revised: 3/1/12 – annual review, updated signature
Revised: 3/1/13 – annual review, updated logo and definitions
Revised: 3/1/14 – annual review, updated formatting, added approval statement
Revised: 3/1/15 – annual review, updated signature

HPRX02

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Dev. 7/99
Rev. 3/1/22



POLICY NUMBER: 50.0

**POLICY AND PROCEDURE
PHARMACY
MANUAL**

**SECTION: Commercial Drug
SUBJECT: Antihemophilic Agents for
Hemophilia B**

Revised: 3/1/16 – annual review, added formulary alternatives section
Revised: 5/1/16 – updated format, logo, & procedure
Reviewed: 3/1/17 – annual review
Revised: 3/1/18 – annual review, updated signature, updated formatting
Revised: 7/20/18 – updated policy/title to only include hemophilia B, updated diagnosis & indication criteria, added indication chart
Reviewed: 3/1/19 – annual review
Revised: 3/1/20 – annual review, added GHP Kids
Revised: 3/1/21 – annual review, updated logo, added MediSpan approval level
Revised: 3/1/22 – annual review, updated referenced policies & covered LOBs



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 63.0

**SECTION: Commercial Drug
SUBJECT: Elmiron**

Applicable line of business:

Commercial	X	Medicaid	
Medicare		ACA	X
GHP Kids	X	Self-Insured	X

POLICY:

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for Elmiron for GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 487.0 Quantity Limit Exceptions

REQUIRED DEFINITIONS:

1. **Attachment** – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. **Exhibit** – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. **Devised** – the date the policy was implemented.
4. **Revised** – the date of every revision to the policy, including typographical and grammatical changes.
5. **Reviewed** – the date documenting the annual review if the policy has no revisions necessary.

ADDITIONAL DEFINITIONS:

1. **Formulary** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. **Non-formulary products** – those medications that are not included in the Formulary.
3. **Healthcare provider** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
4. **NCQA** – National Committee for Quality Assurance.
5. **Medically Necessary or Medical Necessity** – covered services rendered by a provider that the Health Plan determines are:



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 63.0

**SECTION: Commercial Drug
SUBJECT: Elmiron**

- A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
- B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
- C. In accordance with current standards of medical practice;
- D. Not primarily for the convenience of the Member, or the Member's Provider; and
- E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

PROCEDURE:

A formulary exception for coverage of Elmiron may be made for members who meet **all** of the following criteria:

- Medical record documentation of a diagnosis of interstitial cystitis **AND**
- Medical record documentation that Elmiron is prescribed by a urologist or a gynecologist

MEDISPAN AUTHORIZATION LEVEL: GPI-12

If a formulary exception is approved, Elmiron will be paid for under the member's prescription drug benefit.

Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.

FORMULARY ALTERNATIVES:

none

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE
STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND
FEDERAL REGULATORY ENTITIES.**

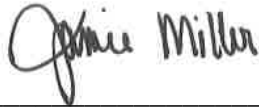
**THIS POLICY WILL BE REVISED AS NECESSARY AND
REVIEWED NO LESS THAN ANNUALLY.**

Geisinger

**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 63.0

**SECTION: Commercial Drug
SUBJECT: Elmiron**



Signed: _____

Title: Director, Pharmacy Services

Date: March 1, 2022

Devised: 4/02
Effective: 4/02
Revised: 7/02
Revised: 3/03
Revised: 3/04 – updated to reflect allowance of prescribing by a gynecologist
Revised: 3/05 – updated title
Revised: 3/06 – updated title
Reviewed: 3/07
Revised: 4/07 – added signature
Reviewed: 3/08 – annual review
Reviewed: 4/09 – annual review
Reviewed: 3/10 – annual review
Reviewed: 3/1/11 – annual review
Revised: 3/1/12 – annual review, updated signature
Revised: 3/1/13 – annual review, updated logo and definitions
Revised: 3/1/14 – annual review, updated formatting
Revised: 3/1/15 – annual review, updated signature
Revised: 3/1/16 – annual review, added formulary alternatives section
Revised: 5/1/16 – updated format, logo, & procedure
Reviewed: 3/1/17 – annual review
Revised: 3/1/18 – annual review, updated signature, updated prescriber formatting
Reviewed: 3/1/19 – annual review
Revised: 3/1/20- annual review, added GHP Kids
Revised: 3/1/21 – annual review, updated logo, added MediSpan approval level
Revised: 3/1/22 – annual review, updated referenced policies & covered LOBs



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 67.0

**SECTION: Commercial Drug
SUBJECT: Pimecrolimus Cream**

Applicable line of business:

Commercial	X	Medicaid	
Medicare		ACA	X
GHP Kids	X	Self-Insured	X

POLICY:

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for pimecrolimus cream for GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 487.0 Quantity Limit Exceptions

REQUIRED DEFINITIONS:

1. **Attachment** – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. **Exhibit** – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. **Devised** – the date the policy was implemented.
4. **Revised** – the date of every revision to the policy, including typographical and grammatical changes.
5. **Reviewed** – the date documenting the annual review if the policy has no revisions necessary.

ADDITIONAL DEFINITIONS:

1. **Formulary** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. **Non-formulary products** – those medications that are not included in the Formulary.
3. **Healthcare provider** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
4. **NCQA** – National Committee for Quality Assurance.
5. **Medically Necessary or Medical Necessity** – covered services rendered by a provider that the Health Plan determines are:



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 67.0

**SECTION: Commercial Drug
SUBJECT: Pimecrolimus Cream**

- A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
- B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
- C. In accordance with current standards of medical practice;
- D. Not primarily for the convenience of the Member, or the Member's Provider; and
- E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

PROCEDURE:

A formulary exception for coverage of pimecrolimus cream may be made for members who meet **all** of the following criteria:

- Medical record documentation of a diagnosis of atopic dermatitis **AND**
- Medical record documentation of contraindication to, intolerance to, or therapeutic failure on tacrolimus ointment **AND**
- Medical record documentation of contraindication to, intolerance to or therapeutic failure on at least two formulary topical corticosteroids unless deemed inadvisable due to potential risks such as (a) use on sensitive skin areas (face, axillae, or groin) **or** (b) patient is between 2 and 15 years of age

MEDISPAN AUTHORIZATION LEVEL: GPI-12

If a formulary exception is approved, pimecrolimus cream will be paid for under the member's prescription drug benefit.

Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.

FORMULARY ALTERNATIVES:

tacrolimus ointment

Low-potency topical corticosteroids: alclometasone dipropionate 0.5% cream and ointment (Acloivate); fluocinolone acetonide 0.01% soln. (Synalar); hydrocortisone 2.5% cream, ointment, and lotion (Hytone)

Medium-potency topical corticosteroids: betamethasone valerate 0.1% cream (Valisone); fluocinolone acetonide 0.025% cream and ointment (Synalar); fluticasone propionate 0.05% cream, ointment, and lotion (Cutivate); triamcinolone 0.1% cream, ointment and lotion



POLICY NUMBER: 67.0

POLICY AND PROCEDURE
PHARMACY
MANUAL

SECTION: Commercial Drug
SUBJECT: Pimecrolimus Cream

(Kenalog); triamcinolone acetonide 0.025% cream, ointment and lotion (Kenalog);
triamcinolone acetonide 0.147 mg/g aerosol (Kenalog Spray)

High-potency topical corticosteroids: augmented betamethasone dipropionate 0.05%
cream (Diprolene AF); betamethasone valerate 0.1% ointment (Valisone); triamcinolone
0.5% cream (Kenalog); fluocinonide 0.05% cream, ointment and gel (Lidex)

Very high-potency topical corticosteroids: augmented betamethasone dipropionate
0.05% ointment, gel and lotion (Diprolene); clobetasol 0.05% cream, ointment, and scalp
lotion (Temovate) diflorasone diacetate 0.05% cream and ointment (ApexiCon/Psorcon)

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE
STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND
FEDERAL REGULATORY ENTITIES.**

**THIS POLICY WILL BE REVISED AS NECESSARY AND
REVIEWED NO LESS THAN ANNUALLY.**

Signed: _____

Title: Director, Pharmacy Services

Date: March 1, 2022

Devised: 4/02
Effective: 4/02
Revised: 7/02
Revised: 3/03
Reviewed: 3/04
Revised: 10/04 – added Protopic ointment to the policy
Reviewed: 3/05
Revised: 3/06 – updated title
Reviewed: 3/07
Revised: 4/07 – added signature
Reviewed: 3/08 – annual review
Reviewed: 4/09 – annual review
Revised: 4/09 – updated criteria
Reviewed: 3/10 – annual review
Reviewed: 3/1/11 – annual review
Revised: 3/1/12 – annual review, updated signature
Revised: 3/1/13 – annual review, updated logo and definitions
Revised: 3/1/14 – annual review, updated formatting, corrected typo
Revised: 12/1/14 – removed requirement that RX be written by a specialist, updated signature
Revised: 3/1/15 – annual review, changed Protopic to Tacrolimus, removed **AND** from second criterion

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Dev. 4/02
Rev. 3/1/22

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**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 67.0

**SECTION: Commercial Drug
SUBJECT: Pimecrolimus Cream**

Reviewed: 3/1/16 – annual review
Revised: 5/1/16 – updated format, logo, & procedure
Revised: 3/1/17 – annual review, updated FA
Revised: 8/8/17 – removed PA from tac. oint, added failure of tac. oint to Elidel, updated FA
Revised: 3/1/18 – annual review, updated signature
Reviewed: 3/1/19 – annual review
Revised: 11/21/19 – renamed Elidel to generic pimecrolimus
Revised: 3/1/20 – annual review, added GHP Kids
Revised: 3/1/21 – annual review, updated logo, added MediSpan approval level
Revised: 3/1/22 – annual review, updated referenced policies & covered LOBs



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 71.0

**SECTION: Commercial Drug
SUBJECT: Kineret**

Applicable line of business:

Commercial	X	Medicaid	
Medicare		ACA	X
GHP Kids	X	Self-Insured	X

POLICY:

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for Kineret for GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 487.0 Quantity Limit Exceptions

REQUIRED DEFINITIONS:

1. **Attachment** – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. **Exhibit** – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. **Devised** – the date the policy was implemented.
4. **Revised** – the date of every revision to the policy, including typographical and grammatical changes.
5. **Reviewed** – the date documenting the annual review if the policy has no revisions necessary.

ADDITIONAL DEFINITIONS:

1. **Formulary** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. **Non-formulary products** – those medications that are not included in the Formulary.
3. **Healthcare provider** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
4. **NCQA** – National Committee for Quality Assurance.
5. **Medically Necessary or Medical Necessity** – covered services rendered by a provider that the Health Plan determines are:

- A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
- B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
- C. In accordance with current standards of medical practice;
- D. Not primarily for the convenience of the Member, or the Member's Provider; and
- E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

PROCEDURE:

New members to the plan already established on therapy may be eligible for continuity of care coverage as long as there is medical record documentation that the safety and effectiveness of use for the prescribed indication is supported by Food and Drug Administration (FDA) approval or adequate medical and scientific evidence in the medical literature.

For Rheumatoid Arthritis:

A formulary exception for coverage of Kineret may be made for members who meet all of the following criteria:

- Medical record documentation of a diagnosis of moderate to severe rheumatoid arthritis made in accordance with the American College of Rheumatology Criteria for the Classification and Diagnosis of Rheumatoid Arthritis **AND**
- Medical record documentation of age greater than or equal to 18 years **AND**
- Medical record documentation that Kineret is prescribed by a rheumatologist **AND**
- Medical record documentation of therapeutic failure on, intolerance to, or contraindication to a minimum 3 month trial of Humira*, Rinvoq*, **OR** Xeljanz* **AND**
- Medical record documentation that Kineret is not being used concurrently with a tumor necrosis factor (TNF) blocker or other biologic agent

MEDISPAN AUTHORIZATION LEVEL: GPI-12

QUANTITY LIMIT: *QLs must be entered within the authorization. Start date is the same for both authorizations.*

1. In PA Hub: Add PA, number of claims authorized = 1, enter for the remainder of the calendar year
2. In Darwin: Add OQL, DS max quantity dispensed 0.67, min day supply 28, max day supply 28, with an end date of 12/31/2099



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 71.0

**SECTION: Commercial Drug
SUBJECT: Kineret**

- QL FOR LETTER: 0.67 ml per day, 28 day supply per fill

RE-AUTHORIZATION CRITERIA: Kineret is configured as a prior authorization for new starts only. Kineret will no longer be covered if it is identified that the member is not receiving appropriate follow-up care from the prescribing specialist or if the member has greater than or equal to a 90 day break in therapy.

- Medical record documentation that the member is receiving appropriate follow-up care from the prescribing specialist

FORMULARY ALTERNATIVES:

Humira*, Rinvoq*, Xeljanz*

*prior authorization required



POLICY NUMBER: 71.0

**POLICY AND PROCEDURE
PHARMACY
MANUAL**

**SECTION: Commercial Drug
SUBJECT: Kineret**

For Neonatal-Onset Multisystem Inflammatory Disease

A formulary exception for coverage of Kineret may be made for members who meet all of the following criteria:

- Medical record documentation of diagnosis of Neonatal-Onset Multisystem Inflammatory Disease (NOMID) **AND**
- Medical record documentation that Kineret is prescribed by an immunologist, rheumatologist, or allergist

MEDISPAN AUTHORIZATION LEVEL: GPI-12, number of claims authorized = 1, enter for the remainder of the calendar year

RE-AUTHORIZATION CRITERIA: Kineret is configured as a prior authorization for new starts only. Kineret will no longer be covered if it is identified that the member is not receiving appropriate follow-up care from the prescribing specialist or if the member has greater than or equal to a 90 day break in therapy.

- Medical record documentation that the member is receiving appropriate follow-up care from the prescribing specialist

FORMULARY ALTERNATIVES:

none



POLICY NUMBER: 71.0

**POLICY AND PROCEDURE
PHARMACY
MANUAL**

**SECTION: Commercial Drug
SUBJECT: Kineret**

For Cryopyrin-Associated Periodic Syndrome (CAPS)

A formulary exception for coverage of Kineret may be made for members who meet all of the following criteria:

- Medical record documentation of diagnosis of Cryopyrin–Associated Periodic Syndrome (CAPS), including Familial Cold Autoinflammatory Syndrome (FCAS), and Muckle-Wells Syndrome (MWS) supported by documentation of genetic testing to identify the CIAS1/NLRP-3 gene mutation **AND**
- Medical record documentation that Kineret is prescribed by an immunologist, rheumatologist, or allergist

MEDISPAN AUTHORIZATION LEVEL: GPI-12, number of claims authorized = 1, enter for the remainder of the calendar year

RE-AUTHORIZATION CRITERIA: Kineret is configured as a prior authorization for new starts only. Kineret will no longer be covered if it is identified that the member is not receiving appropriate follow-up care from the prescribing specialist or if the member has greater than or equal to a 90 day break in therapy.

- Medical record documentation that the member is receiving appropriate follow-up care from the prescribing specialist

FORMULARY ALTERNATIVES:

none



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 71.0

**SECTION: Commercial Drug
SUBJECT: Kineret**

For Deficiency of Interleukin-1 Receptor Antagonist (DIRA)

A formulary exception for coverage of Kineret may be made for members who meet all of the following criteria:

- Medical record documentation of a diagnosis of Deficiency of Interleukin-1 Receptor Antagonist (DIRA) supported by documentation of a homozygous or compound heterozygous mutation in IL1RN (Interleukin 1 Receptor Antagonist gene) **AND**
- Medical record documentation that Kineret is prescribed by or in consultation with a rheumatologist, geneticist, dermatologist, or a physician specializing in the treatment of autoinflammatory disorders

MEDISPAN AUTHORIZATION LEVEL: GPI-12, number of claims authorized = 1, enter for the remainder of the calendar year

RE-AUTHORIZATION CRITERIA: Kineret is configured as a prior authorization for new starts only. Kineret will no longer be covered if it is identified that the member is not receiving appropriate follow-up care from the prescribing specialist or if the member has greater than or equal to a 90 day break in therapy.

- Medical record documentation that the member is receiving appropriate follow-up care from the prescribing specialist

FORMULARY ALTERNATIVES:

none

If a formulary exception is approved, Kineret will be paid for under the member's prescription drug benefit.

Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE
STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND
FEDERAL REGULATORY ENTITIES.**

**THIS POLICY WILL BE REVISED AS NECESSARY AND
REVIEWED NO LESS THAN ANNUALLY.**



Signed: _____

Title: Director, Pharmacy Services

Date: March 1, 2022

Devised: 7/02
Effective: 7/02
Revised: 12/02
Revised: 3/03
Reviewed: 3/04
Revised: 3/05 – updated title
Revised: 10/05 – updated for generic Arava availability
Revised: 3/06 – updated title
Reviewed: 3/07
Revised: 4/07 – added signature
Reviewed: 3/08 – annual review
Revised: 5/08 – updated criteria
Reviewed: 4/09 – annual review
Reviewed: 3/10 – annual review
Reviewed: 3/1/11 – annual review
Revised: 3/1/12 – annual review, updated sig
Revised: 9/17/12 – updated authorization duration and file location
Revised: 3/1/13 – annual review, updated logo and definitions
Revised: 5/4/13 – added NOMID indication
Revised: 3/1/14 – annual review, fixed typo, updated formatting
Revised: 3/20/14 – updated RA criteria to require failure on Humira and Enbrel specifically
Revised: 9/22/14 – updated RA clinical & alternative criteria, updated RA auth duration wording, & updated FA to include only Humira & Cimzia, updated signature
Revised: 2/9/15 – updated RA criteria to require failure on Enbrel instead of Cimzia, added approval statement
Reviewed: 3/1/15 – annual review
Revised: 9/19/15 – removed joint count criteria from initial and renewal requirements
Revised: 3/1/16 – annual review, updated policy format to improve readability
Revised: 5/1/16 – updated format, logo, & procedure
Reviewed: 3/1/17 – annual review
Revised: 3/27/17 – removed COE requirement from NOMID
Revised: 6/2/17 – updated format, added CAPS, added auth duration to NOMID
Revised: 3/1/18 – annual review, updated signature, added grandfather language, updated formatting
Revised: 10/1/18 – removed failure of Enbrel, updated FA, added concurrent biologic crit. (RA)
Revised: 3/1/19 – annual review, corrected typo, defined TNF
Revised: 5/29/19 – added QL to RA indication
Revised: 1/28/20 – updated RA FA and added failure of Rinvoq and Xeljanz
Revised: 3/1/20 – annual review, added GHP Kids
Revised: 3/1/21 – annual review, updated logo, added MediSpan approval level, updated QL statement
Revised: 9/1/21 – corrected typo in CAPS header, added DIRA indication



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 71.0

**SECTION: Commercial Drug
SUBJECT: Kineret**

- Revised: 12/2/21 – added one-time PA to approval crit., removed auth duration & added re-auth crit., updated QL auth entry to account for PA NSO
- Revised: 3/1/22 – annual review, updated referenced policies & covered LOBs, updated RA QL entry



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 72.0

**SECTION: Commercial Drug
SUBJECT: Actimmune**

Applicable line of business:

Commercial	X	Medicaid	
Medicare		ACA	X
GHP Kids	X	Self-Insured	X

POLICY:

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for Actimmune for GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 487.0 Quantity Limit Exceptions

REQUIRED DEFINITIONS:

1. **Attachment** – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. **Exhibit** – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. **Devised** – the date the policy was implemented.
4. **Revised** – the date of every revision to the policy, including typographical and grammatical changes.
5. **Reviewed** – the date documenting the annual review if the policy has no revisions necessary.

ADDITIONAL DEFINITIONS:

1. **Formulary** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. **Non-formulary products** – those medications that are not included in the Formulary.
3. **Healthcare provider** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
4. **NCQA** – National Committee for Quality Assurance.
5. **Medically Necessary or Medical Necessity** – covered services rendered by a provider that the Health Plan determines are:



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 72.0

**SECTION: Commercial Drug
SUBJECT: Actimmune**

- A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
- B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
- C. In accordance with current standards of medical practice;
- D. Not primarily for the convenience of the Member, or the Member's Provider; and
- E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

PROCEDURE:

An exception for coverage of Actimmune may be made for members who meet the following criterion:

- Medical record documentation of a diagnosis of chronic granulomatous disease **OR** osteopetrosis

MEDISPAN AUTHORIZATION LEVEL: GPI-12

If an exception is made, Actimmune will be paid for under the member's prescription drug benefit.

Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.

FORMULARY ALTERNATIVES:

none

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE
STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND
FEDERAL REGULATORY ENTITIES.**

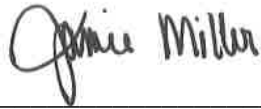
**THIS POLICY WILL BE REVISED AS NECESSARY AND
REVIEWED NO LESS THAN ANNUALLY.**

Geisinger

**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 72.0

**SECTION: Commercial Drug
SUBJECT: Actimmune**



Signed: _____

Title: Director, Pharmacy Services

Date: March 1, 2022

Devised: 10/02
Effective: 10/02
Revised: 3/03
Reviewed: 3/04
Revised: 3/05 – updated title
Revised: 3/06 – updated title
Reviewed: 3/07
Revised: 4/07 – added signature
Reviewed: 3/08 – annual review
Reviewed: 4/09 – annual review
Reviewed: 3/10 – annual review
Reviewed: 3/1/11 – annual review
Revised: 3/1/12 – annual review
Revised: 3/1/13 – annual review, updated logo and definitions
Revised: 3/1/14 – annual review, updated formatting
Revised: 3/1/15 – annual review, updated signature
Reviewed: 3/1/16 – annual review
Revised: 5/1/16 – updated format, logo, & procedure
Reviewed: 3/1/17 – annual review
Revised: 3/1/18 – annual review, updated signature, updated formatting
Reviewed: 3/1/19 – annual review
Revised: 3/1/20 – annual review, added GHP Kids
Revised: 3/1/21 – annual review, updated logo, added MediSpan approval level
Revised: 3/1/22 – annual review, updated referenced policies & covered LOBs



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 73.0

**SECTION: Commercial Drug
SUBJECT: Sirolimus**

Applicable line of business:

Commercial	X	Medicaid	
Medicare		ACA	X
GHP Kids	X	Self-Insured	X

POLICY:

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for sirolimus for GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 487.0 Quantity Limit Exceptions

REQUIRED DEFINITIONS:

1. **Attachment** – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. **Exhibit** – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. **Devised** – the date the policy was implemented.
4. **Revised** – the date of every revision to the policy, including typographical and grammatical changes.
5. **Reviewed** – the date documenting the annual review if the policy has no revisions necessary.

ADDITIONAL DEFINITIONS:

1. **Formulary** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. **Non-formulary products** – those medications that are not included in the Formulary.
3. **Healthcare provider** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
4. **NCQA** – National Committee for Quality Assurance.
5. **Medically Necessary or Medical Necessity** – covered services rendered by a provider that the Health Plan determines are:



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 73.0

**SECTION: Commercial Drug
SUBJECT: Sirolimus**

- A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
- B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
- C. In accordance with current standards of medical practice;
- D. Not primarily for the convenience of the Member, or the Member's Provider; and
- E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

PROCEDURE:

New members to the plan already established on therapy may be eligible for continuity of care coverage as long as there is medical record documentation that the safety and effectiveness of use for the prescribed indication is supported by Food and Drug Administration (FDA) approval or adequate medical and scientific evidence in the medical literature.

An exception for coverage of sirolimus may be made for members who meet **all** of the following criteria:

- Medical record documentation of age greater than or equal to 13 years **AND**
- Medical record documentation of a renal transplant

OR

- Medical record documentation of a diagnosis of lymphangioleiomyomatosis

OR

- Medical record documentation of use for graft versus host disease prophylaxis **AND**
- Medical record documentation of treatment with a calcineurin inhibitors **AND** one of the following:
 - Medical record documentation of therapeutic failure on, intolerance to, or contraindication to methotrexate or mycophenolate mofetil **OR**
 - Use of triple therapy with a calcineurin inhibitor, methotrexate or mycophenolate mofetil, and sirolimus

MEDISPAN AUTHORIZATION LEVEL: GPI-10, generic only



POLICY NUMBER: 73.0

**POLICY AND PROCEDURE
PHARMACY
MANUAL**

**SECTION: Commercial Drug
SUBJECT: Sirolimus**

If an exception is made, sirolimus will be paid for under the member's prescription drug benefit.

Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.

FORMULARY ALTERNATIVES:

Renal Transplant: azathioprine, cyclosporine, mycophenolate, tacrolimus
Graft versus Host Disease: methotrexate, mycophenolate mofetil

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE
STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND
FEDERAL REGULATORY ENTITIES.**

**THIS POLICY WILL BE REVISED AS NECESSARY AND
REVIEWED NO LESS THAN ANNUALLY.**

Signed: _____

Title: Director, Pharmacy Services

Date: March 1, 2022

- Devised: 10/02
- Effective: 10/02
- Revised: 3/03
- Reviewed: 3/04
- Revised: 3/05 – updated title
- Revised: 3/06 – updated title
- Reviewed: 3/07
- Revised: 4/07 – added signature
- Reviewed: 3/08 – annual review
- Reviewed: 4/09 – annual review
- Revised: 3/10 – annual review, updated alternatives
- Reviewed: 3/1/11 – annual review
- Revised: 3/1/12 – annual review, updated signature & alternatives
- Revised: 3/1/13 – annual review, updated logo and definitions
- Revised: 3/1/14 – annual review, updated formatting
- Revised: 3/1/15 – annual review, added sirolimus tablets to policy, updated signature
- Revised: 7/22/15 – added lymphangioleiomyomatosis indication, updated formulary alternatives



POLICY NUMBER: 73.0

**POLICY AND PROCEDURE
PHARMACY
MANUAL**

**SECTION: Commercial Drug
SUBJECT: Sirolimus**

Reviewed: 3/1/16 – annual review
Revised: 5/1/16 – updated format, logo, & procedure
Reviewed: 3/1/17 – annual review
Revised: 3/1/18 – annual review, updated signature, added grandfather language, updated formatting
Reviewed: 3/1/19 – annual review
Revised: 3/1/20 – annual review, added GHP Kids
Revised: 6/9/20 – added GVHD prophylaxis
Revised: 3/1/21 – annual review, updated logo, added MediSpan approval level, updated all references to Rapamune solution to generic
Revised: 3/1/22 – annual review, updated referenced policies & covered LOBs



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 81.0

**SECTION: Commercial Drug
SUBJECT: Zelnorm**

Applicable line of business:

Commercial	X	Medicaid	
Medicare		ACA	X
GHP Kids	X	Self-Insured	X

POLICY:

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for Zelnorm for GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 487.0 Quantity Limit Exceptions

REQUIRED DEFINITIONS:

1. **Attachment** – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. **Exhibit** – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. **Devised** – the date the policy was implemented.
4. **Revised** – the date of every revision to the policy, including typographical and grammatical changes.
5. **Reviewed** – the date documenting the annual review if the policy has no revisions necessary.

ADDITIONAL DEFINITIONS:

1. **Formulary** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. **Non-formulary products** – those medications that are not included in the Formulary.
3. **Healthcare provider** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
4. **NCQA** – National Committee for Quality Assurance.
5. **Medically Necessary or Medical Necessity** – covered services rendered by a provider that the Health Plan determines are:

- A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
- B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
- C. In accordance with current standards of medical practice;
- D. Not primarily for the convenience of the Member, or the Member's Provider; and
- E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

PROCEDURE:

An exception for coverage of Zelnorm may be made for members who meet the following criteria:

- Medical record documentation of a diagnosis of irritable bowel syndrome with constipation (IBS-D) **AND**
- Medical record documentation that member is a female between the ages of 18 and 65 years **AND**
- Medical record documentation of therapeutic failure on, intolerance to, or contraindication to lubiprostone **AND** Linzess

MEDISPAN AUTHORIZATION LEVEL: GPI-12

QUANTITY LIMIT: *No QLs need to be entered within the authorization unless the requested quantity exceeds the QL.*

- **QL FOR LETTER ONLY:** 2 tablets per day

If a formulary exception is approved, Zelnorm will be paid for under the member's prescription drug benefit.

Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.

FORMULARY ALTERNATIVES:

lubiprostone, Linzess

Geisinger

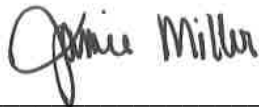
**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 81.0

**SECTION: Commercial Drug
SUBJECT: Zelnorm**

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE
STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND
FEDERAL REGULATORY ENTITIES.**

**THIS POLICY WILL BE REVISED AS NECESSARY AND
REVIEWED NO LESS THAN ANNUALLY.**



Signed: _____

Title: Director, Pharmacy Services

Date: March 1, 2022

Devised:	01/03
Effective:	01/03
Revised:	03/03
Reviewed:	03/04
Revised:	03/05- updated title
Revised:	03/06-updated title
Revised:	03/07-updated formulary alternatives
Revised:	05/07 – added signature
Retired:	03/08 – drug removed from market
Reinstated:	10/1/19 – reinstated with new criteria due to reintroduction to market
Revised:	3/1/20 – annual review, added GHP Kids
Revised:	3/1/21 – annual review, updated logo, added MediSpan approval level, updated QL statement, updated Amitiza to generic
Revised:	3/1/22 – annual review, updated referenced policies & covered LOBs



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 83.0

**SECTION: Commercial Drug
SUBJECT: Lumigan**

Applicable line of business:

Commercial	X	Medicaid	
Medicare		ACA	X
GHP Kids	X	Self-Insured	X

POLICY:

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for Lumigan for GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 487.0 Quantity Limit Exceptions

REQUIRED DEFINITIONS:

1. **Attachment** – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. **Exhibit** – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. **Devised** – the date the policy was implemented.
4. **Revised** – the date of every revision to the policy, including typographical and grammatical changes.
5. **Reviewed** – the date documenting the annual review if the policy has no revisions necessary.

ADDITIONAL DEFINITIONS:

1. **Formulary** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. **Non-formulary products** – those medications that are not included in the Formulary.
3. **Healthcare provider** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
4. **NCQA** – National Committee for Quality Assurance.
5. **Medically Necessary or Medical Necessity** – covered services rendered by a provider that the Health Plan determines are:



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 83.0

**SECTION: Commercial Drug
SUBJECT: Lumigan**

- A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
- B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
- C. In accordance with current standards of medical practice;
- D. Not primarily for the convenience of the Member, or the Member's Provider; and
- E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

PROCEDURE:

An exception for coverage of Lumigan may be made for members who meet the following criteria:

- Electronic step therapy of on-line prescription drug claims history showing 15 days use of latanoprost (generic Xalatan), Zioptan, **AND** travoprost within the previous 180 days. If this electronic step is met, the claim will automatically adjudicate **OR**
- Medical record documentation of intolerance to, contraindication to, or therapeutic failure on latanoprost (generic Xalatan), Zioptan, **AND** travoprost

MEDISPAN AUTHORIZATION LEVEL: GPI-12

If an exception is made, Lumigan will be paid for under the member's prescription drug benefit.

Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.

FORMULARY ALTERNATIVES:

latanoprost (generic Xalatan), travoprost, Zioptan*

*prior authorization required

Geisinger

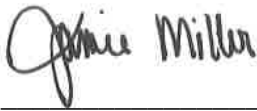
**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 83.0

**SECTION: Commercial Drug
SUBJECT: Lumigan**

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE
STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND
FEDERAL REGULATORY ENTITIES.**

**THIS POLICY WILL BE REVISED AS NECESSARY AND
REVIEWED NO LESS THAN ANNUALLY.**



Signed: _____

Title: Director, Pharmacy Services

Date: March 1, 2022

Devised: 1/03
Effective: 1/03
Revised: 3/03
Reviewed: 3/04
Revised: 3/05 – updated title
Revised: 3/06 – updated title
Reviewed: 3/07
Revised: 5/07 – added signature
Reviewed: 3/08 – annual review
Reviewed: 4/09 – annual review
Reviewed: 3/10 – annual review
Reviewed: 3/1/11 – annual review
Revised: 3/1/12 – annual review, updated signature & alternatives
Revised: 7/18/12 – added Zioptan to policy, changed Travatan to Travatan Z
Revised: 3/1/13 – annual review, updated logo and definitions
Revised: 7/29/13 – updated alternatives to include travoprost
Reviewed: 3/1/14 – annual review
Revised: 3/1/15 – annual review, updated signature
Reviewed: 3/1/16 – annual review
Revised: 5/1/16 – updated format, logo, & procedure
Reviewed: 3/1/17 – annual review
Revised: 12/22/17 – removed Rescula (obsolete), updated signature
Reviewed: 3/1/18 – annual review
Revised: 5/30/18 – removed travoprost
Revised: 8/21/18 – removed PA from Zioptan, updated Lumigan to step, added failure of Zioptan, updated FA
Reviewed: 3/1/19 – annual review
Revised: 3/1/20 – annual review, added GHP Kids
Revised: 3/1/21 – annual review, updated logo, added MediSpan approval level, updated Travatan to generic, updated formulary alternatives



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 83.0

**SECTION: Commercial Drug
SUBJECT: Lumigan**

Revised: 3/1/22 – annual review, updated referenced policies & covered LOBs



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 84.0

**SECTION: Commercial Drug
SUBJECT: Humira**

Applicable line of business:

Commercial	X	Medicaid	
Medicare		ACA	X
GHP Kids	X	Self-Insured	X

POLICY:

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for Humira for GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 487.0 Quantity Limit Exceptions

REQUIRED DEFINITIONS:

1. **Attachment** – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. **Exhibit** – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. **Devised** – the date the policy was implemented.
4. **Revised** – the date of every revision to the policy, including typographical and grammatical changes.
5. **Reviewed** – the date documenting the annual review if the policy has no revisions necessary.

ADDITIONAL DEFINITIONS:

1. **Formulary** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. **Non-formulary products** – those medications that are not included in the Formulary.
3. **Healthcare provider** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
4. **NCQA** – National Committee for Quality Assurance.
5. **Medically Necessary or Medical Necessity** – covered services rendered by a provider that the Health Plan determines are:



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 84.0

**SECTION: Commercial Drug
SUBJECT: Humira**

- A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
- B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
- C. In accordance with current standards of medical practice;
- D. Not primarily for the convenience of the Member, or the Member's Provider; and
- E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

PROCEDURE:

New members to the plan already established on therapy may be eligible for continuity of care coverage as long as there is medical record documentation that the safety and effectiveness of use for the prescribed indication is supported by Food and Drug Administration (FDA) approval or adequate medical and scientific evidence in the medical literature.

For Adult Rheumatoid Arthritis

An exception for coverage of **BIWEEKLY (every other week) administration** of Humira (which is self-administered) may be made for members who meet all the following criteria:

- Medical record documentation of a diagnosis of moderate to severe rheumatoid arthritis (made in accordance with the American College of Rheumatology Criteria for the Classification and Diagnosis of Rheumatoid Arthritis) **AND**
- Medical record documentation that Humira is prescribed by a rheumatologist **AND**
- Medical record documentation of an inadequate response to a minimum 3 month trial of methotrexate or other disease modifying anti-rheumatic drug (DMARD) if methotrexate is not tolerated or contraindicated **OR** medical record documentation of a therapeutic failure on or intolerance to prior biologic therapy **AND**
- Medical record documentation of age greater than or equal to 18 years **AND**
- Medical record documentation that Humira is not being used concurrently with a tumor necrosis factor (TNF) blocker or other biologic agent

An exception for coverage of **WEEKLY administration** of Humira (which is self-administered) may be made for members who meet the following criteria:

- Medical record documentation of a diagnosis of moderate to severe rheumatoid arthritis (made in accordance with the American College of Rheumatology Criteria for the Classification and Diagnosis of Rheumatoid Arthritis) **AND**
- Medical record documentation that Humira is prescribed by a rheumatologist **AND**
- Medical record documentation of age greater than or equal to 18 years **AND**
- Medical record documentation of an inadequate response to a minimum 3 month trial of methotrexate or other disease modifying anti-rheumatic drug (DMARD) if methotrexate is not tolerated or contraindicated **OR** medical record documentation of a therapeutic failure on or intolerance to prior biologic therapy **AND**
- Medical record documentation that the member has been compliant with BIWEEKLY administration of Humira **AND**
- Medical record documentation of a contraindication to, intolerance to, or therapeutic failure on BIWEEKLY (every other week) administration of Humira **AND**
- Medical record documentation that Humira is not being used concurrently with a tumor necrosis factor (TNF) blocker or other biologic agent

RE-AUTHORIZATION CRITERIA: Humira is configured as a prior authorization for new starts only. Humira will no longer be covered if it is identified that the member is not receiving appropriate follow-up care from the prescribing specialist or if the member has greater than or equal to a 90 day break in therapy.

- Medical record documentation that the member is receiving appropriate follow-up care from the prescribing specialist

MEDISPAN AUTHORIZATION LEVEL: GPI-10

QUANTITY LIMIT: *QLs must be entered within the authorization. Start date is the same for both authorizations.*

- **Biweekly Dosing**
 1. In PA Hub: Add PA, number of claims authorized 1, enter for the remainder of the calendar year
 2. In Darwin: Add OQL, DS, max quantity dispensed 2, max day supply 28, min day supply 28, with an end date of 12/31/2099
 - QL FOR LETTER: 2 per 28 days
- **Weekly Dosing –**
 1. In PA Hub: Add PA, number of claims authorized 1, enter for the remainder of the calendar year
 2. In Darwin: Add OQL, DS, max quantity dispensed 4, max day supply 28, min day supply 28, with an end date of 12/31/2099

Geisinger

**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 84.0

**SECTION: Commercial Drug
SUBJECT: Humira**

- **QL FOR LETTER: 4 per 28 days**

FORMULARY ALTERNATIVES:

azathioprine, cyclosporine, hydroxychloroquine, methotrexate, sulfasalazine, leflunomide, Depen, Ridaura

For treatment of polyarticular juvenile idiopathic arthritis or juvenile rheumatoid arthritis

An exception for coverage of **BIWEEKLY (every other week) administration** of Humira (which is self-administered) may be made for members who meet all the following criteria:

- Medical record documentation of age greater than or equal to 2 years **AND**
- Medical record documentation that Humira is prescribed by a rheumatologist **AND**
- Medical record documentation of a diagnosis of active polyarticular juvenile idiopathic arthritis or juvenile rheumatoid arthritis **AND**
- Medical record documentation of an inadequate response to a minimum 3 month trial of both nonsteroidal anti-inflammatory drug (NSAID) therapy **AND** methotrexate or other disease modifying anti-rheumatic drug (DMARD) if methotrexate therapy is contraindicated **OR** medical record documentation of a therapeutic failure on or intolerance to prior biologic therapy
- Medical record documentation that Humira is being dosed at a maximum of 40 mg every other week **OR** medical record documentation of peer-reviewed literature citing well-designed clinical trials to indicate that the member's healthcare outcome will be improved by dosing that exceeds Food and Drug Administration (FDA) approved labeling **AND**
- Medical record documentation that Humira is not being used concurrently with a tumor necrosis factor (TNF) blocker or other biologic agent

RE-AUTHORIZATION CRITERIA: Humira is configured as a prior authorization for new starts only. Humira will no longer be covered if it is identified that the member is not receiving appropriate follow-up care from the prescribing specialist or if the member has greater than or equal to a 90 day break in therapy.

- Medical record documentation that the member is receiving appropriate follow-up care from the prescribing specialist

MEDISPAN AUTHORIZATION LEVEL: GPI-10

QUANTITY LIMIT: *QLs must be entered within the authorization.*

- **Biweekly Dosing**
 1. In PA Hub: Add PA, number of claims authorized 1, enter for the remainder of the calendar year
 2. In Darwin: Add OQL, DS, max quantity dispensed 2, max day supply 28, min day supply 28, with an end date of 12/31/2099
 - QL FOR LETTER: 2 per 28 days

Geisinger

**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 84.0

**SECTION: Commercial Drug
SUBJECT: Humira**

FORMULARY ALTERNATIVES:
methotrexate, sulfasalazine

For Psoriatic Arthritis

An exception for coverage of **BIWEEKLY (every other week) administration** of Humira (which is self-administered) may be made for members who meet all the following criteria:

- Medical record documentation of a diagnosis of moderately to severely active psoriatic arthritis which must include the following:
 - Documentation of either active psoriatic lesions or a documented history of psoriasis **AND**
- Medical record documentation that Humira is prescribed by a rheumatologist or dermatologist **AND**
- Medical record documentation of age greater than or equal to 18 years **AND**
- **For peripheral disease**: Medical record documentation of an intolerance to, contraindication to, or therapeutic failure on methotrexate **AND** an adequate trial of at least two (2) formulary nonsteroidal anti-inflammatory drugs (NSAIDs) **OR** medical record documentation of a therapeutic failure on or intolerance to prior biologic therapy **OR**
- **For axial disease**: Medical record documentation of an intolerance to, contraindication to, or therapeutic failure to an adequate trial of at least two (2) formulary nonsteroidal anti-inflammatory drugs (NSAIDs) **OR** medical record documentation of a therapeutic failure on or intolerance to prior biologic therapy **AND**
- Medical record documentation that Humira is being dosed at a maximum of 40 mg every other week **OR** medical record documentation of peer-reviewed literature citing well-designed clinical trials to indicate that the member's healthcare outcome will be improved by dosing that exceeds Food and Drug Administration (FDA) approved labeling **AND**
- Medical record documentation that Humira is not being used concurrently with a tumor necrosis factor (TNF) blocker or other biologic agent

RE-AUTHORIZATION CRITERIA: Humira is configured as a prior authorization for new starts only. Humira will no longer be covered if it is identified that the member is not receiving appropriate follow-up care from the prescribing specialist or if the member has greater than or equal to a 90 day break in therapy.

- Medical record documentation that the member is receiving appropriate follow-up care from the prescribing specialist

MEDISPAN AUTHORIZATION LEVEL: GPI-10

Geisinger

**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 84.0

**SECTION: Commercial Drug
SUBJECT: Humira**

QUANTITY LIMIT: *QLs must be entered within the authorization.*

- **Biweekly Dosing**

1. In PA Hub: Add PA, number of claims authorized 1, enter for the remainder of the calendar year
2. In Darwin: Add OQL, DS, max quantity dispensed 2, max day supply 28, min day supply 28, with an end date of 12/31/2099
 - QL FOR LETTER: 2 per 28 days

FORMULARY ALTERNATIVES:

methotrexate, celecoxib, choline magnesium salicylate, diclofenac, diclofenac extended release, diflunisal, etodolac, etodolac extended release, fenoprofen, flurbiprofen, ibuprofen, indomethacin, indomethacin sustained release, ketoprofen, ketorolac, meclofenamate, meloxicam, nabumetone, naproxen, naproxen sodium, naproxen EC, oxaprozin, piroxicam, salsalate, sulindac, tolmetin

For Ankylosing Spondylitis

An exception for coverage of **BIWEEKLY (every other week) administration** of Humira (which is self-administered) may be made for members who meet all the following criteria:

- Medical record documentation that Humira is prescribed by a rheumatologist **AND**
- Medical record documentation of age greater than or equal to 18 years **AND**
- Medical record documentation of a diagnosis of ankylosing spondylitis **AND**
- Physician documentation of a therapeutic failure on, contraindication to, or intolerance to an adequate trial of at least two (2) nonsteroidal anti-inflammatory drugs (NSAIDS) **OR** medical record documentation of a therapeutic failure on or intolerance to prior biologic therapy
- Medical record documentation that Humira is being dosed at a maximum of 40 mg every other week **OR** medical record documentation of peer-reviewed literature citing well-designed clinical trials to indicate that the member's healthcare outcome will be improved by dosing that exceeds Food and Drug Administration (FDA) approved labeling **AND**
- Medical record documentation that Humira is not being used concurrently with a tumor necrosis factor (TNF) blocker or other biologic agent

RE-AUTHORIZATION CRITERIA: Humira is configured as a prior authorization for new starts only. Humira will no longer be covered if it is identified that the member is not receiving appropriate follow-up care from the prescribing specialist or if the member has greater than or equal to a 90 day break in therapy.

- Medical record documentation that the member is receiving appropriate follow-up care from the prescribing specialist

MEDISPAN AUTHORIZATION LEVEL: GPI-10

QUANTITY LIMIT: *QLs must be entered within the authorization.*

- **Biweekly Dosing**
 1. In PA Hub: Add PA, number of claims authorized 1, enter for the remainder of the calendar year
 2. In Darwin: Add OQL, DS, max quantity dispensed 2, max day supply 28, min day supply 28, with an end date of 12/31/2099
 - QL FOR LETTER: 2 per 28 days



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 84.0

**SECTION: Commercial Drug
SUBJECT: Humira**

FORMULARY ALTERNATIVES:

celecoxib, choline magnesium salicylate, diclofenac, diclofenac extended release, diflunisal, etodolac, etodolac extended release, fenoprofen, flurbiprofen, ibuprofen, indomethacin, indomethacin sustained release, ketoprofen, ketorolac, meclufenamate, meloxicam, nabumetone, naproxen, naproxen sodium, naproxen EC, oxaprozin, piroxicam, salsalate, sulindac, tolmetin

For Crohn's Disease

An exception for coverage of **BIWEEKLY (every other week) administration** of Humira (which is self-administered) may be made for members who meet all the following criteria:

- Medical record documentation that Humira is prescribed by a gastroenterologist **AND**
- Medical record documentation of age greater than or equal to 6 years **AND**
- Medical record documentation of a diagnosis of moderately or severely active Crohn's disease **AND**
- Medical record documentation of one of the following:
 - Medical record documentation of therapeutic failure on, intolerance to, or contraindication to corticosteroids **AND** immunomodulators (e.g. azathioprine and 6-mercaptopurine) **OR** medical record documentation of a therapeutic failure on or intolerance to prior biologic therapy **OR**
 - Medical record documentation of moderate/high risk patient as defined by age at initial diagnosis less than 30 years, extensive anatomic involvement, perianal and/or severe rectal disease, deep ulcers, prior surgical resection, and structuring and/or penetrating behavior **AND**
- Medical record documentation that Humira is not being used concurrently with a tumor necrosis factor (TNF) blocker or other biologic agent

An exception for coverage of **WEEKLY administration** of Humira (which is self-administered) may be made for members who meet the following criteria:

- Medical record documentation that Humira is prescribed by a gastroenterologist **AND**
- Medical record documentation of age greater than or equal to 6 years **AND**
- Medical record documentation of a diagnosis of moderately or severely active Crohn's disease **AND**
- Medical record documentation of one of the following:
 - Medical record documentation of therapeutic failure on, intolerance to, or contraindication to corticosteroids **AND** immunomodulators (e.g. azathioprine and 6-mercaptopurine) **OR** medical record documentation of a therapeutic failure on or intolerance to prior biologic therapy **OR**
 - Medical record documentation of moderate/high risk patient as defined by age at initial diagnosis less than 30 years, extensive anatomic involvement, perianal and/or severe rectal disease, deep ulcers, prior surgical resection, and structuring and/or penetrating behavior **AND**
- Medical record documentation that Humira is not being used concurrently with a tumor necrosis factor (TNF) blocker or other biologic agent **AND**
- Medical record documentation of a contraindication to, intolerance to, or therapeutic failure on BIWEEKLY (every other week) administration of Humira **AND**

- Medical record documentation that the member has been compliant with BIWEEKLY administration of Humira **AND**
- Medical record documentation of inadequate drug trough level (less than 7.5mcg/mL) to support weekly dosing, per American Gastroenterological Association (AGA) guidelines

NOTE:

- For patients with an adequate drug trough, American Gastroenterological Association (AGA) does not recommend antibody levels to guide therapy. Patients should be switched to another agent.
- For patients with an inadequate drug trough & undetectable antibodies, a dose increase may be warranted.
- For patients with an inadequate drug trough & detectable antibodies, a switch to another agent is recommended. However, patients with low antibody levels may be considered for a dose increase, in hopes of overcoming antibody level and achieving response.

RE-AUTHORIZATION CRITERIA: Humira is configured as a prior authorization for new starts only. Humira will no longer be covered if it is identified that the member is not receiving appropriate follow-up care from the prescribing specialist or if the member has greater than or equal to a 90 day break in therapy.

- Medical record documentation that the member is receiving appropriate follow-up care from the prescribing specialist

MEDISPAN AUTHORIZATION LEVEL: GPI-10

QUANTITY LIMIT:

- **Adults and pediatrics > 40 kg: 160 mg on day 1, 80 mg 2 weeks later, then 40 mg biweekly – Two authorizations must be entered.**
 1. In PA Hub: Add PA, number of claims authorized 1, enter for the remainder of the calendar year
 2. In Darwin: Add OQL, DS, max quantity dispensed 2, min day supply 28, max day supply 28, with an end date of 12/31/2099. Start date of this authorization is 3 weeks after approval date.
 - QL FOR LETTER: Loading dose: 160 mg on day 1, 80 mg 2 weeks later; Maintenance dose: 40 mg every other week (2 pens/syringes per 28 days)
- **Pediatrics < 40 kg: 80 mg on day 1, 40 mg 2 weeks later, then 20 mg biweekly – Two authorizations must be entered.**
 1. In PA Hub: Add PA, number of claims authorized 1, enter for the remainder of the calendar year

2. In Darwin: Add OQL, DS, max quantity dispensed 2, min day supply 28, max day supply 28, with an end date of 12/31/2099. Start date of this authorization is 3 weeks after approval date.
 - **QL FOR LETTER:** Loading dose: 80 mg on day 1, 40 mg 2 weeks later; Maintenance dose: 20 mg every other week (2 pens/syringes per 28 days)
- **Weekly Dosing** – *QL must be entered within the authorization.*
 1. In PA Hub: Add PA, number of claims authorized 1, enter for the remainder of the calendar year
 2. In Darwin: Add OQL, DS, max quantity dispensed 4, max day supply 28, min day supply 28, with an end date of 12/31/2099
 - **QL FOR LETTER:** 4 per 28 days

FORMULARY ALTERNATIVES:

Corticosteroids: prednisone, budesonide

Immunomodulators: azathioprine, 6-mercaptopurine

For the treatment of moderate to severe Plaque Psoriasis

An exception for coverage of **BIWEEKLY (every other week) administration** of Humira (which is self-administered) may be made for members who meet all the following criteria:

- Medical record documentation that Humira is prescribed by a dermatologist **AND**
- Medical record documentation of age greater than or equal to 18 years **AND**
- Medical record documentation of a diagnosis of moderate to severe plaque psoriasis characterized by greater than or equal to 5% of body surface area involved or disease involving crucial body areas such as the hands, feet, face, or genitals **AND**
- Medical record documentation of a therapeutic failure on, intolerance to, or contraindication to topical corticosteroids **AND** at least two to three months of systemic therapy (including but not limited to methotrexate and/or cyclosporine) or phototherapy **OR** medical record documentation of a therapeutic failure on or intolerance to prior biologic therapy
- Medical record documentation that Humira is being dosed at a maximum of 40 mg every other week **OR** medical record documentation of peer-reviewed literature citing well-designed clinical trials to indicate that the member's healthcare outcome will be improved by dosing that exceeds Food and Drug Administration (FDA) approved labeling **AND**
- Medical record documentation that Humira is not being used concurrently with a tumor necrosis factor (TNF) blocker or other biologic agent

RE-AUTHORIZATION CRITERIA: Humira is configured as a prior authorization for new starts only. Humira will no longer be covered if it is identified that the member is not receiving appropriate follow-up care from the prescribing specialist or if the member has greater than or equal to a 90 day break in therapy.

- Medical record documentation that the member is receiving appropriate follow-up care from the prescribing specialist

MEDISPAN AUTHORIZATION LEVEL: GPI-10

QUANTITY LIMIT: *Two authorizations must be entered.*

- **80 mg on day 1, then 40 mg biweekly**
 1. In PA Hub: Add PA, number of claims authorized 1, enter for the remainder of the calendar year
 2. In Darwin: Add OQL, DS, max quantity dispensed 2, min day supply 28, max day supply 28, with an end date of 12/31/2099. Start date of this authorization is 3 weeks after initial approval date.
 - **QL FOR LETTER:** Loading dose: 80 mg on day 1; Maintenance dose: 40 mg every other week (2 pens/syringes per 28 days)

FORMULARY ALTERNATIVES:

cyclosporine, methotrexate

Low-potency topical corticosteroids: alclometasone dipropionate 0.5% cream and ointment (Aclovate); fluocinolone acetonide 0.01% soln. (Synalar); hydrocortisone 2.5% cream, ointment, and lotion (Hytone)

Medium-potency topical corticosteroids: betamethasone valerate 0.1% cream (Valisone); fluocinolone acetonide 0.025% cream and ointment (Synalar); fluticasone propionate 0.05% cream, ointment, and lotion (Cutivate); triamcinolone 0.1% cream, ointment and lotion (Kenalog); triamcinolone acetonide 0.025% cream, ointment and lotion (Kenalog); triamcinolone acetonide 0.147 mg/g aerosol (Kenalog Spray)

High-potency topical corticosteroids: augmented betamethasone dipropionate 0.05% cream (Diprolene AF); betamethasone valerate 0.1% ointment (Valisone); triamcinolone 0.5% cream (Kenalog); fluocinonide 0.05% cream, ointment and gel (Lidex)

Very high-potency topical corticosteroids: augmented betamethasone dipropionate 0.05% ointment, gel and lotion (Diprolene); clobetasol 0.05% cream, ointment, and scalp lotion (Temovate) diflorasone diacetate 0.05% cream and ointment (ApexiCon/Psorcon)

For Ulcerative Colitis

An exception for coverage of **BIWEEKLY (every other week) administration** of Humira (which is self-administered) may be made for members who meet all the following criteria:

- Medical record documentation of a diagnosis of moderate to severe ulcerative colitis **AND**
- Medical record documentation that Humira is prescribed by a gastroenterologist **AND**
- Medical record documentation of age greater than or equal to 5 years **AND**
- Medical record documentation of therapeutic failure on, intolerance to, at least one conventional therapy: corticosteroids, aminosalicylates, or immunomodulators (azathioprine or 6-mercaptopurine (6-MP)) **AND**
- Medical record documentation that Humira is not being used concurrently with a tumor necrosis factor (TNF) blocker or other biologic agent

An exception for coverage of **WEEKLY administration** of Humira (which is self-administered) may be made for members who meet all the following criteria:

- Medical record documentation of a diagnosis of moderate to severe ulcerative colitis **AND**
- Medical record documentation that Humira is prescribed by a gastroenterologist **AND**
- Medical record documentation of age greater than or equal to 5 years **AND**
- Medical record documentation of therapeutic failure on, intolerance to, or contraindication to at least one conventional therapy: corticosteroids, aminosalicylates, or immunomodulators (e.g. 6-mercaptopurine or azathioprine) **AND**
- Medical record documentation that Humira is not being used concurrently with a tumor necrosis factor (TNF) blocker or other biologic agent **AND**
- Medical record documentation of one of the following:
 - For an adult:
 - Medical record documentation of a contraindication to, intolerance to, or therapeutic failure on BIWEEKLY (every other week) administration of Humira **AND**
 - Medical record documentation that the member has been compliant with BIWEEKLY administration of Humira **AND**
 - Medical record documentation of inadequate drug trough level (less than 7.5mcg/mL) to support weekly dosing, per American Gastroenterological Association (AGA) guidelines
 - OR**
 - Medical record documentation that weekly dosing was initiated prior to the member turning 18 years and the member is well-controlled on this dose
- For a member less than or equal to 18 years of age:
 - Medical record documentation that the member is less than 18 years of age and receiving an appropriate dose based on body weight

NOTE:

- For patients with an adequate drug trough, American Gastroenterological Association (AGA) does not recommend antibody levels to guide therapy. Patients should be switched to another agent.
- For patients with an inadequate drug trough & undetectable antibodies, a dose increase may be warranted.
- For patients with an inadequate drug trough & detectable antibodies, a switch to another agent is recommended. However, patients with low antibody levels may be considered for a dose increase, in hopes of overcoming antibody level and achieving response.

RE-AUTHORIZATION CRITERIA: Humira is configured as a prior authorization for new starts only. Humira will no longer be covered if it is identified that the member is not receiving appropriate follow-up care from the prescribing specialist or if the member has greater than or equal to a 90 day break in therapy.

- Medical record documentation that the member is receiving appropriate follow-up care from the prescribing specialist

MEDISPAN AUTHORIZATION LEVEL: GPI-10

QUANTITY LIMIT:

- **Adults: 160 mg on day 1, 80 mg 2 weeks later, then 40 mg biweekly – Two authorizations must be entered.**
 1. In PA Hub: Add PA, number of claims authorized 1, enter for the remainder of the calendar year
 2. In Darwin: Add OQL, DS, max quantity dispensed 2, min day supply 28, max day supply 28, with an end date of 12/31/2099. Start date of this authorization is 3 weeks after initial approval date.
 - QL FOR LETTER: Loading dose: 160 mg on day 1, 80 mg 2 weeks later; Maintenance dose: 40 mg every other week (2 pens/syringes per 28 days)
- **Adult Weekly Dosing – QL must be entered within the authorization.**
 1. In PA Hub: Add PA, number of claims authorized 1, enter for the remainder of the calendar year
 2. In Darwin: Add OQL, DS, max quantity dispensed 4, max day supply 28, min day supply 28, with an end date of 12/31/2099
 - QL FOR LETTER: 4 per 28 days
- **Pediatrics 20 kg to 40 kg: 80 mg on day 1, 40 mg on day 8 and day 15, then 40 mg every other week – Two authorizations must be entered.**
 1. In PA Hub: Add PA, number of claims authorized 1, enter for the remainder of the calendar year

2. In Darwin: Add OQL, DS, max quantity dispensed 2, min day supply 28, max day supply 28, with an end date of 12/31/2099. Start date of this authorization is 3 weeks after initial approval date.
 - **QL FOR LETTER:** Loading dose: 80 mg on day 1, 40 mg on day 8 and day 15; Maintenance dose: 40 mg every other week (2 pens/syringes per 28 days)
- **Pediatrics 20 kg to 40 kg: 80 mg on day 1, 40 mg on day 8 and day 15, then 20 mg every week – Two authorizations must be entered.**
 1. In PA Hub: Add PA, number of claims authorized 1, enter for the remainder of the calendar year
 2. In Darwin: Add OQL, DS, max quantity dispensed 4, min day supply 28, max day supply 28, with an end date of 12/31/2099. Start date of this authorization is 3 weeks after initial approval date.
 - **QL FOR LETTER:** Loading dose: 80 mg on day 1, 40 mg on day 8 and day 15; Maintenance dose: 20 mg every week (4 pens/syringes per 28 days)
- **Pediatrics greater than 40 kg: 160 mg on day 1, 80 mg on day 8 and day 15, then 80 mg every other week – Two authorizations must be entered.**
 1. In PA Hub: Add PA, number of claims authorized 1, enter for the remainder of the calendar year
 2. In Darwin: Add OQL, DS, max quantity dispensed 2, min day supply 28, max day supply 28, with an end date of 12/31/2099. Start date of this authorization is 3 weeks after initial approval date.
 - **QL FOR LETTER:** Loading dose: 160 mg on day 1, 80 mg on day 8 and day 15; Maintenance dose: 80 mg every other week (2 pens/syringes per 28 days)
- **Pediatrics greater than 40 kg: 160 mg on day 1, 80 mg on day 8 and day 15, then 40 mg every week – Two authorizations must be entered.**
 1. In PA Hub: Add PA, number of claims authorized 1, enter for the remainder of the calendar year
 2. In Darwin: Add OQL, DS, max quantity dispensed 4, min day supply 28, max day supply 28, with an end date of 12/31/2099. Start date of this authorization is 3 weeks after initial approval date.
 - **QL FOR LETTER:** Loading dose: 160 mg on day 1, 80 mg on day 8 and day 15; Maintenance dose: 40 mg every week (4 pens/syringes per 28 days)

FORMULARY ALTERNATIVES:
azathioprine, 6-mercaptopurine

For Hidradenitis Suppurativa (HS)

An exception for coverage of **WEEKLY administration** of Humira (which is self-administered) may be made for members who meet all the following criteria:

- Medical record documentation that Humira is prescribed by a dermatologist **AND**
- Medical record documentation of age greater than or equal to 12 years **AND**
- Medical record documentation of a diagnosis of moderate to severe hidradenitis suppurativa (HS), defined as Stage II or III on the Hurley staging system*
- Medical record documentation of at least 3 abscesses or inflammatory nodules **AND**
- Medical record documentation of concomitant use of oral or systemic antibiotics **AND**
- Medical record documentation that the member has received counseling on weight management (if overweight) and smoking cessation (if the member is an active smoker) **AND**
- For members 12 to 18 years of age weighing 30 to less than 60 kg: medical record documentation of Humira being dosed at a maximum dose of 40 mg every other week **AND**
- Medical record documentation that Humira is not being used concurrently with a tumor necrosis factor (TNF) blocker or other biologic agent

*Hurley staging system:

- Stage I: A single lesion without sinus tract formation.
- Stage II: More than one lesion or area, but with limited tunneling.
- Stage III: Multiple lesions, with more extensive sinus tracts and scarring.

RE-AUTHORIZATION CRITERIA: Humira is configured as a prior authorization for new starts only. Humira will no longer be covered if it is identified that the member is not receiving appropriate follow-up care from the prescribing specialist or if the member has greater than or equal to a 90 day break in therapy.

- Medical record documentation that the member is receiving appropriate follow-up care from the prescribing specialist

MEDISPAN AUTHORIZATION LEVEL: GPI-10

QUANTITY LIMIT FOR INITIAL APPROVALS:

- **Adults & Age 12 – 18 years weighing \geq 60 kg: 160 mg on day 1, 80 mg 2 weeks later, then 40 mg weekly – *Two authorizations must be entered.***
- 1. In PA Hub: Add PA, number of claims authorized 1, enter for the remainder of the calendar year
- 2. In Darwin: Add OQL, DS, max quantity dispensed 4, min day supply 28, max day supply 28, with an end date of 12/31/2099. Start date of this authorization is 3 weeks after initial approval date.

- QL FOR LETTER: Loading dose: 160 mg on day 1, 80 mg 2 weeks later; Maintenance dose: 40 mg every week (4 pens/syringes per 28 days)
- **Adults & Age 12 – 18 years weighing \geq 60 kg: 160 mg on day 1, 80 mg 2 weeks later, then 80 mg biweekly – *Two authorizations must be entered.***
- 1. In PA Hub: Add PA, number of claims authorized 1, enter for the remainder of the calendar year
- 2. In Darwin: Add OQL, DS, max quantity dispensed 2, min day supply 28, max day supply 28, with an end date of 12/31/2099. Start date of this authorization is 3 weeks after initial approval date.
 - QL FOR LETTER: Loading dose: 160 mg on day 1, 80 mg 2 weeks later; Maintenance dose: 80 mg every other week (2 pens/syringes per 28 days)
- **Age 12 – 18 years weighing 30 to < 60 kg: 80 mg on day 1, then 40 mg biweekly – *Two authorizations must be entered.***
- 1. In PA Hub: Add PA, number of claims authorized 1, enter for the remainder of the calendar year
- 2. In Darwin: Add OQL, DS, max quantity dispensed 2, min day supply 28, max day supply 28, with an end date of 12/31/2099. Start date of this authorization is 3 weeks after initial approval date.
 - QL FOR LETTER: Loading dose: 80 mg on day 1; Maintenance dose: 40 mg every other week (2 pens/syringes per 28 days)

FORMULARY ALTERNATIVES:

none

For the treatment of Non-Infectious Intermediate, Posterior and Panuveitis

An exception for coverage of **BIWEEKLY (every other week) administration** of Humira (which is self-administered) may be made for members who meet all the following criteria:

- Medical record documentation that Humira is prescribed by an ophthalmologist or rheumatologist **AND**
- Medical record documentation of age greater than or equal to 2 years **AND**
- Medical record documentation of a diagnosis of non-infectious intermediate, posterior or panuveitis **AND**
- Medical record documentation of:
 - Therapeutic failure on, intolerance to, or contraindication to local/systemic corticosteroids **AND** an immunosuppressant (methotrexate, azathioprine, mycophenolate, cyclosporine, or tacrolimus) **OR**
 - For members 2-18 years of age: therapeutic failure on, intolerance to, or contraindication to local/systemic corticosteroids **AND** methotrexate **AND**
- For members 2-18 years of age: medical record documentation that Humira is being given in combination with methotrexate **OR** medical record documentation of contraindication to methotrexate **AND**
- Medical record documentation that member is receiving appropriate dose of Humira based on weight and age **AND**
- Medical record documentation that Humira is not being used concurrently with a tumor necrosis factor (TNF) blocker or other biologic agent

RE-AUTHORIZATION CRITERIA: Humira is configured as a prior authorization for new starts only. Humira will no longer be covered if it is identified that the member is not receiving appropriate follow-up care from the prescribing specialist or if the member has greater than or equal to a 90 day break in therapy.

- Medical record documentation that the member is receiving appropriate follow-up care from the prescribing specialist

MEDISPAN AUTHORIZATION LEVEL: GPI-10

QUANTITY LIMIT FOR INITIAL APPROVALS: *Two authorizations must be entered.*

- **Adult 80 mg on day 1, then 40 mg biweekly – Two authorizations must be entered.**
 1. In PA Hub: Add PA, number of claims authorized 1, enter for the remainder of the calendar year
 2. In Darwin: Add OQL, DS, max quantity dispensed 2, min day supply 28, max day supply 28, with an end date of 12/31/2099. Start date of this authorization is 3 weeks after initial approval date.

Geisinger

**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 84.0

**SECTION: Commercial Drug
SUBJECT: Humira**

- QL FOR LETTER: Loading dose: 80 mg on day 1; Maintenance dose: 40 mg every other week (2 pens/syringes per 28 days)
- **Pediatric Uveitis** – *Two authorizations must be entered.*
 1. In PA Hub: Add PA, number of claims authorized 1, enter for the remainder of the calendar year
 2. In Darwin: Add OQL, DS, max quantity dispensed 2, max day supply 28, min day supply 28, with an end date of 12/31/2099
 - QL FOR LETTER: 2 per 28 days

FORMULARY ALTERNATIVES:

Immunosuppressants: methotrexate, azathioprine, mycophenolate, cyclosporine, tacrolimus

Steroids: prednisone, methylprednisolone, dexamethasone, prednisolone, budesonide



POLICY NUMBER: 84.0

**POLICY AND PROCEDURE
PHARMACY
MANUAL**

**SECTION: Commercial Drug
SUBJECT: Humira**

If an exception is made, Humira will be paid for under the member's prescription drug benefit.

Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE
STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND
FEDERAL REGULATORY ENTITIES.**

**THIS POLICY WILL BE REVISED AS NECESSARY AND
REVIEWED NO LESS THAN ANNUALLY.**

Signed: _____

Title: Director, Pharmacy Services

Date: March 1, 2022

Devised: 1/03
Effective: 1/03
Revised: 7/03 – updated per July P&T Meeting
Reviewed: 3/04
Revised: 3/05 – updated title
Revised: 2/06 – updated qty limit
Revised: 3/06 – updated title
Reviewed: 3/07
Revised: 5/07
Revised: 1/08 – update criteria for coverage
Reviewed: 3/08 – annual review
Revised: 5/08 – updated criteria
Revised: 7/08 – added psoriasis criteria
Reviewed: 4/09 – annual review
Reviewed: 3/10 – annual review
Reviewed: 3/1/11 – annual review
Revised: 3/1/12 – annual review, updated signature
Revised: 6/21/12 – added criteria for ankylosing spondylitis
Revised: 9/17/12 – updated authorization duration, changed rheumatoid arthritis to psoriatic arthritis under psoriatic arthritis reauthorization criteria
Revised: 11/7/12 – added ulcerative colitis indication
Revised: 3/1/13 – annual review, updated logo & definitions, fixed typo in Ankylosing Spondylitis
Revised: 3/1/14 – annual review, updated formulary alternatives
Revised: 9/22/14 – updated criteria and formulary alternatives and auth duration for all indications, updated signature, added or capitalized AND between criteria for each indication



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 84.0

**SECTION: Commercial Drug
SUBJECT: Humira**

- Revised: 11/21/14 – updated age criteria for PJIA and Crohn's, updated formulary alternative criteria and alternative list for PsA, removed weekly dosing criteria for PsA and PsO.
- Revised: 2/9/15 – updated prescriber criteria for PsA
- Reviewed: 3/1/15 – annual review
- Revised: 7/22/15 – added dosing requirement to JRA, PsA, PsO, AS, UC, CD, removed failure of aminosalicylates from CD, added high risk criterion to CD, removed one copay per injection requirement, added review criteria under procedure, added quantity limits, moved formulary alternatives to each indication, updated formatting, added celecoxib to AS formulary alternatives
- Revised: 9/19/15 – removed joint count criteria from initial and renewal requirements
- Revised: 1/29/16 – added hidradenitis suppurativa indication
- Revised: 3/1/16 – annual review, updated policy formatting
- Revised: 3/23/16 – corrected typos in 1st and 5th bullets of HS criteria
- Revised: 5/1/16 – updated format, logo, & procedure
- Revised: 7/18/16 – updated HS QL to reflect P&T approved recommendation
- Revised: 11/22/16 – added Uveitis indication
- Revised: 3/1/17 – annual review, updated HS auth duration to weekly, updated FA
- Revised: 3/27/17 – axial vs. peripheral for PsA, updated FA
- Revised: 3/1/18 – annual review, updated signature, added grandfather language, updated formatting, corrected typo
- Revised: 5/30/18 – added combination with other biologic agents
- Revised: 12/28/18 – updated initial RA auth duration, added weekly CD/UC criteria, updated CD/UC QL, added note to CD/UC, removed dosing criteria from biweekly CD/UC
- Revised: 3/1/19 – annual review, defined abbreviations
- Revised: 3/28/19 – added pediatric uveitis, updated adult uveitis alternative criteria, updated uveitis FA, updated uveitis prescriber to include rheumatologist, added pediatric HS
- Revised: 5/24/19 – updated QL's to account for new strengths, package sizes, and CF formulation
- Revised: 7/24/19 – added authorization parameters
- Revised: 9/17/19 – corrected initial auth duration to 1 week for CD, PP, UC, HS, and uveitis
- Revised: 3/1/20 – annual review, added GHP Kids
- Revised: 10/13/20 – added weekly QL for UC
- Revised: 3/1/21 – annual review, updated logo, added MediSpan approval level, updated QL statements
- Revised: 3/26/21 – updated MediSpan approval level to GPI-10 for all indications
- Revised: 6/8/21 – corrected adult HS QL in Darwin
- Revised: 8/24/21 – UC Indication: changed age to 5 years, updated alternative requirements, added additional weekly dosing criteria, updated QL
- Revised: 12/2/21 – added one-time PA to approval crit., removed auth duration & added re-auth crit., updated QL auth entry to account for PA NSO
- Revised: 3/1/22 – annual review, updated referenced policies & covered LOBs, updated QL entry



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 93.0

**SECTION: Commercial Drug
SUBJECT: Voriconazole**

Applicable line of business:

Commercial	X	Medicaid	
Medicare		ACA	X
GHP Kids	X	Self-Insured	X

POLICY:

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for voriconazole for GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 487.0 Quantity Limit Exceptions

REQUIRED DEFINITIONS:

1. **Attachment** – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. **Exhibit** – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. **Devised** – the date the policy was implemented.
4. **Revised** – the date of every revision to the policy, including typographical and grammatical changes.
5. **Reviewed** – the date documenting the annual review if the policy has no revisions necessary.

ADDITIONAL DEFINITIONS:

1. **Formulary** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. **Non-formulary products** – those medications that are not included in the Formulary.
3. **Healthcare provider** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
4. **NCQA** – National Committee for Quality Assurance.
5. **Medically Necessary or Medical Necessity** – covered services rendered by a provider that the Health Plan determines are:



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 93.0

**SECTION: Commercial Drug
SUBJECT: Voriconazole**

- A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
- B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
- C. In accordance with current standards of medical practice;
- D. Not primarily for the convenience of the Member, or the Member's Provider; and
- E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

PROCEDURE:

An exception for coverage of voriconazole may be made for members who meet **ALL** of the following criteria:

- Medical record documentation of age greater than or equal to 12 years **AND**
- Medical record documentation of a diagnosis of invasive aspergillosis, esophageal candidiasis, or fungal infection caused by *Scedosporium apiospermum* or fungal infection caused by *Fusarium* species with an Infectious Disease consult, preferably with a culture report to back the diagnosis **OR**
- Medical record documentation of a diagnosis of candidemia in a non-neutropenic patient or disseminated candida infections of the skin, abdomen, bladder wall, kidney and wounds with failure on, intolerance to, or contraindication to IV amphotericin B and/or fluconazole as determined by Infectious Disease consult, preferably with a culture to back the diagnosis **AND**
- Medical record documentation of initiation of intravenous therapy with voriconazole in the hospital

MEDISPAN AUTHORIZATION LEVEL: GPI-12, generic only

If an exception is made, voriconazole will be paid for under the member's prescription drug benefit.

Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.



POLICY NUMBER: 93.0

**POLICY AND PROCEDURE
PHARMACY
MANUAL**

**SECTION: Commercial Drug
SUBJECT: Voriconazole**

FORMULARY ALTERNATIVES:

itraconazole * (for applicable indications)

*prior authorization required

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE
STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND
FEDERAL REGULATORY ENTITIES.**

**THIS POLICY WILL BE REVISED AS NECESSARY AND
REVIEWED NO LESS THAN ANNUALLY.**

Signed: _____

Title: Director, Pharmacy Services

Date: March 1, 2022

Devised: 7/03
Effective: 7/03
Reviewed: 3/04
Revised: 3/05 – updated title
Revised: 6/05 – added criteria #3
Revised: 3/06 – updated title
Reviewed: 3/07
Revised: 5/07 – added signature
Revised: 3/08 – annual review; updated alternatives
Reviewed: 4/09 – annual review
Reviewed: 3/10 – annual review
Reviewed: 3/11 – annual review
Revised: 3/12 – annual review, updated signature, clarified voriconazole and Vfend
Revised: 3/13 – annual review, updated logo and definitions
Revised: 3/14 – annual review, updated formatting
Revised: 3/15 – annual review, updated signature
Reviewed: 3/16 – annual review
Revised: 5/16 – updated format, logo, & procedure
Revised: 3/17 – annual review, removed brand name Vfend
Revised: 6/2/17 – added esophageal candidiasis, removed Unicode characters
Revised: 3/1/18 – annual review, updated signature, updated formatting
Reviewed: 3/1/19 – annual review
Revised: 3/1/20 – annual review, added GHP Kids
Revised: 3/1/21 – annual review, updated logo, added MediSpan approval level



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 93.0

**SECTION: Commercial Drug
SUBJECT: Voriconazole**

Revised: 3/1/22 – annual review, updated referenced policies & covered LOBs



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 94.0

**SECTION: Commercial Drug
SUBJECT: Stimulants for ADHD**

Applicable line of business:

Commercial	X	Medicaid	
Medicare		ACA	X
GHP Kids	X	Self-Insured	X

POLICY:

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for stimulants for ADHD for GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 487.0 Quantity Limit Exceptions

REQUIRED DEFINITIONS:

1. **Attachment** – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. **Exhibit** – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. **Devised** – the date the policy was implemented.
4. **Revised** – the date of every revision to the policy, including typographical and grammatical changes.
5. **Reviewed** – the date documenting the annual review if the policy has no revisions necessary.

ADDITIONAL DEFINITIONS:

1. **Formulary** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. **Non-formulary products** – those medications that are not included in the Formulary.
3. **Healthcare provider** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
4. **NCQA** – National Committee for Quality Assurance.
5. **Medically Necessary or Medical Necessity** – covered services rendered by a provider that the Health Plan determines are:

- A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
 - B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
 - C. In accordance with current standards of medical practice;
 - D. Not primarily for the convenience of the Member, or the Member's Provider; and
 - E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.
6. **ADHD** – attention deficit hyperactivity disorder

PROCEDURE:

New members to the plan already established on therapy may be eligible for continuity of care coverage as long as there is medical record documentation that the safety and effectiveness of use for the prescribed indication is supported by Food and Drug Administration (FDA) approval or adequate medical and scientific evidence in the medical literature.

An exception for coverage of Adhansia XR, methylphenidate XR (generic Aptensio XR), Azstarys, Daytrana, dexamethylphenidate HCl ER, Jornay PM, QuilliChew ER, or Quillivant XR may be made for members who meet the following criteria:

- Medical record documentation of a diagnosis of attention deficit disorder (ADD) or attention deficit hyperactivity disorder (ADHD) **AND**
- Medical record documentation of therapeutic failure on, intolerance to, or contraindication to Metadate CD^Ω **AND** amphetamine/dextroamphetamine SR combination

^Ω = From the Metadate CD package insert, "Metadate CD may be swallowed whole with the aid of liquids, or alternately, the capsule may be opened and the capsule contents sprinkled onto a small amount (tablespoon) of applesauce and given immediately, and not stored for future use. Drinking some fluids e.g. water, should follow the intake of the sprinkles with applesauce. The capsules and the capsule contents must not be crushed or chewed."

MEDISPAN AUTHORIZATION LEVEL: GPI-12, if request is for methylphenidate XR (generic Aptensio XR) or dexamethylphenidate HCl ER include generic only.



POLICY NUMBER: 94.0

**POLICY AND PROCEDURE
PHARMACY
MANUAL**

**SECTION: Commercial Drug
SUBJECT: Stimulants for ADHD**

QUANTITY LIMIT: *No QLs need to be entered within the authorization unless the requested quantity exceeds the QL.*

- **QL FOR LETTER ONLY:**
 - **Adhansia XR:** 1 capsule per day
 - **Azstarys:** 1 capsule per day
 - **Jornay PM:** 1 capsule per day

If an exception is made, Adhansia XR, methylphenidate XR (Aptensio XR), Azstarys, Daytrana, dextromethylphenidate HCl ER, Jornay PM, QuilliChew ER, or Quillivant XR will be paid for under the member's prescription drug benefit.

Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.

FORMULARY ALTERNATIVES:

dextroamphetamine, dextroamphetamine/amphetamine combination, dextroamphetamine/amphetamine SR combination, methylphenidate, methylphenidate sustained-release, methylphenidate extended-release, Metadate CD, guanfacine ER, atomoxetine

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE
STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND
FEDERAL REGULATORY ENTITIES.**

**THIS POLICY WILL BE REVISED AS NECESSARY AND
REVIEWED NO LESS THAN ANNUALLY.**

Signed: _____

Title: Director, Pharmacy Services

Date: March 1, 2022

Devised: 7/03
Effective: 7/03
Revised: 3/04 – updated formulary alternative section
Revised: 3/05 – updated title

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Dev. 7/03
Rev. 3/1/22

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POLICY NUMBER: 94.0

**POLICY AND PROCEDURE
PHARMACY
MANUAL**

**SECTION: Commercial Drug
SUBJECT: Stimulants for ADHD**

- Revised: 3/06 – updated title
- Revised: 3/07 – updated generics
- Revised: 5/07 – added signature
- Revised: 7/07 – added Daytrana, Focalin XR to policy, Adderall XR to alternatives
- Revised: 3/08 – annual review; updated alternatives
- Revised: 4/09 – annual review, updated alt.
- Reviewed: 3/10 – annual review
- Revised: 6/10 – updated criteria, added Concerta and Vyvanse to policy
- Reviewed: 3/1/11 – annual review
- Revised: 3/1/12 – annual review, updated signature, removed Ritalin LA & Concerta
- Revised: 3/1/13 – annual review, updated logo and definitions
- Reviewed: 3/1/14 – annual review
- Revised: 3/1/15 – annual review, updated signature, added dexamethylphenidate HCl ER
- Revised: 7/22/15 – moved Vyvanse to policy 384.0
- Reviewed: 3/1/16 – annual review
- Revised: 5/1/16 – updated format, logo, & procedure, updated title, added guanfacine ER to FA
- Revised: 7/22/16 – added Aptensio XR, QuilliChew ER, and Quillivant XR to policy
- Revised: 3/1/17 – annual review, removed brand name Focalin XR
- Revised: 3/1/18 – annual review, updated signature, updated formatting & FA, corrected typo, added grandfather language
- Reviewed: 3/1/19 – annual review
- Revised: 01/16/20 – added Adhansia XR and Jornay PM
- Revised: 3/1/20 – annual review, added GHP Kids
- Revised: 3/1/21 – annual review, updated logo, added MediSpan approval level, updated QL statement, updated Aptensio to generic
- Revised: 1/4/22 – renamed policy, added Azstarys
- Revised: 3/1/22 – annual review, updated referenced policies & covered LOBs, added ADHD to definitions, corrected typo

Applicable line of business:

Commercial	X	Medicaid	
Medicare		ACA	X
GHP Kids	X	Self-Insured	X

POLICY:

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for Beconase AQ, Omnaris, Qnasl, and Zetonna for GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 487.0 Quantity Limit Exceptions

REQUIRED DEFINITIONS:

1. **Attachment** – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. **Exhibit** – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. **Devised** – the date the policy was implemented.
4. **Revised** – the date of every revision to the policy, including typographical and grammatical changes.
5. **Reviewed** – the date documenting the annual review if the policy has no revisions necessary.

ADDITIONAL DEFINITIONS:

1. **Formulary** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. **Non-formulary products** – those medications that are not included in the Formulary.
3. **Healthcare provider** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
4. **NCQA** – National Committee for Quality Assurance.
5. **Medically Necessary or Medical Necessity** – covered services rendered by a provider that the Health Plan determines are:

- A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
- B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
- C. In accordance with current standards of medical practice;
- D. Not primarily for the convenience of the Member, or the Member's Provider; and
- E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

PROCEDURE:

An exception for coverage of **Beconase AQ** may be made for members who meet **one** of the following criteria:

- Medical record documentation of failure on, contraindication to, or intolerance to fluticasone propionate, triamcinolone acetonide, **AND** mometasone furoate **OR**
- Medical record documentation that the member is being treated for the prevention of nasal polyps with failure on, contraindication to, or intolerance to mometasone furoate

An exception for coverage of **Omnaris, Qnasl, or Zetonna** may be made for members who meet the following criteria:

- Medical record documentation of failure on, contraindication to, or intolerance to fluticasone propionate, triamcinolone acetonide, **AND** mometasone furoate

MEDISPAN AUTHORIZATION LEVEL: GPI-12

If an exception is made, Beconase AQ, Omnaris, Qnasl, or Zetonna will be paid for under the member's prescription drug benefit.

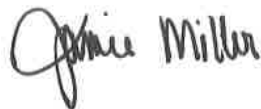
Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.

FORMULARY ALTERNATIVES:

fluticasone propionate, triamcinolone acetonide, mometasone furoate

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE
STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND
FEDERAL REGULATORY ENTITIES.**

**THIS POLICY WILL BE REVISED AS NECESSARY AND
REVIEWED NO LESS THAN ANNUALLY.**



Signed: _____

Title: Director, Pharmacy Services

Date: March 1, 2022

Devised: 7/03
Effective: 7/03
Reviewed: 3/04
Revised: 12/04 – updated Beconase AQ criteria to include Nasonex being FDA approved for nasal polyps
Revised: 3/05 – updated title
Revised: 3/06 – updated title
Reviewed: 3/07
Revised: 5/07 – added signature
Reviewed: 3/08 – annual review
Revised: 1/09 – added Omnaris
Reviewed: 4/09 – annual review
Reviewed: 3/10 – annual review
Reviewed: 3/1/11 – annual review
Revised: 6/29/11 – removed Nasacort Aq, updated criteria and formulary alternatives
Revised: 3/1/12 – annual review, updated signature, added Veramyst
Revised: 7/18/12 – added Zetonna to policy
Revised: 9/17/12 – added Qnasl to policy
Revised: 3/1/13 – annual review, updated logo and definitions
Revised: 3/1/14 – annual review, updated formatting
Revised: 3/1/15 – annual review, updated signature
Reviewed: 3/1/16 – annual review
Revised: 5/1/16 – updated format, logo, & procedure, update Nasonex to mometasone furoate
Revised: 3/1/17 – annual review, updated Rhinocort to budesonide
Revised: 3/1/18 – annual review, updated signature, corrected typo
Reviewed: 3/1/19 – annual review
Revised: 7/16/19 – removed Veramyst from policy (product discontinued)
Revised: 9/25/19 – removed budesonide from criteria and formulary alternatives (product discontinued)
Revised: 3/1/20 – annual review, added GHP Kids
Revised: 3/1/21 – annual review, updated logo, added MediSpan approval level
Revised: 3/1/22 – annual review, updated referenced policies & covered LOBs



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 96.0

**SECTION: Commercial Drug
SUBJECT: Lilly Insulin**

Applicable line of business:

Commercial	X	Medicaid	
Medicare		ACA	X
GHP Kids	X	Self-Insured	X

POLICY:

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for agents to Lilly insulin for GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 487.0 Quantity Limit Exceptions

REQUIRED DEFINITIONS:

1. **Attachment** – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. **Exhibit** – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. **Devised** – the date the policy was implemented.
4. **Revised** – the date of every revision to the policy, including typographical and grammatical changes.
5. **Reviewed** – the date documenting the annual review if the policy has no revisions necessary.

ADDITIONAL DEFINITIONS:

1. **Formulary** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. **Non-formulary products** – those medications that are not included in the Formulary.
3. **Healthcare provider** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
4. **NCQA** – National Committee for Quality Assurance.
5. **Medically Necessary or Medical Necessity** – covered services rendered by a provider that the Health Plan determines are:



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 96.0

**SECTION: Commercial Drug
SUBJECT: Lilly Insulin**

- A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
- B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
- C. In accordance with current standards of medical practice;
- D. Not primarily for the convenience of the Member, or the Member's Provider; and
- E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

PROCEDURE:

A formulary exception for coverage of Lilly Insulin may be made for members who meet the following criteria:

- Medical record documentation that the requested insulin requires dilution **OR**
- Medical record documentation of a therapeutic failure on, contraindication to, or intolerance to comparable Novo Nordisk brand insulin (**with the exception of Fiasp**)

MEDISPAN AUTHORIZATION LEVEL: GPI-10

If a formulary exception is approved, the requested Lilly Insulin will be paid for under the member's prescription drug benefit.

Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.

FORMULARY ALTERNATIVES:

Novo Nordisk Insulins (vials and pens): Novolin R, Novolin N, Novolin 70/30, Novolog, NovoLog Mix 70/30, Levemir

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE
STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND
FEDERAL REGULATORY ENTITIES.**

**THIS POLICY WILL BE REVISED AS NECESSARY AND
REVIEWED NO LESS THAN ANNUALLY.**



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 96.0

**SECTION: Commercial Drug
SUBJECT: Lilly Insulin**

Signed: _____

Title: Director, Pharmacy Services

Date: March 1, 2022

- Devised: 10/03
- Effective: 10/03
- Reviewed: 3/04
- Revised: 3/05 – updated title
- Revised: 3/06 – updated title
- Reviewed: 3/07
- Revised: 5/07 – added signature
- Reviewed: 3/08 – annual review
- Revised: 11/08 – added dilution criterion
- Revised: 4/09 – annual review; updated alt.
- Reviewed: 3/10 – annual review
- Reviewed: 3/01/11 – annual review
- Revised: 3/01/12 – annual review, updated signature
- Revised: 3/01/13 – annual review, updated logo and definitions
- Reviewed: 3/01/14 – annual review
- Revised: 12/01/14 – updated policy to apply to all Lilly Insulin, updated signature
- Revised: 3/01/15 – annual review, removed vial from Policy section 1, updated formatting
- Reviewed: 3/01/16 – annual review
- Revised: 5/1/16 – updated format, logo, & procedure
- Reviewed: 3/1/17 – annual review
- Revised: 3/1/18 – annual review, updated signature, updated formatting of dilution criteria
- Revised: 7/20/18 – added Fiasp exclusion to criteria
- Reviewed: 3/1/19 – annual review
- Revised: 3/1/20 – annual review, added GHP Kids
- Revised: 3/1/21 – annual review, updated logo, added MediSpan approval level
- Revised: 3/1/22 – annual review, updated referenced policies & covered LOBs



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 99.0

**SECTION: Commercial Drug
SUBJECT: Iressa**

Applicable line of business:

Commercial	X	Medicaid	
Medicare		ACA	X
GHP Kids	X	Self-Insured	X

POLICY:

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for Iressa for GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 487.0 Quantity Limit Exceptions

REQUIRED DEFINITIONS:

1. **Attachment** – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. **Exhibit** – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. **Devised** – the date the policy was implemented.
4. **Revised** – the date of every revision to the policy, including typographical and grammatical changes.
5. **Reviewed** – the date documenting the annual review if the policy has no revisions necessary.

ADDITIONAL DEFINITIONS:

1. **Formulary** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. **Non-formulary products** – those medications that are not included in the Formulary.
3. **Healthcare provider** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
4. **NCQA** – National Committee for Quality Assurance.
5. **Medically Necessary or Medical Necessity** – covered services rendered by a provider that the Health Plan determines are:



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 99.0

**SECTION: Commercial Drug
SUBJECT: Iressa**

- A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
- B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
- C. In accordance with current standards of medical practice;
- D. Not primarily for the convenience of the Member, or the Member's Provider; and
- E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

PROCEDURE:

New members to the plan already established on therapy may be eligible for continuity of care coverage as long as there is medical record documentation that the safety and effectiveness of use for the prescribed indication is supported by Food and Drug Administration (FDA) approval or adequate medical and scientific evidence in the medical literature.

A formulary exception for coverage of Iressa may be made for members who meet the following criteria:

- Medical record documentation that Iressa is prescribed by a hematologist or oncologist **AND**
- Medical record documentation of metastatic non-small cell lung cancer **AND**
- Medical record documentation of one of the following EGFR mutations as detected by an FDA approved test
 - Exon 19 deletion
 - Exon 21 (L858R) substitution

MEDISPAN AUTHORIZATION LEVEL: GPI-12, number of claims authorized = 1, enter for the remainder of the calendar year

QUANTITY LIMIT: *No QLs need to be entered within the authorization unless the requested quantity exceeds the QL.*

- **QL FOR LETTER ONLY:** 1 tablet per day, 30 day supply per fill



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 99.0

**SECTION: Commercial Drug
SUBJECT: Iressa**

RE-AUTHORIZATION CRITERIA: Iressa is configured as a prior authorization for new starts only. Iressa will no longer be covered if it is identified that the member is not receiving appropriate follow-up care from the prescribing specialist or if the member has greater than or equal to a 90 day break in therapy.

- Medical record documentation that the member is receiving appropriate follow-up care from the prescribing specialist

If a formulary exception is approved Iressa will be paid for under the member's prescription drug benefit.

Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.

FORMULARY ALTERNATIVES:

Gilotrif*, erlotinib*

*prior authorization required

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE
STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND
FEDERAL REGULATORY ENTITIES.**

**THIS POLICY WILL BE REVISED AS NECESSARY AND
REVIEWED NO LESS THAN ANNUALLY.**

Signed: _____

Title: Director, Pharmacy Services

Date: March 1, 2022

Devised: 10/03
Effective: 10/03
Reviewed: 3/04
Revised: 3/05 – updated title
Revised: 7/05 – updated criteria #3
Revised: 3/06 – updated title



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 99.0

**SECTION: Commercial Drug
SUBJECT: Iressa**

Reviewed: 3/07
Revised: 5/07 – added signature
Reviewed: 3/08 – annual review
Reviewed: 4/09 – annual review
Reviewed: 3/10 – annual review
Reviewed: 3/1/11 – annual review
Revised: 3/1/12 – annual review, updated signature
Retired: 2012
Revised: 11/25/15 – policy reinstated, updated logo, removed failure of platinum/docetaxel, added EGFR requirements, added auth duration, QL, FA, updated signature
Reviewed: 3/1/16 – annual review
Revised: 5/1/16 – updated format, logo, & procedure
Revised: 3/1/17 – annual review, indicated PA required for Tarceva
Revised: 10/10/17 – increased authorization duration to 12 months
Revised: 3/1/18 – annual review, updated signature, added grandfather language, updated format of prescriber criteria
Revised: 3/1/19 – annual review, added QL approval note
Revised: 3/1/20 – annual review, added GHP Kids
Revised: 3/1/21 – annual review, updated logo, added MediSpan approval level, updated QL statement, updated Tarceva to generic
Revised: 11/24/21 – added one-time PA to approval crit., removed auth duration & added re-auth crit.
Revised: 3/1/22 – annual review, updated referenced policies & covered LOBs



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 104.0

**SECTION: Commercial Drug
SUBJECT: Somavert**

Applicable line of business:

Commercial	X	Medicaid	
Medicare		ACA	X
GHP Kids	X	Self-Insured	X

POLICY:

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for Somavert for GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 487.0 Quantity Limit Exceptions

REQUIRED DEFINITIONS:

1. **Attachment** – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. **Exhibit** – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. **Devised** – the date the policy was implemented.
4. **Revised** – the date of every revision to the policy, including typographical and grammatical changes.
5. **Reviewed** – the date documenting the annual review if the policy has no revisions necessary.

ADDITIONAL DEFINITIONS:

1. **Formulary** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. **Non-formulary products** – those medications that are not included in the Formulary.
3. **Healthcare provider** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
4. **NCQA** – National Committee for Quality Assurance.
5. **Medically Necessary or Medical Necessity** – covered services rendered by a provider that the Health Plan determines are:



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 104.0

**SECTION: Commercial Drug
SUBJECT: Somavert**

- A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
- B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
- C. In accordance with current standards of medical practice;
- D. Not primarily for the convenience of the Member, or the Member's Provider; and
- E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

PROCEDURE:

An exception for coverage of Somavert may be made for members who meet **ALL** of the following criteria:

- Medical record documentation that Somavert is prescribed by an endocrinologist **AND**
- Medical record documentation of a diagnosis of acromegaly **AND**
- Medical record documentation of age greater than or equal to 18 years **AND**
- Medical record documentation of failure, intolerance to or contraindication with somatostatin analogs (octreotide or octreotide LAR)

MEDISPAN AUTHORIZATION LEVEL: GPI-12

If an exception is made, Somavert will be paid for under the member's prescription drug benefit.

Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.

FORMULARY ALTERNATIVES:

bromocriptine, octreotide



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 104.0

**SECTION: Commercial Drug
SUBJECT: Somavert**

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE
STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND
FEDERAL REGULATORY ENTITIES.**

**THIS POLICY WILL BE REVISED AS NECESSARY AND
REVIEWED NO LESS THAN ANNUALLY.**

Signed: _____

Title: Director, Pharmacy Services

Date: March 1, 2022

Devised: 10/03
Effective: 10/03
Reviewed: 3/04
Revised: 2/05 – updated title
Reviewed: 3/05
Revised: 3/0 – updated title
Reviewed: 3/07
Revised: 5/07 – added signature
Reviewed: 3/08 – annual review
Revised: 4/09 – annual review, updated alt
Reviewed: 3/10 – annual review
Reviewed: 3/1/11 – annual review
Revised: 3/2/12 – annual review, updated signature
Revised: 3/1/13 – annual review, updated logo and definitions, fixed typo
Revised: 3/1/14 – annual review, updated formatting
Revised: 3/1/15 – annual review, updated signature
Reviewed: 3/1/16 – annual review
Revised: 5/1/16 – updated format, logo, & procedure
Revised: 3/1/17 – annual review, updated formatting
Revised: 3/1/18 – annual review, updated signature, updated format of prescriber/age criteria
Reviewed: 3/1/19 – annual review
Revised: 3/1/20 – annual review, added GHP Kids
Revised: 3/1/21 – annual review, updated logo, added MediSpan approval level
Revised: 3/1/22 – annual review, updated referenced policies & covered LOBs



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 105.0

**SECTION: Commercial Drug
SUBJECT: Teriparatide**

Applicable line of business:

Commercial	X	Medicaid	
Medicare		ACA	X
GHP Kids	X	Self-Insured	X

POLICY:

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for teriparatide for GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 487.0 Quantity Limit Exceptions

REQUIRED DEFINITIONS:

1. **Attachment** – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. **Exhibit** – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. **Devised** – the date the policy was implemented.
4. **Revised** – the date of every revision to the policy, including typographical and grammatical changes.
5. **Reviewed** – the date documenting the annual review if the policy has no revisions necessary.

ADDITIONAL DEFINITIONS:

1. **Formulary** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. **Non-formulary products** – those medications that are not included in the Formulary.
3. **Healthcare provider** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
4. **NCQA** – National Committee for Quality Assurance.
5. **Medically Necessary or Medical Necessity** – covered services rendered by a provider that the Health Plan determines are:

- A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
- B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
- C. In accordance with current standards of medical practice;
- D. Not primarily for the convenience of the Member, or the Member's Provider; and
- E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

PROCEDURE:

An exception for coverage of teriparatide may be made for members who meet the following criteria:

- There is no medical record documentation of increased baseline risk of osteosarcoma [Paget's disease, open epiphyses (pediatric or young adult patients), prior radiation therapy involving the skeleton, unexplained elevations of alkaline phosphatase] **AND**
 - **For women:**
 - There is medical record documentation of a diagnosis of osteoporosis **AND**
 - There is medical record documentation of postmenopausal status or glucocorticoid induced osteoporosis **AND**
 - There is medical record documentation that member has not previously been on a parathyroid hormone analog for greater than 2 years **AND**
 - There is medical record documentation of an attempt of therapy with or contraindication to bisphosphonates **OR**
 - There is medical record documentation of a previous osteoporotic fracture or high risk of fracture (T-score -2.5 or below with documented risk factors)
- OR**
- **For men:**
 - There is medical record documentation of a diagnosis of osteoporosis **AND**
 - There is medical record documentation of an attempt of therapy with or contraindication to bisphosphonate therapy **OR**
 - There is medical record documentation of a previous osteoporotic fracture or high risk of fracture (T-score <-2.5)

MEDISPAN AUTHORIZATION LEVEL: GPI-12, generic only

QUANTITY LIMIT: *No QLs need to be entered within the authorization unless the requested quantity exceeds the QL.*

- Forteo QL FOR LETTER ONLY: 2.4 mL per 28 days
- Teriparatide QL FOR LETTER ONLY: 2.48 per 28 days

AUTHORIZATION DURATION: Approval will be for 2 years, or less if there is medical record documentation of a previous incomplete course of therapy with a parathyroid hormone analog. Cumulative use of parathyroid hormone analogs for more than 2 years during a patient's lifetime is not recommended.

NOTE: Cumulative use of parathyroid hormone analogs for more than 2 years during a patient's lifetime is not recommended.

Risk Factors Included in the WHO Fracture Risk Assessment Model

- Current age
- Gender
- A prior osteoporotic fracture (including morphometric vertebral fracture)
- Femoral neck BMD
- Low body mass index (kg/m²)
- Oral glucocorticoids ≥ 5 mg/d of prednisone for ≥ 3 mo (ever)
- Rheumatoid arthritis
- Secondary osteoporosis
- Parental history of hip fracture
- Current smoking
- Alcohol intake (3 or more drinks/d)

From: WHO Technical Report.8

If an exception is made, teriparatide will be paid for under the member's prescription drug benefit.

Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.

FORMULARY ALTERNATIVES:

alendronate, ibandronate, risedronate, Tymlos*

*prior authorization required



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 105.0

**SECTION: Commercial Drug
SUBJECT: Teriparatide**

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE
STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND
FEDERAL REGULATORY ENTITIES.**

**THIS POLICY WILL BE REVISED AS NECESSARY AND
REVIEWED NO LESS THAN ANNUALLY.**

Signed: _____

Title: Director, Pharmacy Services

Date: March 1, 2022

Devised: 10/03
Effective: 10/03
Reviewed: 3/04
Revised: 2/05 – updated title
Reviewed: 3/05
Revised: 3/06 – updated title
Reviewed: 3/07
Revised: 5/07 – added signature
Reviewed: 3/08 – annual review
Reviewed: 4/09 – annual review
Reviewed: 3/10 – annual review
Revised: 3/1/11 – annual review-updated alts.
Revised: 3/1/12 – annual review, updated signature
Revised: 3/1/13 – annual review, updated logo & definitions, updated alternatives, removed typo
Revised: 3/1/14 – annual review, updated formatting, corrected typo
Revised: 3/1/15 – annual review, updated signature
Revised: 3/1/16 – annual review, updated policy formatting, changed Actonel to risedronate
Revised: 5/1/16 – updated format, logo, & procedure
Reviewed: 3/1/17 – annual review
Revised: 3/27/17 – removed prescriber, updated T-scores, bisphosphonate OR high risk
Revised: 6/2/17 – added glucocorticoid inducing osteoporosis
Revised: 9/28/17 – added no prior PTH, added QL/ risk factors, updated auth duration/note
Revised: 3/1/18 – annual review, updated signature
Revised: 3/1/19 – annual review, added QL approval note, updated FA
Revised: 3/1/20 – annual review, added GHP Kids
Revised: 3/1/21 – annual review, updated logo, added MediSpan approval level, updated Forteo to generic
Revised: 8/24/21 – added separate QL for teriparatide, corrected DS on Forteo QL
Revised: 3/1/22 – annual review, updated referenced policies & covered LOBs, added generic only



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 110.0

**SECTION: Commercial Drug
SUBJECT: Gelclair**

Applicable line of business:

Commercial	X	Medicaid	
Medicare		ACA	X
GHP Kids	X	Self-Insured	X

POLICY:

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for Gelclair for GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 487.0 Quantity Limit Exceptions

REQUIRED DEFINITIONS:

1. **Attachment** – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. **Exhibit** – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. **Devised** – the date the policy was implemented.
4. **Revised** – the date of every revision to the policy, including typographical and grammatical changes.
5. **Reviewed** – the date documenting the annual review if the policy has no revisions necessary.

ADDITIONAL DEFINITIONS:

1. **Formulary** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. **Non-formulary products** – those medications that are not included in the Formulary.
3. **Healthcare provider** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
4. **NCQA** – National Committee for Quality Assurance.
5. **Medically Necessary or Medical Necessity** – covered services rendered by a provider that the Health Plan determines are:



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 110.0

**SECTION: Commercial Drug
SUBJECT: Gelclair**

- A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
- B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
- C. In accordance with current standards of medical practice;
- D. Not primarily for the convenience of the Member, or the Member's Provider; and
- E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

PROCEDURE:

An exception for coverage of Gelclair may be made for members who meet the following criteria:

- Medical record documentation of a diagnosis of oral mucositis secondary to chemotherapy or radiation

MEDISPAN AUTHORIZATION LEVEL: GPI-12

If an exception is made, Gelclair will be paid for under the member's prescription drug benefit.

Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.

FORMULARY ALTERNATIVES:

sucralfate tablets

Maalox + viscous lidocaine + (otc) Benadryl liquid = Magic Mouthwash Compound

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE
STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND
FEDERAL REGULATORY ENTITIES.**

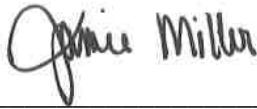
**THIS POLICY WILL BE REVISED AS NECESSARY AND
REVIEWED NO LESS THAN ANNUALLY.**

Geisinger

**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 110.0

**SECTION: Commercial Drug
SUBJECT: Gelclair**



Signed: _____

Title: Director, Pharmacy Services

Date: March 1, 2022

Devised: 1/04
Effective: 1/04
Reviewed: 3/04
Revised: 3/05 – updated title and formulary alts.
Revised: 3/06 – updated title
Reviewed: 3/07
Revised: 5/07 – added signature
Reviewed: 3/08 – annual review
Reviewed: 4/09 – annual review
Revised: 4/09 – updated criteria
Reviewed: 3/10 – annual review
Reviewed: 3/1/11 – annual review
Revised: 3/1/12 – annual review, updated signature
Revised: 3/1/13 – annual review, updated logo and definitions
Reviewed: 3/1/14 – annual review
Revised: 3/1/15 – annual review, updated signature
Reviewed: 3/1/16 – annual review
Revised: 5/1/16 – updated format, logo, & procedure
Reviewed: 3/1/17 – annual review
Revised: 3/1/18 – annual review, updated signature
Reviewed: 3/1/19 – annual review
Revised: 3/1/20 – annual review, added GHP Kids
Revised: 3/1/21 – annual review, updated logo, added MediSpan approval level
Revised: 3/1/22 – annual review, updated referenced policies & covered LOBs



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 112.0

**SECTION: Commercial Drug
SUBJECT: Azelaic Acid Gel and
Finacea Foam**

Applicable line of business:

Commercial	X	Medicaid	
Medicare		ACA	X
GHP Kids	X	Self-Insured	X

POLICY:

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for azelaic acid gel and Finacea foam for GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 487.0 Quantity Limit Exceptions

REQUIRED DEFINITIONS:

1. **Attachment** – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. **Exhibit** – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. **Devised** – the date the policy was implemented.
4. **Revised** – the date of every revision to the policy, including typographical and grammatical changes.
5. **Reviewed** – the date documenting the annual review if the policy has no revisions necessary.

ADDITIONAL DEFINITIONS:

1. **Formulary** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. **Non-formulary products** – those medications that are not included in the Formulary.
3. **Healthcare provider** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
4. **NCQA** – National Committee for Quality Assurance.
5. **Medically Necessary or Medical Necessity** – covered services rendered by a provider that the Health Plan determines are:



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 112.0

**SECTION: Commercial Drug
SUBJECT: Azelaic Acid Gel and
Finacea Foam**

- A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
- B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
- C. In accordance with current standards of medical practice;
- D. Not primarily for the convenience of the Member, or the Member's Provider; and
- E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

PROCEDURE:

A formulary exception for coverage of azelaic acid gel or Finacea may be made for members who meet the following criteria:

- Medical record documentation of a diagnosis of rosacea **AND**
- Medical record documentation of therapeutic failure on, intolerance to, or contraindication to topical metronidazole

MEDISPAN AUTHORIZATION LEVEL: GPI-12, if request is for azelaic acid gel include generic only.

If a formulary exception is approved, azelaic acid gel or Finacea Foam will be paid for under the member's prescription drug benefit.

Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.

FORMULARY ALTERNATIVES:

metronidazole cream, metronidazole gel, metronidazole lotion

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE
STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND
FEDERAL REGULATORY ENTITIES.**

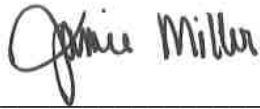
**THIS POLICY WILL BE REVISED AS NECESSARY AND
REVIEWED NO LESS THAN ANNUALLY.**

Geisinger

**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 112.0

**SECTION: Commercial Drug
SUBJECT: Azelaic Acid Gel and
Finacea Foam**



Signed: _____

Title: Director, Pharmacy Services

Date: March 1, 2022

Devised: 04/04
Effective: 04/04
Revised: 3/05 – updated title
Revised: 3/06 – updated title
Reviewed: 3/07
Revised: 5/07 – added signature
Reviewed: 3/08 – annual review
Reviewed: 4/09 – annual review
Reviewed: 3/10 – annual review
Reviewed: 3/1/11 – annual review
Revised: 3/1/12 – annual review, updated signature
Revised: 3/1/13 – annual review, updated logo and definitions, updated alternatives
Revised: 3/1/14 – annual review, updated formatting
Revised: 3/1/15 – annual review, updated signature
Reviewed: 3/1/16 – annual review
Revised: 5/1/16 – updated format, logo, & procedure
Reviewed: 3/1/17 – annual review
Revised: 3/1/18 – annual review, updated signature
Reviewed: 3/1/19 – annual review
Revised: 3/1/20 – annual review, added GHP Kids
Revised: 3/1/21 – annual review, updated logo, added MediSpan approval level, updated Finacea gel to generic
Revised: 3/1/22 – annual review, updated referenced policies & covered LOBs



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 118.0

**SECTION: Commercial Drug
SUBJECT: Modafinil**

Applicable line of business:

Commercial	X	Medicaid	
Medicare		ACA	X
GHP Kids	X	Self-Insured	X

POLICY:

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for modafinil for GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 487.0 Quantity Limit Exceptions

REQUIRED DEFINITIONS:

1. **Attachment** – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. **Exhibit** – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. **Devised** – the date the policy was implemented.
4. **Revised** – the date of every revision to the policy, including typographical and grammatical changes.
5. **Reviewed** – the date documenting the annual review if the policy has no revisions necessary.

ADDITIONAL DEFINITIONS:

1. **Formulary** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. **Non-formulary products** – those medications that are not included in the Formulary.
3. **Healthcare provider** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
4. **NCQA** – National Committee for Quality Assurance.
5. **Medically Necessary or Medical Necessity** – covered services rendered by a provider that the Health Plan determines are:



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 118.0

**SECTION: Commercial Drug
SUBJECT: Modafinil**

- A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
- B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
- C. In accordance with current standards of medical practice;
- D. Not primarily for the convenience of the Member, or the Member's Provider; and
- E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

PROCEDURE:

An exception for coverage of modafinil may be made for members who meet **ONE** of the following criteria:

- Medical record documentation of a diagnosis of obstructive sleep apnea/hypopnea syndrome requiring treatment with nasal CPAP **OR**
- Medical record documentation of a diagnosis of narcolepsy **OR**
- Medical record documentation of a diagnosis of shift-work disorder **OR**
- Medical record documentation of fatigue associated with a diagnosis of multiple sclerosis **OR**
- Medical record documentation of a diagnosis of idiopathic hypersomnia

MEDISPAN AUTHORIZATION LEVEL: GPI-12, generic only

If an exception is made, modafinil will be paid for under the member's prescription drug benefit.

Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.

FORMULARY ALTERNATIVES:

none



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 118.0

**SECTION: Commercial Drug
SUBJECT: Modafinil**

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE
STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND
FEDERAL REGULATORY ENTITIES.**

**THIS POLICY WILL BE REVISED AS NECESSARY AND
REVIEWED NO LESS THAN ANNUALLY.**

Signed: _____

Title: Director, Pharmacy Services

Date: March 1, 2022

Devised: 10/04
Effective: 10/04
Reviewed: 3/05
Revised: 3/06 – updated title
Reviewed: 3/07
Revised: 5/07 – added signature
Reviewed: 3/08 – annual review
Revised: 4/09 – annual review, updated alt.
Revised: 1/10 – removed failure on stimulant for narcolepsy, removed formulary alt.
Reviewed: 3/10 – annual review
Reviewed: 3/1/11 – annual review
Revised: 3/1/12 – annual review, updated signature
Revised: 6/5/12 – added generic modafinil to policy
Revised: 3/1/13 – annual review, updated logo & definitions, removed brand Provigil from policy
Revised: 11/15/13 – added shift-work disorder & fatigue assoc. with multiple sclerosis indications
Revised: 3/1/14 – annual review, updated formatting
Revised: 3/1/15 – annual review, updated signature
Reviewed: 3/1/16 – annual review
Revised: 5/1/16 – updated format, logo, & procedure
Reviewed: 3/1/17 – annual review
Revised: 3/1/18 – annual review, updated signature
Reviewed: 3/1/19 – annual review
Revised: 3/1/20 – annual review, added GHP Kids
Revised: 3/1/21 – annual review, updated logo, added MediSpan approval level
Revised: 1/21/22 – added idiopathic hypersomnia to approved indications
Revised: 3/1/22 – annual review, updated referenced policies & covered LOBs



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 120.0

**SECTION: Commercial Drug
SUBJECT: Ezetimibe/Simvastatin**

Applicable line of business:

Commercial	X	Medicaid	
Medicare		ACA	X
GHP Kids	X	Self-Insured	X

POLICY:

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for ezetimibe/simvastatin for GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 487.0 Quantity Limit Exceptions

REQUIRED DEFINITIONS:

1. **Attachment** – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. **Exhibit** – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. **Devised** – the date the policy was implemented.
4. **Revised** – the date of every revision to the policy, including typographical and grammatical changes.
5. **Reviewed** – the date documenting the annual review if the policy has no revisions necessary.

ADDITIONAL DEFINITIONS:

1. **Formulary** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. **Non-formulary products** – those medications that are not included in the Formulary.
3. **Healthcare provider** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
4. **NCQA** – National Committee for Quality Assurance.
5. **Medically Necessary or Medical Necessity** – covered services rendered by a provider that the Health Plan determines are:

- A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
- B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
- C. In accordance with current standards of medical practice;
- D. Not primarily for the convenience of the Member, or the Member's Provider; and
- E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

PROCEDURE:

An exception for coverage of ezetimibe/simvastatin may be made for members who meet the following criteria:

- A diagnosis of primary hypercholesterolemia, mixed hyperlipidemia, or homozygous familial hypercholesterolemia with failure to meet goal LDL (per NCEP guidelines) goals on a combination of ezetimibe and simvastatin

OR

An exception for coverage of high dose ezetimibe/simvastatin (greater than 80 mg of simvastatin) may be made for members who meet the following criteria:

- Medical record documentation that the member has been utilizing simvastatin 80 mg for greater than 12 months **OR**
- Medical record documentation of therapeutic failure on, intolerance to, or contraindication to atorvastatin and rosuvastatin

MEDISPAN AUTHORIZATION LEVEL: GPI-12, generic only

If an exception is made, ezetimibe/simvastatin will be paid for under the member's prescription drug benefit.

Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.

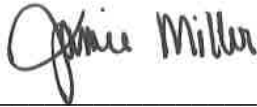
FORMULARY ALTERNATIVES:

atorvastatin, lovastatin, simvastatin, pravastatin, rosuvastatin, ezetimibe

For high dose ezetimibe/simvastatin: atorvastatin and rosuvastatin

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE
STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND
FEDERAL REGULATORY ENTITIES.**

**THIS POLICY WILL BE REVISED AS NECESSARY AND
REVIEWED NO LESS THAN ANNUALLY.**



Signed: _____

Title: Director, Pharmacy Services

Date: March 1, 2022

Devised: 4/05
Revised: 3/06 – updated title
Reviewed: 3/07
Revised: 5/07 – added signature
Revised: 3/08 – annual review; updated alternatives
Revised: 7/08 – removed failure on Lipitor/Crestor monotherapy from criteria
Revised: 4/09 – annual review
Revised: 3/10 – annual review, updated alt
Revised: 3/1/11 – annual review-updated alts.
Revised: 9/11 – added criteria for high dose simvastatin
Revised: 3/1/12 – annual review, updated signature
Revised: 8/21/12 – changed Lipitor to atorvastatin
Revised: 3/1/13 – annual review, updated logo and definitions, fixed typo, updated alternatives
Reviewed: 3/1/14 – annual review
Revised: 3/1/15 – annual review, updated signature
Revised: 3/1/16 – annual review, update policy formatting
Revised: 5/1/16 – updated format, logo, & procedure
Revised: 5/27/16 – updated Crestor to rosuvastatin
Revised: 3/1/17 – annual review, updated Zetia to ezetimibe
Revised: 3/1/18 – annual review, updated signature, updated Vytorin to ezetimibe/simvastatin
Reviewed: 3/1/19 – annual review
Revised: 3/1/20 – annual review, added GHP Kids
Revised: 3/1/21 – annual review, updated logo, added MediSpan approval level
Revised: 3/1/22 – annual review, updated referenced policies & covered LOBs



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 121.0

**SECTION: Commercial Drug
SUBJECT: Alomide, Bepreve, Emadine,
Lastacaft, and Pazeo**

Applicable line of business:

Commercial	X	Medicaid	
Medicare		ACA	X
GHP Kids	X	Self-Insured	X

POLICY:

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for Alomide, Bepreve, Emadine, Lastacaft, and Pazeo for GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 487.0 Quantity Limit Exceptions

REQUIRED DEFINITIONS:

1. **Attachment** – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. **Exhibit** – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. **Devised** – the date the policy was implemented.
4. **Revised** – the date of every revision to the policy, including typographical and grammatical changes.
5. **Reviewed** – the date documenting the annual review if the policy has no revisions necessary.

ADDITIONAL DEFINITIONS:

1. **Formulary** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. **Non-formulary products** – those medications that are not included in the Formulary.
3. **Healthcare provider** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
4. **NCQA** – National Committee for Quality Assurance.
5. **Medically Necessary or Medical Necessity** – covered services rendered by a provider that the Health Plan determines are:

- A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
- B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
- C. In accordance with current standards of medical practice;
- D. Not primarily for the convenience of the Member, or the Member's Provider; and
- E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

PROCEDURE:

An exception for coverage of Alomide, Bepreve, Emadine, Lastacaft, or Pazeo may be made for members who meet the following criteria:

- Medical record documentation of allergic conjunctivitis **AND**
- Medical record documentation of failure on, intolerance to or contraindication to azelastine eye drops, epinastine eye drops, olopatadine eye drops (generic Pataday or Patanol) **AND** OTC Zaditor

MEDISPAN AUTHORIZATION LEVEL: GPI-12

If an exception is made Alomide, Bepreve, Emadine, Lastacaft, or Pazeo will be paid for under the member's prescription drug benefit.

Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.

FORMULARY ALTERNATIVES:

azelastine eye drops (generic Optivar), epinastine (generic Elestat), olopatadine (generic Pataday or Patanol)



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 121.0

**SECTION: Commercial Drug
SUBJECT: Alomide, Bepreve, Emadine,
Lastacraft, and Pazeo**

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE
STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND
FEDERAL REGULATORY ENTITIES.**

**THIS POLICY WILL BE REVISED AS NECESSARY AND
REVIEWED NO LESS THAN ANNUALLY.**

Signed: _____

Title: Director, Pharmacy Services

Date: March 1, 2022

Devised: 4/05
Revised: 6/05 added Emadine
Revised: 3/06 – updated title
Revised: 3/07 – deleted ketotifen from formulary alternatives (now OTC)
Revised: 5/07 – added signature
Revised: 1/08 – added Optivar and Pataday, changed criteria
Reviewed: 3/08 – annual review
Reviewed: 4/09 – annual review
Reviewed: 3/10 – annual review
Revised: 3/1/11 – annual review; updated criteria and alts. to reflect generics
Revised: 9/11 – added Lastacraft, removed epinastine (now generic), updated alternatives
Revised: 3/1/12 – annual review, updated signature, logo, fixed typo, updated alternatives
Revised: 3/1/13 – annual review, updated logo, definitions, and signature
Reviewed: 3/1/14 – annual review
Revised: 3/1/15 – annual review, updated signature
Reviewed: 3/1/16 – annual review
Revised: 5/1/16 – updated format, logo, & procedure
Revised: 7/27/16 – removed Patanol from policy since no PA required, added olopatadine to FA
Reviewed: 3/1/17 – annual review
Revised: 11/27/17 – added Bepreve & Pazeo, updated criteria to failure to include epinastine, olopatadine (generic Pataday/Patanol), removed brand Pataday, updated FA, updated signature
Reviewed: 3/1/18 – annual review
Reviewed: 3/1/19 – annual review
Revised: 3/1/20 – annual review, added GHP Kids
Revised: 3/1/21 – annual review, updated logo, added MediSpan approval level
Revised: 3/1/22 – annual review, updated referenced policies & covered LOBs



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 124.0

**SECTION: Commercial Drug
SUBJECT: Revlimid**

Applicable line of business:

Commercial	X	Medicaid	
Medicare		ACA	X
GHP Kids	X	Self-Insured	X

POLICY:

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for Revlimid for GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 487.0 Quantity Limit Exceptions

REQUIRED DEFINITIONS:

1. **Attachment** – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. **Exhibit** – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. **Devised** – the date the policy was implemented.
4. **Revised** – the date of every revision to the policy, including typographical and grammatical changes.
5. **Reviewed** – the date documenting the annual review if the policy has no revisions necessary.

ADDITIONAL DEFINITIONS:

1. **Formulary** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. **Non-formulary products** – those medications that are not included in the Formulary.
3. **Healthcare provider** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
4. **NCQA** – National Committee for Quality Assurance.
5. **Medically Necessary or Medical Necessity** – covered services rendered by a provider that the Health Plan determines are:

- A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
- B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
- C. In accordance with current standards of medical practice;
- D. Not primarily for the convenience of the Member, or the Member's Provider; and
- E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

PROCEDURE:

New members to the plan already established on therapy may be eligible for continuity of care coverage as long as there is medical record documentation that the safety and effectiveness of use for the prescribed indication is supported by Food and Drug Administration (FDA) approval or adequate medical and scientific evidence in the medical literature.

An exception for coverage of Revlimid may be made for members who meet the following criteria:

For Myelodysplastic Syndromes (MDS)

- Medical record documentation that Revlimid is prescribed by a hematologist/oncologist **AND**
- Medical record documentation of the treatment of a patient with myelodysplastic syndromes (MDS) associated with a deletion 5q cytogenetic abnormality with or without additional cytogenetic abnormalities

OR

With no deletion 5q cytogenetic abnormality:

- Medical record documentation of initial use in lower risk patient with symptomatic anemia and serum erythropoietin levels greater than 500 mU/mL and a low probability of response to immunosuppressive therapy* **OR**
- Medical record documentation of lower risk patient with symptomatic anemia and no response to initial treatment with epoetin alfa or darbepoetin alfa, hypomethylating agents, or immunosuppressive therapy

*Low probability is defined as members who lack any of the following features: age less than or equal to 60, those with hypocellular marrows, HLA-DR15 or PNH clone positivity

OR



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 124.0

**SECTION: Commercial Drug
SUBJECT: Revlimid**

For Multiple Myeloma

- Medical record documentation that Revlimid is prescribed by a hematologist/oncologist **AND**
- Medical record documentation of a diagnosis of multiple myeloma

OR

For Non-Hodgkin Lymphomas (NHL)

- Medical record documentation that Revlimid is prescribed by a hematologist/oncologist **AND**
- Medical record documentation of a diagnosis of NHL (relapsed, refractory, progressive disease, or members who are not candidates for high dose therapy)

OR

For Mantle Cell Lymphoma

- Medical record documentation that Revlimid is prescribed by a hematologist/oncologist **AND**
- Medical record documentation of relapsed, refractory, or progressive mantle cell lymphoma **AND**
- Medical record documentation of therapeutic failure on, intolerance to, or contraindication to one prior therapy

OR

For Follicular Lymphoma

- Medical record documentation that Revlimid is prescribed by a hematologist/oncologist **AND**
- Medical record documentation of a diagnosis of follicular lymphoma **AND**
- Medical record documentation of therapeutic failure on, intolerance to, or contraindication to at least one prior therapy **AND**
- Medical record documentation that Revlimid is being used in combination with a rituximab product

OR

For Marginal Zone Lymphoma

- Medical record documentation that Revlimid is prescribed by a hematologist/oncologist **AND**
- Medical record documentation of a diagnosis of marginal zone lymphoma **AND**



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 124.0

**SECTION: Commercial Drug
SUBJECT: Revlimid**

- Medical record documentation of therapeutic failure on, intolerance to, or contraindication to at least one prior therapy **AND**
- Medical record documentation that Revlimid is being used in combination with a rituximab product

MEDISPAN AUTHORIZATION LEVEL: GPI-12, number of claims authorized = 1, enter for the remainder of the calendar year

QUANTITY LIMIT: *No QLs need to be entered within the authorization unless the requested quantity exceeds the QL.*

- **QL FOR LETTER ONLY:**
 - 2.5 mg, 5 mg, and 10 mg capsules: 1 capsule per day, 28 day supply per fill
 - 15 mg, 20 mg, and 25 mg capsules: 21 capsules per 28 days

RE-AUTHORIZATION CRITERIA: Revlimid is configured as a prior authorization for new starts only. Revlimid will no longer be covered if it is identified that the member is not receiving appropriate follow-up care from the prescribing specialist or if the member has greater than or equal to a 90 day break in therapy.

- Medical record documentation that the member is receiving appropriate follow-up care from the prescribing specialist

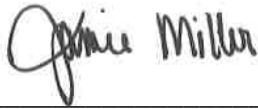
If a formulary exception is approved, Revlimid will be paid for under the member's prescription drug benefit.

Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.

FORMULARY ALTERNATIVES:
none

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE
STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND
FEDERAL REGULATORY ENTITIES.**

**THIS POLICY WILL BE REVISED AS NECESSARY AND
REVIEWED NO LESS THAN ANNUALLY.**



Signed: _____

Title: Director, Pharmacy Services

Date: March 1, 2022

Devised: 4/06
Reviewed: 3/07
Revised: 5/07 – added multiple myeloma indication; added signature
Reviewed: 3/08 – annual review
Reviewed: 4/09 – annual review
Reviewed: 3/10 – annual review
Reviewed: 3/1/11 – annual review
Revised: 3/1/12 – annual review, updated signature
Revised: 7/18/12 – added non-Hodgkin Lymphoma indication, altered myelodysplastic syndrome & multiple myeloma indications to match NCCN recommendation
Revised: 3/1/13 – annual review, updated logo and definitions
Revised: 10/7/13 – added mantle cell lymphoma indication
Reviewed: 3/1/14 – annual review
Revised: 3/1/15 – annual review, updated signature
Reviewed: 3/1/16 – annual review
Revised: 5/1/16 – updated format, logo, & procedure
Revised: 3/1/17 – annual review, removed Unicode characters
Revised: 6/2/17 – added QL
Revised: 10/10/17 – added authorization duration
Revised: 3/1/18 – annual review, updated signature, added grandfather and approval language
Revised: 6/1/18 – updated QL
Revised: 3/1/19 – annual review, added QL approval note
Revised: 7/23/19 – added follicular lymphoma and marginal zone lymphoma indications
Revised: 3/1/20 – annual review, added GHP Kids
Revised: 8/4/20 – corrected typo
Revised: 3/1/21 – annual review, updated logo, added MediSpan approval level, updated QL statement, added prescriber criteria to each indication
Revised: 12/1/21 – added one-time PA to approval crit., removed auth duration & added re-auth crit.
Revised: 3/1/22 – annual review, updated referenced policies & covered LOBs



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 125.0

**SECTION: Commercial Drug
SUBJECT: Sprycel**

Applicable line of business:

Commercial	X	Medicaid	
Medicare		ACA	X
GHP Kids	X	Self-Insured	X

POLICY:

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for Sprycel for GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 487.0 Quantity Limit Exceptions

REQUIRED DEFINITIONS:

1. **Attachment** – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. **Exhibit** – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. **Devised** – the date the policy was implemented.
4. **Revised** – the date of every revision to the policy, including typographical and grammatical changes.
5. **Reviewed** – the date documenting the annual review if the policy has no revisions necessary.

ADDITIONAL DEFINITIONS:

1. **Formulary** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. **Non-formulary products** – those medications that are not included in the Formulary.
3. **Healthcare provider** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
4. **NCQA** – National Committee for Quality Assurance.
5. **Medically Necessary or Medical Necessity** – covered services rendered by a provider that the Health Plan determines are:

- A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
- B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
- C. In accordance with current standards of medical practice;
- D. Not primarily for the convenience of the Member, or the Member's Provider; and
- E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

PROCEDURE:

New members to the plan already established on therapy may be eligible for continuity of care coverage as long as there is medical record documentation that the safety and effectiveness of use for the prescribed indication is supported by Food and Drug Administration (FDA) approval or adequate medical and scientific evidence in the medical literature.

An exception for coverage of Sprycel may be made for members who meet the following criteria:

- Medical record documentation that Sprycel is prescribed by a hematologist or oncologist **AND**
- Medical record documentation of the use of Sprycel to treat newly diagnosed chronic phase Philadelphia chromosome-positive (Ph+) chronic myeloid leukemia (CML) **OR**
- Medical record documentation of the use of Sprycel to treat chronic, accelerated, or myeloid/lymphoid blast phase Philadelphia chromosome-positive (Ph+) chronic myeloid leukemia (CML) with resistance or intolerance to prior therapy including imatinib **OR**
- Medical record documentation of use of Sprycel to treat Philadelphia chromosome-positive (Ph+) acute lymphoblastic leukemia (ALL) with resistance or intolerance to prior therapy **OR**
- Medical record documentation of use of Sprycel to treat newly diagnosed Philadelphia chromosome positive (Ph+) acute lymphoblastic leukemia (ALL) in pediatric patients 1 year and older in combination with chemotherapy

MEDISPAN AUTHORIZATION LEVEL: GPI-12, number of claims authorized = 1, enter for the remainder of the calendar year

QUANTITY LIMIT: *No QLs need to be entered within the authorization unless the requested quantity exceeds the QL.*

- **QL FOR LETTER ONLY:**
 - 20 mg tablet: 3 tablets per day, 30 day supply per fill
 - 50 mg, 70 mg, 80 mg, 100 mg, and 140 mg tablets: 1 tablet per day, 30 day supply per fill

RE-AUTHORIZATION CRITERIA: Sprycel is configured as a prior authorization for new starts only. Sprycel will no longer be covered if it is identified that the member is not receiving appropriate follow-up care from the prescribing specialist or if the member has greater than or equal to a 90 day break in therapy.

- Medical record documentation that the member is receiving appropriate follow-up care from the prescribing specialist

If an exception is made Sprycel will be paid for under the member's prescription drug benefit.

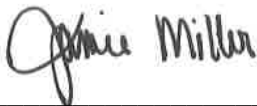
Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.

FORMULARY ALTERNATIVES:

Chronic, Accelerated, or Myeloid/Lymphoid Blast Phase Ph+ CML: imatinib

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE
STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND
FEDERAL REGULATORY ENTITIES.**

**THIS POLICY WILL BE REVISED AS NECESSARY AND
REVIEWED NO LESS THAN ANNUALLY.**

Signed:  _____

Title: Director, Pharmacy Services

Date: March 1, 2022



POLICY NUMBER: 125.0

**POLICY AND PROCEDURE
PHARMACY
MANUAL**

**SECTION: Commercial Drug
SUBJECT: Sprycel**

Devised: 10/06
Reviewed: 3/07
Revised: 5/07 – added signature
Reviewed: 3/08 – annual review
Reviewed: 4/09 – annual review
Reviewed: 3/10 – annual review
Revised: 12/10 – added criteria to support new FDA approved indication
Reviewed: 3/1/11 – annual review
Revised: 3/1/12 – annual review, updated signature
Revised: 3/1/13 – annual review, updated logo and definitions
Revised: 3/1/14 – annual review, corrected typo, updated formatting, added approval statement
Revised: 3/1/15 – annual review, updated signature
Reviewed: 3/1/16 – annual review
Revised: 3/24/16 – removed copay per 15 day supply requirement
Revised: 5/1/16 – updated format, logo, & procedure, updated note to authorization duration
Revised: 3/1/17 – annual review, updated Gleevec to imatinib
Revised: 8/8/17 – updated FA, added newly diagnosis to chronic phase CML, clarified criteria for Ph+ CML
Revised: 10/10/17 – increased authorization duration to 12 months
Revised: 1/17/18 – updated prescriber criteria, added Ph+ to newly diagnoses CML, defined abbreviations, updated signature
Revised: 3/1/18 – annual review, added grandfather language
Revised: 6/1/18 – added QL
Revised: 3/1/19 – annual review, added QL approval note
Revised: 3/28/19 – added pediatric ALL indication
Revised: 3/1/20 – annual review, added GHP Kids
Revised: 3/1/21 – annual review, updated logo, added MediSpan approval level, updated QL statement
Revised: 12/1/21 – added one-time PA to approval crit., removed auth duration & added re-auth crit.
Revised: 3/1/22 – annual review, updated referenced policies & covered LOBs



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 127.0

**SECTION: Commercial Drug
SUBJECT: Antara**

Applicable line of business:

Commercial	X	Medicaid	
Medicare		ACA	X
GHP Kids	X	Self-Insured	X

POLICY:

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for Antara for GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 487.0 Quantity Limit Exceptions

REQUIRED DEFINITIONS:

1. **Attachment** – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. **Exhibit** – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. **Devised** – the date the policy was implemented.
4. **Revised** – the date of every revision to the policy, including typographical and grammatical changes.
5. **Reviewed** – the date documenting the annual review if the policy has no revisions necessary.

ADDITIONAL DEFINITIONS:

1. **Formulary** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. **Non-formulary products** – those medications that are not included in the Formulary.
3. **Healthcare provider** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
4. **NCQA** – National Committee for Quality Assurance.
5. **Medically Necessary or Medical Necessity** – covered services rendered by a provider that the Health Plan determines are:



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 127.0

**SECTION: Commercial Drug
SUBJECT: Antara**

- A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
- B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
- C. In accordance with current standards of medical practice;
- D. Not primarily for the convenience of the Member, or the Member's Provider; and
- E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

PROCEDURE:

An exception for coverage of Antara may be made for members who meet all the following criteria:

- Medical record documentation of a therapeutic failure on, intolerance to, or contraindication to gemfibrozil and fenofibrate

MEDISPAN AUTHORIZATION LEVEL: GPI-12

If an exception is made, Antara will be paid for under the member's prescription drug benefit.

Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.

FORMULARY ALTERNATIVES:

gemfibrozil, fenofibrate, cholestyramine, colestipol, atorvastatin, lovastatin, simvastatin, pravastatin, rosuvastatin, ezetimibe, niacin ER, omega-3 fatty acids (generic Lovaza)

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE
STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND
FEDERAL REGULATORY ENTITIES.**

**THIS POLICY WILL BE REVISED AS NECESSARY AND
REVIEWED NO LESS THAN ANNUALLY.**



POLICY NUMBER: 127.0

**POLICY AND PROCEDURE
PHARMACY
MANUAL**

**SECTION: Commercial Drug
SUBJECT: Antara**

Signed:  _____

Title: Director, Pharmacy Services

Date: March 1, 2022

Devised: 10/06
Reviewed: 3/07
Revised: 5/07 – added signature
Revised: 3/08 – annual review; updated alternatives
Revised: 4/09 – annual review, removed Tricor from title, updated alt.
Revised: 3/10 – annual review, updated alt.
Reviewed: 3/1/11 – annual review-updated alts
Revised: 3/1/12 – annual review, updated signature
Revised: 3/1/13 – annual review, updated logo and definitions, updated alternatives
Revised: 3/1/14 – annual review, removed Lofibra from policy based on generic availability,
added approval statement
Revised: 3/1/15 – annual review, updated signature, changed Niaspan to generic Niacin ER
Reviewed: 3/1/16 – annual review
Revised: 5/1/16 – updated format, logo, & procedure
Revised: 5/27/16 – updated Crestor to rosuvastatin
Revised: 3/1/17 – annual review, updated FA
Revised: 3/1/18 – annual review, updated signature
Revised: 3/1/19 – annual review, updated FA
Revised: 3/1/20 – annual review, added GHP Kids
Revised: 3/1/21 – annual review, updated logo, added MediSpan approval level
Revised: 3/1/22 – annual review, updated referenced policies & covered LOBs



POLICY NUMBER: 129.0

**POLICY AND PROCEDURE
PHARMACY
MANUAL**

**SECTION: Commercial Drug
SUBJECT: Apidra**

Applicable line of business:

Commercial	X	Medicaid	
Medicare		ACA	X
GHP Kids	X	Self-Insured	X

POLICY:

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for Apidra for GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 487.0 Quantity Limit Exceptions

REQUIRED DEFINITIONS:

1. **Attachment** – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. **Exhibit** – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. **Devised** – the date the policy was implemented.
4. **Revised** – the date of every revision to the policy, including typographical and grammatical changes.
5. **Reviewed** – the date documenting the annual review if the policy has no revisions necessary.

ADDITIONAL DEFINITIONS:

1. **Formulary** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. **Non-formulary products** – those medications that are not included in the Formulary.
3. **Healthcare provider** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
4. **NCQA** – National Committee for Quality Assurance.
5. **Medically Necessary or Medical Necessity** – covered services rendered by a provider that the Health Plan determines are:



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 129.0

**SECTION: Commercial Drug
SUBJECT: Apidra**

- A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
- B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
- C. In accordance with current standards of medical practice;
- D. Not primarily for the convenience of the Member, or the Member's Provider; and
- E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

PROCEDURE:

An exception for coverage of Apidra may be made for members who meet all the following criteria:

- Medical record documentation of therapeutic failure on, intolerance to, or contraindication to Novolog

MEDISPAN AUTHORIZATION LEVEL: GPI-10

If an exception is made, Apidra will be paid for under the member's prescription drug benefit.

Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.

FORMULARY ALTERNATIVES:

Novolog, insulin aspart

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE
STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND
FEDERAL REGULATORY ENTITIES.**

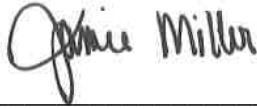
**THIS POLICY WILL BE REVISED AS NECESSARY AND
REVIEWED NO LESS THAN ANNUALLY.**

Geisinger

**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 129.0

**SECTION: Commercial Drug
SUBJECT: Apidra**



Signed: _____

Title: Director, Pharmacy Services

Date: March 1, 2022

Devised: 10/06
Reviewed: 3/07
Revised: 5/07 – added signature
Reviewed: 3/08 – annual review
Reviewed: 4/09 – annual review
Reviewed: 3/10 – annual review
Reviewed: 3/1/11 – annual review
Revised: 3/1/12 – annual review, updated signature
Revised: 3/1/13 – annual review, updated logo and definitions
Revised: 3/1/14 – annual review, added approval statement
Revised: 3/1/15 – annual review, updated signature
Reviewed: 3/1/16 – annual review
Revised: 5/1/16 – updated format, logo, & procedure
Revised: 3/1/17 – annual review, corrected typo
Revised: 3/1/18 – annual review, updated signature
Reviewed: 3/1/19 – annual review
Revised: 3/1/20 – annual review, added GHP Kids
Revised: 3/1/21 – annual review, updated logo, added MediSpan approval level, updated FA
Revised: 3/1/22 – annual review, updated referenced policies & covered LOBs



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 130.0

**SECTION: Commercial Drug
SUBJECT: Symlin**

Applicable line of business:

Commercial	X	Medicaid	
Medicare		ACA	X
GHP Kids	X	Self-Insured	X

POLICY:

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for Symlin for GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 487.0 Quantity Limit Exceptions

REQUIRED DEFINITIONS:

1. **Attachment** – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. **Exhibit** – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. **Devised** – the date the policy was implemented.
4. **Revised** – the date of every revision to the policy, including typographical and grammatical changes.
5. **Reviewed** – the date documenting the annual review if the policy has no revisions necessary.

ADDITIONAL DEFINITIONS:

1. **Formulary** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. **Non-formulary products** – those medications that are not included in the Formulary.
3. **Healthcare provider** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
4. **NCQA** – National Committee for Quality Assurance.
5. **Medically Necessary or Medical Necessity** – covered services rendered by a provider that the Health Plan determines are:



POLICY NUMBER: 130.0

**POLICY AND PROCEDURE
PHARMACY
MANUAL**

**SECTION: Commercial Drug
SUBJECT: Symlin**

- A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
- B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
- C. In accordance with current standards of medical practice;
- D. Not primarily for the convenience of the Member, or the Member's Provider; and
- E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

PROCEDURE:

An exception for coverage of Symlin may be made for members who meet all the following criteria:

- Medical record documentation of Symlin being used as an adjunct treatment in patients who use mealtime insulin therapy **AND**
- Medical record documentation of failure to achieve desired glucose control despite optimal insulin therapy, which may be with or without a concurrent sulfonylurea agent and/or metformin for those with Type 2 diabetes

MEDISPAN AUTHORIZATION LEVEL: GPI-12

If an exception is made, Symlin will be paid for under the member's prescription drug benefit.

Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.

FORMULARY ALTERNATIVES:

Lantus, Toujeo, Levemir, Tresiba, Novolin N, Novolin R, Novolin 70/30, Novolog, Novolog 70/30, insulin aspart, insulin aspart protamine/insulin aspart 70/30

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE
STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND
FEDERAL REGULATORY ENTITIES.**

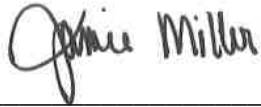
**THIS POLICY WILL BE REVISED AS NECESSARY AND
REVIEWED NO LESS THAN ANNUALLY.**

Geisinger

**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 130.0

**SECTION: Commercial Drug
SUBJECT: Symlin**



Signed: _____

Title: Director, Pharmacy Services

Date: March 1, 2022

Devised: 10/06
Reviewed: 3/07
Revised: 5/07 – added signature
Reviewed: 3/08 – annual review
Reviewed: 4/09 – annual review
Reviewed: 3/10 – annual review
Reviewed: 3/1/11 – annual review
Revised: 3/1/12 – annual review, updated signature
Revised: 3/1/13 – annual review, updated logo and definitions
Revised: 3/1/14 – annual review, updated formatting, added approval statement
Revised: 3/1/15 – annual review, updated signature
Revised: 3/1/16 – annual review, added Toujeo to FA
Revised: 5/1/16 – updated format, logo, & procedure
Reviewed: 3/1/17 – annual review
Revised: 3/1/18 – annual review, updated signature, updated FA
Reviewed: 3/1/19 – annual review
Revised: 3/1/20 – annual review, added GHP Kids
Revised: 3/1/21 – annual review, updated logo, added MediSpan approval level, updated FA
Revised: 3/1/22 – annual review, updated referenced policies & covered LOBs



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 131.0

**SECTION: Commercial Drug
SUBJECT: Byetta**

Applicable line of business:

Commercial	X	Medicaid	
Medicare		ACA	X
GHP Kids	X	Self-Insured	X

POLICY:

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for Byetta for GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 487.0 Quantity Limit Exceptions

REQUIRED DEFINITIONS:

1. **Attachment** – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. **Exhibit** – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. **Devised** – the date the policy was implemented.
4. **Revised** – the date of every revision to the policy, including typographical and grammatical changes.
5. **Reviewed** – the date documenting the annual review if the policy has no revisions necessary.

ADDITIONAL DEFINITIONS:

1. **Formulary** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. **Non-formulary products** – those medications that are not included in the Formulary.
3. **Healthcare provider** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
4. **NCQA** – National Committee for Quality Assurance.
5. **Medically Necessary or Medical Necessity** – covered services rendered by a provider that the Health Plan determines are:



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 131.0

**SECTION: Commercial Drug
SUBJECT: Byetta**

- A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
- B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
- C. In accordance with current standards of medical practice;
- D. Not primarily for the convenience of the Member, or the Member's Provider; and
- E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

PROCEDURE:

An exception for coverage of Byetta may be made for members who meet the following criteria:

- Medical record documentation of a diagnosis of Type 2 diabetes **AND**
- Medical record documentation of therapeutic failure on, intolerance to, or contraindication to Victoza **AND** either Ozempic or Rybelsus

MEDISPAN AUTHORIZATION LEVEL: GPI-12

QUANTITY LIMIT: *No QLs need to be entered within the authorization unless the requested quantity exceeds the QL.*

- **QL FOR LETTER ONLY:**
 - 5 mcg Pen: 0.04 mL per day
 - 10 mcg Pen: 0.08 mL per day

If an exception is made, Byetta will be paid for under the member's prescription drug benefit.

Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.



POLICY NUMBER: 131.0

**POLICY AND PROCEDURE
PHARMACY
MANUAL**

**SECTION: Commercial Drug
SUBJECT: Byetta**

FORMULARY ALTERNATIVES:

Ozempic, Victoza, Rybelsus, Trulicity, metformin, glyburide, glipizide, glipizide sustained-release, chlorpropamide, glimepiride, acarbose, miglitol, repaglinide, pioglitazone, Jardiance, Synjardy, Invokana, Invokamet, Tradjenta, Jentadueto, Glyxambi, Xultophy*, Lantus, Toujeo, Tresiba, Levemir, Novolin N, Novolin R, Novolin 70/30, Novolog, Novolog 70/30, insulin aspart, insulin aspart protamine/insulin aspart 70/30

*Step therapy or prior authorization required

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE
STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND
FEDERAL REGULATORY ENTITIES.**

**THIS POLICY WILL BE REVISED AS NECESSARY AND
REVIEWED NO LESS THAN ANNUALLY.**

Signed: _____

Title: Director, Pharmacy Services

Date: March 1, 2022

Devised: 10/06
Reviewed: 3/07
Revised: 5/07 – added signature
Revised: 3/08 – annual review; updated alternatives
Revised: 4/09 – annual review, updated alt.
Reviewed: 3/10 – annual review
Revised: 8/10 – updated criteria
Reviewed: 3/1/11 – annual review
Revised: 3/1/12 – annual review, updated signature
Revised: 6/21/12 – added Bydureon to policy
Revised: 3/1/13 – annual review, updated logo and definitions, updated alternatives
Revised: 1/2/14 – added failure of Victoza to Byetta criteria, updated formulary alternatives
Revised: 3/1/14 – annual review, updated alternatives based on generic availability of Prandin, added approval statement
Revised: 1/13/15 – removed Bydureon from policy, updated FA, updated signature
Reviewed: 3/1/15 – annual review
Revised: 3/1/16 – annual review, added Toujeo, Jardiance, Synjardy, Invokana, & Invokamet to FA, updated PA/ST language
Revised: 5/1/16 – updated format, logo, & procedure
Reviewed: 3/1/17 – annual review

HPRX02

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Dev. 10/06

Rev. 3/1/22



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 131.0

**SECTION: Commercial Drug
SUBJECT: Byetta**

- Revised: 3/27/17 – failure of Tanzeum, added QL
- Revised: 6/2/17 – removed failure of other antidiabetic
- Revised: 1/17/18 – updated failure from Tanzeum to Ozempic, updated QL to add both authorizations, updated FA, updated signature
- Revised: 3/1/18 – annual review, updated FA
- Revised: 3/1/19 – annual review, updated QL approval note & FA, removed step indicator from alts.
- Revised: 1/28/20 – added failure of Rybelsus and updated FA
- Revised: 3/1/20 – annual review, added GHP Kids
- Revised: 3/1/21 – annual review; updated logo, FA, & QL statement; added MediSpan approval level
- Revised: 3/1/22 – annual review, updated referenced policies & covered LOBs, updated FA



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 132.0

**SECTION: Commercial Drug
SUBJECT: Nexavar**

POLICY:

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for Nexavar for GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 487.0 Quantity Limit Exceptions

REQUIRED DEFINITIONS:

1. **Attachment** – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. **Exhibit** – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. **Devised** – the date the policy was implemented.
4. **Revised** – the date of every revision to the policy, including typographical and grammatical changes.
5. **Reviewed** – the date documenting the annual review if the policy has no revisions necessary.

ADDITIONAL DEFINITIONS:

1. **Formulary** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. **Non-formulary products** – those medications that are not included in the Formulary.
3. **Healthcare provider** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
4. **NCQA** – National Committee for Quality Assurance.
5. **Medically Necessary or Medical Necessity** – covered services rendered by a provider that the Health Plan determines are:
 - A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
 - B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
 - C. In accordance with current standards of medical practice;
 - D. Not primarily for the convenience of the Member, or the Member's Provider; and



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 132.0

**SECTION: Commercial Drug
SUBJECT: Nexavar**

- E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

PROCEDURE:

New members to the plan already established on therapy may be eligible for continuity of care coverage as long as there is medical record documentation that the safety and effectiveness of use for the prescribed indication is supported by Food and Drug Administration (FDA) approval or adequate medical and scientific evidence in the medical literature.

An exception for coverage of Nexavar may be made for members who meet all the following criteria:

- Medical record documentation of the use of Nexavar for a Food and Drug Administration (FDA) approved indication **AND**
- Medical record documentation that Nexavar is prescribed by an oncologist

MEDISPAN AUTHORIZATION LEVEL: GPI-12, number of claims authorized = 1, enter for the remainder of the calendar year

QUANTITY LIMIT: *No QLs need to be entered within the authorization unless the requested quantity exceeds the QL.*

- **QL FOR LETTER ONLY:** 4 tablets per day, 30 day supply per fill

RE-AUTHORIZATION CRITERIA: Nexavar is configured as a prior authorization for new starts only. Nexavar will no longer be covered if it is identified that the member is not receiving appropriate follow-up care from the prescribing specialist or if the member has greater than or equal to a 90 day break in therapy.

- Medical record documentation that the member is receiving appropriate follow-up care from the prescribing specialist

If an exception is made, Nexavar will be paid for under the member's prescription drug benefit.

Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 132.0

**SECTION: Commercial Drug
SUBJECT: Nexavar**

FORMULARY ALTERNATIVES:

none

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE
STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND
FEDERAL REGULATORY ENTITIES.**

**THIS POLICY WILL BE REVISED AS NECESSARY AND
REVIEWED NO LESS THAN ANNUALLY.**

Signed: _____

Title: Director, Pharmacy Services

Date: March 1, 2022

Devised: 8/06
Reviewed: 3/07
Revised: 5/07 – added signature
Reviewed: 3/08 – annual review
Reviewed: 4/09 – annual review
Reviewed: 3/10 – annual review
Reviewed: 3/1/11 – annual review
Revised: 3/1/12 – annual review, updated signature
Revised: 3/1/13 – annual review, updated logo and definitions
Revised: 3/1/14 – annual review, updated formatting, corrected typo, added approval statement
Revised: 3/1/15 – annual review, updated signature
Reviewed: 3/1/16 – annual review
Revised: 3/24/16 – removed copay per 15 day supply requirement
Revised: 5/1/16 – updated format, logo, & procedure, changed note to authorization duration
Reviewed: 3/1/17 – annual review
Revised: 10/10/17 – increased authorization duration to 12 months.
Revised: 3/1/18 – annual review, updated signature & format, added grandfather language
Revised: 6/1/18 – added QL
Revised: 3/1/19 – annual review, added QL approval note
Revised: 3/1/20 – annual review, added GHP Kids
Revised: 3/1/21 – annual review, updated logo, added MediSpan approval level, updated QL statement
Revised: 11/30/21 – added one-time PA to approval crit., removed auth duration & added re-auth crit.
Revised: 3/1/22 – annual review, updated referenced policies & covered LOBs



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 133.0

**SECTION: Commercial Drug
SUBJECT: Sunitinib**

Applicable line of business:

Commercial	X	Medicaid	
Medicare		ACA	X
GHP Kids	X	Self-Insured	X

POLICY:

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for sunitinib for GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 487.0 Quantity Limit Exceptions

REQUIRED DEFINITIONS:

1. **Attachment** – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. **Exhibit** – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. **Devised** – the date the policy was implemented.
4. **Revised** – the date of every revision to the policy, including typographical and grammatical changes.
5. **Reviewed** – the date documenting the annual review if the policy has no revisions necessary.

ADDITIONAL DEFINITIONS:

1. **Formulary** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. **Non-formulary products** – those medications that are not included in the Formulary.
3. **Healthcare provider** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
4. **NCQA** – National Committee for Quality Assurance.
5. **Medically Necessary or Medical Necessity** – covered services rendered by a provider that the Health Plan determines are:



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 133.0

**SECTION: Commercial Drug
SUBJECT: Sunitinib**

- A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
- B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
- C. In accordance with current standards of medical practice;
- D. Not primarily for the convenience of the Member, or the Member's Provider; and
- E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

PROCEDURE:

New members to the plan already established on therapy may be eligible for continuity of care coverage as long as there is medical record documentation that the safety and effectiveness of use for the prescribed indication is supported by Food and Drug Administration (FDA) approval or adequate medical and scientific evidence in the medical literature.

An exception for coverage of sunitinib may be made for members who meet all the following criteria:

Gastrointestinal Stromal Tumor (GIST)

- Medical record documentation that sunitinib is prescribed by an oncologist **OR** gastroenterologist **AND**
- Medical record documentation of a diagnosis of gastrointestinal stromal tumor (GIST) **AND**
- Medical record documentation of therapeutic failure on, intolerance to, or contraindication to imatinib (Gleevec)

Pancreatic Neuroendocrine Tumors (pNET)

- Medical record documentation that sunitinib is prescribed by an oncologist **AND**
- Medical record documentation of a diagnosis of progressive, well-differentiated pancreatic neuroendocrine tumors (pNET) in a member with unresectable locally advanced or metastatic disease

Advanced Renal Cell Carcinoma (RCC)

- Medical record documentation that sunitinib is prescribed by an oncologist **AND**
- Medical record documentation of a diagnosis of advanced renal cell carcinoma



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 133.0

**SECTION: Commercial Drug
SUBJECT: Sunitinib**

Renal Cell Carcinoma, adjuvant treatment

- Medical record documentation that sunitinib is prescribed by an oncologist **AND**
- Medical record documentation that member is an adult at high risk** of recurrent renal cell carcinoma following nephrectomy

****NOTE:** In clinical trials, high risk disease was defined as a score of greater than or equal to T3 on the University of California Los Angeles Integrated Staging System and/or node positive tumors.

MEDISPAN AUTHORIZATION LEVEL: GPI-12, generic only, number of claims authorized = 1, enter for the remainder of the calendar year

QUANTITY LIMIT: *No QLs need to be entered within the authorization unless the requested quantity exceeds the QL.*

- **QL FOR LETTER ONLY:** 1 capsule per day, 28 day supply per fill

RE-AUTHORIZATION CRITERIA: Sunitinib is configured as a prior authorization for new starts only. Sunitinib will no longer be covered if it is identified that the member is not receiving appropriate follow-up care from the prescribing specialist or if the member has greater than or equal to a 90 day break in therapy.

- Medical record documentation that the member is receiving appropriate follow-up care from the prescribing specialist

If an exception is made, sunitinib will be paid for under the member's prescription drug benefit.

Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.

FORMULARY ALTERNATIVES:
Gleevec for treatment of GIST

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE
STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND
FEDERAL REGULATORY ENTITIES.**

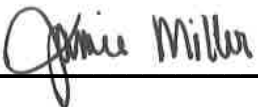
**THIS POLICY WILL BE REVISED AS NECESSARY AND
REVIEWED NO LESS THAN ANNUALLY.**



POLICY NUMBER: 133.0

**POLICY AND PROCEDURE
PHARMACY
MANUAL**

**SECTION: Commercial Drug
SUBJECT: Sunitinib**

Signed:  _____

Title: Director, Pharmacy Services

Date: March 1, 2022

- Devised: 8/06
- Reviewed: 3/07
- Revised: 5/07 – added signature
- Reviewed: 3/08 – annual review
- Reviewed: 4/09 – annual review
- Reviewed: 3/10 – annual review
- Reviewed: 3/1/11 – annual review
- Revised: 3/1/12 – annual review, updated signature
- Revised: 3/1/13 – annual review, updated logo and definitions
- Revised: 3/1/14 – annual review, corrected typo, added approval statement
- Revised: 3/1/15 – annual review, updated signature
- Reviewed: 3/1/16 – annual review
- Revised: 3/24/16 – removed copay per 15 day supply requirement, updated note
- Revised: 5/1/16 – updated format, logo, & procedure
- Revised: 3/1/17 – annual review, updated FA
- Revised: 10/10/17 – increased authorization duration to 12 months
- Revised: 1/17/18 – updated policy to include description of FDA indications, updated FA, added note, added QL, updated signature
- Revised: 3/1/18 – annual review, added grandfather language
- Revised: 3/1/19 – annual review, added QL approval note
- Revised: 3/1/20 – annual review, added GHP Kids
- Revised: 3/1/21 – annual review, updated logo, added MediSpan approval level, updated QL statement
- Revised: 12/2/21 – added one-time PA to approval crit., removed auth duration & added re-auth crit., updated Sutent to generic, added generic only approval
- Revised: 3/1/22 – annual review, updated referenced policies & covered LOBs



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 135.0

**SECTION: Commercial Drug
SUBJECT: Ranolazine ER**

Applicable line of business:

Commercial	X	Medicaid	
Medicare		ACA	X
GHP Kids	X	Self-Insured	X

POLICY:

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for ranolazine ER for GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 487.0 Quantity Limit Exceptions

REQUIRED DEFINITIONS:

1. **Attachment** – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. **Exhibit** – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. **Devised** – the date the policy was implemented.
4. **Revised** – the date of every revision to the policy, including typographical and grammatical changes.
5. **Reviewed** – the date documenting the annual review if the policy has no revisions necessary.

ADDITIONAL DEFINITIONS:

1. **Formulary** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. **Non-formulary products** – those medications that are not included in the Formulary.
3. **Healthcare provider** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
4. **NCQA** – National Committee for Quality Assurance.
5. **Medically Necessary or Medical Necessity** – covered services rendered by a provider that the Health Plan determines are:

- A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
- B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
- C. In accordance with current standards of medical practice;
- D. Not primarily for the convenience of the Member, or the Member's Provider; and
- E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

PROCEDURE:

An exception for coverage of ranolazine ER may be made for members who meet all the following criteria:

- Medical record documentation of use for the treatment of chronic angina not adequately responding to other antianginal drugs **AND**
- Medical record documentation of use with combination of amlodipine, beta-blockers, or nitrates **AND**
- No medical record documentation of concurrent use of potent/moderately potent CYP3A4 inhibitors (diltiazem, verapamil, azoles, macrolides, etc.) or QT prolonging medications **AND**
- Medical record documentation that ranolazine ER is prescribed by a cardiologist

MEDISPAN AUTHORIZATION LEVEL: GPI-12, generic only

If an exception is made, ranolazine ER will be paid for under the member's prescription drug benefit.

Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.

FORMULARY ALTERNATIVES:

Beta-blockers: acebutolol, atenolol, InnoPran XL, metoprolol, nadolol, propranolol, metoprolol XL

Calcium channel blockers: felodipine, nifedipine, nifedipine SR, amlodipine, isradipine, nimodipine

Nitrates: isosorbide dinitrate, isosorbide mononitrate, nitroglycerin



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 135.0

**SECTION: Commercial Drug
SUBJECT: Ranolazine ER**

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE
STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND
FEDERAL REGULATORY ENTITIES.**

**THIS POLICY WILL BE REVISED AS NECESSARY AND
REVIEWED NO LESS THAN ANNUALLY.**

Signed: _____

Title: Director, Pharmacy Services

Date: March 1, 2022

Devised: 1/07
Revised: 3/07-typo fixed, updated formulary alternatives
Revised: 5/07 – added signature
Revised: 3/08 – annual review; updated alternatives
Revised: 4/09 – annual review, updated alt.
Reviewed: 3/10 – annual review
Revised: 5/10 – updated form alt. removed diltiazem and verapamil
Reviewed: 3/1/11 – annual review
Revised: 3/1/12 – annual review, updated signature
Revised: 3/1/13 – annual review, updated logo and definitions
Revised: 3/1/14 – annual review, updated formatting, added approval statement
Revised: 3/1/15 – annual review, updated signature
Reviewed: 3/1/16 – annual review
Revised: 5/1/16 – updated format, logo, & procedure
Reviewed: 3/1/17 – annual review
Revised: 3/1/18 – annual review, updated signature, updated format of prescriber criteria
Reviewed: 3/1/19 – annual review
Revised: 11/21/19 – updated Ranexa to generic ranolazine ER
Revised: 3/1/20 – annual review, added GHP Kids
Revised: 3/1/21 – annual review, updated logo, added MediSpan approval level
Revised: 3/1/22 – annual review, updated referenced policies & covered LOBs



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 139.0

**SECTION: Commercial Drug
SUBJECT: Miglustat**

Applicable line of business:

Commercial	X	Medicaid	
Medicare		ACA	X
GHP Kids	X	Self-Insured	X

POLICY:

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for miglustat for GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 487.0 Quantity Limit Exceptions

REQUIRED DEFINITIONS:

1. **Attachment** – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. **Exhibit** – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. **Devised** – the date the policy was implemented.
4. **Revised** – the date of every revision to the policy, including typographical and grammatical changes.
5. **Reviewed** – the date documenting the annual review if the policy has no revisions necessary.

ADDITIONAL DEFINITIONS:

1. **Formulary** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. **Non-formulary products** – those medications that are not included in the Formulary.
3. **Healthcare provider** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
4. **NCQA** – National Committee for Quality Assurance.
5. **Medically Necessary or Medical Necessity** – covered services rendered by a provider that the Health Plan determines are:

- A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
- B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
- C. In accordance with current standards of medical practice;
- D. Not primarily for the convenience of the Member, or the Member's Provider; and
- E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

PROCEDURE:

An exception for coverage of miglustat may be made for members who meet the following criteria:

- Medical record documentation of miglustat being used to treat an adult patient with mild to moderate Type 1 Gaucher disease for whom enzyme replacement therapy is not a therapeutic option (e.g. due to constraints such as allergy, hypersensitivity, or poor venous access) **AND**
- Miglustat is recommended by a metabolic specialist with experience in treating Gaucher disease

MEDISPAN AUTHORIZATION LEVEL: GPI-12, generic only

QUANTITY LIMIT: *No QLs need to be entered within the authorization unless the requested quantity exceeds the QL.*

- **QL FOR LETTER ONLY:** 3 capsules per day, 30 day supply per fill

If an exception is made, miglustat will be paid for under the member's prescription drug benefit.

Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.

FORMULARY ALTERNATIVES:

None for pharmacy. Cerezyme and Elelyso require prior authorization under the medical benefit.

Geisinger

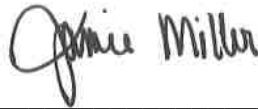
**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 139.0

**SECTION: Commercial Drug
SUBJECT: Miglustat**

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE
STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND
FEDERAL REGULATORY ENTITIES.**

**THIS POLICY WILL BE REVISED AS NECESSARY AND
REVIEWED NO LESS THAN ANNUALLY.**



Signed: _____

Title: Director, Pharmacy Services

Date: March 1, 2022

Devised: 1/06
Reviewed: 3/07
Revised: 5/07 – added signature
Reviewed: 3/08 – annual review
Reviewed: 4/09 –annual review
Reviewed: 3/10 – annual review
Reviewed: 3/1/11 – annual review-updated criteria to add metabolic specialist
Revised: 3/1/12 – annual review, updated signature
Revised: 3/1/13 – annual review, updated logo and definitions, updated alternatives
Revised: 3/1/14 – annual review, updated formatting, added approval statement
Revised: 3/1/15 – annual review, updated signature
Reviewed: 3/1/16 – annual review
Revised: 5/1/16 – updated format, logo, & procedure
Reviewed: 3/1/17 – annual review
Revised: 3/1/18 – annual review, updated signature
Revised: 6/1/18 – added QL
Revised: 3/1/19 – annual review, added QL approval note
Revised: 11/21/19 – updated Zavesca to generic miglustat
Revised: 3/1/20 – annual review, added GHP Kids
Revised: 3/1/21 – annual review, updated logo, added MediSpan approval level, updated QL statement
Revised: 3/1/22 – annual review, updated referenced policies & covered LOBs



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 140.0

**SECTION: Commercial Drug
SUBJECT: Quinine Sulfate**

Applicable line of business:

Commercial	X	Medicaid	
Medicare		ACA	X
GHP Kids	X	Self-Insured	X

POLICY:

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for quinine sulfate for GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 487.0 Quantity Limit Exceptions

REQUIRED DEFINITIONS:

1. **Attachment** – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. **Exhibit** – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. **Devised** – the date the policy was implemented.
4. **Revised** – the date of every revision to the policy, including typographical and grammatical changes.
5. **Reviewed** – the date documenting the annual review if the policy has no revisions necessary.

ADDITIONAL DEFINITIONS:

1. **Formulary** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. **Non-formulary products** – those medications that are not included in the Formulary.
3. **Healthcare provider** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
4. **NCQA** – National Committee for Quality Assurance.
5. **Medically Necessary or Medical Necessity** – covered services rendered by a provider that the Health Plan determines are:



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 140.0

**SECTION: Commercial Drug
SUBJECT: Quinine Sulfate**

- A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
- B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
- C. In accordance with current standards of medical practice;
- D. Not primarily for the convenience of the Member, or the Member's Provider; and
- E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

PROCEDURE:

An exception for coverage of quinine sulfate may be made for members who meet the following criteria:

- Medical record documentation of a diagnosis of malaria or babesiosis

MEDISPAN AUTHORIZATION LEVEL: GPI-10, generic only

If an exception is made, quinine sulfate will be paid for under the member's prescription drug benefit.

Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.

FORMULARY ALTERNATIVES:

hydroxychloroquine, pyrimethamine*, chloroquine, mefloquine

*prior authorization required

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE STANDARDS
OF NCQA AND ANY OTHER APPLICABLE STATE AND FEDERAL REGULATORY
ENTITIES.**

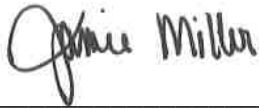
**THIS POLICY WILL BE REVISED AS NECESSARY AND
REVIEWED NO LESS THAN ANNUALLY.**

Geisinger

**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 140.0

**SECTION: Commercial Drug
SUBJECT: Quinine Sulfate**



Signed: _____

Title: Director, Pharmacy Services

Date: March 1, 2022

Devised: 5/07
Reviewed: 3/08 – annual review
Reviewed: 4/09 – annual review
Reviewed: 3/10 – annual review
Reviewed: 3/1/11 – annual review
Revised: 3/1/12 – annual review, updated signature
Revised: 3/1/13 – annual review, updated logo and definitions
Revised: 3/1/14 – annual review, added approval statement, updated alternatives based on availability of generic Lariam
Revised: 3/1/15 – annual review, updated signature, changed Quaaliquin to quinine sulfate, removed Fansidar from alternatives
Reviewed: 3/1/16 – annual review
Revised: 5/1/16 – updated format, logo, & procedure, updated Quaaliquin to quinine sulfate
Reviewed: 3/1/17 – annual review
Revised: 3/1/18 – annual review, updated signature
Reviewed: 3/1/19 – annual review
Revised: 3/1/20 – annual review, added GHP Kids
Revised: 3/1/21 – annual review, updated logo, added MediSpan approval level, updated FA
Revised: 3/1/22 – annual review, updated referenced policies & covered LOBs



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 141.0

**SECTION: Commercial Drug
SUBJECT: Januvia**

Applicable line of business:

Commercial	X	Medicaid	
Medicare		ACA	X
GHP Kids	X	Self-Insured	X

POLICY:

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for Januvia for GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 487.0 Quantity Limit Exceptions

REQUIRED DEFINITIONS:

1. **Attachment** – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. **Exhibit** – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. **Devised** – the date the policy was implemented.
4. **Revised** – the date of every revision to the policy, including typographical and grammatical changes.
5. **Reviewed** – the date documenting the annual review if the policy has no revisions necessary.

ADDITIONAL DEFINITIONS:

1. **Formulary** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. **Non-formulary products** – those medications that are not included in the Formulary.
3. **Healthcare provider** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
4. **NCQA** – National Committee for Quality Assurance.
5. **Medically Necessary or Medical Necessity** – covered services rendered by a provider that the Health Plan determines are:



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 141.0

**SECTION: Commercial Drug
SUBJECT: Januvia**

- A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
- B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
- C. In accordance with current standards of medical practice;
- D. Not primarily for the convenience of the Member, or the Member's Provider; and
- E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

PROCEDURE:

An exception for coverage of Januvia may be made for members who meet the following criteria:

- Medical record documentation of therapeutic failure on, intolerance to, or contraindication to Tradjenta

MEDISPAN AUTHORIZATION LEVEL: GPI-12

QUANTITY LIMIT: *No QLs need to be entered within the authorization unless the requested quantity exceeds the QL.*

- **QL FOR LETTER ONLY:** 1 tablet per day

If an exception is made, Januvia will be paid for under the member's prescription drug benefit.

Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.

FORMULARY ALTERNATIVES:

metformin, Tradjenta, Jentadueto, Jentadueto XR



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 141.0

**SECTION: Commercial Drug
SUBJECT: Januvia**

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE
STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND
FEDERAL REGULATORY ENTITIES.**

**THIS POLICY WILL BE REVISED AS NECESSARY AND
REVIEWED NO LESS THAN ANNUALLY.**

Signed: _____

Title: Director, Pharmacy Services

Date: March 1, 2022

Devised: 5/07
Revised: 6/07 – Removed criterion 3 (concomitant use with sulfonylurea/insulin)
Reviewed: 3/08 – annual review
Revised: 4/09 – annual review, updated alt.
Reviewed: 3/10 – annual review
Revised: 3/1/11 – annual review-updated alts.
Revised: 3/1/12 – annual review, updated signature
Revised: 3/1/13 – annual review, updated logo and definitions, updated alternatives
Revised: 3/1/14 – annual review, added approval statement
Revised: 3/1/15 – annual review, updated signature
Reviewed: 3/1/16 – annual review
Revised: 5/1/16 – updated format, logo, & procedure
Reviewed: 3/1/17 – annual review
Revised: 11/28/17 – updated to failure of metformin, updated FA, updated signature, added ST language, added QL, added new starts vs. existing failure of Tradjenta
Revised: 2/2/18 – removed old criteria requiring step through metformin
Revised: 3/1/18 – annual review, updated FA
Revised: 3/1/19 – annual review, added QL approval note, removed step indicator from alts.
Revised: 3/1/20 – annual review, added GHP Kids
Revised: 3/1/21 – annual review, updated logo, added MediSpan approval level
Revised: 3/1/22 – annual review, updated referenced policies & covered LOBs



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 142.0

**SECTION: Commercial Drug
SUBJECT: Posaconazole**

Applicable line of business:

Commercial	X	Medicaid	
Medicare		ACA	X
GHP Kids	X	Self-Insured	X

POLICY:

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for posaconazole for GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 487.0 Quantity Limit Exceptions

REQUIRED DEFINITIONS:

1. **Attachment** – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. **Exhibit** – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. **Devised** – the date the policy was implemented.
4. **Revised** – the date of every revision to the policy, including typographical and grammatical changes.
5. **Reviewed** – the date documenting the annual review if the policy has no revisions necessary.

ADDITIONAL DEFINITIONS:

1. **Formulary** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. **Non-formulary products** – those medications that are not included in the Formulary.
3. **Healthcare provider** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
4. **NCQA** – National Committee for Quality Assurance.
5. **Medically Necessary or Medical Necessity** – covered services rendered by a provider that the Health Plan determines are:

- A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
- B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
- C. In accordance with current standards of medical practice;
- D. Not primarily for the convenience of the Member, or the Member's Provider; and
- E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

PROCEDURE:

An exception for coverage of posaconazole may be made for members who meet the following criteria:

Prophylaxis of Invasive Aspergillus or Candida Infections

- Medical record documentation that posaconazole is prescribed by an oncologist, hematologist, infectious disease specialist, or transplant service provider **AND**
- Medical record documentation of use for prophylaxis of invasive Aspergillus or Candida infections in patients at high risk of developing these infections due to being severely immunocompromised **AND**
- Medical record documentation of one of the following:
 - If request is for Noxafil oral suspension: medical record documentation of age greater than or equal to 13 years **OR**
 - If request is for posaconazole delayed release tablets: medical record documentation of age greater than or equal to 2 years and documentation of weight greater than 40 kilograms

Treatment of Invasive Aspergillosis

- Medical record documentation that posaconazole is prescribed by an oncologist, hematologist, infectious disease specialist, or transplant service provider **AND**
- Medical record documentation of use for treatment of invasive aspergillosis **AND**
- Medical record documentation of age greater than or equal to 13 years

Treatment of Oropharyngeal Candidiasis

- Medical record documentation that posaconazole is prescribed by an oncologist, hematologist, infectious disease specialist, or transplant service provider **AND**
- Medical record documentation of age greater than or equal to 13 years **AND**

- Medical record documentation of treatment of oropharyngeal candidiasis with therapeutic failure on, contraindication to, or intolerance to fluconazole or itraconazole*

MEDISPAN AUTHORIZATION LEVEL: GPI-14, if request is for tablets add generic only

QUANTITY LIMIT:

• **100 mg tablets –**

- Initial approval: Two authorizations must be entered.
 1. In PA Hub: Add ST, PA, and PE. Start date of this authorization is one-day after loading dose ends.
 2. In Darwin: Add ST, PA, PE, OQL, enter 1 in max number of claims authorized, and max quantity dispensed 93 per 28 days with a duration of one-week.
- Renewal: *No QLs need to be entered within the authorization unless the requested quantity exceeds the QL.*
- INITIAL QL FOR LETTER: Loading dose: 93 tablets per 30 days; Maintenance dose: 90 tablets per 30 days
- RENEWAL QL FOR LETTER: 90 tablets per 30 days

- **200 mg/5 mL suspension –** *No QLs need to be entered within the authorization unless the requested quantity exceeds the QL.*
 - QL FOR LETTER: 20 mL per day

AUTHORIZATION DURATION:

- **For prophylaxis of invasive aspergillus and candida infections:** Initial approval will be for 3 months or less if the reviewing provider feels it is medically appropriate. Subsequent approvals will be for an additional 6 months or less if the reviewing provider feels it is medically appropriate. The medication will no longer be covered if the member recovers from neutropenia and/or immunosuppression.
- **For treatment of invasive aspergillus and candida infections:** 3 months or less if the reviewing provider feels it is medically appropriate
- **For oropharyngeal candidiasis:** One-time, 28 days authorization

If an exception is made, posaconazole will be paid for under the member's prescription drug benefit.

Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.



POLICY NUMBER: 142.0

**POLICY AND PROCEDURE
PHARMACY
MANUAL**

**SECTION: Commercial Drug
SUBJECT: Posaconazole**

FORMULARY ALTERNATIVES:

fluconazole, itraconazole*, voriconazole*

* prior authorization required

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE
STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND
FEDERAL REGULATORY ENTITIES.**

**THIS POLICY WILL BE REVISED AS NECESSARY AND
REVIEWED NO LESS THAN ANNUALLY.**

Signed: _____

Title: Director, Pharmacy Services

Date: March 1, 2022

Devised: 5/07
Reviewed: 3/08 – annual review
Reviewed: 4/09 – annual review
Reviewed: 3/10 – annual review
Reviewed: 3/1/11 – annual review
Revised: 3/1/12 – annual review, updated signature & alternatives
Revised: 3/1/13 – annual review, updated logo and definitions, updated alternatives
Revised: 3/1/14 – annual review, added approval statement
Revised: 3/1/15 – annual review, update signature
Reviewed: 3/1/16 – annual review
Revised: 5/1/16 – updated format, logo, & procedure
Reviewed: 3/1/17 – annual review
Revised: 3/1/18 – annual review, updated signature, updated formatting
Reviewed: 3/1/19 – annual review
Revised: 5/29/19 – added auth duration and QL
Revised: 3/1/20 – annual review, added GHP Kids
Revised: 3/1/21 – annual review, updated logo, added MediSpan approval level, updated QL statement, updated Noxafil to generic
Revised: 11/24/21 – separated indications, updated age requirements for prophylaxis, added treatment of aspergillus, updated generic only to only tablets
Revised: 3/1/22 – annual review, updated referenced policies & covered LOBs



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 147.0

**SECTION: Commercial Drug
SUBJECT: Epogen, Procrit, Aranesp,
and Retacrit**

Applicable line of business:

Commercial	X	Medicaid	
Medicare		ACA	X
GHP Kids	X	Self-Insured	X

POLICY:

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for Epogen, Procrit, Aranesp, and Retacrit for GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 487.0 Quantity Limit Exceptions

REQUIRED DEFINITIONS:

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ADDITIONAL DEFINITIONS:

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2. **Non-formulary products** – those medications that are not included in the Formulary.
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4. **NCQA** – National Committee for Quality Assurance.
5. **Medically Necessary or Medical Necessity** – covered services rendered by a provider that the Health Plan determines are:

- A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
- B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
- C. In accordance with current standards of medical practice;
- D. Not primarily for the convenience of the Member, or the Member's Provider; and
- E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

PROCEDURE:

An exception for coverage of Epogen, Procrit, Aranesp, or Retacrit may be made for members for the following indications when reversible or correctable conditions including but not limited to, vitamin B12 deficiency, hemolysis, iron or folate deficiency and blood loss have been ruled out and when all of the indication specific criteria are met:

Medical record documentation of:

1. Treatment of symptomatic anemia of chronic renal insufficiency, chronic renal failure, including end stage renal disease either requiring or not requiring dialysis when all of the following criteria are met:
 - Hemoglobin less than or equal to 10 g/dL for new starts or less than 11 g/dL for continuation of therapy **OR** medical record documentation that the dose will be reduced or interrupted if hemoglobin exceeds 11g/d **AND**
 - Ferritin greater than or equal to 100 ng/mL or transferrin saturation level greater than or equal to 20% or history of chelation therapy for iron
2. Treatment of symptomatic anemia in zidovudine-treated HIV infected insured individuals when all of the following criteria are met:
 - Endogenous erythropoietin levels of 500 MU/mL or less **AND**
 - Ferritin greater than or equal to 100 ng/mL or transferrin saturation level greater than or equal to 20% or history of chelation therapy for iron **AND**
 - Zidovudine doses of 4200 mg or less per week **AND**
 - Hemoglobin less than 12 g/dL for continuation therapy or less than 10 g/dL for new starts

Treatment should not last longer than 3 months following the discontinuation of zidovudine.

3. Treatment of anemia secondary to myelosuppressive chemotherapy in non-myeloid malignancies when all of the following criteria are met:
- Hemoglobin less than or equal to 12 g/dL for continuation therapy or less than 10 g/dL for new starts **AND**
 - Insured individual is currently on anemia-inducing chemotherapy and there is a minimum of two additional months of planned chemotherapy **AND**
 - Ferritin greater than or equal to 100 ng/mL or transferrin saturation level greater than or equal to 20% or history of chelation therapy for iron

Non-myeloid malignancies include all types of carcinoma, sarcoma, melanoma, multiple myeloma, lymphoma, and lymphocytic leukemia.

4. Treatment of symptomatic anemia secondary to myelodysplastic syndrome (MDS) when all of the following criteria are met:
- Hemoglobin less than or equal to 12 g/dL for continuation therapy or less than 10 g/dL for new starts **AND**
 - Ferritin greater than or equal to 100ng/dL or transferrin level saturation greater than or equal to 20% or a history of chelation therapy for iron **AND**
 - Baseline endogenous erythropoietin levels of 500 MU/mL or less (NCCN Clinical Practice Guidelines in Oncology – Myelodysplastic Syndromes v2.2010)
5. Treatment of symptomatic anemia of chronic disease (rheumatoid arthritis, inflammatory bowel disease, systemic lupus erythematosus, and hepatitis C undergoing treatment) when all of the following criteria are met:
- Hemoglobin less than 12 g/dL for continuation therapy or less than 10 g/dL for new starts **AND**
 - Ferritin greater than or equal to 100ng/dL or transferrin level saturation greater than or equal to 20% or a history of chelation therapy for iron **AND**
 - Insured individual has a severe comorbidity (e.g. severe angina, pulmonary disease, heart failure, cerebrovascular disease causing transient ischemic attacks, lymphoma, myeloma, etc.) **AND**
 - Insured individual's anemia is manifested by impairments such as, but not limited to, exercise intolerance, tachycardia or shortness of breath with minimal activity, or inability to perform activities of daily living

6. Reduction of allogeneic blood transfusion in anemic insured individuals undergoing surgery when all of the following criteria are met:
- Hemoglobin less than 13 g/dL **AND**
 - Ferritin greater than or equal to 100ng/dL or transferrin level saturation greater than or equal to 20% or a history of chelation therapy for iron **AND**
 - Anemia is related to chronic disease state (limited to rheumatoid arthritis, inflammatory bowel disease, systemic lupus erythematosus, and hepatitis C undergoing treatment) **AND**
 - Insured individual is scheduled to undergo elective, non-cardiac, non-vascular surgery in which anticipated blood loss is greater than 2 units and the need for allogeneic blood transfusion is anticipated.

Authorization will be for a duration of 1 month. Request for use beyond 4 weeks will require medical record documentation indicating medical necessity.

Note: Erythropoietin therapy (epoetin alfa) is not indicated for anemic patients who are able and willing to donate autologous blood.

MEDISPAN AUTHORIZATION LEVEL: GPI-10

AUTHORIZATION DURATION:

Except for the indication for use in anemic surgical patients, approval for Epogen, Procrit, Aranesp, or Retacrit therapy will be given for an initial duration of 12 months. Subsequent authorization will be considered based on the stated criteria.

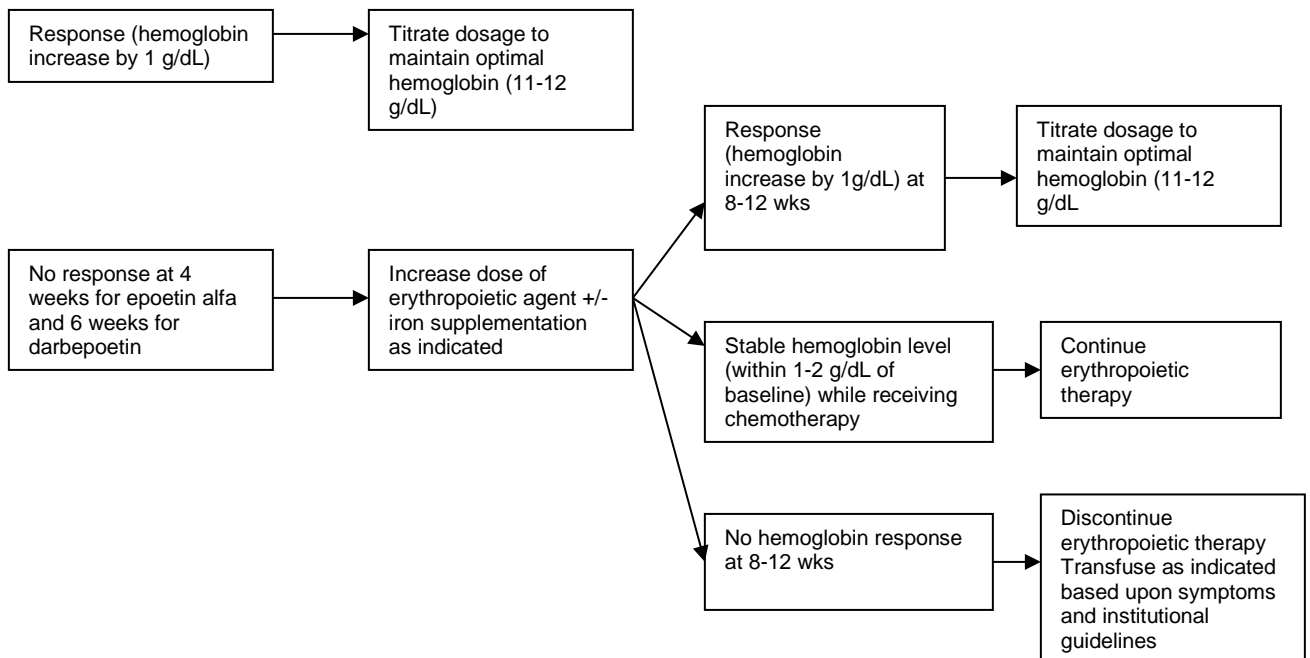
GENERAL GUIDANCE:

- For continuation of therapy, a repeat Hgb should be submitted after 12 months of therapy.
- In individuals whose Hgb is greater than or equal to 12g/dL or rises by 1g/dL in any two-week period, additional doses should be withheld. (In insured individuals with Hgb of greater than or equal to 12 g/dL Erythropoietin or Darbepoetin therapy will not be covered according to FDA recommendations, except when being used for reduction of allogeneic blood transfusion in anemic insured individuals undergoing surgery).
- For initiation or continuation of therapy, a ferritin level no greater than 3 months old and/ or transferrin saturation level no greater than 6 months old should be submitted.
- The member should receive supplemental iron if serum ferritin is less than 100ng/ml and transferrin saturation is less than 20 percent.

LIMITATIONS:

For treatment of anemia in MDS and non-myeloid cancer (on chemotherapy):

**Initial Response Assessment
Subsequent response Assessment**



Adapted from NCCN, Clinical Practice Guidelines in Oncology, v3, 2007

An initial response assessment distinguishes individuals with a response (Hgb increase by 1 g/dL) from those with no response to erythropoietic therapy. In individuals with a response, erythropoietin should be continued to maintain an optimal hemoglobin (12 g/dL). Assessment of individuals with no response to therapy should be performed at 4 weeks for epoetin alfa and 6 weeks for darbepoetin. If no response is detected, a dose increase of the erythropoietic agent is recommended with or without iron supplementation as indicated. If the hemoglobin level increases by 1 g/dL at 8-12 weeks of erythropoietic therapy then a dosage titration should be performed to maintain an optimal hemoglobin level at 12 g/dL. Erythropoietic therapy should be discontinued and transfusion initiated as indicated if there is no hemoglobin response at 8-12 weeks of therapy.



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 147.0

**SECTION: Commercial Drug
SUBJECT: Epogen, Procrit, Aranesp,
and Retacrit**

EXCLUSIONS:

Erythropoietin and Darbepoetin therapy is not covered for the following conditions because current clinical data indicates that erythropoietin stimulating agents have been shown to impart either a deleterious effect on the underlying disease, or that the underlying disease increases the risk of adverse effects related to use of erythropoietin stimulating agents.

These conditions include but are not limited to:

- Anemia of cancer not related to cancer treatment;
- Anemia related to myelosuppressive chemotherapy when the cancer treatment goal is cure (e.g. early stage breast cancer, Hodgkin lymphoma, non-Hodgkin's lymphoma, testicular cancer, Early stage non-small cell lung cancer, small cell lung cancer)
- Anemia associated only with radiotherapy;
- Anemia due to cancer treatment in insured individuals with uncontrolled hypertension;
- Anemia associated with the treatment of acute and/or chronic myelogenous leukemias (CML or AML), or erythroid cancers;
- Anemia in cancer or in cancer treatment due to folate deficiency, iron deficiency, vitamin B-12 deficiency, bleeding, hemolysis, or bone marrow fibrosis;
- Prophylactic use of erythropoietin stimulating agents to prevent chemotherapy-induced anemia;
- Prophylactic use of erythropoietin stimulating agents to reduce tumor hypoxia;
- Erythropoietin-type resistance due to neutralizing antibodies

If an exception is made, Epogen, Procrit, Aranesp, or Retacrit will be paid for under the member's prescription drug benefit.

Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.

FORMULARY ALTERNATIVES:

none

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE
STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND
FEDERAL REGULATORY ENTITIES.**

**THIS POLICY WILL BE REVISED AS NECESSARY AND
REVIEWED NO LESS THAN ANNUALLY.**



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 147.0

**SECTION: Commercial Drug
SUBJECT: Epogen, Procrit, Aranesp,
and Retacrit**

Signed: _____

Title: Director, Pharmacy Services

Date: March 1, 2022

- Devised: 6/07
- Reviewed: 3/08 – annual review
- Revised: 7/08 – updated criteria
- Reviewed: 4/09 – annual review
- Reviewed: 3/10 – annual review
- Reviewed: 3/11 – annual review
- Revised: 3/11/12 – annual review, updated signature
- Revised: 3/1/13 – annual review, updated logo and definitions, fixed typos
- Revised: 3/1/14 – annual review, fixed two typos
- Revised: 3/1/15 – annual review, updated signature, updated formatting
- Revised: 3/1/16 – annual review, updated policy formatting
- Revised: 3/24/16 – updated Hgb requirement for CKD (11 & 12 to 10 & 11), zidovudine-treated HIV (11 to 10), myelosuppressive chemo (11 to 10), MDS (11 to 10), chronic disease (11 to 10); updated myelosuppressive chemo heading; updated chemo requirement for myelosuppressive chemo; added list of non-myeloid malignancies; removed Hep C chemo; added list of chronic diseases; removed Hgb > 10 for allogeneic blood transfusion; added auth duration to allogeneic blood transfusion; removed MM requirements; removed original auth duration & added new language; added general guidance; updated exclusion section
- Revised: 5/1/16 – updated format, logo, & procedure
- Revised: 7/8/16 – updated Hgb requir. under general guidance, corrected typos under exclusions
- Reviewed: 3/1/17 – annual review
- Revised: 3/1/18 – annual review, updated signature
- Revised: 11/26/18 – added Retacrit, added “or history of chelation therapy for iron,” defined abbreviations, added hep C to section 5, added listing of chronic diseases to section 6
- Reviewed: 3/1/19 – annual review
- Revised: 3/1/20 – annual review, added GHP Kids
- Revised: 3/1/21 – annual review, updated logo, added MediSpan approval level
- Revised: 3/1/22 – annual review, updated referenced policies & covered LOBs



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 148.0

**SECTION: Commercial Drug
SUBJECT: Paliperidone Extended
Release**

Applicable line of business:

Commercial	X	Medicaid	
Medicare		ACA	X
GHP Kids	X	Self-Insured	X

POLICY:

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for paliperidone extended release for GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 487.0 Quantity Limit Exceptions

REQUIRED DEFINITIONS:

1. **Attachment** – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. **Exhibit** – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. **Devised** – the date the policy was implemented.
4. **Revised** – the date of every revision to the policy, including typographical and grammatical changes.
5. **Reviewed** – the date documenting the annual review if the policy has no revisions necessary.

ADDITIONAL DEFINITIONS:

1. **Formulary** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. **Non-formulary products** – those medications that are not included in the Formulary.
3. **Healthcare provider** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
4. **NCQA** – National Committee for Quality Assurance.
5. **Medically Necessary or Medical Necessity** – covered services rendered by a provider that the Health Plan determines are:



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 148.0

**SECTION: Commercial Drug
SUBJECT: Paliperidone Extended
Release**

- A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
- B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
- C. In accordance with current standards of medical practice;
- D. Not primarily for the convenience of the Member, or the Member's Provider; and
- E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

PROCEDURE:

New members to the plan already established on therapy may be eligible for continuity of care coverage as long as there is medical record documentation that the safety and effectiveness of use for the prescribed indication is supported by Food and Drug Administration (FDA) approval or adequate medical and scientific evidence in the medical literature.

An exception for coverage of paliperidone extended release may be made for members who meet the following criteria:

- Medical record documentation of therapeutic failure on, intolerance to, or contraindication to risperidone, olanzapine, quetiapine, **AND** aripiprazole

MEDISPAN AUTHORIZATION LEVEL: GPI-12, generic only

If an exception is made, paliperidone extended release will be paid for under the member's prescription drug benefit.

Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.

FORMULARY ALTERNATIVES:

risperidone, olanzapine, quetiapine fumarate, aripiprazole

Geisinger

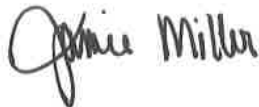
**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 148.0

**SECTION: Commercial Drug
SUBJECT: Paliperidone Extended
Release**

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE
STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND
FEDERAL REGULATORY ENTITIES.**

**THIS POLICY WILL BE REVISED AS NECESSARY AND
REVIEWED NO LESS THAN ANNUALLY.**



Signed: _____

Title: Director, Pharmacy Services

Date: March 1, 2022

Devised: 7/07
Reviewed: 3/08 – annual review
Revised: 4/09 – annual review, updated alt.
Reviewed: 3/10 – annual review
Reviewed: 3/1/11 – annual review
Revised: 3/1/12 – annual review, updated signature & alternatives
Revised: 3/1/13 – annual review, updated logo and definitions, updated alternatives
Revised: 3/1/14 – annual review, added approval statement
Revised: 3/1/15 – annual review, updated signature
Revised: 3/1/16 – annual review, updated policy formatting, changed Abilify to aripiprazole
Revised: 5/1/16 – updated format, logo, & procedure, changed Seroquel to quetiapine
Revised: 3/1/17 – annual review, updated Invega to paliperidone extended release
Revised: 3/1/18 – annual review, updated signature, added grandfather language
Reviewed: 3/1/19 – annual review
Revised: 3/1/20 – annual review, added GHP Kids
Revised: 3/1/21 – annual review, updated logo, added MediSpan approval level
Revised: 3/1/22 – annual review, updated referenced policies & covered LOBs



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 151.0

**SECTION: Commercial Drug
SUBJECT: Verdeso**

Applicable line of business:

Commercial	X	Medicaid	
Medicare		ACA	X
GHP Kids	X	Self-Insured	X

POLICY:

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for Verdeso for GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 487.0 Quantity Limit Exceptions

REQUIRED DEFINITIONS:

1. **Attachment** – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. **Exhibit** – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. **Devised** – the date the policy was implemented.
4. **Revised** – the date of every revision to the policy, including typographical and grammatical changes.
5. **Reviewed** – the date documenting the annual review if the policy has no revisions necessary.

ADDITIONAL DEFINITIONS:

1. **Formulary** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. **Non-formulary products** – those medications that are not included in the Formulary.
3. **Healthcare provider** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
4. **NCQA** – National Committee for Quality Assurance.
5. **Medically Necessary or Medical Necessity** – covered services rendered by a provider that the Health Plan determines are:



POLICY NUMBER: 151.0

**POLICY AND PROCEDURE
PHARMACY
MANUAL**

**SECTION: Commercial Drug
SUBJECT: Verdeso**

- A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
- B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
- C. In accordance with current standards of medical practice;
- D. Not primarily for the convenience of the Member, or the Member's Provider; and
- E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

PROCEDURE:

An exception for coverage of Verdeso may be made for members who meet the following criteria:

- Medical record documentation of therapeutic failure on, intolerance to, or contraindication to formulary low-potency topical steroids

MEDISPAN AUTHORIZATION LEVEL: GPI-12

If an exception is made, Verdeso will be paid for under the member's prescription drug benefit.

Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.

FORMULARY ALTERNATIVES:

Low-potency topical corticosteroids: alclometasone dipropionate 0.5% cream and ointment (Aclovate); fluocinolone acetonide 0.01% soln. (Synalar); hydrocortisone 2.5% cream, ointment, and lotion (Hytone)

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE
STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND
FEDERAL REGULATORY ENTITIES.**

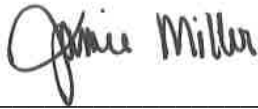
**THIS POLICY WILL BE REVISED AS NECESSARY AND
REVIEWED NO LESS THAN ANNUALLY.**

Geisinger

**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 151.0

**SECTION: Commercial Drug
SUBJECT: Verdeso**



Signed: _____

Title: Director, Pharmacy Services

Date: March 1, 2022

Devised: 7/07
Reviewed: 3/08 – Annual review
Reviewed: 4/09 – annual review
Reviewed: 3/10 – annual review
Reviewed: 3/11 – annual review
Revised: 3/1/12 – annual review, updated signature
Revised: 3/1/13 – annual review, updated logo & definitions
Revised: 3/1/14 – annual review, added approval statement
Revised: 3/1/15 – annual review, updated signature, updated formatting
Revised: 3/1/16 – annual review, removed extra roman numeral from FA
Revised: 5/1/16 – updated format, logo, & procedure
Revised: 3/1/17 – annual review, updated FA
Revised: 3/1/18 – annual review, updated signature
Reviewed: 3/1/19 – annual review
Revised: 3/1/20 – annual review, added GHP Kids
Revised: 3/1/21 – annual review, updated logo, added MediSpan approval level
Revised: 3/1/22 – annual review, updated referenced policies & covered LOBs



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 152.0

**SECTION: Commercial Drug
SUBJECT: Zolinza**

Applicable line of business:

Commercial	X	Medicaid	
Medicare		ACA	X
GHP Kids	X	Self-Insured	X

POLICY:

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for Zolinza for GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 487.0 Quantity Limit Exceptions

REQUIRED DEFINITIONS:

1. **Attachment** – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. **Exhibit** – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. **Devised** – the date the policy was implemented.
4. **Revised** – the date of every revision to the policy, including typographical and grammatical changes.
5. **Reviewed** – the date documenting the annual review if the policy has no revisions necessary.

ADDITIONAL DEFINITIONS:

1. **Formulary** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. **Non-formulary products** – those medications that are not included in the Formulary.
3. **Healthcare provider** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
4. **NCQA** – National Committee for Quality Assurance.
5. **Medically Necessary or Medical Necessity** – covered services rendered by a provider that the Health Plan determines are:

- A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
- B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
- C. In accordance with current standards of medical practice;
- D. Not primarily for the convenience of the Member, or the Member's Provider; and
- E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

PROCEDURE:

New members to the plan already established on therapy may be eligible for continuity of care coverage as long as there is medical record documentation that the safety and effectiveness of use for the prescribed indication is supported by Food and Drug Administration (FDA) approval or adequate medical and scientific evidence in the medical literature.

An exception for coverage of Zolinza may be made for members who meet the following criteria:

- Medical record documentation of use of Zolinza to treat cutaneous manifestations in patients with cutaneous T-cell lymphoma **AND**
- Medical record documentation of resistance or intolerance to two prior therapies **AND**
- Medical record documentation that Zolinza is prescribed by a hematologist or oncologist

MEDISPAN AUTHORIZATION LEVEL: GPI-12, number of claims authorized = 1, enter for the remainder of the calendar year

RE-AUTHORIZATION CRITERIA: Zolinza is configured as a prior authorization for new starts only. Zolinza will no longer be covered if it is identified that the member is not receiving appropriate follow-up care from the prescribing specialist or if the member has greater than or equal to a 90 day break in therapy.

- Medical record documentation that the member is receiving appropriate follow-up care from the prescribing specialist

QUANTITY LIMIT: *No QLs need to be entered within the authorization unless the requested quantity exceeds the QL.*

- 4 capsules per day, 30 day supply per fill



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 152.0

**SECTION: Commercial Drug
SUBJECT: Zolinza**

If an exception is made, Zolinza will be paid for under the member's prescription drug benefit.

Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.

FORMULARY ALTERNATIVES:

none

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE
STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND
FEDERAL REGULATORY ENTITIES.**

**THIS POLICY WILL BE REVISED AS NECESSARY AND
REVIEWED NO LESS THAN ANNUALLY.**

Signed: _____

Title: Director, Pharmacy Services

Date: March 1, 2022

- Devised: 7/07
- Reviewed: 3/08 – annual review
- Reviewed: 4/09 – annual review
- Reviewed: 3/10 – annual review
- Reviewed: 3/1/11 – annual review
- Revised: 3/1/12 – annual review, updated signature
- Revised: 3/1/13 – annual review, updated logo and definitions
- Revised: 3/1/14 – annual review, updated formatting, added approval statement
- Revised: 3/1/15 – annual review, updated signature
- Revised: 3/1/16 – annual review, updated policy formatting
- Revised: 5/1/16 – updated format, logo, & procedure
- Reviewed: 3/1/17 – annual review
- Revised: 10/10/17 – added authorization duration
- Revised: 3/1/18 – annual review, updated signature & format, added grandfather language
- Revised: 6/1/18 – added QL
- Revised: 3/1/19 – annual review, added QL approval note
- Revised: 3/1/20 – annual review, added GHP Kids
- Revised: 3/1/21 – annual review, updated logo, added MediSpan approval level, updated QL statement
- Revised: 12/2/21 – added one-time PA to approval crit., removed auth duration & added re-auth crit.
- Revised: 3/1/22 – annual review, updated referenced policies & covered LOBs



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 154.0

**SECTION: Commercial Drug
SUBJECT: Aliskiren**

Applicable line of business:

Commercial	X	Medicaid	
Medicare		ACA	X
GHP Kids	X	Self-Insured	X

POLICY:

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for aliskiren for GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 487.0 Quantity Limit Exceptions

REQUIRED DEFINITIONS:

1. **Attachment** – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. **Exhibit** – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. **Devised** – the date the policy was implemented.
4. **Revised** – the date of every revision to the policy, including typographical and grammatical changes.
5. **Reviewed** – the date documenting the annual review if the policy has no revisions necessary.

ADDITIONAL DEFINITIONS:

1. **Formulary** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. **Non-formulary products** – those medications that are not included in the Formulary.
3. **Healthcare provider** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
4. **NCQA** – National Committee for Quality Assurance.
5. **Medically Necessary or Medical Necessity** – covered services rendered by a provider that the Health Plan determines are:



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 154.0

**SECTION: Commercial Drug
SUBJECT: Aliskiren**

- A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
 - B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
 - C. In accordance with current standards of medical practice;
 - D. Not primarily for the convenience of the Member, or the Member's Provider; and
 - E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.
6. **ACE Inhibitor** – angiotensin converting enzyme inhibitor
 7. **ARB** – angiotensin receptor blocker

PROCEDURE:

An exception for coverage of aliskiren may be made for members who meet the following criteria:

- Medical record documentation of a therapeutic failure on, intolerance to, or contraindication to three classes of formulary blood pressure medications, one of which must be an angiotensin converting enzyme (ACE) inhibitor and one of which must be an angiotensin receptor blocker (ARB)

MEDISPAN AUTHORIZATION LEVEL: GPI-12, generic only

If an exception is made, aliskiren will be paid for under the member's prescription drug benefit.

Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.

FORMULARY ALTERNATIVES:

ACE inhibitors: benazepril, captopril, enalapril, fosinopril, lisinopril, moexipril, quinapril, trandolapril, ramipril

ACE inhibitors/Diuretics: captopril/hctz, benazepril/hctz, enalapril/hctz, lisinopril/hctz, moexipril/hctz

Alpha-Beta Blockers: labetalol, carvedilol

Antiadrenergic (Peripheral Acting): prazosin, doxazosin, terazosin

Antiadrenergic (Central Acting): clonidine, methyldopa, guanfacine

ARBs: losartan, irbesartan, valsartan



POLICY NUMBER: 154.0

**POLICY AND PROCEDURE
PHARMACY
MANUAL**

**SECTION: Commercial Drug
SUBJECT: Aliskiren**

ARBs/Diuretics: losartan/hctz, irbesartan/hctz, valsartan/hctz
Beta Blockers: acebutolol, pindolol, nadolol, atenolol, propranolol, metoprolol
Beta Blockers/Diuretics: bisoprolol/hctz
Calcium Channel Blockers: verapamil, nifedipine, diltiazem, felodipine, amlodipine, isradipine, nimodipine
Calcium Channel Blockers/Ace Inhibitor: amlodipine/benazepril
Diuretics: furosemide, hydrochlorothiazide, spironolactone, chlorthalidone, spironolactone/ hctz, triamterene/ hctz, bumetanide, metolazone, torsemide

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE
STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND
FEDERAL REGULATORY ENTITIES.**

**THIS POLICY WILL BE REVISED AS NECESSARY AND
REVIEWED NO LESS THAN ANNUALLY.**

Signed: _____

Title: Director, Pharmacy Services

Date: March 1, 2022

Devised: 10/07
Revised: 3/08 – annual review; updated alternatives
Reviewed: 4/09 – annual review, updated alt.
Revised: 3/10 – added Valtorna to policy
Revised: 4/10 – updated alternatives
Reviewed: 3/1/11 – annual review
Revised: 3/1/12 – annual review, updated signature and alternatives
Revised: 3/1/13 – annual review, updated logo and definitions
Revised: 3/1/14 – annual review, updated formatting, added valsartan/hctz to FA, corrected two typos, Valtorna D/C by manufacturer and removed from policy
Revised: 3/1/15 – annual review, updated signature, added irbesartan & irbesartan/hctz as FA
Reviewed: 3/1/16 – annual review
Revised: 5/1/16 – updated format, logo, & procedure, added ACE & ARB to definitions
Revised: 3/1/17 – annual review, updated FA
Revised: 3/1/18 – annual review, updated signature, corrected typo, updated FA
Revised: 3/1/19 – annual review, defined abbreviations
Revised: 11/21/19 – updated Tektorna to generic Aliskiren
Revised: 3/1/20 – annual review, added GHP Kids
Revised: 3/1/21 – annual review, updated logo, added MediSpan approval level
Revised: 3/1/22 – annual review, updated referenced policies & covered LOBs

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Dev. 10/07
Rev. 3/1/22



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 158.0

**SECTION: Commercial Drug
SUBJECT: Altabax**

Applicable line of business:

Commercial	X	Medicaid	
Medicare		ACA	X
GHP Kids	X	Self-Insured	X

POLICY:

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for Altabax for GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 487.0 Quantity Limit Exceptions

REQUIRED DEFINITIONS:

1. **Attachment** – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. **Exhibit** – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. **Devised** – the date the policy was implemented.
4. **Revised** – the date of every revision to the policy, including typographical and grammatical changes.
5. **Reviewed** – the date documenting the annual review if the policy has no revisions necessary.

ADDITIONAL DEFINITIONS:

1. **Formulary** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. **Non-formulary products** – those medications that are not included in the Formulary.
3. **Healthcare provider** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
4. **NCQA** – National Committee for Quality Assurance.
5. **Medically Necessary or Medical Necessity** – covered services rendered by a provider that the Health Plan determines are:



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 158.0

**SECTION: Commercial Drug
SUBJECT: Altabax**

- A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
- B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
- C. In accordance with current standards of medical practice;
- D. Not primarily for the convenience of the Member, or the Member's Provider; and
- E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

PROCEDURE:

An exception for coverage of Altabax may be made for members who meet the following criteria:

- Medical record documentation of a diagnosis of impetigo **AND**
- Medical record documentation that patient's age is greater than 9 months **AND**
- Medical record documentation of therapeutic failure on, intolerance to, or contraindication to mupirocin ointment **AND** oral antibiotic therapy

AUTHORIZATION DURATION: 5 days, RX count 1

MEDISPAN AUTHORIZATION LEVEL: GPI-12

If an exception is made, Altabax will be paid for under the member's prescription drug benefit.

Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.

FORMULARY ALTERNATIVES:

mupirocin ointment, gentamicin cream and ointment, cephalexin, dicloxacillin, erythromycin, clarithromycin, clindamycin, sulfamethoxazole/trimethoprim, doxycycline



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 158.0

**SECTION: Commercial Drug
SUBJECT: Altabax**

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE
STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND
FEDERAL REGULATORY ENTITIES.**

**THIS POLICY WILL BE REVISED AS NECESSARY AND
REVIEWED NO LESS THAN ANNUALLY.**

Signed: _____

Title: Director, Pharmacy Services

Date: March 1, 2022

Devised: 10/07
Reviewed: 3/08 – annual review
Reviewed: 4/09 – annual review
Reviewed: 3/10 – annual review
Reviewed: 3/1/11 – annual review
Revised: 3/1/12 – annual review, updated signature
Revised: 3/1/13 – annual review, updated logo and definitions
Revised: 3/1/14 – annual review, updated formatting
Revised: 3/1/15 – annual review, updated signature
Revised: 3/1/16 – annual review, updated policy formatting
Revised: 5/1/16 – updated format, logo, & procedure
Reviewed: 3/1/17 – annual review
Revised: 3/1/18 – annual review, updated signature
Revised: 3/1/19 – annual review, updated FA to define appropriate oral abx
Revised: 4/1/19 – added auth duration
Revised: 3/1/20 – annual review, added GHP Kids
Revised: 3/1/21 – annual review, updated logo, added MediSpan approval level
Revised: 3/1/22 – annual review, updated referenced policies & covered LOBs



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 159.0

**SECTION: Commercial Drug
SUBJECT: Amlodipine/valsartan and
Amlodipine/valsartan/hctz**

Applicable line of business:

Commercial	X	Medicaid	
Medicare		ACA	X
GHP Kids	X	Self-Insured	X

POLICY:

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for amlodipine/valsartan and amlodipine/valsartan/hctz for GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 487.0 Quantity Limit Exceptions

REQUIRED DEFINITIONS:

1. **Attachment** – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. **Exhibit** – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. **Devised** – the date the policy was implemented.
4. **Revised** – the date of every revision to the policy, including typographical and grammatical changes.
5. **Reviewed** – the date documenting the annual review if the policy has no revisions necessary.

ADDITIONAL DEFINITIONS:

1. **Formulary** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. **Non-formulary products** – those medications that are not included in the Formulary.
3. **Healthcare provider** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
4. **NCQA** – National Committee for Quality Assurance.
5. **Medically Necessary or Medical Necessity** – covered services rendered by a provider that the Health Plan determines are:



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 159.0

**SECTION: Commercial Drug
SUBJECT: Amlodipine/valsartan and
Amlodipine/valsartan/hctz**

- A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
- B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
- C. In accordance with current standards of medical practice;
- D. Not primarily for the convenience of the Member, or the Member's Provider; and
- E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

PROCEDURE:

An exception for coverage of amlodipine/valsartan or amlodipine/valsartan/hctz may be made for members who meet the following criteria:

- Medical record documentation of therapeutic failure on, intolerance to, or contraindication to three preferred formulary angiotensin receptor blockers, one of which must be valsartan, used in combination with amlodipine

MEDISPAN AUTHORIZATION LEVEL: GPI-12, generic only

If an exception is made, amlodipine/valsartan or amlodipine/valsartan/hctz will be paid for under the member's prescription drug benefit.

Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.

FORMULARY ALTERNATIVES:

ARB component: candesartan (generic Atacand), losartan (generic Cozaar), irbesartan (generic Avapro), olmesartan (generic Benicar), telmisartan (generic Micardis), valsartan (generic Diovan)

ARBs/Diuretic component: losartan/hctz (generic Hyzaar), valsartan/hctz (generic Diovan HCT), irbesartan/hctz (generic Avapro HCT) candesartan/hctz (generic Atacand HCT), olmesartan/hctz (generic Benicar HCT), telmisartan/hctz (generic Micardis HCT), valsartan (generic Diovan)

Calcium Channel Blocker component: amlodipine (generic Norvasc)



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 159.0

**SECTION: Commercial Drug
SUBJECT: Amlodipine/valsartan and
Amlodipine/valsartan/hctz**

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE
STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND
FEDERAL REGULATORY ENTITIES.**

**THIS POLICY WILL BE REVISED AS NECESSARY AND
REVIEWED NO LESS THAN ANNUALLY.**

Signed: _____

Title: Director, Pharmacy Services

Date: March 1, 2022

Devised: 1/08
Revised: 3/08 – annual review; updated alternatives
Revised: 4/09 – annual review, updated alt.
Revised: 11/09 – added Exforge HCT, updated alt.
Reviewed: 3/10 – annual review
Revised: 4/10 – updated alternatives
Revised: 3/1/11 – annual review-clarified criteria and alternatives
Revised: 3/1/12 – annual review, updated signature
Revised: 3/1/13 – annual review, updated logo and definitions
Revised: 3/1/14 – annual review, updated formatting, updated FA to include valsartan/hctz
Revised: 12/1/14 – added failure of irbesartan, updated FA, updated signature
Reviewed: 3/1/15 – annual review
Revised: 9/19/15 – added failure of valsartan, updated FA
Revised: 3/1/16 – annual review, updated brand names to generic
Revised: 5/1/16 – updated format, logo, & procedure
Reviewed: 3/1/17 – annual review
Revised: 3/1/18 – annual review, updated signature, updated FA
Revised: 3/1/19 – annual review, updated FA
Revised: 5/29/19 – updated criteria to 3 preferred ARBs, updated FA, deleted note
Revised: 3/1/20 – annual review, added GHP Kids
Revised: 3/1/21 – annual review, updated logo, added MediSpan approval level
Revised: 3/1/22 – annual review, updated referenced policies & covered LOBs



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 162.0

**SECTION: Commercial Drug
SUBJECT: Neupogen, Neulasta,
Fulphila, Udenyca, Ziextenzo,
Leukine, Zarxio, Granix,
and Nivestym**

Applicable line of business:

Commercial	X	Medicaid	
Medicare		ACA	X
GHP Kids	X	Self-Insured	X

POLICY:

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.00T Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for Neupogen, Neulasta, Fulphila, Udenyca, Ziextenzo, Leukine, Zarxio, Granix, and Nivestym for GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 487.0 Quantity Limit Exceptions

REQUIRED DEFINITIONS:

1. **Attachment** – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. **Exhibit** – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. **Devised** – the date the policy was implemented.
4. **Revised** – the date of every revision to the policy, including typographical and grammatical changes.
5. **Reviewed** – the date documenting the annual review if the policy has no revisions necessary.

ADDITIONAL DEFINITIONS:

1. **Formulary** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. **Non-formulary products** – those medications that are not included in the Formulary.
3. **Healthcare provider** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
4. **NCQA** – National Committee for Quality Assurance.



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 162.0

**SECTION: Commercial Drug
SUBJECT: Neupogen, Neulasta,
Fulphila, Udenyca, Ziextenzo,
Leukine, Zarxio, Granix,
and Nivestym**

5. **Medically Necessary or Medical Necessity** – covered services rendered by a provider that the Health Plan determines are:
- A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
 - B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
 - C. In accordance with current standards of medical practice;
 - D. Not primarily for the convenience of the Member, or the Member's Provider; and
 - E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

PROCEDURE:

An exception for coverage of Neupogen, Neulasta, Fulphila, Udenyca, Ziextenzo, Leukine, Zarxio, Granix, or Nivestym may be made for members who meet the following criteria:

NEUPOGEN, NEULASTA, FULPHILA, LEUKINE, UDENYCA, ZIEXTENZO, ZARXIO, GRANIX AND NIVESTYM

- **Medical record documentation of a diagnosis of cancer, and when any of the following FDA labeled indications or uses supported by clinical guidelines are present:**

Primary Prophylaxis – For the prevention of febrile neutropenia (FN) when the risk of FN due to the myelosuppressive chemotherapy regimen is 20% or greater. Those regimens include but are not limited to:

- TC (paclitaxel/cisplatin, or cyclophosphamide/docetaxel or docetaxel/cisplatin or paclitaxel/carboplatin)
- MVAC (methotrexate, vinblastine, doxorubicin, cisplatin)
- AC (doxorubicin, cyclophosphamide, docetaxel)
- AT (doxorubicin, paclitaxel)
- TIC (paclitaxel, ifosfamide, mesna, cisplatin)
- VAPEC-B (vincristine, doxorubicin, prednisolone, etoposide, cyclophosphamide, bleomycin)
- DHAP (dexamethasone, cisplatin, cytarabine)

AND



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 162.0

**SECTION: Commercial Drug
SUBJECT: Neupogen, Neulasta,
Fulphila, Udenyca, Ziextenzo,
Leukine, Zarxio, Granix,
and Nivestym**

- For requests for Neulasta/Neulasta Onpro, medical record documentation of a therapeutic failure on, intolerance to, or contraindication to Ziextenzo, Udenyca, **AND** Fulphila

NOTE: Regimens not specified in this document must be listed on a nationally recognized guideline stating risk of FN of greater than 20%.

OR

For the prevention of FN when the risk of developing FN is less than 20%, but **any** other risk factor listed below is present:

- Age 65 years or greater
- Poor performance status
- Previous history of FN
- Extensive prior radiation or chemotherapy treatment
- Poor nutritional status
- Recent surgery or open wounds or active infection
- Advanced cancer
- Persistent neutropenia
- Bone marrow involvement by tumor
- Liver dysfunction (bilirubin greater than 2.0)
- Renal dysfunction (CrCl less than 50)

AND

- For requests for Neulasta/Neulasta Onpro, medical record documentation of a therapeutic failure on, intolerance to, or contraindication to Ziextenzo, Udenyca, **AND** Fulphila

NEUPOGEN, NEULASTA, FULPHILA, LEUKINE, UDENYCA, ZIEXTENZO, ZARXIO, AND NIVESTYM

- **Medical record documentation of any of the following FDA labeled indications or uses supported by clinical guidelines:**

Secondary Prophylaxis – prevention of FN when a previous cycle of chemotherapy resulted in a neutropenic complication and for which primary prophylaxis was not received, and a dose reduction will compromise disease-free or overall survival or treatment outcome

AND

- For requests for Neulasta/Neulasta Onpro, medical record documentation of a therapeutic failure on, intolerance to, or contraindication to Ziextenzo, Udenyca, **AND** Fulphila

Treatment of Febrile Neutropenia – as an adjunct to antibiotics in high-risk individuals with FN who are at high risk for infection related complications or when **any** of the following prognostic factors are documented:

- Age 65 years or greater
- Anticipated prolonged and profound neutropenia
- Uncontrolled primary disease
- Pneumonia
- Invasive fungal infection
- Hypotension
- Multi-organ dysfunction
- Hospitalized at the time of development of the fever

AND

- For requests for Neulasta/Neulasta Onpro, medical record documentation of a therapeutic failure on, intolerance to, or contraindication to Ziextenzo, Udenyca, **AND** Fulphila

Dose Dense Therapy – specifically in the treatment of node positive breast cancer, small cell lung cancer, and diffuse aggressive non-Hodgkin's lymphoma

AND

- For requests for Neulasta/Neulasta Onpro, medical record documentation of a therapeutic failure on, intolerance to, or contraindication to Ziextenzo, Udenyca, **AND** Fulphila

Stem Cell Transplantation – when one of the following is met:

- Bone marrow transplant (BMT) –
 - Documentation of a non-myeloid malignancy undergoing myeloablative chemotherapy followed by autologous or allogenic bone marrow transplant (G-CSF is given after BMT)

OR

- Peripheral Blood Progenitor Cell (Mobilization) Transplant (PBPC)
 - Used for mobilization of autologous hematopoietic progenitor cells into the peripheral blood for collection by leukapheresis. (G-CSF is given prior to and throughout leukapheresis)

AND

- For requests for Neulasta/Neulasta Onpro, medical record documentation of a therapeutic failure on, intolerance to, or contraindication to Ziextenzo, Udenyca, **AND** Fulphila

NOTE: Neulasta, Udenyca, Ziextenzo, and Fulphila are considered off-label for PBPC mobilization.

Leukemia or Myelodysplastic Syndromes – insured individuals with:

- Acute myeloid leukemia (AML) receiving induction or consolidation chemotherapy
- Acute lymphoblastic leukemia (ALL) after completion of the first few days of chemotherapy of the initial induction or the first post-remission course
- Myelodysplastic syndrome with less than 15% blasts in the bone marrow, or recurrent neutropenic infections are experienced

AND

- For requests for Neulasta/Neulasta Onpro, medical record documentation of a therapeutic failure on, intolerance to, or contraindication to Ziextenzo, Udenyca, **AND** Fulphila

Lymphoma – Age 65 years or greater treated with curative chemotherapy, e.g., CHOP (cyclophosphamide, doxorubicin, vincristine, prednisone)

AND

- For requests for Neulasta/Neulasta Onpro, medical record documentation of a therapeutic failure on, intolerance to, or contraindication to Ziextenzo, Udenyca, **AND** Fulphila

Radiation therapy –

- If prolonged delays secondary to neutropenia are anticipated
- As treatment for radiation injury secondary to doses of 3-10 Grays (Gy) or greater

AND

- For requests for Neulasta/Neulasta Onpro, medical record documentation of a therapeutic failure on, intolerance to, or contraindication to Ziextenzo, Udenyca, **AND** Fulphila

NOTE: Fulphila, Ziextenzo, and Udenyca are considered off-label for radiation injury syndrome; however, the biosimilars are considered medically accepted for this use by the NCCN guidelines.



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 162.0

**SECTION: Commercial Drug
SUBJECT: Neupogen, Neulasta,
Fulphila, Udenyca, Ziextenzo,
Leukine, Zarxio, Granix,
and Nivestym**

NEUPOGEN, ZARXIO, AND NIVESTYM

- **Medical record documentation of any of the following FDA labeled indications or uses supported by clinical guidelines:**

Severe Chronic Neutropenia – when the following criteria are met:

- Diagnosis of congenital, cyclic, or idiopathic neutropenia **AND**
- Documentation of an absolute neutrophil count (ANC) <500 cells/mm³ on three separate occasions during a 6 month period (for congenital or idiopathic neutropenia) **OR** five consecutive days of ANC <500 cells/mm³ per cycle (for cyclic neutropenia) **AND**
- Documentation that the member experienced a clinically significant infection, fever, or oropharyngeal ulcer during the past 12 months
- prolonged delays secondary to neutropenia are anticipated.

LEUKINE

- **Medical record documentation of any of the following FDA labeled indications or uses supported by clinical guidelines:**

Delayed Neutrophil Recovery or Graft Failure

- Medical record documentation that the member has had an allogeneic or autologous bone marrow transplant and neutrophil recovery* has not occurred.

*Note to reviewer: Neutrophil engraftment is defined as the first day of three consecutive days where the neutrophil count (ANC) is 500 cells/mm³ or greater.

MEDISPAN AUTHORIZATION LEVEL: GPI-10

AUTHORIZATION DURATION: 6 months

NEULASTA/FULPHILA/ZIEXTENZO/UDENYCA QUANTITY LIMIT: *No QLs need to be entered within the authorization unless the requested quantity exceeds the QL.*

- **QL FOR LETTER ONLY:** 1 syringe per 14 days (0.043 mL per day)



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 162.0

**SECTION: Commercial Drug
SUBJECT: Neupogen, Neulasta,
Fulphila, Udenyca, Ziextenzo,
Leukine, Zarxio, Granix,
and Nivestym**

If an exception is made, Neupogen, Neulasta, Fulphila, Leukine, Udenyca, Ziextenzo, Zarxio, or Granix will be paid for under the member's prescription drug benefit.

EXCLUSIONS:

There is insufficient evidence in the published, peer reviewed medical literature to clearly establish that the use of colony stimulating factors (CSF) improves the health outcomes in any of the following indications. The use of CSF's for the following indications is considered not medically necessary and are **NOT COVERED**:

- Routine use as prophylaxis on most chemotherapy regimens; or
- Use as prophylaxis during chemotherapy regimens with a febrile neutropenia risk of less than 20% and no high risk for complications; or
- Use in insured members who are neutropenic but afebrile and not meeting any of the above criteria; or
- Use as an adjunct to antibiotics in uncomplicated febrile neutropenia; or use in relapsed or refractory myeloid leukemia; or
- Use in chemo-sensitization of myeloid leukemias; or
- Use prior to or concurrent with chemotherapy for acute myeloid leukemia; or
- Use prior to or concurrently with chemotherapy for "priming" effect; or
- Use to allow an increase in the dose-intensity of cytotoxic chemotherapy beyond the established dose ranges for these regimens; or
- Use during concomitant chemotherapy and radiation therapy; or
- Continued use if no response is seen within 45 days.

Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.

FORMULARY ALTERNATIVES:

none

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE
STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND
FEDERAL REGULATORY ENTITIES.**

**THIS POLICY WILL BE REVISED AS NECESSARY AND
REVIEWED NO LESS THAN ANNUALLY.**



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 162.0

**SECTION: Commercial Drug
SUBJECT: Neupogen, Neulasta,
Fulphila, Udenyca, Ziextenzo,
Leukine, Zarxio, Granix,
and Nivestym**

Signed: _____

Title: Director, Pharmacy Services

Date: March 1, 2022

Devised: 3/08
Reviewed: 4/09 – annual review
Reviewed: 3/10 – annual review
Reviewed: 3/1/11 – annual review
Revised: 3/1/12 – annual review, updated signature
Revised: 3/1/13 – annual review, updated logo and definitions
Revised: 3/1/14 – annual review, corrected typo
Revised: 12/1/14 – added Neulasta QL, updated signature
Reviewed: 3/1/15 – annual review
Revised: 11/20/15 – added Zarxio to policy
Revised: 12/26/15 – add: “uses supported by clinical guidelines” to policy
Revised: 3/1/16 – annual review, added Zarxio to approval statement
Revised: 5/1/16 – updated format, logo, & procedure
Reviewed: 3/1/17 – annual review
Revised: 3/1/18 – annual review, updated signature
Revised: 6/1/18 – updated TC regimen, added notes regarding 20% risk regimens not listed, added additional risk factors to primary prophylaxis, added hospitalized to treatment of neutropenia, added stem cell transplant indication, removed progenitor cell transplant indication, removed non-myeloid malignancy indication, added severe chronic neutropenia for Neupogen/Zarxio
Revised: 10/8/18 – Added Granix to cancer diag.; added Neulasta to secondary prophylaxis, treatment of FN, dose dense therapy, stem cell transplant, Leukemia/MDS, lymphoma and radiation diags.; added Leukine delayed neutrophil recovery or graft failure indication
Revised: 11/26/18 – added Fulphila to policy
Revised: 2/6/19 – removed A(N)CVB due to no availability in USA
Reviewed: 3/1/19 – annual review
Revised: 3/21/19 – added Nivestym to policy
Revised: 5/24/19 – added Udenyca to policy, corrected 2 typos
Revised: 10/8/19 – corrected “supported” typo throughout policy
Revised: 3/1/20 – annual review, added GHP Kids
Revised: 7/28/20 – added Ziextenzo to policy, updated QL to 1 per 14 days, added failure of biosimilar
Revised: 3/1/21 – annual review, updated logo, added MediSpan approval level, updated QL statement
Revised: 3/1/22 – annual review, updated referenced policies & covered LOBs



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 163.0

**SECTION: Commercial Drug
SUBJECT: Neupro**

Applicable line of business:

Commercial	X	Medicaid	
Medicare		ACA	X
GHP Kids	X	Self-Insured	X

POLICY:

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for Neupro for GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 487.0 Quantity Limit Exceptions

REQUIRED DEFINITIONS:

1. **Attachment** – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. **Exhibit** – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. **Devised** – the date the policy was implemented.
4. **Revised** – the date of every revision to the policy, including typographical and grammatical changes.
5. **Reviewed** – the date documenting the annual review if the policy has no revisions necessary.

ADDITIONAL DEFINITIONS:

1. **Formulary** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. **Non-formulary products** – those medications that are not included in the Formulary.
3. **Healthcare provider** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
4. **NCQA** – National Committee for Quality Assurance.
5. **Medically Necessary or Medical Necessity** – covered services rendered by a provider that the Health Plan determines are:



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 163.0

**SECTION: Commercial Drug
SUBJECT: Neupro**

- A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
- B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
- C. In accordance with current standards of medical practice;
- D. Not primarily for the convenience of the Member, or the Member's Provider; and
- E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

PROCEDURE:

An exception for coverage of Neupro may be made for members who meet the following criteria:

- Medical record documentation therapeutic failure on, intolerance to, or contraindication to pramipexole **AND** ropinirole

MEDISPAN AUTHORIZATION LEVEL: GPI-12

If an exception is made, Neupro will be paid for under the member's prescription drug benefit.

Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.

FORMULARY ALTERNATIVES:

pramipexole, ropinirole, ropinirole ER

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE
STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND
FEDERAL REGULATORY ENTITIES.**

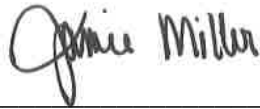
**THIS POLICY WILL BE REVISED AS NECESSARY AND
REVIEWED NO LESS THAN ANNUALLY.**

Geisinger

**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 163.0

**SECTION: Commercial Drug
SUBJECT: Neupro**



Signed: _____

Title: Director, Pharmacy Services

Date: March 1, 2022

Devised: 5/8/08
Revised: 11/21/12 – updated Mirapex and Requip to generic alternatives
Revised: 3/1/13 – annual review, updated logo and definitions
Revised: 3/1/14 – annual review, updated formatting
Revised: 3/1/15 – annual review, updated signature
Reviewed: 3/1/16 – annual review
Revised: 5/1/16 – updated format, logo, & procedure
Reviewed: 3/1/17 – annual review
Revised: 3/1/18 – annual review, updated signature, corrected typo
Reviewed: 3/1/19 – annual review
Revised: 3/1/20 – annual review, added GHP Kids
Revised: 3/1/21 – annual review, updated logo, added MediSpan approval level
Revised: 3/1/22 – annual review, updated referenced policies & covered LOBs



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 164.0

**SECTION: Commercial Drug
SUBJECT: Veregen**

Applicable line of business:

Commercial	X	Medicaid	
Medicare		ACA	X
GHP Kids	X	Self-Insured	X

POLICY:

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for Veregen for GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 487.0 Quantity Limit Exceptions

REQUIRED DEFINITIONS:

1. **Attachment** – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. **Exhibit** – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. **Devised** – the date the policy was implemented.
4. **Revised** – the date of every revision to the policy, including typographical and grammatical changes.
5. **Reviewed** – the date documenting the annual review if the policy has no revisions necessary.

ADDITIONAL DEFINITIONS:

1. **Formulary** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. **Non-formulary products** – those medications that are not included in the Formulary.
3. **Healthcare provider** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
4. **NCQA** – National Committee for Quality Assurance.
5. **Medically Necessary or Medical Necessity** – covered services rendered by a provider that the Health Plan determines are:



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 164.0

**SECTION: Commercial Drug
SUBJECT: Veregen**

- A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
- B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
- C. In accordance with current standards of medical practice;
- D. Not primarily for the convenience of the Member, or the Member's Provider; and
- E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

PROCEDURE:

An exception for coverage of Veregen may be made for members who meet the following criteria:

- Medical record documentation of age greater than or equal to 18 years **AND**
- Medical record documentation that member is immunocompetent **AND**
- Medical record documentation of therapeutic failure on, intolerance to, or contraindication to podofilox solution/Condylox gel **AND** imiquimod (generic Aldara)

MEDISPAN AUTHORIZATION LEVEL: GPI-12

If an exception is made, Veregen will be paid for under the member's prescription drug benefit.

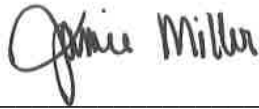
Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.

FORMULARY ALTERNATIVES:

podofilox solution, Condylox gel, imiquimod (generic Aldara)

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE
STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND
FEDERAL REGULATORY ENTITIES.**

**THIS POLICY WILL BE REVISED AS NECESSARY AND
REVIEWED NO LESS THAN ANNUALLY.**



Signed: _____

Title: Director, Pharmacy Services

Date: March 1, 2022

Devised: 5/08
Reviewed: 4/09 – annual review
Reviewed: 3/10 – annual review
Revised: 3/1/11 – annual review-updated with generic Aldara
Revised: 3/1/12 – annual review, updated signature
Revised: 3/1/13 – annual review, updated logo and definitions
Revised: 10/7/13 – removed Neupro from policy
Revised: 3/1/14 – annual review, updated formatting
Revised: 3/1/15 – annual review, updated signature
Reviewed: 3/1/16 – annual review
Revised: 5/1/16 – updated format, logo, & procedure
Reviewed: 3/1/17 – annual review
Revised: 3/1/18 – annual review, updated signature, updated criteria format
Reviewed: 3/1/19 – annual review
Revised: 3/1/20 – annual review, added GHP Kids
Revised: 3/1/21 – annual review, updated logo, added MediSpan approval level
Revised: 3/1/22 – annual review, updated referenced policies & covered LOBs



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 165.0

**SECTION: Commercial Drug
SUBJECT: Xyrem**

Applicable line of business:

Commercial	X	Medicaid	
Medicare		ACA	X
GHP Kids	X	Self-Insured	X

POLICY:

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for Xyrem for GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 487.0 Quantity Limit Exceptions

REQUIRED DEFINITIONS:

1. **Attachment** – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. **Exhibit** – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. **Devised** – the date the policy was implemented.
4. **Revised** – the date of every revision to the policy, including typographical and grammatical changes.
5. **Reviewed** – the date documenting the annual review if the policy has no revisions necessary.

ADDITIONAL DEFINITIONS:

1. **Formulary** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. **Non-formulary products** – those medications that are not included in the Formulary.
3. **Healthcare provider** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
4. **NCQA** – National Committee for Quality Assurance.
5. **Medically Necessary or Medical Necessity** – covered services rendered by a provider that the Health Plan determines are:



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 165.0

**SECTION: Commercial Drug
SUBJECT: Xyrem**

- A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
- B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
- C. In accordance with current standards of medical practice;
- D. Not primarily for the convenience of the Member, or the Member's Provider; and
- E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

PROCEDURE:

An exception for coverage of Xyrem may be made for members who meet the following criteria:

- Medical record documentation of use for a Food and Drug Administration (FDA) approved indication **AND**
- Medical record documentation of therapeutic failure on modafinil **AND** methylphenidate immediate release or amphetamine/dextroamphetamine immediate release

MEDISPAN AUTHORIZATION LEVEL: GPI-12

QUANTITY LIMIT: *No QLs need to be entered within the authorization unless the requested quantity exceeds the QL.*

- QL FOR LETTER ONLY: 18 mL per day, 30 day supply per fill

AUTHORIZATION DURATION:

Initial approval will be for 12 months or less if the reviewing provider feels it is medically appropriate. For continued coverage, the following is required:

- Medical record documentation of reduction in frequency of cataplexy attacks **OR**
- Medical record documentation of reduction in symptoms of excessive daytime sleepiness

After the initial 12 month approval, subsequent approvals will be for a duration of 12 months. Reevaluation will be every 12 months requiring the following:

- Medical record documentation of continued or sustained reduction in frequency of cataplexy attacks **OR**
- Medical record documentation of continued or sustained reduction in symptoms of excessive daytime sleepiness



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 165.0

**SECTION: Commercial Drug
SUBJECT: Xyrem**

If an exception is made, Xyrem will be paid for under the member's prescription drug benefit.

Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.

FORMULARY ALTERNATIVES:

armodafinil*, modafinil*, dextroamphetamine, dextroamphetamine/amphetamine immediate release, methylphenidate immediate release

*prior authorization required

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE
STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND
FEDERAL REGULATORY ENTITIES.**

**THIS POLICY WILL BE REVISED AS NECESSARY AND
REVIEWED NO LESS THAN ANNUALLY.**

Signed: _____

Title: Director, Pharmacy Services

Date: March 1, 2022

Devised: 5/08
Reviewed: 4/09 – annual review
Reviewed: 3/10 – annual review
Revised: 7/10 – added phone number of the Xyrem pharmacy
Reviewed: 3/1/11 – annual review
Revised: 3/1/12 – annual review, updated signature
Revised: 3/1/13 – annual review, updated logo and definitions, updated alternatives
Revised: 3/1/14 – annual review, updated formatting
Revised: 3/1/15 – annual review, updated signature
Revised: 3/1/16 – annual review, removed non-FDA approved FA
Revised: 5/1/16 – updated format, logo, & procedure
Reviewed: 3/1/17 – annual review
Revised: 3/1/18 – annual review, updated signature, update criteria format
Reviewed: 3/1/19 – annual review
Revised: 3/28/19 – removed REMS criteria, updated FA criteria, updated FA, added QL
Revised: 3/1/20 – annual review, added GHP Kids
Revised: 11/18/20 – added authorization duration, updated FA



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 165.0

**SECTION: Commercial Drug
SUBJECT: Xyrem**

Revised: 3/1/21 – annual review, updated logo, added MediSpan approval level, updated QL statement
Revised: 3/1/22 – annual review, updated referenced policies & covered LOBs

Applicable line of business:

Commercial	X	Medicaid	
Medicare		ACA	X
GHP Kids	X	Self-Insured	X

POLICY:

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for sildenafil (generic Revatio) for GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 487.0 Quantity Limit Exceptions

REQUIRED DEFINITIONS:

1. **Attachment** – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. **Exhibit** – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. **Devised** – the date the policy was implemented.
4. **Revised** – the date of every revision to the policy, including typographical and grammatical changes.
5. **Reviewed** – the date documenting the annual review if the policy has no revisions necessary.

ADDITIONAL DEFINITIONS:

1. **Formulary** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. **Non-formulary products** – those medications that are not included in the Formulary.
3. **Healthcare provider** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
4. **NCQA** – National Committee for Quality Assurance.
5. **Medically Necessary or Medical Necessity** – covered services rendered by a provider that the Health Plan determines are:

- A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
- B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
- C. In accordance with current standards of medical practice;
- D. Not primarily for the convenience of the Member, or the Member's Provider; and
- E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

PROCEDURE:

An exception for coverage of sildenafil (generic Revatio) may be made for members who meet the following criteria:

- Medical record documentation that sildenafil is prescribed by a cardiologist or pulmonologist **AND**
- Medical record documentation of a diagnosis of functional class 2, 3, or 4 pulmonary arterial hypertension **AND**
- See no medical record documentation of organic nitrate therapy

MEDISPAN AUTHORIZATION LEVEL: GPI-10, generic only

If an exception is made, sildenafil (generic Revatio) will be paid for under the member's prescription drug benefit.

Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.

FORMULARY ALTERNATIVES:

none



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 167.0

**SECTION: Commercial Drug
SUBJECT: Sildenafil (generic Revatio)**

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE
STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND
FEDERAL REGULATORY ENTITIES.**

**THIS POLICY WILL BE REVISED AS NECESSARY AND
REVIEWED NO LESS THAN ANNUALLY.**

Signed: _____

Title: Director, Pharmacy Services

Date: March 1, 2022

Devised: 5/08
Reviewed: 4/09 – annual review
Reviewed: 3/10 – annual review
Revised: 6/10 – updated criteria to include pulm/cardio
Reviewed: 3/1/11 – annual review
Revised: 3/1/12 – annual review, updated signature & alternatives
Revised: 3/1/13 – annual review, updated logo and definitions
Revised: 3/1/14 – annual review, updated policy title based on generic availability
Revised: 9/22/14 – added Tracleer criteria, removed Tracleer as FA, updated signature
Reviewed: 3/1/15 – annual review
Reviewed: 3/1/16 – annual review
Revised: 5/1/16 – updated format, logo, & procedure
Revised: 7/21/16 – removed in combination with Tracleer
Reviewed: 3/1/17 – annual review, clarified that policy is for generic Revatio
Revised: 3/1/18 – annual review, updated signature, updated prescriber criteria
Reviewed: 3/1/19 – annual review
Revised: 3/1/20 – annual review, added GHP Kids
Revised: 3/1/21 – annual review, updated logo, added MediSpan approval level
Revised: 3/1/22 – annual review, updated referenced policies & covered LOBs



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 168.0

**SECTION: Commercial Drug
SUBJECT: Ambrisentan**

Applicable line of business:

Commercial	X	Medicaid	
Medicare		ACA	X
GHP Kids	X	Self-Insured	X

POLICY:

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for ambrisentan for GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 487.0 Quantity Limit Exceptions

REQUIRED DEFINITIONS:

1. **Attachment** – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. **Exhibit** – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. **Devised** – the date the policy was implemented.
4. **Revised** – the date of every revision to the policy, including typographical and grammatical changes.
5. **Reviewed** – the date documenting the annual review if the policy has no revisions necessary.

ADDITIONAL DEFINITIONS:

1. **Formulary** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. **Non-formulary products** – those medications that are not included in the Formulary.
3. **Healthcare provider** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
4. **NCQA** – National Committee for Quality Assurance.
5. **Medically Necessary or Medical Necessity** – covered services rendered by a provider that the Health Plan determines are:



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 168.0

**SECTION: Commercial Drug
SUBJECT: Ambrisentan**

- A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
- B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
- C. In accordance with current standards of medical practice;
- D. Not primarily for the convenience of the Member, or the Member's Provider; and
- E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

PROCEDURE:

An exception for coverage of ambrisentan may be made for members who meet the following criteria:

- Medical record documentation that ambrisentan is prescribed by a pulmonologist or cardiologist **AND**
- Medical record documentation of a diagnosis of functional class 2 or 3 pulmonary arterial hypertension **AND**
- Medical record documentation of one of the following:
 - Therapeutic failure on, intolerance to, or contraindication to sildenafil (generic Revatio) **OR**
 - Use as first line therapy in combination with tadalafil (generic Adcirca) in patients with WHO Group 1, function class II or III symptoms

MEDISPAN AUTHORIZATION LEVEL: GPI-12, generic only

QUANTITY LIMIT: *No QLs need to be entered within the authorization unless the requested quantity exceeds the QL.*

- **QL FOR LETTER ONLY:** 1 tablet per day, 30 day supply per fill

If an exception is made, ambrisentan will be paid for under the member's prescription drug benefit

Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.



POLICY NUMBER: 168.0

**POLICY AND PROCEDURE
PHARMACY
MANUAL**

**SECTION: Commercial Drug
SUBJECT: Ambrisentan**

FORMULARY ALTERNATIVES:

Uptravi*, Orenitram*, treprostinil* (generic Remodulin), Tyvaso*, Ventavis*, Adempas*,
Opsumit*, bosentan*, tadalafil* (generic Adcirca), sildenafil* (generic Revatio)

*prior authorization required

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE
STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND
FEDERAL REGULATORY ENTITIES.**

**THIS POLICY WILL BE REVISED AS NECESSARY AND
REVIEWED NO LESS THAN ANNUALLY.**

Signed: _____

Title: Director, Pharmacy Services

Date: March 1, 2022

- Devised: 5/08
- Reviewed: 4/09 – annual review
- Reviewed: 3/10 – annual review
- Revised: 6/10 – updated criteria to include pulm/cardio
- Reviewed: 3/1/11 – annual review
- Revised: 3/1/12 – annual review, updated signature
- Revised: 3/1/13 – annual review, updated logo and definitions
- Revised: 3/1/14 – annual review, updated Revatio to sildenafil based on generic availability
- Revised: 9/22/14 – removed failure of Tracleer, removed Tracleer from FA, updated signature
- Reviewed: 3/1/15 – annual review
- Reviewed: 3/1/16 – annual review
- Revised: 3/24/16 – updated formatting, added use as first line therapy in combo with Adcirca
- Revised: 5/1/16 – updated format, logo, & procedure
- Revised: 7/22/16 – added QL, updated FA
- Reviewed: 3/1/17 – annual review
- Revised: 3/1/18 – annual review, updated signature & prescriber criteria, defined PA abbrev.
- Revised: 3/1/19 – annual review, added QL approval note
- Revised: 11/21/19 – updated Letairis to generic ambrisentan, updated all others w/ available generics
- Revised: 3/1/20 – annual review, added GHP Kids
- Revised: 3/1/21 – annual review, updated logo, added MediSpan approval level, updated QL statement
- Revised: 3/1/22 – annual review, updated referenced policies & covered LOBs



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 169.0

**SECTION: Commercial Drug
SUBJECT: Ventavis**

Applicable line of business:

Commercial	X	Medicaid	
Medicare		ACA	X
GHP Kids	X	Self-Insured	X

POLICY:

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for Ventavis for GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 487.0 Quantity Limit Exceptions

REQUIRED DEFINITIONS:

1. **Attachment** – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. **Exhibit** – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. **Devised** – the date the policy was implemented.
4. **Revised** – the date of every revision to the policy, including typographical and grammatical changes.
5. **Reviewed** – the date documenting the annual review if the policy has no revisions necessary.

ADDITIONAL DEFINITIONS:

1. **Formulary** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. **Non-formulary products** – those medications that are not included in the Formulary.
3. **Healthcare provider** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
4. **NCQA** – National Committee for Quality Assurance.
5. **Medically Necessary or Medical Necessity** – covered services rendered by a provider that the Health Plan determines are:



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 169.0

**SECTION: Commercial Drug
SUBJECT: Ventavis**

- A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
- B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
- C. In accordance with current standards of medical practice;
- D. Not primarily for the convenience of the Member, or the Member's Provider; and
- E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

PROCEDURE:

An exception for coverage of Ventavis may be made for members who meet the following criteria:

- Medical record documentation that Ventavis is prescribed by a pulmonologist or cardiologist **AND**
- Medical record documentation of a diagnosis of functional class 3 or 4 pulmonary arterial hypertension **AND**
- Medical record documentation of a therapeutic failure on, intolerance to, or contraindication to sildenafil* **AND** bosentan*

MEDISPAN AUTHORIZATION LEVEL: GPI-12

If an exception is made, Ventavis will be paid for under the member's prescription drug benefit.

Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.

FORMULARY ALTERNATIVES:

sildenafil*, bosentan* oral tablet, Tracleer Soluble oral tablet*

*prior authorization required



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 169.0

**SECTION: Commercial Drug
SUBJECT: Ventavis**

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE
STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND
FEDERAL REGULATORY ENTITIES.**

**THIS POLICY WILL BE REVISED AS NECESSARY AND
REVIEWED NO LESS THAN ANNUALLY.**

Signed: _____

Title: Director, Pharmacy Services

Date: March 1, 2022

Devised: 5/08
Reviewed: 4/09 – annual review
Reviewed: 3/10 – annual review
Revised: 6/10 – updated criteria to include pulm/cardio
Reviewed: 3/1/11 – annual review
Revised: 3/1/12 – annual review
Revised: 3/1/13 – annual review, updated logo
Revised: 3/1/14 – annual review, updated Revatio to sildenafil based on generic availability
Revised: 3/1/15 – annual review, updated signature
Reviewed: 3/1/16 – annual review
Revised: 5/1/16 – updated format, logo, & procedure
Revised: 3/1/17 – annual review, added PA indicator to Tracleer
Revised: 3/1/18 – annual review, updated signature, updated prescribed criteria
Reviewed: 3/1/19 – annual review
Revised: 3/1/20 – annual review, added GHP Kids
Revised: 3/1/21 – annual review, updated logo, added MediSpan approval level, updated Tracleer tablet to generic
Revised: 3/1/22 – annual review, updated referenced policies & covered LOBs



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 170.0

**SECTION: Commercial Drug
SUBJECT: Treprostinil
(generic Remodulin)**

Applicable line of business:

Commercial	X	Medicaid	
Medicare		ACA	X
GHP Kids	X	Self-Insured	X

POLICY:

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for treprostinil (generic Remodulin) for GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 487.0 Quantity Limit Exceptions

REQUIRED DEFINITIONS:

1. **Attachment** – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. **Exhibit** – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. **Devised** – the date the policy was implemented.
4. **Revised** – the date of every revision to the policy, including typographical and grammatical changes.
5. **Reviewed** – the date documenting the annual review if the policy has no revisions necessary.

ADDITIONAL DEFINITIONS:

1. **Formulary** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. **Non-formulary products** – those medications that are not included in the Formulary.
3. **Healthcare provider** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
4. **NCQA** – National Committee for Quality Assurance.
5. **Medically Necessary or Medical Necessity** – covered services rendered by a provider that the Health Plan determines are:



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 170.0

**SECTION: Commercial Drug
SUBJECT: Treprostinil
(generic Remodulin)**

- A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
- B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
- C. In accordance with current standards of medical practice;
- D. Not primarily for the convenience of the Member, or the Member's Provider; and
- E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

PROCEDURE:

An exception for coverage of treprostinil (generic Remodulin) may be made for members who meet the following criteria:

- Medical record documentation that treprostinil is prescribed by a pulmonologist or cardiologist **AND**
- Medical record documentation that treprostinil is being administered subcutaneously **AND**
- Medical record documentation of a diagnosis of functional class 2, 3, or 4 pulmonary arterial hypertension **AND**
- Medical record documentation of therapeutic failure on, intolerance to or contraindication to, or use in combination with sildenafil (generic Revatio) **AND** an appropriate second line agent (an endothelin receptor antagonist or Uptravi) used with sildenafil (generic Revatio)

MEDISPAN AUTHORIZATION LEVEL: GPI-10, generic only

If an exception is made, treprostinil (generic Remodulin) will be paid for under the member's prescription drug benefit.

Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.



POLICY NUMBER: 170.0

**POLICY AND PROCEDURE
PHARMACY
MANUAL**

**SECTION: Commercial Drug
SUBJECT: Trepstinil
(generic Remodulin)**

FORMULARY ALTERNATIVES:

Uptravi*, Orenitram*, Tyvaso*, Ventavis*, Adempas*, Opsumit*, ambrisentan*, bosentan*,
tadalafil* (generic Adcirca), sildenafil* (generic Revatio)

*prior authorization required

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE
STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND
FEDERAL REGULATORY ENTITIES.**

**THIS POLICY WILL BE REVISED AS NECESSARY AND
REVIEWED NO LESS THAN ANNUALLY.**

Signed: _____

Title: Director, Pharmacy Services

Date: March 1, 2022

Devised: 5/08
Reviewed: 4/09 – annual review
Reviewed: 3/10 – annual review
Revised: 6/10 – updated criteria to include pulm/cardio
Reviewed: 3/1/11 – annual review
Revised: 3/1/12 – annual review, updated signature
Revised: 3/1/13 – annual review, updated logo and policy definitions
Revised: 3/1/14 – annual review, updated formatting, updated Revatio to sildenafil
Revised: 9/22/14 – removed failure of Tracleer, removed Tracleer from FA, updated signature
Reviewed: 3/1/15 – annual review
Revised: 3/1/15 – annual review, added prior authorization note
Revised: 5/1/16 – updated format, logo, & procedure
Revised: 7/27/16 – revised FA requirement, updated FA
Reviewed: 3/1/17 – annual review
Revised: 3/1/18 – annual review, updated signature, updated prescriber criteria
Reviewed: 3/1/19 – annual review
Revised: 11/21/19 – updated Remodulin to generic treprostiniil, updated all others w/ available generics
Revised: 3/1/20 – annual review, added GHP Kids
Revised: 3/1/21 – annual review, updated logo, added MediSpan approval level
Revised: 3/1/22 – annual review, updated referenced policies & covered LOBs



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 172.0

**SECTION: Commercial Drug
SUBJECT: Sapropterin**

Applicable line of business:

Commercial	X	Medicaid	
Medicare		ACA	X
GHP Kids	X	Self-Insured	X

POLICY:

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for sapropterin for GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 487.0 Quantity Limit Exceptions

REQUIRED DEFINITIONS:

1. **Attachment** – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. **Exhibit** – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. **Devised** – the date the policy was implemented.
4. **Revised** – the date of every revision to the policy, including typographical and grammatical changes.
5. **Reviewed** – the date documenting the annual review if the policy has no revisions necessary.

ADDITIONAL DEFINITIONS:

1. **Formulary** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. **Non-formulary products** – those medications that are not included in the Formulary.
3. **Healthcare provider** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
4. **NCQA** – National Committee for Quality Assurance.
5. **Medically Necessary or Medical Necessity** – covered services rendered by a provider that the Health Plan determines are:

- A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
- B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
- C. In accordance with current standards of medical practice;
- D. Not primarily for the convenience of the Member, or the Member's Provider; and
- E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

PROCEDURE:

An exception for coverage of sapropterin may be made for members who meet the following criteria:

- Medical record documentation that sapropterin is prescribed by a metabolic specialist **AND**
- Medical record documentation of a diagnosis of hyperphenylalaninemia (baseline blood Phe level greater than or equal to 360 $\mu\text{mol/L}$) **AND**
- Medical record documentation of baseline Phe level **AND**
- Medical record documentation that the member is on and compliant with a Phe-restricted diet

MEDISPAN AUTHORIZATION LEVEL: GPI-10, generic only

AUTHORIZATION DURATION: Approval for new starts will be given for an initial authorization duration of eight (8) weeks. For continuation of coverage, the following criteria is required:

- Medical record documentation of a response to sapropterin defined by a reduction in blood Phe levels from baseline **OR**
- Medical record documentation of an increase in Phe tolerance (addition of Phe in diet with stable Phe level)

After the initial 8 week approval, subsequent approvals will be for a duration of one (1) year. Reevaluation of coverage will be every one (1) year requiring the following:

- Medical record documentation of a sustained reduction in blood Phe levels **OR**
- Medical record documentation of improvement in neuropsychiatric symptoms or an increase in Phe tolerance



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 172.0

**SECTION: Commercial Drug
SUBJECT: Sapropterin**

If an exception is made, sapropterin will be paid for under the member's prescription drug benefit.

Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.

FORMULARY ALTERNATIVES:

none

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE
STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND
FEDERAL REGULATORY ENTITIES.**

**THIS POLICY WILL BE REVISED AS NECESSARY AND
REVIEWED NO LESS THAN ANNUALLY.**

Signed: _____

Title: Director, Pharmacy Services

Date: March 1, 2022

- Devised: 7/08
- Reviewed: 4/09 – annual review
- Reviewed: 3/10 – annual review
- Reviewed: 3/1/11 – annual review
- Revised: 3/1/12 – annual review, updated signature
- Revised: 3/1/13 – annual review, updated logo and definitions
- Revised: 3/1/14 – annual review, updated formatting, updated subject to Kuvan
- Revised: 3/1/15 – annual review, updated signature
- Reviewed: 3/1/16 – annual review
- Revised: 5/1/16 – updated format, logo, & procedure
- Reviewed: 3/1/17 – annual review
- Revised: 3/1/18 – annual review, updated signature, updated prescriber criteria
- Reviewed: 3/1/19 – annual review
- Revised: 5/29/19 – updated auth duration, updated baseline Phe level to 360
- Revised: 3/1/20 – annual review, added GHP Kids
- Revised: 3/1/21 – annual review, updated logo, added MediSpan approval level, updated Kuvan to generic
- Revised: 3/1/22 – annual review, updated referenced policies & covered LOBs



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 173.0

**SECTION: Commercial Drug
SUBJECT: Somatuline Depot**

Applicable line of business:

Commercial	X	Medicaid	
Medicare		ACA	X
GHP Kids	X	Self-Insured	X

POLICY:

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for Somatuline Depot for GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 487.0 Quantity Limit Exceptions

REQUIRED DEFINITIONS:

1. **Attachment** – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. **Exhibit** – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. **Devised** – the date the policy was implemented.
4. **Revised** – the date of every revision to the policy, including typographical and grammatical changes.
5. **Reviewed** – the date documenting the annual review if the policy has no revisions necessary.

ADDITIONAL DEFINITIONS:

1. **Formulary** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. **Non-formulary products** – those medications that are not included in the Formulary.
3. **Healthcare provider** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
4. **NCQA** – National Committee for Quality Assurance.
5. **Medically Necessary or Medical Necessity** – covered services rendered by a provider that the Health Plan determines are:



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 173.0

**SECTION: Commercial Drug
SUBJECT: Somatuline Depot**

- A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
- B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
- C. In accordance with current standards of medical practice;
- D. Not primarily for the convenience of the Member, or the Member's Provider; and
- E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

PROCEDURE:

An exception for coverage of Somatuline Depot may be made for members who meet the following criteria:

- Medical record documentation of treatment of an acromegalic patient who has had an inadequate response to or cannot be treated with surgery and/or radiotherapy

MEDISPAN AUTHORIZATION LEVEL: GPI-12

If an exception is made, Somatuline Depot will be paid for under the member's prescription drug benefit.

Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.

FORMULARY ALTERNATIVES:

octreotide

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE
STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND
FEDERAL REGULATORY ENTITIES.**

**THIS POLICY WILL BE REVISED AS NECESSARY AND
REVIEWED NO LESS THAN ANNUALLY.**



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 173.0

**SECTION: Commercial Drug
SUBJECT: Somatuline Depot**

Signed: _____

Title: Director, Pharmacy Services

Date: March 1, 2022

Devised: 7/08
Reviewed: 4/09 – annual review
Reviewed: 3/10 – annual review
Reviewed: 3/1/11 – annual review
Revised: 3/1/12 – annual review, updated signature
Revised: 3/1/13 – annual review, updated logo and definitions
Revised: 3/1/14 – annual review, updated formatting
Revised: 3/1/15 – annual review, updated signature
Revised: 3/1/16 – annual review, update policy formatting
Revised: 5/1/16 – updated format, logo, & procedure
Reviewed: 3/1/17 – annual review
Revised: 3/1/18 – annual review, updated signature
Reviewed: 3/1/19 – annual review
Revised: 3/1/20 – annual review, added GHP Kids
Revised: 3/1/21 – annual review, updated logo, added MediSpan approval level
Revised: 3/1/22 – annual review, updated referenced policies & covered LOBs



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 174.0

**SECTION: Commercial Drug
SUBJECT: Tassigna**

Applicable line of business:

Commercial	X	Medicaid	
Medicare		ACA	X
GHP Kids	X	Self-Insured	X

POLICY:

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for Tassigna for GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 487.0 Quantity Limit Exceptions

REQUIRED DEFINITIONS:

1. **Attachment** – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. **Exhibit** – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. **Devised** – the date the policy was implemented.
4. **Revised** – the date of every revision to the policy, including typographical and grammatical changes.
5. **Reviewed** – the date documenting the annual review if the policy has no revisions necessary.

ADDITIONAL DEFINITIONS:

1. **Formulary** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. **Non-formulary products** – those medications that are not included in the Formulary.
3. **Healthcare provider** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
4. **NCQA** – National Committee for Quality Assurance.
5. **Medically Necessary or Medical Necessity** – covered services rendered by a provider that the Health Plan determines are:

- A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
- B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
- C. In accordance with current standards of medical practice;
- D. Not primarily for the convenience of the Member, or the Member's Provider; and
- E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

PROCEDURE:

New members to the plan already established on therapy may be eligible for continuity of care coverage as long as there is medical record documentation that the safety and effectiveness of use for the prescribed indication is supported by Food and Drug Administration (FDA) approval or adequate medical and scientific evidence in the medical literature.

An exception for coverage of Tasigna may be made for members who meet the following criteria:

- Medical record documentation that Tasigna is prescribed by a hematologist or oncologist **AND**
- Medical record documentation of the use of Tasigna to treat newly diagnosed (not previously treated) chronic phase Philadelphia chromosome-positive chronic myelogenous leukemia (Ph+ CML) in adult or pediatric patients greater than or equal to 1 year of age **OR**
- Medical record documentation of the use of Tasigna to treat chronic or accelerated phase Ph+ CML in adult patients with resistance to prior therapy including Gleevec (imatinib) **OR**
- Medical record documentation of the use of Tasigna to treat chronic or accelerated phase Philadelphia chromosome-positive chronic myelogenous leukemia (Ph+ CML) in pediatric patients greater than or equal to 1 year of age with resistance or intolerance to prior tyrosine-kinase inhibitor therapy

MEDISPAN AUTHORIZATION LEVEL: GPI-12, number of claims authorized = 1, enter for the remainder of the calendar year



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 174.0

**SECTION: Commercial Drug
SUBJECT: Tasigna**

QUANTITY LIMIT: *No QLs need to be entered within the authorization unless the requested quantity exceeds the QL.*

- **QL FOR LETTER ONLY:**
 - 50 mg capsule: 4 capsules per day, 30 day supply per fill
 - 150 mg and 200 mg capsule: 4 capsules per day, 28 day supply per fill

RE-AUTHORIZATION CRITERIA: Tasigna is configured as a prior authorization for new starts only. Tasigna will no longer be covered if it is identified that the member is not receiving appropriate follow-up care from the prescribing specialist or if the member has greater than or equal to a 90 day break in therapy.

- Medical record documentation that the member is receiving appropriate follow-up care from the prescribing specialist

If an exception is made, Tasigna will be paid for under the member's prescription drug benefit.

Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.

FORMULARY ALTERNATIVES:

Gleevec (imatinib), Sprycel*

*prior authorization required

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE
STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND
FEDERAL REGULATORY ENTITIES.**

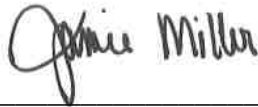
**THIS POLICY WILL BE REVISED AS NECESSARY AND
REVIEWED NO LESS THAN ANNUALLY.**

Geisinger

**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 174.0

**SECTION: Commercial Drug
SUBJECT: Tasigna**



Signed: _____

Title: Director, Pharmacy Services

Date: March 1, 2022

Devised: 7/08
Reviewed: 4/09 – annual review
Reviewed: 3/10 – annual review
Revised: 10/10 – updated to add new FDA indication per rec. from P&T
Reviewed: 3/1/11—annual review
Revised: 3/1/12 – annual review, updated signature
Revised: 3/1/13 – annual review, updated logo and definitions
Reviewed: 3/1/14 – annual review
Revised: 3/1/15 – annual review
Revised: 3/1/16 – annual review, updated policy formatting
Revised: 3/24/16 – removed copay/15 day supply requirement, removed QL indicator from FA
Revised: 5/1/16 – updated format, logo, & procedure
Revised: 3/1/17 – annual review, changed Gleevec to imatinib
Revised: 10/10/17 – increased authorization duration to 12 months
Revised: 3/1/18 – annual review, updated signature & prescriber criteria, added grandfather language
Revised: 5/31/18 – added adult/pediatric to newly diagnosed CML, added adult to failure of Gleevec, defined imatinib, pediatric CML with prior TKI therapy, updated FA, added QL
Revised: 3/1/19 – annual review, defined abbreviations, added QL approval note
Revised: 3/1/20 – annual review, added GHP Kids
Revised: 3/1/21 – annual review, updated logo, added MediSpan approval level, updated QL statement
Revised: 11/24/21 – added treatment of accelerated phase Ph+ CML, added PANSO note, removed auth duration and added re-auth criteria
Revised: 3/1/22 – annual review, updated referenced policies & covered LOBs



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 175.0

**SECTION: Commercial Drug
SUBJECT: Lapatinib**

Applicable line of business:

Commercial	X	Medicaid	
Medicare		ACA	X
GHP Kids	X	Self-Insured	X

POLICY:

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for lapatinib for GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 487.0 Quantity Limit Exceptions

REQUIRED DEFINITIONS:

1. **Attachment** – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. **Exhibit** – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. **Devised** – the date the policy was implemented.
4. **Revised** – the date of every revision to the policy, including typographical and grammatical changes.
5. **Reviewed** – the date documenting the annual review if the policy has no revisions necessary.

ADDITIONAL DEFINITIONS:

1. **Formulary** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. **Non-formulary products** – those medications that are not included in the Formulary.
3. **Healthcare provider** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
4. **NCQA** – National Committee for Quality Assurance.
5. **Medically Necessary or Medical Necessity** – covered services rendered by a provider that the Health Plan determines are:

- A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
- B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
- C. In accordance with current standards of medical practice;
- D. Not primarily for the convenience of the Member, or the Member's Provider; and
- E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

PROCEDURE:

New members to the plan already established on therapy may be eligible for continuity of care coverage as long as there is medical record documentation that the safety and effectiveness of use for the prescribed indication is supported by Food and Drug Administration (FDA) approval or adequate medical and scientific evidence in the medical literature.

An exception for coverage of lapatinib may be made for members who meet the following criteria:

- Medical record documentation that lapatinib is prescribed by an oncologist **AND**
- Medical record documentation of use in combination with letrozole for the treatment of postmenopausal women with hormone receptor-positive (HER2+) metastatic breast cancer **OR**
- Medical record documentation of use in combination with capecitabine for advanced or metastatic breast cancer whose tumors overexpress human epidermal growth factor receptor type 2 (HER2) and have received prior therapy including an anthracycline, a taxane, and trastuzumab (Herceptin)

MEDISPAN AUTHORIZATION LEVEL: GPI-12, generic only, number of claims authorized = 1, enter for the remainder of the calendar year

QUANTITY LIMIT: *No QLs need to be entered within the authorization unless the requested quantity exceeds the QL.*

- **QL FOR LETTER ONLY:** 6 tablets per day, 30 day supply per fill

RE-AUTHORIZATION CRITERIA: Lapatinib is configured as a prior authorization for new starts only. Lapatinib will no longer be covered if it is identified that the member is not receiving appropriate follow-up care from the prescribing specialist or if the member has greater than or equal to a 90 day break in therapy.

- Medical record documentation that the member is receiving appropriate follow-up care from the prescribing specialist

If a formulary exception is approved lapatinib will be paid for under the member's prescription drug benefit.

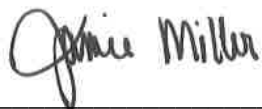
Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.

FORMULARY ALTERNATIVES:

none

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE
STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND
FEDERAL REGULATORY ENTITIES.**

**THIS POLICY WILL BE REVISED AS NECESSARY AND
REVIEWED NO LESS THAN ANNUALLY.**



Signed: _____

Title: Director, Pharmacy Services

Date: March 1, 2022

Devised: 7/08
Reviewed: 4/09 – annual review
Revised: 2/10 – added Femara combination agent
Reviewed: 3/10 – annual review
Reviewed: 3/1/11 – annual review
Revised: 3/1/12 – annual review, updated alternatives
Revised: 3/29/12 – added failure of an anthracycline to criteria #4
Revised: 3/1/13 – annual review, updated logo and definitions
Revised: 5/4/13 – updated criteria to reflect age requirements, fixed typo

HPRX02

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Dev. 7/08

Rev. 3/1/22



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 175.0

**SECTION: Commercial Drug
SUBJECT: Lapatinib**

Revised: 3/1/14 – annual review, updated formatting
Revised: 3/1/15 – annual review, updated signature
Reviewed: 3/1/16 – annual review
Revised: 5/1/16 – updated format, logo, & procedure
Reviewed: 3/1/17 – annual review
Revised: 10/10/17 – added authorization duration
Revised: 3/1/18 – annual review, updated signature & prescriber criteria, added grandfather info
Revised: 6/1/18 – added QL
Revised: 3/1/19 – annual review, defined abbreviations, added QL approval note
Revised: 3/1/20 – annual review, added GHP Kids
Revised: 3/1/21 – annual review, updated logo, added MediSpan approval level, updated QL statement, updated Tykerb to generic
Revised: 11/24/21 – added one-time PA to approval crit., removed auth duration & added re-auth crit.
Revised: 3/1/22 – annual review, updated referenced policies & covered LOBs



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 177.0

**SECTION: Commercial Drug
SUBJECT: Xifaxan**

Applicable line of business:

Commercial	X	Medicaid	
Medicare		ACA	X
GHP Kids	X	Self-Insured	X

POLICY:

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for Xifaxan for GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 487.0 Quantity Limit Exceptions

REQUIRED DEFINITIONS:

1. **Attachment** – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. **Exhibit** – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. **Devised** – the date the policy was implemented.
4. **Revised** – the date of every revision to the policy, including typographical and grammatical changes.
5. **Reviewed** – the date documenting the annual review if the policy has no revisions necessary.

ADDITIONAL DEFINITIONS:

1. **Formulary** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. **Non-formulary products** – those medications that are not included in the Formulary.
3. **Healthcare provider** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
4. **NCQA** – National Committee for Quality Assurance.
5. **Medically Necessary or Medical Necessity** – covered services rendered by a provider that the Health Plan determines are:



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 177.0

**SECTION: Commercial Drug
SUBJECT: Xifaxan**

- A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
- B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
- C. In accordance with current standards of medical practice;
- D. Not primarily for the convenience of the Member, or the Member's Provider; and
- E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

PROCEDURE:

An exception for coverage of Xifaxan may be made for members who meet the following criteria:

Traveler's Diarrhea

- Medical record documentation of use for treatment of travelers' diarrhea **AND**
- Medical record documentation of age greater than or equal to 12 years **AND**
- Medical record documentation of therapeutic failure on, intolerance to, or contraindication to azithromycin and one oral fluoroquinolone

MEDISPAN AUTHORIZATION LEVEL: GPI-12

QUANTITY LIMIT: *QLs must be entered within the authorization.*

- Add ST, PA, PE, OQL, and 3 tablets per day, min/max day supply 3
- QL FOR LETTER: 3 tablets per day, 3 day supply per fill

AUTHORIZATION DURATION: 3 days, RX count 1

Hepatic Encephalopathy

- Medical record documentation of use for the treatment of hepatic encephalopathy **AND**
- Medical record documentation of concomitant therapy with lactulose or medical record documentation of therapeutic failure on, intolerance to, or contraindication to lactulose

MEDISPAN AUTHORIZATION LEVEL: GPI-12

Irritable Bowel Syndrome with Diarrhea (IBS-D)

- Medical record documentation of a diagnosis of moderate to severe irritable bowel syndrome with diarrhea (IBS-D) **AND**
- Medical record documentation that the member is at least 18 years of age **AND**
- Medical record documentation that the correct Food and Drug Administration (FDA) approved strength/dosing is being prescribed (550 mg three times daily for 14 days) **AND**
- Medical record documentation of a therapeutic failure on, intolerance to, or contraindication to dicyclomine **AND** loperamide

MEDISPAN AUTHORIZATION LEVEL: GPI-12

QUANTITY LIMIT: *QLs must be entered within the authorization.*

- Add ST, PA, PE, OQL, and 3 tablets per day, min/max day supply 14
- QL FOR LETTER: 3 tablets per day, 14 day supply per fill

AUTHORIZATION DURATION: 14 days, RX count 1

Reauthorization will require the following:

- Medical record documentation that the patient is having a recurrence of symptoms related to irritable bowel syndrome with diarrhea (IBS-D) **AND**
- Medical record documentation that the patient has not received more than two previous courses of Xifaxan treatment for irritable bowel syndrome with diarrhea (IBS-D)

NOTE: Patients who experience recurrence of symptoms can be retreated up to two times, for a maximum of three cycles.

Small Intestinal Bacterial Overgrowth

- Medical record documentation of a diagnosis of small intestinal bacterial overgrowth **AND**
- Medical record documentation that the bacteria is hydrogen predominant as evidenced by a hydrogen breath test

MEDISPAN AUTHORIZATION LEVEL: GPI-12

QUANTITY LIMIT: *QLs must be entered within the authorization.*

- Add ST, PA, PE, OQL, and 3 tablets per day, min/max day supply 14
- QL FOR LETTER: 3 tablets per day, 14 day supply per fill

AUTHORIZATION DURATION: 14 days, RX count 1



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 177.0

**SECTION: Commercial Drug
SUBJECT: Xifaxan**

If an exception is made, Xifaxan will be paid for under the member’s prescription drug benefit.

Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.

FORMULARY ALTERNATIVES:

- Travelers Diarrhea: ciprofloxacin, azithromycin, levofloxacin
- Hepatic encephalopathy: lactulose
- irritable bowel syndrome with diarrhea (IBS-D): dicyclomine, loperamide
- Small Intestinal Bacterial Overgrowth (SIBO): ciprofloxacin, metronidazole, neomycin, amoxicillin-clavulanate

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE
STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND
FEDERAL REGULATORY ENTITIES.**

**THIS POLICY WILL BE REVISED AS NECESSARY AND
REVIEWED NO LESS THAN ANNUALLY.**

Signed: _____

Title: Director, Pharmacy Services

Date: March 1, 2022

- Devised: 11/08
- Reviewed: 4/09 – annual review
- Reviewed: 3/10 – annual review
- Revised: 4/10 – updated criteria to include HE and updated alternatives
- Reviewed: 3/1/11 – annual review
- Revised: 3/1/12 – annual review, updated signature & alternatives
- Revised: 3/1/13 – annual review, updated logo and definitions
- Revised: 3/1/14 – annual review, updated formatting
- Revised: 3/1/15 – annual review, updated signature
- Revised: 9/18/15 – added IBS-D indication criteria, updated formulary alternatives
- Reviewed: 3/1/16 – annual review
- Revised: 5/1/16 – updated format, logo, & procedure
- Revised: 3/1/17 – annual review, removed Unicode characters
- Revised: 3/1/18 – annual review, updated signature, updated criteria format of travelers’ diarrhea
- Revised: 3/1/19 – annual review, defined abbreviations, added IBS-D note

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Dev. 11/08
Rev. 3/1/22



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 177.0

**SECTION: Commercial Drug
SUBJECT: Xifaxan**

- Revised: 5/24/19 – updated policy format, added QL/duration & clarified 1 FQ for travelers' diarrhea
- Revised: 7/24/19 – corrected typo, added SIBO indication
- Revised: 01/21/20- updated authorization duration
- Revised: 3/1/20 – annual review, added GHP Kids
- Revised: 3/1/21 – annual review, updated logo, added MediSpan approval level, updated QL/auth duration Statements
- Revised: 3/1/22 – annual review, updated referenced policies & covered LOBs



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 178.0

**SECTION: Commercial Drug
SUBJECT: Brovana and Perforomist**

Applicable line of business:

Commercial	X	Medicaid	
Medicare		ACA	X
GHP Kids	X	Self-Insured	X

POLICY:

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for Brovana and Perforomist for GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 487.0 Quantity Limit Exceptions

REQUIRED DEFINITIONS:

1. **Attachment** – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. **Exhibit** – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. **Devised** – the date the policy was implemented.
4. **Revised** – the date of every revision to the policy, including typographical and grammatical changes.
5. **Reviewed** – the date documenting the annual review if the policy has no revisions necessary.

ADDITIONAL DEFINITIONS:

1. **Formulary** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. **Non-formulary products** – those medications that are not included in the Formulary.
3. **Healthcare provider** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
4. **NCQA** – National Committee for Quality Assurance.
5. **Medically Necessary or Medical Necessity** – covered services rendered by a provider that the Health Plan determines are:



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 178.0

**SECTION: Commercial Drug
SUBJECT: Brovana and Perforomist**

- A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
- B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
- C. In accordance with current standards of medical practice;
- D. Not primarily for the convenience of the Member, or the Member's Provider; and
- E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

PROCEDURE:

An exception for coverage of Brovana or Perforomist may be made for members who meet the following criteria:

- Medical record documentation of a diagnosis of chronic obstructive pulmonary disease (COPD) **AND**
- Medical record documentation of age greater than or equal to 18 years **AND**
- Medical record documentation of therapeutic failure on, intolerance to, or contraindication to Serevent **OR** that member is unable to use an inhaler

MEDISPAN AUTHORIZATION LEVEL: GPI-12

If an exception is made, Brovana or Perforomist will be paid for under the member's prescription drug benefit.

Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.

FORMULARY ALTERNATIVES:

Serevent



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 178.0

**SECTION: Commercial Drug
SUBJECT: Brovana and Perforomist**

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE
STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND
FEDERAL REGULATORY ENTITIES.**

**THIS POLICY WILL BE REVISED AS NECESSARY AND
REVIEWED NO LESS THAN ANNUALLY.**

Signed: _____

Title: Director, Pharmacy Services

Date: March 1, 2022

Devised: 11/08
Reviewed: 4/09 – annual review
Reviewed: 3/10 – annual review
Reviewed: 3/1/11 – annual review
Revised: 3/1/12 – annual review, updated signature
Revised: 3/1/13 – annual review, updated logo and definitions
Revised: 3/1/14 – annual review, updated formatting
Revised: 3/1/15 – annual review, updated signature
Reviewed: 3/1/16 – annual review
Revised: 5/1/16 – updated format, logo, & procedure
Revised: 1/25/17 – removed failure of Foradil due to products discontinuation
Revised: 3/1/17 – annual review, removed Unicode characters
Revised: 3/1/18 – annual review, updated signature, update format of criteria
Reviewed: 3/1/19 – annual review
Revised: 3/1/20 – annual review, added GHP Kids
Revised: 3/1/21 – annual review, updated logo, added MediSpan approval level
Revised: 3/1/22 – annual review, updated referenced policies & covered LOBs



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 179.0

**SECTION: Commercial Drug
SUBJECT: Lidocaine Patch**

Applicable line of business:

Commercial	X	Medicaid	
Medicare		ACA	X
GHP Kids	X	Self-Insured	X

POLICY:

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for lidocaine patch for GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 487.0 Quantity Limit Exceptions

REQUIRED DEFINITIONS:

1. **Attachment** – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. **Exhibit** – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. **Devised** – the date the policy was implemented.
4. **Revised** – the date of every revision to the policy, including typographical and grammatical changes.
5. **Reviewed** – the date documenting the annual review if the policy has no revisions necessary.

ADDITIONAL DEFINITIONS:

1. **Formulary** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. **Non-formulary products** – those medications that are not included in the Formulary.
3. **Healthcare provider** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
4. **NCQA** – National Committee for Quality Assurance.
5. **Medically Necessary or Medical Necessity** – covered services rendered by a provider that the Health Plan determines are:



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 179.0

**SECTION: Commercial Drug
SUBJECT: Lidocaine Patch**

- A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
- B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
- C. In accordance with current standards of medical practice;
- D. Not primarily for the convenience of the Member, or the Member's Provider; and
- E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

PROCEDURE:

An exception for coverage of lidocaine patch may be made for members who meet the following criteria:

- Medical record documentation of a Food and Drug Administration (FDA) approved indication (postherpetic neuralgia)

MEDISPAN AUTHORIZATION LEVEL: GPI-14, generic only

If an exception is made, lidocaine patch will be paid for under the member's prescription drug benefit.

Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.

FORMULARY ALTERNATIVES:

none

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE
STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND
FEDERAL REGULATORY ENTITIES.**

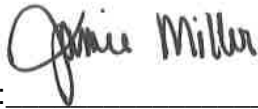
**THIS POLICY WILL BE REVISED AS NECESSARY AND
REVIEWED NO LESS THAN ANNUALLY.**

Geisinger

**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 179.0

**SECTION: Commercial Drug
SUBJECT: Lidocaine Patch**



Signed: _____

Title: Director, Pharmacy Services

Date: March 1, 2022

Devised: 11/08
Reviewed: 4/09 – annual review
Reviewed: 3/10 – annual review
Reviewed: 3/1/11 – annual review
Revised: 3/1/12 – annual review, updated signature
Revised: 3/1/13 – annual review, updated logo and definitions
Revised: 3/1/14 – annual review, updated policy title based on generic availability
Revised: 3/1/15 – annual review, updated signature, added postherpetic neuralgia
Reviewed: 3/1/16 – annual review
Revised: 5/1/16 – updated format, logo, & procedure
Reviewed: 3/1/17 – annual review
Revised: 3/1/18 – annual review, updated signature, defined FDA
Reviewed: 3/1/19 – annual review
Revised: 3/1/20 – annual review, added GHP Kids
Revised: 3/1/21 – annual review, updated logo, added MediSpan approval level
Revised: 3/1/22 – annual review, updated referenced policies & covered LOBs



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 180.0

**SECTION: Commercial Drug
SUBJECT: Sumatriptan/Naproxen**

Applicable line of business:

Commercial	X	Medicaid	
Medicare		ACA	X
GHP Kids	X	Self-Insured	X

POLICY:

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for sumatriptan/naproxen for GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 296.0 Triptan Quantity Limit Exceptions
- Policy 487.0 Quantity Limit Exceptions

REQUIRED DEFINITIONS:

1. **Attachment** – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. **Exhibit** – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. **Devised** – the date the policy was implemented.
4. **Revised** – the date of every revision to the policy, including typographical and grammatical changes.
5. **Reviewed** – the date documenting the annual review if the policy has no revisions necessary.

ADDITIONAL DEFINITIONS:

1. **Formulary** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. **Non-formulary products** – those medications that are not included in the Formulary.
3. **Healthcare provider** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
4. **NCQA** – National Committee for Quality Assurance.

5. **Medically Necessary or Medical Necessity** – covered services rendered by a provider that the Health Plan determines are:
- A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
 - B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
 - C. In accordance with current standards of medical practice;
 - D. Not primarily for the convenience of the Member, or the Member's Provider; and
 - E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

PROCEDURE:

An exception for coverage of sumatriptan/naproxen may be made for members who meet the following criteria:

- Medical record documentation of a diagnosis of migraine **AND**
- Member is not using concurrent opioid or barbiturate therapy for migraine treatment **AND**
- Medical record documentation of a therapeutic failure on, intolerance to, or contraindication to (two) formulary triptans (one of which must be sumatriptan) with concurrent use of naproxen **OR** if member is 12 to less than 18 years of age, medical record documentation of a therapeutic failure on, intolerance to, or contraindication to rizatriptan **AND** almotriptan with concurrent use of naproxen

MEDISPAN AUTHORIZATION LEVEL: GPI-12, generic only

QUANTITY LIMIT: *No QLs need to be entered within the authorization unless the requested quantity exceeds the QL.*

- **QL FOR LETTER ONLY:** 16 doses per 28 days (Dose limit applies across all oral triptan products.)

If an exception is made, sumatriptan/naproxen will be paid for under the member's prescription drug benefit.

Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.

Geisinger

**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 180.0

**SECTION: Commercial Drug
SUBJECT: Sumatriptan/Naproxen**

FORMULARY ALTERNATIVES:

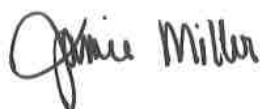
Members greater than or equal to 18 years of age: naproxen, sumatriptan**, Cafergot, rizatriptan**, Migranal, DHE 45, naratriptan**, almotriptan**

Members 12 to less than 18 years of age: naproxen, rizatriptan**, almotriptan**

** quantity limits apply

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE
STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND
FEDERAL REGULATORY ENTITIES.**

**THIS POLICY WILL BE REVISED AS NECESSARY AND
REVIEWED NO LESS THAN ANNUALLY.**



Signed: _____

Title: Director, Pharmacy Services

Date: March 1, 2022

Devised: 1/09
Reviewed: 4/09 – annual review
Revised: 5/09 – updated QL
Reviewed: 3/10 – annual review
Reviewed: 3/1/11 – annual review-updated generics
Revised: 9/11 – updated criteria. Removed Midrin and ergot derivatives from criteria
Revised: 3/1/12 – annual review, updated signature & alternatives
Revised: 3/1/13 – annual review, updated logo, definitions, and alternatives
Revised: 9/25/13 – added quantity limit
Reviewed: 3/1/14 – annual review
Revised: 3/1/15 – annual review, updated signature
Revised: 9/19/15 – added pediatric indication, updated formulary alternatives
Reviewed: 3/1/16 – annual review
Revised: 5/1/16 – updated format, logo, & procedure
Revised: 3/1/17 – annual review, removed Unicode characters
Revised: 3/1/18 – annual review, updated signature
Reviewed: 3/1/19 – annual review
Revised: 11/21/19 – updated Treximet to generic, updated FA, removed QL indicator from criteria
Revised: 3/1/20 – annual review, added GHP Kids
Revised: 3/1/21 – annual review, updated logo, added MediSpan approval level, updated QL statement
Revised: 3/1/22 – annual review, updated referenced policies & covered LOBs



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 182.0

**SECTION: Commercial Drug
SUBJECT: Amlodipine/Olmesartan**

Applicable line of business:

Commercial	X	Medicaid	
Medicare		ACA	X
GHP Kids	X	Self-Insured	X

POLICY:

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for amlodipine/olmesartan for GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 487.0 Quantity Limit Exceptions

REQUIRED DEFINITIONS:

1. **Attachment** – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. **Exhibit** – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. **Devised** – the date the policy was implemented.
4. **Revised** – the date of every revision to the policy, including typographical and grammatical changes.
5. **Reviewed** – the date documenting the annual review if the policy has no revisions necessary.

ADDITIONAL DEFINITIONS:

1. **Formulary** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. **Non-formulary products** – those medications that are not included in the Formulary.
3. **Healthcare provider** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
4. **NCQA** – National Committee for Quality Assurance.
5. **Medically Necessary or Medical Necessity** – covered services rendered by a provider that the Health Plan determines are:



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 182.0

**SECTION: Commercial Drug
SUBJECT: Amlodipine/Olmesartan**

- A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
- B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
- C. In accordance with current standards of medical practice;
- D. Not primarily for the convenience of the Member, or the Member's Provider; and
- E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

PROCEDURE:

An exception for coverage of amlodipine/olmesartan may be made for members who meet the following criteria:

- Medical record documentation of therapeutic failure on, intolerance to, or contraindication to three (3) preferred formulary angiotensin receptor blockers, one of which must be olmesartan, used in combination with amlodipine

If an exception is made, amlodipine/olmesartan will be paid for under the member's prescription drug benefit.

Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.

FORMULARY ALTERNATIVES:

olmesartan and amlodipine, losartan and amlodipine, irbesartan and amlodipine, valsartan and amlodipine, candesartan and amlodipine, telmisartan and amlodipine

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE
STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND
FEDERAL REGULATORY ENTITIES.**

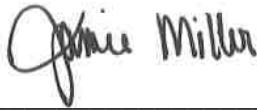
**THIS POLICY WILL BE REVISED AS NECESSARY AND
REVIEWED NO LESS THAN ANNUALLY.**

Geisinger

**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 182.0

**SECTION: Commercial Drug
SUBJECT: Amlodipine/Olmesartan**



Signed: _____

Title: Director, Pharmacy Services

Date: March 1, 2022

Devised: 4/09
Reviewed: 3/10 – annual review
Revised: 4/10 – updated alternatives
Revised: 3/1/11 – annual review, updated alts
Revised: 3/1/12 – annual review, updated signature
Revised: 3/1/13 – annual review, updated logo and definitions
Revised: 3/1/14 – annual review
Revised: 12/1/14 – added failure of irbesartan, updated formulary alternatives, updated signature
Reviewed: 3/1/15 – annual review
Revised: 3/1/16 – annual review, added valsartan and amlodipine to FA
Revised: 5/1/16 – updated format, logo, & procedure
Revised: 3/1/17 – updated policy from Azor to amlodipine/olmesartan
Revised: 3/27/17 – failure of valsartan
Revised: 3/1/18 – annual review, updated signature, corrected typo
Revised: 3/1/19 – annual review, updated FA
Revised: 5/29/19 – deleted note, updated to failure of 3 preferred ARBs
Revised: 3/1/20 – annual review, added GHP Kids
Revised: 3/1/21 – annual review, updated logo, added MediSpan approval level
Revised: 3/1/22 – annual review, updated referenced policies & covered LOBs



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 183.0

**SECTION: Commercial Drug
SUBJECT: Sancuso**

Applicable line of business:

Commercial	X	Medicaid	
Medicare		ACA	X
GHP Kids	X	Self-Insured	X

POLICY:

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for Sancuso for GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 487.0 Quantity Limit Exceptions

REQUIRED DEFINITIONS:

1. **Attachment** – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. **Exhibit** – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. **Devised** – the date the policy was implemented.
4. **Revised** – the date of every revision to the policy, including typographical and grammatical changes.
5. **Reviewed** – the date documenting the annual review if the policy has no revisions necessary.

ADDITIONAL DEFINITIONS:

1. **Formulary** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. **Non-formulary products** – those medications that are not included in the Formulary.
3. **Healthcare provider** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
4. **NCQA** – National Committee for Quality Assurance.
5. **Medically Necessary or Medical Necessity** – covered services rendered by a provider that the Health Plan determines are:

- A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
- B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
- C. In accordance with current standards of medical practice;
- D. Not primarily for the convenience of the Member, or the Member's Provider; and
- E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

PROCEDURE:

An exception for coverage of Sancuso may be made for members who meet **ALL** of the following criteria:

- Medical record documentation of administration of a moderately to highly emetogenic chemotherapy for up to 5 consecutive days **AND**
- Medical record documentation of therapeutic failure on, intolerance to, or contraindication to ondansetron and oral granisetron

MEDISPAN AUTHORIZATION LEVEL: GPI-12

QUANTITY LIMIT: *No QLs need to be entered within the authorization unless the requested quantity exceeds the QL.*

- **QL FOR LETTER ONLY:** 4 patches per 28 days

If an exception is made, Sancuso will be paid for under the member's prescription drug benefit.

Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.

FORMULARY ALTERNATIVES:

ondansetron, granisetron**, aprepitant**

** quantity limits apply



POLICY NUMBER: 183.0

**POLICY AND PROCEDURE
PHARMACY
MANUAL**

**SECTION: Commercial Drug
SUBJECT: Sancuso**

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE
STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND
FEDERAL REGULATORY ENTITIES.**

**THIS POLICY WILL BE REVISED AS NECESSARY AND
REVIEWED NO LESS THAN ANNUALLY.**

Signed: _____

Title: Director, Pharmacy Services

Date: March 1, 2022

Devised: 4/09
Reviewed: 3/10
Reviewed: 3/1/11 – annual review
Revised: 3/1/12 – annual review, updated signature
Revised: 3/1/13 – annual review, updated logo and definitions
Revised: 3/1/14 – annual review, updated formatting, updated Emend to a quantity limit
Revised: 3/1/15 – annual review, updated signature
Revised: 3/1/16 – annual review, added QL indicator to granisetron
Revised: 5/1/16 – updated format, logo, & procedure
Revised: 3/1/17 – annual review, updated Emend to aprepitant
Revised: 3/1/18 – annual review, updated signature
Revised: 6/1/18 – added QL
Revised: 3/1/19 – annual review, added QL approval note
Revised: 3/1/20 – annual review, added GHP Kids
Revised: 3/1/21 – annual review, updated logo, added MediSpan approval level, updated QL statement
Revised: 3/1/22 – annual review, updated referenced policies & covered LOBs



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 184.0

**SECTION: Commercial Drug
SUBJECT: Relistor Injection**

Applicable line of business:

Commercial	X	Medicaid	
Medicare		ACA	X
GHP Kids	X	Self-Insured	X

POLICY:

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for Relistor injection for GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 487.0 Quantity Limit Exceptions

REQUIRED DEFINITIONS:

1. **Attachment** – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. **Exhibit** – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. **Devised** – the date the policy was implemented.
4. **Revised** – the date of every revision to the policy, including typographical and grammatical changes.
5. **Reviewed** – the date documenting the annual review if the policy has no revisions necessary.

ADDITIONAL DEFINITIONS:

1. **Formulary** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. **Non-formulary products** – those medications that are not included in the Formulary.
3. **Healthcare provider** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
4. **NCQA** – National Committee for Quality Assurance.
5. **Medically Necessary or Medical Necessity** – covered services rendered by a provider that the Health Plan determines are:

- A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
- B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
- C. In accordance with current standards of medical practice;
- D. Not primarily for the convenience of the Member, or the Member's Provider; and
- E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

PROCEDURE:

An exception for coverage of Relistor Injection may be made for members who meet **ALL** of the following criteria:

Chronic Non-Cancer Pain

- Medical record documentation of a diagnosis of chronic non-cancer pain, including patients with chronic pain related to prior cancer or its treatment **AND**
- Medical record documentation that member is currently on opioid therapy **AND**
- Medical record documentation of therapeutic failure on two alternative laxative/bowel therapies **AND**
- Medical record documentation of therapeutic failure on, intolerance to, or contraindication to lubiprostone **AND** Movantik

Advanced Illness Receiving Palliative Care

- Medical record documentation of advanced illness receiving palliative care **AND**
- Medical record documentation that member is currently on opioid therapy **AND**
- Medical record documentation of therapeutic failure on two alternative laxative/bowel therapies

MEDISPAN AUTHORIZATION LEVEL: GPI-12

QUANTITY LIMIT: *No QLs need to be entered within the authorization unless the requested quantity exceeds the QL.*

- **QL FOR LETTER ONLY:**
 - 12 mg dose: 0.6 mL (1 syringe) per day
 - 8 mg dose: 6 mL (15 syringes) per 30 days



POLICY NUMBER: 184.0

**POLICY AND PROCEDURE
PHARMACY
MANUAL**

**SECTION: Commercial Drug
SUBJECT: Relistor Injection**

If an exception is made, Relistor will be paid for under the member's prescription drug benefit.

Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.

FORMULARY ALTERNATIVES:

Advanced Illness Receiving Palliative Care: lactulose
Chronic Non-Cancer Pain: lubiprostone, lactulose, Movantik

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE
STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND
FEDERAL REGULATORY ENTITIES.**

**THIS POLICY WILL BE REVISED AS NECESSARY AND
REVIEWED NO LESS THAN ANNUALLY.**

Signed: _____

Title: Director, Pharmacy Services

Date: March 1, 2022

Devised: 4/09
Revised: 5/09 – fixed typo
Reviewed: 3/10 – annual review
Reviewed: 3/1/11 – annual review
Revised: 3/1/12 – annual review, updated signature
Revised: 1/25/13 – removed polyethylene glycol from alternatives and updated path
Revised: 3/1/13 – annual review, updated logo and definitions
Reviewed: 3/1/14 – annual review
Revised: 3/1/15 – annual review, updated signature, updated formatting
Revised: 4/13/15 – added chronic non-cancer pain to policy
Reviewed: 3/1/16 – annual review
Revised: 5/1/16 – updated format, logo, & procedure
Revised: 11/22/16 – removed copay per 14-day supply, updated QL, updated formatting, added failure of Amitiza/Movantik for chronic non-cancer pain, updated FA
Reviewed: 3/1/17 – annual review
Revised: 3/1/18 – annual review, updated signature
Revised: 4/6/18 – updated chronic pain diagnosis criteria to include prior cancer
Revised: 3/1/19 – annual review, added QL approval note



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 184.0

**SECTION: Commercial Drug
SUBJECT: Relistor Injection**

Revised: 3/1/20 – annual review, added GHP Kids

Revised: 3/1/21 – annual review, updated logo, added MediSpan approval level, updated QL statement

Revised: 3/1/22 – annual review, updated referenced policies & covered LOBs, updated Amitiza to lubiprostone



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 185.0

**SECTION: Commercial Drug
SUBJECT: Promacta**

Applicable line of business:

Commercial	X	Medicaid	
Medicare		ACA	X
GHP Kids	X	Self-Insured	X

POLICY:

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for Promacta for GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 487.0 Quantity Limit Exceptions

REQUIRED DEFINITIONS:

1. **Attachment** – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. **Exhibit** – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. **Devised** – the date the policy was implemented.
4. **Revised** – the date of every revision to the policy, including typographical and grammatical changes.
5. **Reviewed** – the date documenting the annual review if the policy has no revisions necessary.

ADDITIONAL DEFINITIONS:

1. **Formulary** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. **Non-formulary products** – those medications that are not included in the Formulary.
3. **Healthcare provider** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
4. **NCQA** – National Committee for Quality Assurance.
5. **Medically Necessary or Medical Necessity** – covered services rendered by a provider that the Health Plan determines are:



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 185.0

**SECTION: Commercial Drug
SUBJECT: Promacta**

- A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
- B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
- C. In accordance with current standards of medical practice;
- D. Not primarily for the convenience of the Member, or the Member's Provider; and
- E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

PROCEDURE:

An exception for coverage of Promacta may be made for members who meet **ALL** of the following criteria:

For Chronic Immune Thrombocytopenic Purpura (ITP)

- Medical record documentation of a diagnosis of chronic immune (idiopathic) thrombocytopenic purpura (ITP) **AND**
- Medical record documentation that Promacta is prescribed by a hematologist **AND**
- Medical record documentation of a therapeutic failure on, or contraindication to ALL of the following: corticosteroids, immunoglobulins, and rituximab* **AND**
- Symptomatic ITP with bleeding symptoms and a platelet count of less than 30,000/ μ L **OR** a documentation history of significant bleeding and a platelet count of less than 30,000/ μ L **OR** a platelet count of less than 20,000/ μ L

MEDISPAN AUTHORIZATION LEVEL: GPI-10

AUTHORIZATION DURATION: If an exception is made, Promacta will be authorized for an **initial period of three (3) months** and continued coverage will require medical record documentation of improvement in symptoms and platelet count response above 20,000/ μ L. Subsequent authorizations will be for a period of **six (6) months** and will then require medical record documentation of dosing to maintain a platelet count between 50,000/ μ L and 100,000/ μ L.

For Chronic Hepatitis C

- Medical record documentation of a diagnosis of chronic hepatitis C and plan to initiate or continue interferon-based therapy **AND**
- Medical record documentation of a platelet count of less than 50,000/ μ L **AND**
- Medical record documentation that Promacta is prescribed by a gastroenterologist, hematologist, hepatologist or infectious disease specialist



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 185.0

**SECTION: Commercial Drug
SUBJECT: Promacta**

MEDISPAN AUTHORIZATION LEVEL: GPI-10

AUTHORIZATION DURATION: If approved, the authorization will be for a time period of 6 months.

For Severe Aplastic Anemia

- Medical record documentation that Promacta is prescribed is written by a hematologist **AND**
- Medical record documentation of a platelet count less than or equal to 30,000/ μ L **AND**
- Medical record documentation of a diagnosis of severe aplastic anemia **AND**
- Medical record documentation of one of the following:
 - Medical record documentation of an inadequate response to at least one prior immunosuppressive therapy (e.g., cyclosporine, mycophenolate mofetil, sirolimus, Atgam® [lymphocyte immune globulin, anti-thymocyte globulin [equine] sterile solution for intravenous use only]) **OR**
 - Medical record documentation that Promacta will be used as first line treatment in combination with standard immunosuppressive therapy (e.g. antithymocyte globulin [equine] and cyclosporine)

MEDISPAN AUTHORIZATION LEVEL: GPI-10

AUTHORIZATION DURATION: If an exception is made, Promacta will be authorized for an **initial period of six (6) months** and continued coverage will require medical record documentation of improvement in symptoms and a hematological response. Subsequent authorizations will be for a period of **six (6) months** and will then require medical record documentation of continued hematological response.

NOTE: Per UpToDate, hematologic response is defined as independence from transfusion, no need for additional immunosuppressive therapy, and/or improvement or peripheral blood counts to the point that they no longer meet criteria for severe aplastic anemia.

If an exception is made, Promacta will be paid for under the member's prescription drug benefit.

Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 185.0

**SECTION: Commercial Drug
SUBJECT: Promacta**

FORMULARY ALTERNATIVES:

none

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE
STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND
FEDERAL REGULATORY ENTITIES.**

**THIS POLICY WILL BE REVISED AS NECESSARY AND
REVIEWED NO LESS THAN ANNUALLY.**

Signed: _____

Title: Director, Pharmacy Services

Date: April 6, 2022

- Devised: 4/09
- Reviewed: 3/10 – annual review
- Reviewed: 3/1/11—annual review
- Revised: 3/1/12 – annual review, updated signature
- Revised: 3/1/13 – annual review, updated logo and definitions
- Revised: 5/4/13 – added chronic hepatitis C indication
- Revised: 10/7/13 – added prescribers and updated platelet units
- Reviewed: 3/1/14 – annual review
- Revised: 12/1/14 – updated require failure on all FA, added platelet count to symptomatic bleeding for ITP, updated auth. dur. for ITP and HCV, updated signature
- Revised: 2/9/15 – corrected typo, added aplastic anemia indication
- Revised: 3/1/15 – annual review, updated formatting
- Revised: 11/20/15 – removed failure of splenectomy for chronic ITP
- Reviewed: 3/1/16 – annual review
- Revised: 5/1/16 – updated format, logo, & procedure
- Revised: 3/1/17 – annual review, removed Unicode characters, corrected typo
- Revised: 3/1/18 – annual review, updated signature
- Reviewed: 3/1/19 – annual review
- Revised: 3/28/19 – added first line aplastic anemia indication, updated aplastic anemia auth duration to 6 months initial, added aplastic anemia note
- Revised: 3/1/20 – annual review, added GHP Kids
- Revised: 3/1/21 – annual review, updated logo, added MediSpan approval level
- Revised: 3/1/22 – annual review, updated referenced policies & covered LOBs
- Revised: 4/6/22 – updated Rituxan to rituximab, added platelet count less than 30,000/ μ L with history of bleeding, removed risk of bleeding from platelet count of less than 20,000/ μ L



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 187.0

**SECTION: Commercial Drug
SUBJECT: Vimpat**

Applicable line of business:

Commercial	X	Medicaid	
Medicare		ACA	X
GHP Kids	X	Self-Insured	X

POLICY:

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for Vimpat for GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 487.0 Quantity Limit Exceptions

REQUIRED DEFINITIONS:

1. **Attachment** – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. **Exhibit** – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. **Devised** – the date the policy was implemented.
4. **Revised** – the date of every revision to the policy, including typographical and grammatical changes.
5. **Reviewed** – the date documenting the annual review if the policy has no revisions necessary.

ADDITIONAL DEFINITIONS:

1. **Formulary** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. **Non-formulary products** – those medications that are not included in the Formulary.
3. **Healthcare provider** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
4. **NCQA** – National Committee for Quality Assurance.
5. **Medically Necessary or Medical Necessity** – covered services rendered by a provider that the Health Plan determines are:

- A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
- B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
- C. In accordance with current standards of medical practice;
- D. Not primarily for the convenience of the Member, or the Member's Provider; and
- E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

PROCEDURE:

New members to the plan already established on therapy may be eligible for continuity of care coverage as long as there is medical record documentation that the safety and effectiveness of use for the prescribed indication is supported by Food and Drug Administration (FDA) approval or adequate medical and scientific evidence in the medical literature.

An exception for coverage of Vimpat may be made for members who meet the following criteria:

Partial-Onset Seizures

- Medical record documentation of a diagnosis of partial-onset seizures **AND**
- Medical record documentation of age greater than or equal to 1 month **AND**
- Medical record documentation of a therapeutic failure on, intolerance to, or contraindication to three (3) formulary alternatives

Primary Generalized Tonic-Clonic Seizures

- Medical record documentation of a diagnosis of primary generalized tonic-clonic seizures **AND**
- Medical record documentation of age greater than or equal to 4 years **AND**
- Medical record documentation of a therapeutic failure on, intolerance to, or contraindication to three (3) formulary alternatives

MEDISPAN AUTHORIZATION LEVEL: GPI-12 (enter both 726000360003 & 726000360020)

If an exception is made, Vimpat will be paid for under the member's prescription drug benefit.

Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.

FORMULARY ALTERNATIVES:

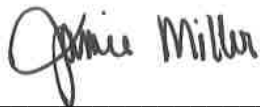
For patients aged ≥ 1 month of age: carbamazepine, levetiracetam IR, phenobarbital, phenytoin, pregabalin

Additional formulary alternatives for patients over certain ages: lamotrigine IR (2+), topiramate IR (2+), topiramate ER (2+)*, gabapentin (3+), oxcarbazepine (4+), divalproex (10+), levetiracetam ER (12+), tiagabine (12+), lamotrigine ER (13+), felbamate (14+), and zonisamide (16+)

*prior authorization required

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE
STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND
FEDERAL REGULATORY ENTITIES.**

**THIS POLICY WILL BE REVISED AS NECESSARY AND
REVIEWED NO LESS THAN ANNUALLY.**



Signed: _____

Title: Director, Pharmacy Services

Date: March 1, 2022

Devised: 7/09
Reviewed: 3/10 – annual review, updated alt.
Reviewed: 3/1/11—annual review
Revised: 2/12 – Added age requirement to criteria
Revised: 3/12 – annual review, updated signature & alternatives
Revised: 6/21/12 – clarified number of alternatives that must be failed
Revised: 3/1/13 – annual review, updated logo and definitions
Reviewed: 3/1/14 – annual review
Revised: 3/1/15 – annual review, updated signature, added language to first line of Section V



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 187.0

**SECTION: Commercial Drug
SUBJECT: Vimpat**

Reviewed: 3/1/16 – annual review
Revised: 5/1/16 – updated format, logo, & procedure
Revised: 3/1/17 – annual review, removed Unicode characters
Revised: 1/17/18 – decreased age to 4 years, updated FA by age, updated signature
Revised: 3/1/18- annual review, updated formatting, added grandfather language
Revised: 8/7/18 – updated FA
Reviewed: 3/1/19 – annual review
Revised: 11/15/19 – corrected policy number typo, updated FA
Revised: 3/1/20 – annual review, added GHP Kids
Revised: 1/22/21 – added tonic-clonic indication, added MediSpan approval level
Revised: 3/1/21 – annual review, updated logo
Revised: 9/1/21 – corrected GPI for Vimpat Solution
Revised: 1/5/22 – separated indications, updated partial-onset indication to 1 month, removed adjunct requirement from tonic-clonic, updated FA
Revised: 3/1/22 – annual review, updated referenced policies & covered LOBs, updated FA



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 188.0

**SECTION: Commercial Drug
SUBJECT: Everolimus (generic Afinitor)**

Applicable line of business:

Commercial	X	Medicaid	
Medicare		ACA	X
GHP Kids	X	Self-Insured	X

POLICY:

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for everolimus (generic Afinitor) for GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 487.0 Quantity Limit Exceptions

REQUIRED DEFINITIONS:

1. **Attachment** – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. **Exhibit** – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. **Devised** – the date the policy was implemented.
4. **Revised** – the date of every revision to the policy, including typographical and grammatical changes.
5. **Reviewed** – the date documenting the annual review if the policy has no revisions necessary.

ADDITIONAL DEFINITIONS:

1. **Formulary** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. **Non-formulary products** – those medications that are not included in the Formulary.
3. **Healthcare provider** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
4. **NCQA** – National Committee for Quality Assurance.
5. **Medically Necessary or Medical Necessity** – covered services rendered by a provider that the Health Plan determines are:



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 188.0

**SECTION: Commercial Drug
SUBJECT: Everolimus (generic Afinitor)**

- A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
- B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
- C. In accordance with current standards of medical practice;
- D. Not primarily for the convenience of the Member, or the Member's Provider; and
- E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

PROCEDURE:

New members to the plan already established on therapy may be eligible for continuity of care coverage as long as there is medical record documentation that the safety and effectiveness of use for the prescribed indication is supported by Food and Drug Administration (FDA) approval or adequate medical and scientific evidence in the medical literature.

An exception for coverage of everolimus (generic Afinitor) may be made for members who meet the following criteria:

Renal Cell Cancer

- Medical record documentation that everolimus (generic Afinitor) is prescribed by an oncologist **AND**
- Medical record documentation of a diagnosis of renal cell cancer **AND**
- Medical record documentation of therapeutic failure on, intolerance to, or contraindication to Sutent (sunitinib) or Nexavar (sorafenib) **AND**
- Medical record documentation of a therapeutic failure on, intolerance to, or contraindication to Opdivo **OR** Cabometyx

Breast Cancer

- Medical record documentation that everolimus (generic Afinitor) is prescribed by an oncologist **AND**
- Medical record documentation of hormone-receptor positive, HER-2 negative advanced breast cancer **AND**
- Medical record documentation of therapeutic failure on, intolerance to, or contraindication to previous endocrine therapy treatment **AND**
- Medical record documentation of everolimus (generic Afinitor) being used in combination with an aromatase inhibitor

Neuroendocrine tumors of pancreatic origin

- Medical record documentation that everolimus (generic Afinitor) is prescribed by an oncologist **AND**
- Medical record documentation of a diagnosis of progressive neuroendocrine tumors of pancreatic origin (PNET) that is unresectable, locally advanced or metastatic (the safety and effectiveness of Afinitor in the treatment of patients with carcinoid tumors have not been established) **OR**
- Medical record documentation of a diagnosis of progressive, well-differentiated, non-functional neuroendocrine tumors (NET) of gastrointestinal origin (GI) or lung origin that are unresectable, locally advanced, or metastatic

Subependymal giant cell astrocytoma

- Medical record documentation that everolimus (generic Afinitor) is prescribed by an oncologist **AND**
- Medical record documentation of a diagnosis of subependymal giant cell astrocytoma (SEGA) associated with tuberous sclerosis (TS) who require therapeutic intervention but are not candidates for curative surgical resection

Renal angiomyolipoma and tuberous sclerosis complex/sporadic lymphangiomyomatosis

- Medical record documentation that everolimus (generic Afinitor) is prescribed by an oncologist, nephrologist, or urologist **AND**
- Medical record documentation of renal angiomyolipoma and tuberous sclerosis complex (TSC)/sporadic lymphangiomyomatosis, not requiring immediate surgery **AND**
- Medical record documentation of age greater than or equal to 18 years **AND**
- Medical record documentation of at least one angiomyolipoma of greater than or equal to 3 cm in longest diameter on CT/MRI based on local radiology assessment

NOTE: Everolimus (generic Afinitor) will no longer be covered if there is medical record documentation of disease progression. Response is defined as: a greater than or equal to 50% reduction in angiomyolipoma volume, absence of new angiomyolipoma lesion greater than or equal to 1 cm, absence of kidney volume increase greater than or equal to 20%, or no angiomyolipoma related bleeding of greater than or equal to Grade 2.

MEDISPAN AUTHORIZATION LEVEL: GPI-12, generic only, number of claims authorized = 1, enter for the remainder of the calendar year



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 188.0

**SECTION: Commercial Drug
SUBJECT: Everolimus (generic Afinitor)**

QUANTITY LIMIT: *No QLs need to be entered within the authorization unless the requested quantity exceeds the QL.*

- **QL FOR LETTER ONLY:** 1 tablet per day, 28 day supply per fill

RE-AUTHORIZATION CRITERIA: Everolimus (generic Afinitor) is configured as a prior authorization for new starts only. Everolimus (generic Afinitor) will no longer be covered if it is identified that the member is not receiving appropriate follow-up care from the prescribing specialist or if the member has greater than or equal to a 90 day break in therapy.

- Medical record documentation that the member is receiving appropriate follow-up care from the prescribing specialist

If a formulary exception is approved, everolimus (generic Afinitor) will be paid for under the member's prescription drug benefit.

Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.

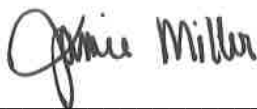
FORMULARY ALTERNATIVES:

Renal cell cancer – sunitinib*, Nexavar*, Cabometyx*

* prior authorization required

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE
STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND
FEDERAL REGULATORY ENTITIES.**

**THIS POLICY WILL BE REVISED AS NECESSARY AND
REVIEWED NO LESS THAN ANNUALLY.**



Signed: _____

Title: Director, Pharmacy Services

Date: March 1, 2022

- Devised: 11/09
- Reviewed: 3/10 – annual review
- Reviewed: 3/1/11 – annual review
- Revised: 3/01/12 – annual review, updated signature
- Revised: 3/29/12 – added breast cancer, pancreatic neuroendocrine tumor, and subependymal giant cell astrocytoma indications
- Revised: 7/18/12 – added renal angiomyolipoma and tuberous sclerosis complex/sporadic lymphangioleiomyomatosis indication
- Revised: 9/17/12 – added hormone-receptor positive, HER-2 negative advanced breast cancer
- Revised: 3/1/13 – annual review, updated logo and definitions
- Revised: 3/1/14 – annual review, corrected typos
- Revised: 3/1/15 – annual review, updated signature, updated formatting
- Reviewed: 3/1/16 – annual review
- Revised: 3/24/16 – removed copay per 15 day supply requirement, removed quantity limit indicator from FA, added failure of Opdivo for RCC
- Revised: 5/1/16 – updated format, logo, & procedure
- Revised: 5/27/16 – added NET of GI or lung origin
- Revised: 7/21/16 – added failure of Cabometyx to RCC
- Revised: 3/1/17 – annual review, removed Unicode characters
- Revised: 10/10/17 – increased authorization duration to 12 months
- Revised: 10/12/17 – updated FA, added AND to TSC criteria
- Revised: 10/16/17 – corrected typo in NET criteria
- Revised: 3/1/18 – annual review, updated signature, corrected typo, added grandfather language
- Revised: 6/1/18 – updated prescriber bullet, added QL
- Revised: 3/1/19 – annual review, added QL approval note
- Revised: 3/1/20 – annual review, added GHP Kids
- Revised: 11/24/21 – updated policy to generic name, added one-time PA language to approval criteria, removed auth duration & added re-auth criteria
- Revised: 3/1/22 – annual review, updated referenced policies & covered LOBs, updated FA



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 189.0

**SECTION: Commercial Drug
SUBJECT: Aplenizin**

Applicable line of business:

Commercial	X	Medicaid	
Medicare		ACA	X
GHP Kids	X	Self-Insured	X

POLICY:

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for Aplenizin for GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 487.0 Quantity Limit Exceptions

REQUIRED DEFINITIONS:

1. **Attachment** – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. **Exhibit** – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. **Devised** – the date the policy was implemented.
4. **Revised** – the date of every revision to the policy, including typographical and grammatical changes.
5. **Reviewed** – the date documenting the annual review if the policy has no revisions necessary.

ADDITIONAL DEFINITIONS:

1. **Formulary** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. **Non-formulary products** – those medications that are not included in the Formulary.
3. **Healthcare provider** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
4. **NCQA** – National Committee for Quality Assurance.
5. **Medically Necessary or Medical Necessity** – covered services rendered by a provider that the Health Plan determines are:



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 189.0

**SECTION: Commercial Drug
SUBJECT: Aplenzin**

- A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
- B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
- C. In accordance with current standards of medical practice;
- D. Not primarily for the convenience of the Member, or the Member's Provider; and
- E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

PROCEDURE:

New members to the plan already established on therapy may be eligible for continuity of care coverage as long as there is medical record documentation that the safety and effectiveness of use for the prescribed indication is supported by Food and Drug Administration (FDA) approval or adequate medical and scientific evidence in the medical literature.

An exception for coverage of Aplenzin may be made for members who meet the following criteria:

- Medical record documentation of diagnosis of Major Depressive Disorder **AND**
- Medical record documentation of a therapeutic failure on, intolerance to, or contraindication to bupropion

OR

- Medical record documentation of a diagnosis of seasonal affective disorder **AND**
- Medical record documentation of a therapeutic failure on, intolerance to, or contraindication to bupropion XL

MEDISPAN AUTHORIZATION LEVEL: GPI-12

If an exception is made, Aplenzin will be paid for under the member's prescription drug benefit.

Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.



POLICY NUMBER: 189.0

**POLICY AND PROCEDURE
PHARMACY
MANUAL**

**SECTION: Commercial Drug
SUBJECT: Aplenzin**

FORMULARY ALTERNATIVES:

Major Depressive Disorder: bupropion, bupropion SR, bupropion XL
Seasonal Affective Disorder: bupropion XL

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE
STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND
FEDERAL REGULATORY ENTITIES.**

**THIS POLICY WILL BE REVISED AS NECESSARY AND
REVIEWED NO LESS THAN ANNUALLY.**

Signed: _____

Title: Director, Pharmacy Services

Date: March 1, 2022

Devised: 11/09
Reviewed: 3/10 – annual review
Reviewed: 3/1/11 – annual review
Revised: 3/1/12 – annual review, updated signature
Revised: 11/08/12 – added seasonal affective disorder indication and changed
Revised: 3/1/13 – annual review, updated logo and definitions
Revised: 3/1/14 – annual review, updated formatting
Revised: 3/1/15 – annual review, updated signature
Reviewed: 3/1/16 – annual review
Revised: 5/1/16 – updated format, logo, & procedure
Reviewed: 3/1/17 – annual review
Revised: 3/1/18 – annual review, updated signature, added grandfather language
Reviewed: 3/1/19 – annual review
Revised: 3/1/20 – annual review, added GHP Kids
Revised: 3/1/21 – annual review, updated logo, added MediSpan approval level
Revised: 3/1/22 – annual review, updated referenced policies & covered LOBs



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 190.0

**SECTION: Commercial Drug
SUBJECT: Mesalamine (generic Apriso)**

Applicable line of business:

Commercial	X	Medicaid	
Medicare		ACA	X
GHP Kids	X	Self-Insured	X

POLICY:

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for mesalamine (generic Apriso) for GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 487.0 Quantity Limit Exceptions

REQUIRED DEFINITIONS:

1. **Attachment** – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. **Exhibit** – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. **Devised** – the date the policy was implemented.
4. **Revised** – the date of every revision to the policy, including typographical and grammatical changes.
5. **Reviewed** – the date documenting the annual review if the policy has no revisions necessary.

ADDITIONAL DEFINITIONS:

1. **Formulary** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. **Non-formulary products** – those medications that are not included in the Formulary.
3. **Healthcare provider** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
4. **NCQA** – National Committee for Quality Assurance.
5. **Medically Necessary or Medical Necessity** – covered services rendered by a provider that the Health Plan determines are:



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 190.0

**SECTION: Commercial Drug
SUBJECT: Mesalamine (generic Apriso)**

- A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
- B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
- C. In accordance with current standards of medical practice;
- D. Not primarily for the convenience of the Member, or the Member's Provider; and
- E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

PROCEDURE:

An exception for coverage of mesalamine (generic Apriso) may be made for members who meet the following criteria:

- Medical record documentation of mild to moderate ulcerative colitis **AND**
- Medical record documentation of therapeutic failure on, intolerance to, or contraindication to sulfasalazine **AND** mesalamine delayed release

MEDISPAN AUTHORIZATION LEVEL: GPI-12, generic only

If an exception is made, mesalamine (generic Apriso) will be paid for under the member's prescription drug benefit.

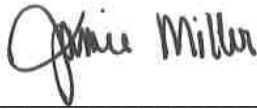
Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.

FORMULARY ALTERNATIVES:

mesalamine delayed release, balsalazide, Canasa Suppositories, Dipentum, mesalamine enema, Pentasa, Rowasa, sulfasalazine, sulfasalazine enteric coated

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE
STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND
FEDERAL REGULATORY ENTITIES.**

**THIS POLICY WILL BE REVISED AS NECESSARY AND
REVIEWED NO LESS THAN ANNUALLY.**



Signed: _____

Title: Director, Pharmacy Services

Date: March 1, 2022

Devised: 11/09
Reviewed: 3/10 – annual review
Reviewed: 3/1/11 – annual review
Revised: 3/1/12 – annual review, updated signature
Revised: 3/1/13 – annual review, updated logo and definitions
Revised: 3/1/14 – annual review, updated Asacol to HD as immed. release was D/C by manuf.
Reviewed: 3/1/14 – annual review
Revised: 3/1/15 – annual review, updated signature, added Delzicol to formulary alternatives
Reviewed: 3/1/16 – annual review
Revised: 5/1/16 – updated format, logo, & procedure
Reviewed: 3/1/17 – annual review
Revised: 3/1/18 – annual review, updated signature, updated Asacol to generic
Reviewed: 3/1/19 – annual review
Revised: 3/1/20 – annual review, added GHP Kids
Revised: 11/18/20 – updated to generic
Revised: 3/1/21 – annual review, updated logo, added MediSpan approval level, updated FA
Revised: 3/1/22 – annual review, updated referenced policies & covered LOBs



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 191.0

**SECTION: Commercial Drug
SUBJECT: Olopatadine Nasal Spray**

Applicable line of business:

Commercial	X	Medicaid	
Medicare		ACA	X
GHP Kids	X	Self-Insured	X

POLICY:

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for olopatadine nasal spray for GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 487.0 Quantity Limit Exceptions

REQUIRED DEFINITIONS:

1. **Attachment** – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. **Exhibit** – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. **Devised** – the date the policy was implemented.
4. **Revised** – the date of every revision to the policy, including typographical and grammatical changes.
5. **Reviewed** – the date documenting the annual review if the policy has no revisions necessary.

ADDITIONAL DEFINITIONS:

1. **Formulary** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. **Non-formulary products** – those medications that are not included in the Formulary.
3. **Healthcare provider** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
4. **NCQA** – National Committee for Quality Assurance.
5. **Medically Necessary or Medical Necessity** – covered services rendered by a provider that the Health Plan determines are:



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 191.0

**SECTION: Commercial Drug
SUBJECT: Olopatadine Nasal Spray**

- A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
- B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
- C. In accordance with current standards of medical practice;
- D. Not primarily for the convenience of the Member, or the Member's Provider; and
- E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

PROCEDURE:

An exception for coverage of olopatadine nasal spray may be made for members who meet the following criteria:

- Medical record documentation of a diagnosis of seasonal allergic rhinitis **AND**
- Medical record documentation that patient is greater than or equal to 2 years of age to less than 6 years of age **AND** medical record documentation of therapeutic failure on, intolerance to, or contraindication to azelastine 0.1% nasal spray, triamcinolone acetonide **AND** mometasone nasal suspension **OR**
- Medical record documentation that patient is greater than or equal to 6 years of age **AND** medical record documentation of a therapeutic failure on, intolerance to, or contraindication to three formulary alternatives, one of which must be azelastine 0.1% nasal spray

MEDISPAN AUTHORIZATION LEVEL: GPI-12, generic only

If an exception is made, olopatadine nasal spray will be paid for under the member's prescription drug benefit.

Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.

FORMULARY ALTERNATIVES:

azelastine nasal spray, budesonide nasal spray, fluticasone nasal spray, flunisolide nasal spray, mometasone furoate nasal spray, triamcinolone acetonide nasal spray



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 191.0

**SECTION: Commercial Drug
SUBJECT: Olopatadine Nasal Spray**

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE
STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND
FEDERAL REGULATORY ENTITIES.**

**THIS POLICY WILL BE REVISED AS NECESSARY AND
REVIEWED NO LESS THAN ANNUALLY.**

Signed: _____

Title: Director, Pharmacy Services

Date: March 1, 2022

Devised: 11/09
Reviewed: 3/10 – annual review
Reviewed: 3/1/11 – annual review
Revised: 3/1/12 – annual review, updated signature and alternatives
Revised: 3/1/13 – annual review, updated logo and definitions
Revised: 2/1/14 – updated criteria and formulary alternatives
Reviewed: 3/1/14 – annual review
Revised: 3/1/15 – annual review, updated signature
Revised: 9/19/15 – added age requirements and split out criteria by age
Reviewed: 3/1/16 – annual review
Revised: 5/1/16 – updated format, logo, & procedure
Revised: 3/1/17 – removed Astepro & all assoc. criteria, Patanase to olopatadine, updated FA
Revised: 3/1/18 – annual review, updated signature, removed Unicode characters
Reviewed: 3/1/19 – annual review, removed duplicate indication headers
Revised: 3/1/20 – annual review, added GHP Kids
Revised: 3/1/21 – annual review, updated logo, added MediSpan approval level, updated Nasonex to generic
Revised: 3/1/22 – annual review, updated referenced policies & covered LOBs



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 192.0

**SECTION: Commercial Drug
SUBJECT: Fanapt**

Applicable line of business:

Commercial	X	Medicaid	
Medicare		ACA	X
GHP Kids	X	Self-Insured	X

POLICY:

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for Fanapt for GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 487.0 Quantity Limit Exceptions

REQUIRED DEFINITIONS:

1. **Attachment** – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. **Exhibit** – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. **Devised** – the date the policy was implemented.
4. **Revised** – the date of every revision to the policy, including typographical and grammatical changes.
5. **Reviewed** – the date documenting the annual review if the policy has no revisions necessary.

ADDITIONAL DEFINITIONS:

1. **Formulary** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. **Non-formulary products** – those medications that are not included in the Formulary.
3. **Healthcare provider** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
4. **NCQA** – National Committee for Quality Assurance.
5. **Medically Necessary or Medical Necessity** – covered services rendered by a provider that the Health Plan determines are:



POLICY NUMBER: 192.0

**POLICY AND PROCEDURE
PHARMACY
MANUAL**

**SECTION: Commercial Drug
SUBJECT: Fanapt**

- A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
- B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
- C. In accordance with current standards of medical practice;
- D. Not primarily for the convenience of the Member, or the Member's Provider; and
- E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

PROCEDURE:

New members to the plan already established on therapy may be eligible for continuity of care coverage as long as there is medical record documentation that the safety and effectiveness of use for the prescribed indication is supported by Food and Drug Administration (FDA) approval or adequate medical and scientific evidence in the medical literature.

An exception for coverage of Fanapt may be made for members who meet the following criteria:

- Medical record documentation of a diagnosis of schizophrenia **AND**
- Medical record documentation of a contraindication, intolerance or therapeutic failure to all formulary agents (risperidone, olanzapine, quetiapine, aripiprazole and ziprasidone)

MEDISPAN AUTHORIZATION LEVEL: GPI-10

If an exception is made, Fanapt will be paid for under the member's prescription drug benefit.

Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.

FORMULARY ALTERNATIVES:

risperidone, olanzapine, ziprasidone, quetiapine, aripiprazole

Geisinger

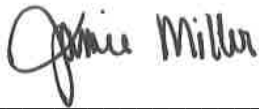
**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 192.0

**SECTION: Commercial Drug
SUBJECT: Fanapt**

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE
STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND
FEDERAL REGULATORY ENTITIES.**

**THIS POLICY WILL BE REVISED AS NECESSARY AND
REVIEWED NO LESS THAN ANNUALLY.**



Signed: _____

Title: Director, Pharmacy Services

Date: March 1, 2022

Devised: 11/09
Reviewed: 3/10 – annual review
Reviewed: 3/1/11—annual review
Revised: 3/1/12 – annual review, updated signature & alternatives
Revised: 3/1/13 – annual review, updated logo and definitions, fixed typo
Reviewed: 3/1/14 – annual review
Revised: 3/1/15 – annual review, updated signature, updated Geodon to ziprasidone & Seroquel to quetiapine
Revised: 3/1/16 – annual review, changed Abilify to aripiprazole
Revised: 5/1/16 – updated format, logo, & procedure
Reviewed: 3/1/17 – annual review
Revised: 3/1/18 – annual review, updated signature & formatting, added grandfather language
Reviewed: 3/1/19 – annual review
Revised: 3/1/20 – annual review, added GHP Kids
Revised: 3/1/21 – annual review, updated logo, added MediSpan approval level
Revised: 3/1/22 – annual review, updated referenced policies & covered LOBs



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 195.0

**SECTION: Commercial Drug
SUBJECT: Silodosin**

Applicable line of business:

Commercial	X	Medicaid	
Medicare		ACA	X
GHP Kids	X	Self-Insured	X

POLICY:

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for silodosin for GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 487.0 Quantity Limit Exceptions

REQUIRED DEFINITIONS:

1. **Attachment** – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. **Exhibit** – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. **Devised** – the date the policy was implemented.
4. **Revised** – the date of every revision to the policy, including typographical and grammatical changes.
5. **Reviewed** – the date documenting the annual review if the policy has no revisions necessary.

ADDITIONAL DEFINITIONS:

1. **Formulary** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. **Non-formulary products** – those medications that are not included in the Formulary.
3. **Healthcare provider** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
4. **NCQA** – National Committee for Quality Assurance.
5. **Medically Necessary or Medical Necessity** – covered services rendered by a provider that the Health Plan determines are:



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 195.0

**SECTION: Commercial Drug
SUBJECT: Silodosin**

- A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
- B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
- C. In accordance with current standards of medical practice;
- D. Not primarily for the convenience of the Member, or the Member's Provider; and
- E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

PROCEDURE:

An exception for coverage of silodosin may be made for members who meet the following criteria:

- Medical record documentation of a therapeutic failure on, intolerance to, or contraindication to two formulary alpha-blockers, one of which must be tamsulosin (Flomax)

MEDISPAN AUTHORIZATION LEVEL: GPI-12, generic only

If an exception is made, silodosin will be paid for under the member's prescription drug benefit.

Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.

FORMULARY ALTERNATIVES:

doxazosin, terazosin, tamsulosin, alfuzosin

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE
STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND
FEDERAL REGULATORY ENTITIES.**

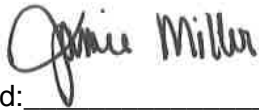
**THIS POLICY WILL BE REVISED AS NECESSARY AND
REVIEWED NO LESS THAN ANNUALLY.**

Geisinger

**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 195.0

**SECTION: Commercial Drug
SUBJECT: Silodosin**



Signed: _____

Title: Director, Pharmacy Services

Date: March 1, 2022

Devised: 1/10
Reviewed: 3/10 – annual review
Revised: 5/10 – combined Uroxatral and updated form. alt to include generic Flomax
Reviewed: 3/1/11 – annual review
Revised: 3/1/12 – annual review, updated signature & alternatives
Revised: 3/1/13 – annual review, updated logo and definitions
Revised: 3/1/14 – annual review, updated formatting
Revised: 3/1/15 – annual review, updated signature
Revised: 3/1/16 – annual review
Revised: 5/1/16 – updated format, logo, & procedure
Reviewed: 3/1/17 – annual review
Revised: 3/1/18 – annual review, updated signature
Revised: 3/1/19 – annual review, updated from Rapaflo to new generic silodosin
Revised: 3/1/20 – annual review, added GHP Kids
Revised: 3/1/21 – annual review, updated logo, added MediSpan approval level
Revised: 3/1/22 – annual review, updated referenced policies & covered LOBs



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 196.0

**SECTION: Commercial Drug
SUBJECT: Alogliptin and Onglyza**

Applicable line of business:

Commercial	X	Medicaid	
Medicare		ACA	X
GHP Kids	X	Self-Insured	X

POLICY:

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for agents to treat insomnia for GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 487.0 Quantity Limit Exceptions

REQUIRED DEFINITIONS:

1. **Attachment** – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. **Exhibit** – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. **Devised** – the date the policy was implemented.
4. **Revised** – the date of every revision to the policy, including typographical and grammatical changes.
5. **Reviewed** – the date documenting the annual review if the policy has no revisions necessary.

ADDITIONAL DEFINITIONS:

1. **Formulary** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. **Non-formulary products** – those medications that are not included in the Formulary.
3. **Healthcare provider** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
4. **NCQA** – National Committee for Quality Assurance.
5. **Medically Necessary or Medical Necessity** – covered services rendered by a provider that the Health Plan determines are:



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 196.0

**SECTION: Commercial Drug
SUBJECT: Alogliptin and Onglyza**

- A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
- B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
- C. In accordance with current standards of medical practice;
- D. Not primarily for the convenience of the Member, or the Member's Provider; and
- E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

PROCEDURE:

An exception for coverage of alogliptin or Onglyza may be made for members who meet the following criteria:

- Medical record documentation of a therapeutic failure on, intolerance to, or contraindication to Tradjenta

MEDISPAN AUTHORIZATION LEVEL: GPI-12, if request is for alogliptin include generic only.

QUANTITY LIMIT: *No QLs need to be entered within the authorization unless the requested quantity exceeds the QL.*

- **QL FOR LETTER ONLY:** 1 tablet per day

If an exception is made, alogliptin or Onglyza will be paid for under the member's prescription drug benefit.

Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.

FORMULARY ALTERNATIVES:

Tradjenta, Jentadueto, Jentadueto XR



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 196.0

**SECTION: Commercial Drug
SUBJECT: Alogliptin and Onglyza**

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE
STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND
FEDERAL REGULATORY ENTITIES.**

**THIS POLICY WILL BE REVISED AS NECESSARY AND
REVIEWED NO LESS THAN ANNUALLY.**

Signed: _____

Title: Director, Pharmacy Services

Date: March 1, 2022

- Devised: 1/10
- Reviewed: 3/10 – annual review
- Reviewed: 3/1/11 – annual review
- Revised: 2/12 – added Tradjenta
- Revised: 3/1/12 – annual review and updated signature
- Revised: 3/1/13 – annual review, updated logo, definitions, and alternatives
- Revised: 6/24/13 – added Nesina to policy
- Revised: 3/1/14 – annual review, updated formatting, updated Prandin to repaglinide
- Revised: 3/1/15 – annual review, updated signature, changed Actos to pioglitazone, added Jardiance, Tanzeum, & Victoza to FA, removed Byetta & Bydureon from FA
- Revised: 3/1/16 – annual review, added Toujeo, Synjardy, Invokana, and Invokamet to FA, updated PA/ST indicator
- Revised: 5/1/16 – updated format, logo, & procedure
- Revised: 3/1/17 – annual review, defined TZD, updated Nesina to alogliptin
- Revised: 11/28/17 – removed Tradjenta, removed diagnosis, updated signature, concomitant use with metformin/TZD, added failure of Januvia or Tradjenta, updated FA, added QL
- Revised: 2/9/18 – removed Januvia from criteria, updated FA
- Reviewed: 3/1/18 – annual review
- Revised: 3/1/19 – annual review, added QL approval note, removed step indicator from FA
- Revised: 3/1/20 – annual review, added GHP Kids
- Revised: 3/1/21 – annual review, updated logo, added MediSpan approval level, updated QL statement
- Revised: 3/1/22 – annual review, updated referenced policies & covered LOBs



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 197.0

**SECTION: Commercial Drug
SUBJECT: Cimzia**

Applicable line of business:

Commercial	X	Medicaid	
Medicare		ACA	X
GHP Kids	X	Self-Insured	X

POLICY:

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for Cimzia for GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 487.0 Quantity Limit Exceptions

REQUIRED DEFINITIONS:

1. **Attachment** – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. **Exhibit** – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. **Devised** – the date the policy was implemented.
4. **Revised** – the date of every revision to the policy, including typographical and grammatical changes.
5. **Reviewed** – the date documenting the annual review if the policy has no revisions necessary.

ADDITIONAL DEFINITIONS:

1. **Formulary** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. **Non-formulary products** – those medications that are not included in the Formulary.
3. **Healthcare provider** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
4. **NCQA** – National Committee for Quality Assurance.
5. **Medically Necessary or Medical Necessity** – covered services rendered by a provider that the Health Plan determines are:

- A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
- B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
- C. In accordance with current standards of medical practice;
- D. Not primarily for the convenience of the Member, or the Member's Provider; and
- E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

PROCEDURE:

New members to the plan already established on therapy may be eligible for continuity of care coverage as long as there is medical record documentation that the safety and effectiveness of use for the prescribed indication is supported by Food and Drug Administration (FDA) approval or adequate medical and scientific evidence in the medical literature.

For Rheumatoid Arthritis

An exception for coverage of Cimzia (which is self-administered) may be made for members who meet the following criteria:

- Medical record documentation of age greater than or equal to 18 years **AND**
- Medical record documentation that Cimzia is prescribed by a rheumatologist **AND**
- Medical record documentation of a diagnosis of moderate to severe rheumatoid arthritis (made in accordance with the American College of Rheumatology Criteria for the Classification of Diagnosis of Rheumatoid Arthritis) **AND**
- Medical record documentation of therapeutic failure on, intolerance to, or contraindication to a minimum 3 month trial of Humira*, Rinvoq*, **OR** Xeljanz* **AND**
- Medical record documentation that Cimzia is not being used concurrently with a tumor necrosis factor (TNF) blocker or other biologic agent

MEDISPAN AUTHORIZATION LEVEL: GPI-12, number of claims authorized = 1, enter for the remainder of the calendar year

QUANTITY LIMIT: *No QLs need to be entered within the authorization unless the requested quantity exceeds the QL.*

- INITIAL QL FOR LETTER ONLY: Loading dose: 3 kits per 28 days; Maintenance dose: 1 kit per 28 days
- MAINTENANCE QL FOR LETTER ONLY: 1 kit per 28 days



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 197.0

**SECTION: Commercial Drug
SUBJECT: Cimzia**

NOTE: This product is billed per kit. Each kit contains two, 200mg syringes.

RE-AUTHORIZATION CRITERIA: Cimzia is configured as a prior authorization for new starts only. Cimzia will no longer be covered if it is identified that the member is not receiving appropriate follow-up care from the prescribing specialist or if the member has greater than or equal to a 90 day break in therapy.

- Medical record documentation that the member is receiving appropriate follow-up care from the prescribing specialist

FORMULARY ALTERNATIVES:

Humira*, Rinvoq*, Xeljanz*

*prior authorization required



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 197.0

**SECTION: Commercial Drug
SUBJECT: Cimzia**

For Crohn's Disease

An exception for coverage of Cimzia (which is self-administered) may be made for members who meet the following criteria:

- Medical record documentation of a diagnosis of moderate to severe Crohn's disease **AND**
- Medical record documentation of age greater than or equal to 18 years **AND**
- Medical record documentation that Cimzia is prescribed by a gastroenterologist **AND**
- Medical record documentation of a therapeutic failure on, intolerance to, or contraindication to Humira* **AND**
- Medical record documentation that Cimzia is not being used concurrently with a tumor necrosis factor (TNF) blocker or other biologic agent

MEDISPAN AUTHORIZATION LEVEL: GPI-12, number of claims authorized = 1, enter for the remainder of the calendar year

QUANTITY LIMIT: *No QLs need to be entered within the authorization unless the requested quantity exceeds the QL.*

- INITIAL QL FOR LETTER ONLY: Loading dose: 3 kits per 28 days; Maintenance dose: 1 kit per 28 days
- MAINTENANCE QL FOR LETTER ONLY: 1 kit per 28 days

NOTE: This product is billed per kit. Each kit contains two, 200mg syringes.

RE-AUTHORIZATION CRITERIA: Cimzia is configured as a prior authorization for new starts only. Cimzia will no longer be covered if it is identified that the member is not receiving appropriate follow-up care from the prescribing specialist or if the member has greater than or equal to a 90 day break in therapy.

- Medical record documentation that the member is receiving appropriate follow-up care from the prescribing specialist

FORMULARY ALTERNATIVES:

Humira*

*prior authorization required



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 197.0

**SECTION: Commercial Drug
SUBJECT: Cimzia**

For Psoriatic Arthritis

An exception for coverage of Cimzia (which is self-administered) may be made for members who meet the following criteria:

- Medical record documentation of a diagnosis of moderately to severely active psoriatic arthritis which must include the following:
 - Documentation of either active psoriatic lesions or a documented history of psoriasis **AND**
- Medical record documentation that Cimzia is prescribed by a rheumatologist or dermatologist **AND**
- Medical record documentation of age greater than or equal to 18 years **AND**
- Medical record documentation of intolerance to, contraindication to, or therapeutic failure on a minimum 3 month trial of Cosentyx* **AND** Humira* **AND**
- Medical record documentation that Cimzia is not being used concurrently with a tumor necrosis factor (TNF) blocker or other biologic agent

MEDISPAN AUTHORIZATION LEVEL: GPI-12, number of claims authorized = 1, enter for the remainder of the calendar year

QUANTITY LIMIT: *No QLs need to be entered within the authorization unless the requested quantity exceeds the QL.*

- INITIAL QL FOR LETTER ONLY: Loading dose: 3 kits per 28 days; Maintenance dose: 1 kit per 28 days
- MAINTENANCE QL FOR LETTER ONLY: 1 kit per 28 days

NOTE: This product is billed per kit. Each kit contains two, 200mg syringes.

RE-AUTHORIZATION CRITERIA: Cimzia is configured as a prior authorization for new starts only. Cimzia will no longer be covered if it is identified that the member is not receiving appropriate follow-up care from the prescribing specialist or if the member has greater than or equal to a 90 day break in therapy.

- Medical record documentation that the member is receiving appropriate follow-up care from the prescribing specialist

FORMULARY ALTERNATIVES:

Cosentyx*, Humira*

*prior authorization required



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 197.0

**SECTION: Commercial Drug
SUBJECT: Cimzia**

For Ankylosing Spondylitis

An exception for coverage of Cimzia (which is self-administered) may be made for members who meet the following criteria:

- Medical record documentation of a diagnosis of ankylosing spondylitis **AND**
- Medical record documentation that Cimzia is prescribed by a rheumatologist **AND**
- Medical record documentation of age greater than or equal to 18 years **AND**
- Medical record documentation of a therapeutic failure on, intolerance to, or contraindication to a minimum 3 month trial of Cosentyx* **AND** Humira* **AND**
- Medical record documentation that Cimzia is not being used concurrently with a tumor necrosis factor (TNF) blocker or other biologic agent

MEDISPAN AUTHORIZATION LEVEL: GPI-12, number of claims authorized = 1, enter for the remainder of the calendar year

QUANTITY LIMIT: *No QLs need to be entered within the authorization unless the requested quantity exceeds the QL.*

- INITIAL QL FOR LETTER ONLY: Loading dose: 3 kits per 28 days; Maintenance dose: 1 kit per 28 days
- MAINTENANCE QL FOR LETTER ONLY: 1 kit per 28 days

NOTE: This product is billed per kit. Each kit contains two, 200mg syringes.

RE-AUTHORIZATION CRITERIA: Cimzia is configured as a prior authorization for new starts only. Cimzia will no longer be covered if it is identified that the member is not receiving appropriate follow-up care from the prescribing specialist or if the member has greater than or equal to a 90 day break in therapy.

- Medical record documentation that the member is receiving appropriate follow-up care from the prescribing specialist

FORMULARY ALTERNATIVES:

Cosentyx*, Humira*

*prior authorization required



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 197.0

**SECTION: Commercial Drug
SUBJECT: Cimzia**

For Plaque Psoriasis

An exception for coverage of Cimzia (which is self-administered) may be made for members who meet the following criteria:

- Medical record documentation of a diagnosis of moderate to severe plaque psoriasis characterized by greater than or equal to 5% of body surface area involved or disease involving crucial body areas such as the hands, feet, face, or genitals **AND**
- Medical record documentation that Cimzia is prescribed by a dermatologist **AND**
- Medical record documentation of age greater than or equal to 18 years **AND**
- Medical record documentation of intolerance to, contraindication to, or therapeutic failure on a minimum 3 month trial of Cosentyx* **AND** Humira* **AND**
- Medical record documentation that Cimzia is not being used concurrently with a tumor necrosis factor (TNF) blocker or other biologic agent

MEDISPAN AUTHORIZATION LEVEL: GPI-12

QUANTITY LIMIT: *Two authorizations must be entered.*

1. In PA Hub: Add PA, number of claims authorized = 1, with a duration of one month
2. In Darwin: Add OQL, DS, max quantity dispensed 2, min day supply 28, max day supply 28, with an end date of 12/31/2099. Start date of this authorization is one-day after loading dose ends.
 - QL FOR LETTER: 2 kits per 28 days

NOTE: This product is billed per kit. Each kit contains two, 200mg syringes.

RE-AUTHORIZATION CRITERIA: Cimzia is configured as a prior authorization for new starts only. Cimzia will no longer be covered if it is identified that the member is not receiving appropriate follow-up care from the prescribing specialist or if the member has greater than or equal to a 90 day break in therapy.

- Medical record documentation that the member is receiving appropriate follow-up care from the prescribing specialist

FORMULARY ALTERNATIVES:

Cosentyx*, Humira*

*prior authorization required



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 197.0

**SECTION: Commercial Drug
SUBJECT: Cimzia**

For Non-Radiographic Axial Spondylarthritis

An exception for coverage of Cimzia (which is self-administered) may be made for members who meet the following criteria:

- Medical record documentation of a diagnosis of non-radiographic axial spondylarthritis **AND**
- Medical record documentation of age greater than or equal to 18 years **AND**
- Medical record documentation that Cimzia is prescribed by a rheumatologist **AND**
- Medical record documentation of at least one of the following:
 - C-reactive protein (CRP) level above the upper limit of normal (10 mg/dL) **OR**
 - Sacroiliitis on magnetic resonance imaging (MRI)

AND

- Medical record documentation of therapeutic failure on, intolerance to, or contraindication to at least two (2) nonsteroidal anti-inflammatory drugs (NSAIDs) **AND**
- Medical record documentation that Cimzia is not being used concurrently with a tumor necrosis factor (TNF) blocker or other biologic agent

MEDISPAN AUTHORIZATION LEVEL: GPI-12, number of claims authorized = 1, enter for the remainder of the calendar year

QUANTITY LIMIT: *No QLs need to be entered within the authorization unless the requested quantity exceeds the QL.*

- INITIAL QL FOR LETTER ONLY: Loading dose: 3 kits per 28 days; Maintenance dose: 1 kit per 28 days
- MAINTENANCE QL FOR LETTER ONLY: 1 kit per 28 days

NOTE: This product is billed per kit. Each kit contains two, 200mg syringes.

RE-AUTHORIZATION CRITERIA: Cimzia is configured as a prior authorization for new starts only. Cimzia will no longer be covered if it is identified that the member is not receiving appropriate follow-up care from the prescribing specialist or if the member has greater than or equal to a 90 day break in therapy.

- Medical record documentation that the member is receiving appropriate follow-up care from the prescribing specialist

FORMULARY ALTERNATIVES:

none



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 197.0

**SECTION: Commercial Drug
SUBJECT: Cimzia**

If an exception is made, Cimzia will be paid for under the member's prescription drug benefit.

Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE
STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND
FEDERAL REGULATORY ENTITIES.**

**THIS POLICY WILL BE REVISED AS NECESSARY AND
REVIEWED NO LESS THAN ANNUALLY.**

Signed: _____

Title: Director, Pharmacy Services

Date: March 1, 2022

Devised: 1/10
Reviewed: 3/10 – annual review
Reviewed: 3/1/11 – annual review
Revised: 3/1/12 – annual review, updated signature
Revised: 9/17/12 – updated authorization duration and updated location
Revised: 3/1/13 – annual review, updated logo and definitions
Revised: 3/1/14 – annual review, updated formatting
Revised: 3/20/14 – updated policy format, added psoriatic arthritis & ankylosing spondylitis
Revised: 9/22/14 – updated alternatives criteria for all indications, updated FA, added and updated criteria for RA and CD, expanded auth duration wording for RA and CD, updated auth duration wording for PsA and AS, and updated signature
Revised: 11/21/14 – updated PsA FA criteria and removed leflunomide from FA list
Revised: 2/9/15 – updated FA criteria for all indications, FA, and prescriber criteria for PsA
Reviewed: 3/1/15 – annual review
Revised: 9/19/15 – removed joint count criteria from initial and renewal requirements
Revised: 3/1/16 – annual review, updated policy formatting to improve readability
Revised: 5/1/16 – updated format, logo, & procedure
Reviewed: 3/1/17 – annual review
Revised: 3/1/18 – annual review, updated signature, updated criteria format, added grandfather language
Revised: 5/30/18 – added QL, added combination with other biologics, removed failure of Enbrel and added failure of Cosentyx (PsA, AS)
Revised: 10/1/18 – removed failure of Enbrel and updated FA (RA)
Revised: 12/28/18 – added PP indication, added QL note to all indications
Revised: 3/1/19 – annual review, defined TNF
Revised: 7/24/19 – added authorization parameters

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Dev. 1/10

Rev. 3/1/22



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 197.0

**SECTION: Commercial Drug
SUBJECT: Cimzia**

- Revised: 10/1/19 – added non-radiographic axial spondylarthritis indication to policy
- Revised: 1/28/20 – updated RA FA and added failure of Rinvoq and Xeljanz
- Revised: 3/1/20 – annual review, added GHP Kids
- Revised: 3/1/21 – annual review, updated logo, added MediSpan approval level, updated QL statement
- Revised: 12/2/21 – added one-time PA to approval crit., removed auth duration & added re-auth crit.
- Revised: 3/1/22 – annual review, updated referenced policies & covered LOBs, updated how QL's are entered



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 198.0

**SECTION: Commercial Drug
SUBJECT: Simponi**

Applicable line of business:

Commercial	X	Medicaid	
Medicare		ACA	X
GHP Kids	X	Self-Insured	X

POLICY:

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for Simponi for GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 487.0 Quantity Limit Exceptions

REQUIRED DEFINITIONS:

1. **Attachment** – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. **Exhibit** – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. **Devised** – the date the policy was implemented.
4. **Revised** – the date of every revision to the policy, including typographical and grammatical changes.
5. **Reviewed** – the date documenting the annual review if the policy has no revisions necessary.

ADDITIONAL DEFINITIONS:

1. **Formulary** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. **Non-formulary products** – those medications that are not included in the Formulary.
3. **Healthcare provider** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
4. **NCQA** – National Committee for Quality Assurance.
5. **Medically Necessary or Medical Necessity** – covered services rendered by a provider that the Health Plan determines are:

- A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
- B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
- C. In accordance with current standards of medical practice;
- D. Not primarily for the convenience of the Member, or the Member's Provider; and
- E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

PROCEDURE:

New members to the plan already established on therapy may be eligible for continuity of care coverage as long as there is medical record documentation that the safety and effectiveness of use for the prescribed indication is supported by Food and Drug Administration (FDA) approval or adequate medical and scientific evidence in the medical literature.

For Rheumatoid Arthritis:

An exception for coverage of Simponi (which is self-administered) may be made for members who meet ALL of the following criteria:

- Medical record documentation that Simponi is prescribed by a rheumatologist **AND**
- Medical record documentation of age greater than or equal to 18 years **AND**
- Medical record documentation of a diagnosis of moderate to severe rheumatoid arthritis (made in accordance with the American College of Rheumatology Criteria for the Classification of Diagnosis of Rheumatoid Arthritis) **AND**
- Medical record documentation of concomitant methotrexate use **AND**
- Medical record documentation of therapeutic failure on, intolerance to, or contraindication to a minimum 3 month trial of Humira*, Rinvoq*, OR Xeljanz* **AND**
- Medical record documentation that Simponi is not being used concurrently with a tumor necrosis factor (TNF) blocker or other biologic agent

MEDISPAN AUTHORIZATION LEVEL: GPI-12 (must enter 6627004000E5 & 6627004000D5), number of claims authorized = 1, enter for the remainder of the calendar year

QUANTITY LIMIT: *No QLs need to be entered within the authorization unless the requested quantity exceeds the QL.*

- QL FOR LETTER ONLY: 0.5 mL per 28 days



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 198.0

**SECTION: Commercial Drug
SUBJECT: Simponi**

RE-AUTHORIZATION CRITERIA: Simponi is configured as a prior authorization for new starts only. Simponi will no longer be covered if it is identified that the member is not receiving appropriate follow-up care from the prescribing specialist or if the member has greater than or equal to a 90 day break in therapy.

- Medical record documentation that the member is receiving appropriate follow-up care from the prescribing specialist

FORMULARY ALTERNATIVES:

Humira*, Rinvoq*, Xeljanz*

*prior authorization required

For Psoriatic Arthritis:

An exception for coverage of Simponi (which is self-administered) may be made for members who meet ALL of the following criteria:

- Medical record documentation of age greater than or equal to 18 years
- Medical record documentation that Simponi is prescribed by a rheumatologist or dermatologist **AND**
- Medical record documentation of active psoriatic arthritis which must include the following:
 - Documentation of either active psoriatic lesions or a documented history of psoriasis**AND**
- Medical record documentation of an intolerance to, contraindication to, or therapeutic failure on a minimum 3 month trial of Cosentyx* **AND** Humira* **AND**
- Medical record documentation that Simponi is not being used concurrently with a tumor necrosis factor (TNF) blocker or other biologic agent

MEDISPAN AUTHORIZATION LEVEL: GPI-12 (must enter 6627004000E5 & 6627004000D5), number of claims authorized = 1, enter for the remainder of the calendar year

QUANTITY LIMIT: *No QLs need to be entered within the authorization unless the requested quantity exceeds the QL.*

- QL FOR LETTER ONLY: 0.5 mL per 28 days

RE-AUTHORIZATION CRITERIA: Simponi is configured as a prior authorization for new starts only. Simponi will no longer be covered if it is identified that the member is not receiving appropriate follow-up care from the prescribing specialist or if the member has greater than or equal to a 90 day break in therapy.

- Medical record documentation that the member is receiving appropriate follow-up care from the prescribing specialist

FORMULARY ALTERNATIVES:

Cosentyx, Humira*

*prior authorization required

For Ankylosing Spondylitis:

An exception for coverage of Simponi (which is self-administered) may be made for members who meet ALL of the following criteria:

- Medical record documentation of age greater than or equal to 18 years **AND**
- Medical record documentation that Simponi is prescribed by a rheumatologist **AND**
- Medical record documentation of a diagnosis of ankylosing spondylitis **AND**
- Medical record documentation of an intolerance to, contraindication to, or therapeutic failure on a minimum 3 month trial of Cosentyx* **AND** Humira* **AND**
- Medical record documentation that Simponi is not being used concurrently with a tumor necrosis factor (TNF) blocker or other biologic agent

MEDISPAN AUTHORIZATION LEVEL: GPI-12 (must enter 6627004000E5 & 6627004000D5), number of claims authorized = 1, enter for the remainder of the calendar year

QUANTITY LIMIT: *No QLs need to be entered within the authorization unless the requested quantity exceeds the QL.*

- QL FOR LETTER ONLY: 0.5 mL per 28 days

RE-AUTHORIZATION CRITERIA: Simponi is configured as a prior authorization for new starts only. Simponi will no longer be covered if it is identified that the member is not receiving appropriate follow-up care from the prescribing specialist or if the member has greater than or equal to a 90 day break in therapy.

- Medical record documentation that the member is receiving appropriate follow-up care from the prescribing specialist

FORMULARY ALTERNATIVES:

Cosentyx, Humira*

*prior authorization required

For Ulcerative Colitis:

An exception for coverage of Simponi (which is self-administered) may be made for members who meet ALL of the following criteria:

- Medical record documentation that Simponi is prescribed by a gastroenterologist **AND**
- Medical record documentation of a diagnosis of moderate to severe ulcerative colitis **AND**
- Medical record documentation of age greater than or equal to 18 years **AND**
- Medical record documentation of therapeutic failure on, intolerance to, or contraindication to Humira* **AND**
- Medical record documentation that Simponi is not being used concurrently with a tumor necrosis factor (TNF) blocker or other biologic agent

MEDISPAN AUTHORIZATION LEVEL: GPI-12 (must enter 6627004000E5 & 6627004000D5)

QUANTITY LIMIT –

1. In PA Hub: Add PA, OQL, DS, max quantity dispensed 3, min day supply 28, max day supply 28, number of claims authorized = 1, with a duration of one month
 - QL FOR LETTER: Loading dose: 3 mL per 28 days; Maintenance dose: 1 mL per 28 days

RE-AUTHORIZATION CRITERIA: Simponi is configured as a prior authorization for new starts only. Simponi will no longer be covered if it is identified that the member is not receiving appropriate follow-up care from the prescribing specialist or if the member has greater than or equal to a 90 day break in therapy.

- Medical record documentation that the member is receiving appropriate follow-up care from the prescribing specialist

FORMULARY ALTERNATIVES:

Humira*

*prior authorization required

If an exception is made, Simponi will be paid for under the member's prescription drug benefit.

Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 198.0

**SECTION: Commercial Drug
SUBJECT: Simponi**

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE STANDARDS OF
NCQA AND ANY OTHER APPLICABLE STATE AND FEDERAL REGULATORY
ENTITIES.**

**THIS POLICY WILL BE REVISED AS NECESSARY AND
REVIEWED NO LESS THAN ANNUALLY.**

Signed: _____

Title: Director, Pharmacy Services

Date: March 1, 2022

Devised: 1/10
Reviewed: 3/10 – annual review
Reviewed: 3/1/11 – annual review
Revised: 3/1/12 – annual review, updated signature
Revised: 9/17/12 – updated authorization duration and file location
Revised: 3/1/13 – annual review, updated logo and definitions
Revised: 7/29/13 – added ulcerative colitis indication
Reviewed: 3/1/14 – annual review
Revised: 9/22/14 – specified & added criteria for each indication (except UC), updated wording for alternative criteria for UC updated auth duration wording for all indications, updated signature and FA
Revised: 2/9/15 – updated FA criteria & FA for RA, PsA, and AS, and prescriber criteria for PsA.
Reviewed: 3/1/15 – annual review
Revised: 09/19/15 – removed joint count criteria from initial and renewal requirements
Revised: 03/01/16 – annual review, updated policy formatting to improve readability
Revised: 5/1/16 – updated format, logo, & procedure
Reviewed: 3/1/17 – annual review
Revised: 3/1/18 – annual review, updated signature, updated criteria format, added grandfather language
Revised: 5/31/18 – added combination with other biologic agents, removed failure of Enbrel and added failure of Cosentyx (PsA, AS), updated FA, added QL
Revised: 10/1/18 – Removed failure of Enbrel & updated FA (RA)
Revised: 3/1/19 – annual review, defined TNF
Revised: 7/24/19 – updated QL and added authorization parameters
Revised: 1/28/20 – updated RA FA and added failure of Rinvoq and Xeljanz
Revised: 3/1/20 – annual review, added GHP Kids
Revised: 3/1/21 – annual review, updated logo, added MediSpan approval level, updated QL statement
Revised: 12/2/21 – added one-time PA to approval crit., removed auth duration & added re-auth crit., updated QL auth entry for PA NSO
Revised: 3/1/22 – annual review, updated referenced policies & covered LOBs, updated how QL's are entered



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 199.0

**SECTION: Commercial Drug
SUBJECT: Armodafinil**

Applicable line of business:

Commercial	X	Medicaid	
Medicare		ACA	X
GHP Kids	X	Self-Insured	X

POLICY:

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for armodafinil for GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 487.0 Quantity Limit Exceptions

REQUIRED DEFINITIONS:

1. **Attachment** – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. **Exhibit** – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. **Devised** – the date the policy was implemented.
4. **Revised** – the date of every revision to the policy, including typographical and grammatical changes.
5. **Reviewed** – the date documenting the annual review if the policy has no revisions necessary.

ADDITIONAL DEFINITIONS:

1. **Formulary** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. **Non-formulary products** – those medications that are not included in the Formulary.
3. **Healthcare provider** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
4. **NCQA** – National Committee for Quality Assurance.
5. **Medically Necessary or Medical Necessity** – covered services rendered by a provider that the Health Plan determines are:



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 199.0

**SECTION: Commercial Drug
SUBJECT: Armodafinil**

- A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
- B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
- C. In accordance with current standards of medical practice;
- D. Not primarily for the convenience of the Member, or the Member's Provider; and
- E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

PROCEDURE:

An exception for coverage of armodafinil may be made for members who meet the following criteria:

- Medical record documentation of:
 - a diagnosis of obstructive sleep apnea/hypopnea syndrome requiring treatment with nasal CPAP **OR**
 - a diagnosis of narcolepsy **OR**
 - a diagnosis of shift-work disorder

MEDISPAN AUTHORIZATION LEVEL: GPI-12, generic only

If an exception is made, armodafinil will be paid for under the member's prescription drug benefit

Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.

FORMULARY ALTERNATIVES:

modafinil*

*prior authorization required



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 199.0

**SECTION: Commercial Drug
SUBJECT: Armodafinil**

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE
STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND
FEDERAL REGULATORY ENTITIES.**

**THIS POLICY WILL BE REVISED AS NECESSARY AND
REVIEWED NO LESS THAN ANNUALLY.**

Signed: _____

Title: Director, Pharmacy Services

Date: March 1, 2022

Devised: 1/10
Reviewed: 3/10 – annual review
Reviewed: 3/1/11 – annual review
Revised: 3/1/12 – annual review, updated signature
Revised: 6/28/12 – removed Provigil from alternatives and added modafinil
Revised: 3/1/13 – annual review, updated logo and definitions
Revised: 11/15/13 – fixed typographical error, updated criteria to failure of modafinil
Revised: 3/1/14 – annual review, updated formatting
Revised: 3/1/15 – annual review, updated signature
Revised: 3/1/16 – annual review, update policy formatting
Revised: 5/1/16 – updated format, logo, & procedure
Revised: 3/1/17 – annual review, updated Nuvigil to armodafinil
Revised: 3/1/18 – annual review, updated signature
Reviewed: 3/1/19 – annual review
Revised: 11/20/19 – removed failure of modafinil
Revised: 3/1/20 – annual review, added GHP Kids
Revised: 3/1/21 – annual review, updated logo, added MediSpan approval level
Revised: 3/1/22 – annual review, updated referenced policies & covered LOBs



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 201.0

**SECTION: Commercial Drug
SUBJECT: Vigabatrin**

Applicable line of business:

Commercial	X	Medicaid	
Medicare		ACA	X
GHP Kids	X	Self-Insured	X

POLICY:

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for vigabatrin for GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 487.0 Quantity Limit Exceptions

REQUIRED DEFINITIONS:

1. **Attachment** – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. **Exhibit** – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. **Devised** – the date the policy was implemented.
4. **Revised** – the date of every revision to the policy, including typographical and grammatical changes.
5. **Reviewed** – the date documenting the annual review if the policy has no revisions necessary.

ADDITIONAL DEFINITIONS:

1. **Formulary** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. **Non-formulary products** – those medications that are not included in the Formulary.
3. **Healthcare provider** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
4. **NCQA** – National Committee for Quality Assurance.
5. **Medically Necessary or Medical Necessity** – covered services rendered by a provider that the Health Plan determines are:



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 201.0

**SECTION: Commercial Drug
SUBJECT: Vigabatrin**

- A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
- B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
- C. In accordance with current standards of medical practice;
- D. Not primarily for the convenience of the Member, or the Member's Provider; and
- E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

PROCEDURE:

New members to the plan already established on therapy may be eligible for continuity of care coverage as long as there is medical record documentation that the safety and effectiveness of use for the prescribed indication is supported by Food and Drug Administration (FDA) approval or adequate medical and scientific evidence in the medical literature.

An exception for coverage of vigabatrin may be made for members who meet the following criteria:

For Infantile Spasms

- Medical record documentation that vigabatrin is prescribed by a neurologist **AND**
- Medical record documentation of use for infantile spasms

For Refractory Complex Partial Seizures

- Medical record documentation that vigabatrin is prescribed by a neurologist **AND**
- Medical record documentation of a diagnosis of refractory complex partial seizures **AND**
- Medical record documentation that vigabatrin is being used concomitantly with another seizure control medication **AND**
- Medical record documentation of therapeutic failure on, intolerance to, or contraindication to three (3) formulary alternatives

MEDISPAN AUTHORIZATION LEVEL: GPI-10, generic only

If an exception is made, vigabatrin will be paid for under the member's prescription drug benefit.



POLICY NUMBER: 201.0

**POLICY AND PROCEDURE
PHARMACY
MANUAL**

**SECTION: Commercial Drug
SUBJECT: Vigabatrin**

Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.

FORMULARY ALTERNATIVES:

For patients > 2 years of age: carbamazepine IR, carbamazepine ER, lamotrigine IR, oxcarbazepine IR, phenobarbital, phenytoin, pregabalin, topiramate IR, topiramate ER (generic Qudexy XR)*

Additional formulary alternatives for patients over certain ages: gabapentin (3+), levetiracetam IR (4+), divalproex (10+), levetiracetam ER (12+), tiagabine (12+), lamotrigine ER (13+), felbamate (14+), and zonisamide (16+)

*prior authorization required

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE
STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND
FEDERAL REGULATORY ENTITIES.**

**THIS POLICY WILL BE REVISED AS NECESSARY AND
REVIEWED NO LESS THAN ANNUALLY.**

Signed: _____

Title: Director, Pharmacy Services

Date: March 1, 2022

- Devised: 1/10
- Reviewed: 3/10 – annual review
- Reviewed: 3/1/11 – annual review
- Revised: 3/1/12 – annual review, updated signature & alternatives
- Revised: 3/1/13 – annual review, updated logo and definitions
- Revised: 3/1/14 – annual review, corrected typo
- Revised: 3/1/15 – annual review, updated signature
- Revised: 3/1/16 – annual review, removed carbatrol from FA, added tiagabine to FA
- Revised: 5/1/16 – updated format, logo, & procedure
- Reviewed: 3/1/17 – annual review
- Revised: 3/1/18 – annual review, updated signature & prescriber, added grandfather language
- Reviewed: 3/1/19 – annual review
- Revised: 11/21/19 – updated Sabril to vigabatrin, updated FA

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Dev. 1/10

Rev. 3/1/22



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 201.0

**SECTION: Commercial Drug
SUBJECT: Vigabatrin**

- Revised: 3/1/20 – annual review, added GHP Kids
- Revised: 4/21/20 – added indication headers, removed failure of all alternatives, added partial seizure diagnosis, adjunctive therapy, and failure of 3 criteria, updated FA
- Revised: 3/1/21 – annual review, updated logo, added MediSpan approval level
- Revised: 3/1/22 – annual review, updated referenced policies & covered LOBs, updated FA



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 202.0

**SECTION: Commercial Drug
SUBJECT: Asenapine**

Applicable line of business:

Commercial	X	Medicaid	
Medicare		ACA	X
GHP Kids	X	Self-Insured	X

POLICY:

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for asenapine for GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 487.0 Quantity Limit Exceptions

REQUIRED DEFINITIONS:

1. **Attachment** – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. **Exhibit** – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. **Devised** – the date the policy was implemented.
4. **Revised** – the date of every revision to the policy, including typographical and grammatical changes.
5. **Reviewed** – the date documenting the annual review if the policy has no revisions necessary.

ADDITIONAL DEFINITIONS:

1. **Formulary** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. **Non-formulary products** – those medications that are not included in the Formulary.
3. **Healthcare provider** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
4. **NCQA** – National Committee for Quality Assurance.
5. **Medically Necessary or Medical Necessity** – covered services rendered by a provider that the Health Plan determines are:



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 202.0

**SECTION: Commercial Drug
SUBJECT: Asenapine**

- A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
- B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
- C. In accordance with current standards of medical practice;
- D. Not primarily for the convenience of the Member, or the Member's Provider; and
- E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

PROCEDURE:

New members to the plan already established on therapy may be eligible for continuity of care coverage as long as there is medical record documentation that the safety and effectiveness of use for the prescribed indication is supported by Food and Drug Administration (FDA) approval or adequate medical and scientific evidence in the medical literature.

An exception for coverage of asenapine may be made for members who meet **BOTH** of the following criteria:

- Medical record documentation of schizophrenia or bipolar disorder **AND**
- Medical record documentation of therapeutic failure on, intolerance to, or contraindication to three (3) formulary alternatives

MEDISPAN AUTHORIZATION LEVEL: GPI-12, generic only

If an exception is made, asenapine will be paid for under the member's prescription drug benefit.

Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.

FORMULARY ALTERNATIVES:

risperidone, olanzapine, aripiprazole, ziprasidone, quetiapine fumarate



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 202.0

**SECTION: Commercial Drug
SUBJECT: Asenapine**

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE
STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND
FEDERAL REGULATORY ENTITIES.**

**THIS POLICY WILL BE REVISED AS NECESSARY AND
REVIEWED NO LESS THAN ANNUALLY.**

Signed: _____

Title: Director, Pharmacy Services

Date: March 1, 2022

Devised: 1/10
Reviewed: 3/10 – annual review
Reviewed: 3/1/11 – annual review
Revised: 3/1/12 – annual review, updated signature and alternatives
Revised: 3/1/13 – annual review, updated logo, alternatives, and definitions
Revised: 3/1/14 – annual review, updated alternatives based on generic Geodon and Seroquel
Revised: 3/20/14 – updated criteria to require failure on 3 formulary alternatives
Revised: 3/1/15 – annual review, updated signature
Revised: 3/1/16 – annual review, changed Abilify to aripiprazole
Revised: 5/1/16 – updated format, logo, & procedure
Reviewed: 3/1/17 – annual review
Revised: 3/1/18 – annual review, updated signature, added grandfather language
Reviewed: 3/1/19 – annual review
Revised: 3/1/20 – annual review, added GHP Kids
Revised: 3/1/21 – annual review, updated logo, added MediSpan approval level, updated Saphris to generic
Revised: 3/1/22 – annual review, updated referenced policies & covered LOBs



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 204.0

**SECTION: Commercial Drug
SUBJECT: Diclofenac Patch**

Applicable line of business:

Commercial	X	Medicaid	
Medicare		ACA	X
GHP Kids	X	Self-Insured	X

POLICY:

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for diclofenac patch for GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 487.0 Quantity Limit Exceptions

REQUIRED DEFINITIONS:

1. **Attachment** – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. **Exhibit** – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. **Devised** – the date the policy was implemented.
4. **Revised** – the date of every revision to the policy, including typographical and grammatical changes.
5. **Reviewed** – the date documenting the annual review if the policy has no revisions necessary.

ADDITIONAL DEFINITIONS:

1. **Formulary** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. **Non-formulary products** – those medications that are not included in the Formulary.
3. **Healthcare provider** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
4. **NCQA** – National Committee for Quality Assurance.
5. **Medically Necessary or Medical Necessity** – covered services rendered by a provider that the Health Plan determines are:

- A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
- B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
- C. In accordance with current standards of medical practice;
- D. Not primarily for the convenience of the Member, or the Member's Provider; and
- E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

PROCEDURE:

An exception for coverage of diclofenac patch may be made for members who meet the following criteria:

- Medical record documentation of use for a Food and Drug Administration (FDA) approved indication (treatment of acute pain due to minor strains, sprains, and contusions) **AND**
- Medical record documentation of therapeutic failure on, intolerance to, or contraindication to three (3) oral formulary NSAIDs

MEDISPAN AUTHORIZATION LEVEL: GPI-12, generic only

QUANTITY LIMIT: *No QLs need to be entered within the authorization unless the requested quantity exceeds the QL.*

- **QL FOR LETTER ONLY:** 30 patches every 15 days

If an exception is made, diclofenac patch will be paid for under the member's prescription drug benefit.

Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.

FORMULARY ALTERNATIVES:

celecoxib, choline magnesium salicylate, diclofenac, diclofenac extended release, diflunisal, etodolac, etodolac extended release, fenoprofen, flurbiprofen, ibuprofen, indomethacin, indomethacin sustained-release, ketoprofen, ketorolac, meclofenamate, meloxicam, nabumetone, naproxen, naproxen sodium, naproxen ec, oxaprozin, piroxicam, salsalate, sulindac, tolmetin



POLICY NUMBER: 204.0

**POLICY AND PROCEDURE
PHARMACY
MANUAL**

**SECTION: Commercial Drug
SUBJECT: Diclofenac Patch**

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE
STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND
FEDERAL REGULATORY ENTITIES.**

**THIS POLICY WILL BE REVISED AS NECESSARY AND
REVIEWED NO LESS THAN ANNUALLY.**

Signed: _____

Title: Director, Pharmacy Services

Date: March 1, 2022

Devised: 1/10
Reviewed: 3/10 – annual review
Reviewed: 3/1/11—annual review
Revised: 3/1/12 – annual review, updated signature
Revised: 3/1/13 – annual review, updated logo and definitions
Revised: 2/1/14 – updated criteria to indicate number of formulary alternatives required
Revised: 3/1/14 – annual review, updated formatting
Revised: 3/1/15 – annual review, updated signature, added celecoxib to FA, updated formatting
Reviewed: 3/1/16 – annual review
Revised: 5/1/16 – updated format, logo, & procedure
Revised: 3/1/17 – annual review, defined FDA and approved indication
Revised: 3/1/18 – annual review, updated signature, corrected typo
Revised: 3/1/19 – annual review, added QL approval note
Revised: 11/21/19 – updated Flector to generic diclofenac
Revised: 3/1/20 – annual review, added GHP Kids
Revised: 3/1/21 – annual review, updated logo, added MediSpan approval level, updated QL statement
Revised: 3/1/22 – annual review, updated referenced policies & covered LOBs



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 205.0

**SECTION: Commercial Drug
SUBJECT: Rufinamide**

Applicable line of business:

Commercial	X	Medicaid	
Medicare		ACA	X
GHP Kids	X	Self-Insured	X

POLICY:

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for rufinamide for GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 487.0 Quantity Limit Exceptions

REQUIRED DEFINITIONS:

1. **Attachment** – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. **Exhibit** – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. **Devised** – the date the policy was implemented.
4. **Revised** – the date of every revision to the policy, including typographical and grammatical changes.
5. **Reviewed** – the date documenting the annual review if the policy has no revisions necessary.

ADDITIONAL DEFINITIONS:

1. **Formulary** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. **Non-formulary products** – those medications that are not included in the Formulary.
3. **Healthcare provider** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
4. **NCQA** – National Committee for Quality Assurance.
5. **Medically Necessary or Medical Necessity** – covered services rendered by a provider that the Health Plan determines are:



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 205.0

**SECTION: Commercial Drug
SUBJECT: Rufinamide**

- A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
- B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
- C. In accordance with current standards of medical practice;
- D. Not primarily for the convenience of the Member, or the Member's Provider; and
- E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

PROCEDURE:

New members to the plan already established on therapy may be eligible for continuity of care coverage as long as there is medical record documentation that the safety and effectiveness of use for the prescribed indication is supported by Food and Drug Administration (FDA) approval or adequate medical and scientific evidence in the medical literature.

An exception for coverage of rufinamide may be made for members who meet the following criteria:

- Medical record documentation of use in adjunctive treatment of seizures associated with Lennox-Gastaut syndrome (LGS) in children greater than or equal to 1 year of age and adults **OR**
- Medical record documentation of use in intractable epilepsy as defined as failure on 2 formulary seizure medications

MEDISPAN AUTHORIZATION LEVEL: GPI-12, if request is for rufinamide suspension include generic only.

If an exception is made, rufinamide will be paid for under the member's prescription drug benefit.

Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.

FORMULARY ALTERNATIVES:

lamotrigine, topiramate, felbamate



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 205.0

**SECTION: Commercial Drug
SUBJECT: Rufinamide**

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE
STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND
FEDERAL REGULATORY ENTITIES.**

**THIS POLICY WILL BE REVISED AS NECESSARY AND
REVIEWED NO LESS THAN ANNUALLY.**

Signed: _____

Title: Director, Pharmacy Services

Date: March 1, 2022

Devised: 1/10
Reviewed: 3/10 – annual review
Reviewed: 3/1/11 – annual review
Revised: 3/1/12 – annual review, updated signature
Revised: 3/1/13 – annual review, updated logo and definitions
Revised: 3/1/14 – annual review, updated formatting
Revised: 5/28/14 – added intractable epilepsy indication, updated signature
Reviewed: 3/1/15 – annual review
Revised: 6/8/15 – updated age requirement for LGS
Reviewed: 3/1/16 – annual review
Revised: 5/1/16 – updated format, logo, & procedure
Reviewed: 3/1/17 – annual review
Revised: 3/1/18 – annual review, updated signature, added grandfather language
Reviewed: 3/1/19 – annual review
Revised: 3/1/20 – annual review, added GHP Kids
Revised: 3/1/21 – annual review, updated logo, added MediSpan approval level, updated Banzel suspension to generic
Revised: 3/1/22 – annual review, updated referenced policies & covered LOBs, updated tablets to generic



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 206.0

**SECTION: Commercial Drug
SUBJECT: Febuxostat**

Applicable line of business:

Commercial	X	Medicaid	
Medicare		ACA	X
GHP Kids	X	Self-Insured	X

POLICY:

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for febuxostat for GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 487.0 Quantity Limit Exceptions

REQUIRED DEFINITIONS:

1. **Attachment** – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. **Exhibit** – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. **Devised** – the date the policy was implemented.
4. **Revised** – the date of every revision to the policy, including typographical and grammatical changes.
5. **Reviewed** – the date documenting the annual review if the policy has no revisions necessary.

ADDITIONAL DEFINITIONS:

1. **Formulary** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. **Non-formulary products** – those medications that are not included in the Formulary.
3. **Healthcare provider** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
4. **NCQA** – National Committee for Quality Assurance.
5. **Medically Necessary or Medical Necessity** – covered services rendered by a provider that the Health Plan determines are:



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 206.0

**SECTION: Commercial Drug
SUBJECT: Febuxostat**

- A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
- B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
- C. In accordance with current standards of medical practice;
- D. Not primarily for the convenience of the Member, or the Member's Provider; and
- E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

PROCEDURE:

An exception for coverage of febuxostat may be made for members who meet the following criteria:

- Medical record documentation of a therapeutic failure on, intolerance to, or contraindication to allopurinol

MEDISPAN AUTHORIZATION LEVEL: GPI-12, generic only

QUANTITY LIMIT: *No QLs need to be entered within the authorization unless the requested quantity exceeds the QL.*

- **QL FOR LETTER ONLY:** 1 tablet per day

If an exception is made, febuxostat will be paid for under the member's prescription drug benefit.

Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.

FORMULARY ALTERNATIVES:

allopurinol, probenecid



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 206.0

**SECTION: Commercial Drug
SUBJECT: Febuxostat**

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE
STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND
FEDERAL REGULATORY ENTITIES.**

**THIS POLICY WILL BE REVISED AS NECESSARY AND
REVIEWED NO LESS THAN ANNUALLY.**

Signed: _____

Title: Director, Pharmacy Services

Date: March 1, 2022

Devised: 1/10
Reviewed: 3/10 – annual review
Reviewed: 3/1/11 – annual review
Revised: 2/12- removed probenecid failure from prior auth criteria
Revised: 3/1/12 – annual review, updated signature
Revised: 3/1/13 – annual review, updated logo and definitions
Reviewed: 3/1/14 – annual review
Revised: 3/1/15 – annual review, updated signature.
Reviewed: 3/1/16 – annual review
Revised: 5/1/16 – updated format, logo, & procedure
Reviewed: 3/1/17 – annual review
Revised: 3/1/18 – annual review, updated signature
Revised: 6/1/18 – added QL
Revised: 3/1/19 – annual review, added QL approval note
Revised: 11/21/19 – updated Uloric to generic febuxostat
Revised: 3/1/20 – annual review, added GHP Kids
Revised: 3/1/21 – annual review, updated logo, added MediSpan approval level, updated QL statement
Revised: 3/1/22 – annual review, updated referenced policies & covered LOBs



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 207.0

**SECTION: Commercial Drug
SUBJECT: Votrient**

Applicable line of business:

Commercial	X	Medicaid	
Medicare		ACA	X
GHP Kids	X	Self-Insured	X

POLICY:

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for Votrient for GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 487.0 Quantity Limit Exceptions

REQUIRED DEFINITIONS:

1. **Attachment** – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. **Exhibit** – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. **Devised** – the date the policy was implemented.
4. **Revised** – the date of every revision to the policy, including typographical and grammatical changes.
5. **Reviewed** – the date documenting the annual review if the policy has no revisions necessary.

ADDITIONAL DEFINITIONS:

1. **Formulary** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. **Non-formulary products** – those medications that are not included in the Formulary.
3. **Healthcare provider** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
4. **NCQA** – National Committee for Quality Assurance.
5. **Medically Necessary or Medical Necessity** – covered services rendered by a provider that the Health Plan determines are:

- A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
- B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
- C. In accordance with current standards of medical practice;
- D. Not primarily for the convenience of the Member, or the Member's Provider; and
- E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

PROCEDURE:

New members to the plan already established on therapy may be eligible for continuity of care coverage as long as there is medical record documentation that the safety and effectiveness of use for the prescribed indication is supported by Food and Drug Administration (FDA) approval or adequate medical and scientific evidence in the medical literature.

An exception for coverage of Votrient may be made for members who meet **ONE** of the following sets of criteria:

Advanced Renal Cell Carcinoma with Clear Cell or Predominantly Clear Cell Histology

- Medical record documentation that Votrient is prescribed by an oncologist **AND**
- Medical record documentation of a diagnosis of advanced renal cell carcinoma with clear cell or predominantly clear cell histology

Advanced Renal Cell Carcinoma with Non-Clear Clear Histology

- Medical record documentation that Votrient is prescribed by an oncologist **AND**
- Medical record documentation of a diagnosis of advanced renal cell carcinoma with non-clear cell histology **AND**
- Medical record documentation of therapeutic failure on, intolerance to, or contraindication to, Torisel **AND** either Sutent* **OR** Nexavar*

Advanced Soft Tissue Sarcoma (STS)

- Medical record documentation that Votrient is prescribed by an oncologist **AND**
- Medical record documentation of a diagnosis of advanced soft tissue sarcoma (STS) **AND**
- Medical record documentation of therapeutic failure on, intolerance to, or contraindication to one prior chemotherapy treatment



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 207.0

**SECTION: Commercial Drug
SUBJECT: Votrient**

NOTE: Will not be approved for gastrointestinal stromal tumors (GIST) or adipocytic sarcoma.

MEDISPAN AUTHORIZATION LEVEL: GPI-12, number of claims authorized = 1, enter for the remainder of the calendar year

QUANTITY LIMIT: *No QLs need to be entered within the authorization unless the requested quantity exceeds the QL.*

- **QL FOR LETTER ONLY:** 4 tablets per day, 30 day supply per fill

RE-AUTHORIZATION CRITERIA: Votrient is configured as a prior authorization for new starts only. Votrient will no longer be covered if it is identified that the member is not receiving appropriate follow-up care from the prescribing specialist or if the member has greater than or equal to a 90 day break in therapy.

- Medical record documentation that the member is receiving appropriate follow-up care from the prescribing specialist

If an exception is made, Votrient will be paid for under the member's prescription drug benefit.

Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.

FORMULARY ALTERNATIVES:

sunitinib*, Nexavar*

*prior authorization required

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE
STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND
FEDERAL REGULATORY ENTITIES.**

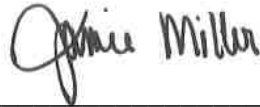
**THIS POLICY WILL BE REVISED AS NECESSARY AND
REVIEWED NO LESS THAN ANNUALLY.**

Geisinger

**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 207.0

**SECTION: Commercial Drug
SUBJECT: Votrient**



Signed: _____

Title: Director, Pharmacy Services

Date: March 1, 2022

Devised: 3/10
Reviewed: 3/1/11 – annual review
Revised: 3/1/12 – annual review, updated signature
Revised: 7/18/12 – added advanced soft tissue sarcoma indication
Revised: 3/1/13 – annual review, updated logo and definitions
Revised: 3/1/14 – annual review, corrected typo
Revised: 3/1/15 – annual review, updated signature
Reviewed: 3/1/16 – annual review
Revised: 3/24/16 – removed copay/15 day supply requirement, removed QL indicator from FA
Revised: 5/1/16 – updated format, logo, & procedure
Reviewed: 3/1/17 – annual review
Revised: 10/10/17 – added authorization duration
Revised: 3/1/18 – annual review, updated signature, updated criteria format, added grandfather language
Revised: 6/1/18 – added QL
Revised: 3/1/19 – annual review, added QL approval note
Revised: 3/1/20 – annual review, added GHP Kids
Revised: 3/1/21 – annual review, updated logo, added MediSpan approval level, updated QL statement
Revised: 3/1/22 – annual review, updated referenced policies & covered LOBs, updated FA, added headers



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 208.0

**SECTION: Commercial Drug
SUBJECT: Arcalyst**

Applicable line of business:

Commercial	X	Medicaid	
Medicare		ACA	X
GHP Kids	X	Self-Insured	X

POLICY:

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for Arcalyst for GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 487.0 Quantity Limit Exceptions

REQUIRED DEFINITIONS:

1. **Attachment** – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. **Exhibit** – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. **Devised** – the date the policy was implemented.
4. **Revised** – the date of every revision to the policy, including typographical and grammatical changes.
5. **Reviewed** – the date documenting the annual review if the policy has no revisions necessary.

ADDITIONAL DEFINITIONS:

1. **Formulary** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. **Non-formulary products** – those medications that are not included in the Formulary.
3. **Healthcare provider** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
4. **NCQA** – National Committee for Quality Assurance.
5. **Medically Necessary or Medical Necessity** – covered services rendered by a provider that the Health Plan determines are:

- A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
- B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
- C. In accordance with current standards of medical practice;
- D. Not primarily for the convenience of the Member, or the Member's Provider; and
- E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

PROCEDURE:

An exception for coverage of Arcalyst may be made for members who meet the following criteria:

Cryopyrin-Associated Periodic Syndrome (CAPS)

- Medical record documentation of diagnosis of Cryopyrin–Associated Periodic Syndrome (CAPS), including Familial Cold Autoinflammatory Syndrome (FCAS), and Muckle-Wells Syndrome (MWS) supported by documentation of genetic testing to identify the CIAS1/NLRP-3 gene mutation **AND**
- Medical record documentation that Arcalyst is prescribed by an immunologist, rheumatologist, or allergist **AND**
- Medical record documentation of therapeutic failure on, intolerance to, or contraindication to Kineret **AND** Ilaris

Deficiency of Interleukin-1 Receptor Antagonist (DIRA)

- Medical record documentation that Arcalyst is prescribed by or in consultation with a cardiologist or rheumatologist **AND**
- Medical record documentation of weight greater than or equal to 10 kg **AND**
- Medical record documentation of a diagnosis of Deficiency of Interleukin-1 Receptor Antagonist (DIRA) supported by documentation of a homozygous or compound heterozygous mutation in IL1RN (Interleukin 1 Receptor Antagonist gene) **AND**
- Medical record documentation that remission of Deficiency of Interleukin-1 Receptor Antagonist (DIRA) was induced by Kineret[†] **AND**
- Medical record documentation Arcalyst (rilonacept) is being used for maintenance of remission of Deficiency of Interleukin-1 Receptor Antagonist (DIRA) **AND**
- Medical record documentation of therapeutic failure on, intolerance to, or contraindication to Kineret

***NOTE:** Inflammatory remission in clinical trial defined as having the following: normal acute-phase reactants (C-reactive protein (CRP) < 0.5 mg/dl), resolution of fever, skin rash and bone pain, and radiological evidence of no active bone lesions on x-ray.

Recurrent Pericarditis (RP)

- Medical record documentation that Arcalyst is prescribed by or in consultation with a cardiologist or rheumatologist **AND**
- Medical record documentation of age greater than or equal to 12 years **AND**
- Medical record documentation of a diagnosis of Recurrent Pericarditis (RP) as evidenced by a recurrence of pericarditis after a symptom free interval of 4 to 6 weeks or longer following a documented episode of acute pericarditis# **AND**
- Medical record documentation of therapeutic failure on, intolerance to, or contraindication to colchicine **AND** a nonsteroidal anti-inflammatory drug (NSAID) or aspirin

#NOTE: The European Society of Cardiology (ESC) defines acute pericarditis to be an inflammatory pericardial syndrome diagnosed with at least 2 of the following 4 criteria: 1) pericarditic chest pain, 2) pericardial rubs, 3) new widespread ST elevations or PR depression on ECG or 4) pericardial effusion (new or worsening).

MEDISPAN AUTHORIZATION LEVEL: GPI-12

AUTHORIZATION DURATION: Initial approval will be for 3 months or less if the reviewing provider feels it is medically appropriate. Subsequent approvals will be for an additional 12 months or less if the reviewing provider feels it is medically appropriate and will require medical record documentation of continued disease improvement or lack of disease progression. The medication will no longer be covered if the member experiences unacceptable toxicity or worsening of disease.

QUANTITY LIMIT

- **Initial Approval** – Two authorizations must be entered.
 1. In PA Hub: Add PA only for the approved authorization duration.
 2. In Darwin: Add OQL, DS, 1 in max number of claims authorized, max quantity dispensed 4, min day supply 21, max day supply 21, with a duration of one-week.
 - **QL FOR LETTER:** Loading dose: 4 mL per 21 days; Maintenance dose: 4 mL per 28 days
- **Renewal** – No QLs need to be entered within the authorization unless the requested quantity exceeds the QL.
 - **QL FOR LETTER:** 4 mL per 28 days



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 208.0

**SECTION: Commercial Drug
SUBJECT: Arcalyst**

If an exception is made, Arcalyst will be paid for under the member's prescription drug benefit.

Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.

FORMULARY ALTERNATIVES:

CAPS: Kineret*, Ilaris*

DIRA: Kineret

RP: colchicine, celecoxib, choline magnesium salicylate, diclofenac, diclofenac extended release, diflunisal, etodolac, etodolac extended release, fenoprofen, flurbiprofen, ibuprofen, indomethacin, indomethacin sustained release, ketoprofen, ketorolac, meclofenamate, meloxicam, nabumetone, naproxen, naproxen sodium, naproxen EC, oxaprozin, piroxicam, salsalate, sulindac, tolmetin, aspirin

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE
STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND
FEDERAL REGULATORY ENTITIES.**

**THIS POLICY WILL BE REVISED AS NECESSARY AND
REVIEWED NO LESS THAN ANNUALLY.**

Signed: _____

Title: Director, Pharmacy Services

Date: March 1, 2022

- Devised: 3/10
- Reviewed: 3/1/11 – annual review
- Revised: 3/1/12 – annual review, updated signature
- Revised: 3/1/13 – annual review, updated logo and definitions
- Revised: 5/4/13 – updated alternatives language
- Revised: 3/1/14 – annual review, updated formatting
- Revised: 3/1/15 – annual review, updated signature
- Reviewed: 3/1/16 – annual review
- Revised: 5/1/16 – updated format, logo, & procedure, added authorization duration indicator
- Reviewed: 3/1/17 – annual review
- Revised: 3/27/17 – removed COE requirement
- Revised: 6/2/17 – added failure of Kineret, removed bolded statement regarding Ilaris/Kineret



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 208.0

**SECTION: Commercial Drug
SUBJECT: Arcalyst**

Revised: 3/1/18 – annual review, updated signature
Reviewed: 3/1/19 – annual review
Revised: 7/24/19 – added QL and authorization parameters
Revised: 3/1/20 – annual review, added GHP Kids
Revised: 3/1/21 – annual review, updated logo, added MediSpan approval level, updated QL statement
Revised: 9/1/21 – added DIRA and RP indications, updated FA, updated auth duration
Revised: 3/1/22 – annual review, updated referenced policies & covered LOBs, updated how QL is entered



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 209.0

**SECTION: Commercial Drug
SUBJECT: Tadalafil
(generic Adcirca)**

Applicable line of business:

Commercial	X	Medicaid	
Medicare		ACA	X
GHP Kids	X	Self-Insured	X

POLICY:

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for tadalafil (generic Adcirca) for GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 487.0 Quantity Limit Exceptions

REQUIRED DEFINITIONS:

1. **Attachment** – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. **Exhibit** – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. **Devised** – the date the policy was implemented.
4. **Revised** – the date of every revision to the policy, including typographical and grammatical changes.
5. **Reviewed** – the date documenting the annual review if the policy has no revisions necessary.

ADDITIONAL DEFINITIONS:

1. **Formulary** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. **Non-formulary products** – those medications that are not included in the Formulary.
3. **Healthcare provider** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
4. **NCQA** – National Committee for Quality Assurance.
5. **Medically Necessary or Medical Necessity** – covered services rendered by a provider that the Health Plan determines are:



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 209.0

**SECTION: Commercial Drug
SUBJECT: Tadalafil
(generic Adcirca)**

- A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
- B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
- C. In accordance with current standards of medical practice;
- D. Not primarily for the convenience of the Member, or the Member's Provider; and
- E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

PROCEDURE:

An exception for coverage of tadalafil (generic Adcirca) may be made for members who meet the following criteria:

- Medical record documentation that tadalafil is prescribed by a cardiologist or pulmonologist **AND**
- Medical record documentation of a diagnosis of functional class 2, 3, or 4 pulmonary arterial hypertension **AND**
- Medical record documentation of one of the following:
 - Therapeutic failure on, intolerance to, or contraindication to sildenafil* (generic Revatio) **OR**
 - Use as first line therapy in combination with ambrisentan in patients with World Health Organization (WHO) Group 1, functional class II or III symptoms

MEDISPAN AUTHORIZATION LEVEL: GPI-12, generic only

QUANTITY LIMIT: *No QLs need to be entered within the authorization unless the requested quantity exceeds the QL.*

- **QL FOR LETTER ONLY:** 2 tablets per day, 30 day supply per fill

If an exception is made, tadalafil (generic Adcirca) will be paid for under the member's prescription drug benefit.

Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 209.0

**SECTION: Commercial Drug
SUBJECT: Tadalafil
(generic Adcirca)**

FORMULARY ALTERNATIVES:

Uptravi*, Orenitram*, treprostini* (generic Remodulin), Tyvaso*, Ventavis*, Adempas*,
Opsumit*, ambrisentan*, bosentan*, sildenafil* (generic Revatio)

*prior authorization required

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE
STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND
FEDERAL REGULATORY ENTITIES.**

**THIS POLICY WILL BE REVISED AS NECESSARY AND
REVIEWED NO LESS THAN ANNUALLY.**

Signed: _____

Title: Director, Pharmacy Services

Date: March 1, 2022

Devised: 6/10
Reviewed: 3/1/11 – annual update
Revised: 3/1/12- annual review, updated signature
Revised: 3/1/13 – annual review, updated logo and definitions
Revised: 3/1/14 – annual review, updated Revatio to sildenafil, updated formatting
Revised: 3/1/15 – annual review, updated signature
Reviewed: 3/1/16 – annual review
Revised: 3/24/16 – added 1st line therapy in combo w/ Letairis, removed 2 copay/34 day supply
Revised: 5/1/16 – updated format, logo, & procedure
Revised: 7/22/16 – added QL, updated FA
Revised: 3/1/17 – annual review, defined WHO
Revised: 3/1/18 – annual review, updated signature, updated prescribed criteria, defined PA
Revised: 3/1/19 – annual review, added QL approval note
Revised: 11/21/19 – updated Adcirca to generic tadalafil, updated all others w/ available generics
Revised: 3/1/20 – annual review, added GHP Kids
Revised: 3/1/21 – annual review, updated logo, added MediSpan approval level, updated QL statement
Revised: 3/1/22 – annual review, updated referenced policies & covered LOBs



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 210.0

**SECTION: Commercial Drug
SUBJECT: Tyvaso**

Applicable line of business:

Commercial	X	Medicaid	
Medicare		ACA	X
GHP Kids	X	Self-Insured	X

POLICY:

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for Tyvaso for GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 487.0 Quantity Limit Exceptions

REQUIRED DEFINITIONS:

1. **Attachment** – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. **Exhibit** – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. **Devised** – the date the policy was implemented.
4. **Revised** – the date of every revision to the policy, including typographical and grammatical changes.
5. **Reviewed** – the date documenting the annual review if the policy has no revisions necessary.

ADDITIONAL DEFINITIONS:

1. **Formulary** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. **Non-formulary products** – those medications that are not included in the Formulary.
3. **Healthcare provider** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
4. **NCQA** – National Committee for Quality Assurance.
5. **Medically Necessary or Medical Necessity** – covered services rendered by a provider that the Health Plan determines are:



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 210.0

**SECTION: Commercial Drug
SUBJECT: Tyvaso**

- A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
- B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
- C. In accordance with current standards of medical practice;
- D. Not primarily for the convenience of the Member, or the Member's Provider; and
- E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

PROCEDURE:

An exception for coverage of Tyvaso may be made for members who meet the following criteria:

Class III or IV Pulmonary Artery Hypertension

- Medical record documentation that Tyvaso is prescribed by a cardiologist or pulmonologist **AND**
- Medical record documentation of a diagnosis of functional class III or IV pulmonary artery hypertension **AND**
- Medical record documentation of therapeutic failure on, intolerance to, or contraindication to, or use in combination with sildenafil* **OR** bosentan*

Pulmonary Hypertension associated with Interstitial Lung Disease

- Medical record documentation that Tyvaso is prescribed by a cardiologist or pulmonologist **AND**
- Medical record documentation of a diagnosis of pulmonary hypertension associated with interstitial lung disease (World Health Organization Group 3 Pulmonary Hypertension)

MEDISPAN AUTHORIZATION LEVEL: GPI-14

If an exception is made, Tyvaso will be paid for under the member's prescription drug benefit.

Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.

Geisinger

**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 210.0

**SECTION: Commercial Drug
SUBJECT: Tyvaso**

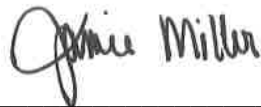
FORMULARY ALTERNATIVES:

Class III or IV Pulmonary Artery Hypertension: Uptravi*, Orenitram*, treprostinil (generic Remodulin)*, Ventavis*, Adempas*, Opsumit*, ambrisentan*, tadalafil (generic Adcirca)*, sildenafil (generic Revatio)*, bosentan*

* prior authorization required

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE
STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND
FEDERAL REGULATORY ENTITIES.**

**THIS POLICY WILL BE REVISED AS NECESSARY AND
REVIEWED NO LESS THAN ANNUALLY.**



Signed: _____

Title: Director, Pharmacy Services

Date: March 1, 2022

Devised: 6/10
Reviewed: 3/1/11 – annual review
Revised: 3/1/12 – annual review, updated signature
Revised: 3/1/13 – annual review, updated logo and definitions
Revised: 3/1/14 – annual review, updated Revatio to sildenafil, updated formatting
Revised: 9/22/14 – removed failure of Tracleer, removed Tracleer from FA, updated signature
Reviewed: 3/1/15 – annual review
Reviewed: 3/1/16 – annual review
Revised: 3/24/16 – removed 2 copay per 30 day supply requirement
Revised: 5/1/16 – updated format, logo, & procedure, added authorization duration indicator
Revised: 7/27/16 – added functional class IV, updated FA requirement, updated FA's
Reviewed: 3/1/17 – annual review
Revised: 3/1/18 – annual review, updated signature, updated prescriber criteria, defined PA
Reviewed: 3/1/19 – annual review
Revised: 3/1/20 – annual review, added GHP Kids
Revised: 3/1/21 – annual review, updated logo, added MediSpan approval level, updated FA to generic name
Revised: 11/1/21 – added interstitial lung disease indication
Revised: 3/1/22 – annual review, updated referenced policies & covered LOBs



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 213.0

**SECTION: Commercial Drug
SUBJECT: Nebivolol**

Applicable line of business:

Commercial	X	Medicaid	
Medicare		ACA	X
GHP Kids	X	Self-Insured	X

POLICY:

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for nebivolol for GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 487.0 Quantity Limit Exceptions

REQUIRED DEFINITIONS:

1. **Attachment** – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. **Exhibit** – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. **Devised** – the date the policy was implemented.
4. **Revised** – the date of every revision to the policy, including typographical and grammatical changes.
5. **Reviewed** – the date documenting the annual review if the policy has no revisions necessary.

ADDITIONAL DEFINITIONS:

1. **Formulary** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. **Non-formulary products** – those medications that are not included in the Formulary.
3. **Healthcare provider** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
4. **NCQA** – National Committee for Quality Assurance.
5. **Medically Necessary or Medical Necessity** – covered services rendered by a provider that the Health Plan determines are:



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 213.0

**SECTION: Commercial Drug
SUBJECT: Nebivolol**

- A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
- B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
- C. In accordance with current standards of medical practice;
- D. Not primarily for the convenience of the Member, or the Member's Provider; and
- E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

PROCEDURE:

An exception for coverage of nebivolol may be made for members who meet the following criteria:

- Medical record documentation of therapeutic failure on, intolerance to, or contraindication to two formulary beta blocker agents

MEDISPAN AUTHORIZATION LEVEL: GPI-12

If an exception is made, nebivolol will be paid for under the member's prescription drug benefit.

Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.

FORMULARY ALTERNATIVES:

acebutolol, atenolol, atenolol-chlorthalidone, betaxolol, bisoprolol, bisoprolol-hctz, carvedilol, labetalol, metoprolol succinate, metoprolol tartrate, metoprolol-hctz, nadolol, pindolol, propranolol, propranolol sa, propranolol-hctz, sotalol, timolol

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE STANDARDS OF
NCQA AND ANY OTHER APPLICABLE STATE AND FEDERAL REGULATORY
ENTITIES.**

**THIS POLICY WILL BE REVISED AS NECESSARY AND
REVIEWED NO LESS THAN ANNUALLY.**



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 213.0

**SECTION: Commercial Drug
SUBJECT: Nebivolol**

Signed: _____

Title: Director, Pharmacy Services

Date: March 1, 2022

- Devised: 6/10
- Reviewed: 3/1/11 – annual review
- Revised: 3/1/12 – annual review, updated signature
- Revised: 3/1/13 – annual review, updated logo and definitions
- Reviewed: 3/1/14 – annual review
- Revised: 3/1/15 – annual review, updated signature
- Revised: 3/1/16 – annual review, added acebutolol, atenolol-Chlorthalidone, betaxolol, bisoprolol-hctz, carvedilol, labetalol, metoprolol tartrate, metoprolol-hctz, nadolol, pindolol, propranolol, propranolol-hctz, sotalol, timolol to FA
- Revised: 5/1/16 – updated format, logo, & procedure
- Reviewed: 3/1/17 – annual review
- Revised: 3/1/18 – annual review, updated signature, updated 2 to two
- Reviewed: 3/1/19 – annual review
- Revised: 3/1/20 – annual review, added GHP Kids
- Revised: 3/1/21 – annual review, updated logo, added MediSpan approval level
- Revised: 3/1/22 – annual review, updated referenced policies & covered LOBs, updated Bystolic to nebivolol



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 218.0

**SECTION: Commercial Drug
SUBJECT: Pradaxa**

Applicable line of business:

Commercial	X	Medicaid	
Medicare		ACA	X
GHP Kids	X	Self-Insured	X

POLICY:

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for Pradaxa for GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 487.0 Quantity Limit Exceptions

REQUIRED DEFINITIONS:

1. **Attachment** – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. **Exhibit** – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. **Devised** – the date the policy was implemented.
4. **Revised** – the date of every revision to the policy, including typographical and grammatical changes.
5. **Reviewed** – the date documenting the annual review if the policy has no revisions necessary.

ADDITIONAL DEFINITIONS:

1. **Formulary** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. **Non-formulary products** – those medications that are not included in the Formulary.
3. **Healthcare provider** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
4. **NCQA** – National Committee for Quality Assurance.
5. **Medically Necessary or Medical Necessity** – covered services rendered by a provider that the Health Plan determines are:



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 218.0

**SECTION: Commercial Drug
SUBJECT: Pradaxa**

- A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
- B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
- C. In accordance with current standards of medical practice;
- D. Not primarily for the convenience of the Member, or the Member's Provider; and
- E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

PROCEDURE:

An exception for coverage of Pradaxa may be made for members who meet the following criteria:

- Electronic step therapy of on-line prescription drug claims history showing 15 days use of Eliquis **OR** Xarelto, within the previous 180 days. If this electronic step is met, the claim will automatically adjudicate **OR**
- Medical record documentation of treatment to reduce the risk of stroke and systemic embolism in patients with nonvalvular atrial fibrillation **OR**
- Medical record documentation of use for the treatment of deep vein thrombosis, pulmonary embolism, or for the reduction in the risk of recurrence of deep vein thrombosis and/or pulmonary embolism **OR**
- Medical record documentation of use for the prophylaxis of DVT and PE in patients who have undergone hip replacement surgery **AND**
- Medical record documentation of therapeutic failure on, intolerance to, or contraindication to Eliquis **OR** Xarelto

MEDISPAN AUTHORIZATION LEVEL: GPI-12

QUANTITY LIMIT: *No QLs need to be entered within the authorization unless the requested quantity exceeds the QL.*

- **QL FOR LETTER ONLY:** 2 capsules per day

If an exception is made, Pradaxa will be paid for under the member's prescription drug benefit.

Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 218.0

**SECTION: Commercial Drug
SUBJECT: Pradaxa**

FORMULARY ALTERNATIVES:

Eliquis, Xarelto

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE STANDARDS
OF NCQA AND ANY OTHER APPLICABLE STATE AND FEDERAL REGULATORY
ENTITIES.**

**THIS POLICY WILL BE REVISED AS NECESSARY AND
REVIEWED NO LESS THAN ANNUALLY.**

Signed: _____

Title: Director, Pharmacy Services

Date: March 1, 2022

Devised: 12/10
Reviewed: 3/01/11 – annual review
Retired: 6/8/11
Revised: 5/28/14 – updated criteria, updated signature, updated logo, updated policy format
Revised: 3/1/15 – annual review, updated DVT/PE criteria to require failure on Eliquis
Revised: 3/1/16 – annual review, removed Hep C/FDA definitions
Revised: 5/1/16 – updated format, logo, & procedure
Revised: 5/27/16 – added DVT/PE prophylaxis
Reviewed: 3/1/17 – annual review
Revised: 1/17/18 – updated policy format, added step language, now requires failure of Eliquis OR Xarelto, added QL, updated signature
Reviewed: 3/1/18 – annual review
Revised: 3/1/19 – annual review, added QL approval note
Revised: 3/1/20 – annual review, added GHP Kids
Revised: 3/1/21 – annual review, updated logo, added MediSpan approval level, updated QL statement
Revised: 3/1/22 – annual review, updated referenced policies & covered LOBs



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 223.0

**SECTION: Commercial Drug
SUBJECT: Acyclovir Cream and
Denavir**

Applicable line of business:

Commercial	X	Medicaid	
Medicare		ACA	X
GHP Kids	X	Self-Insured	X

POLICY:

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for acyclovir cream and Denavir for GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 487.0 Quantity Limit Exceptions

REQUIRED DEFINITIONS:

1. **Attachment** – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. **Exhibit** – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. **Devised** – the date the policy was implemented.
4. **Revised** – the date of every revision to the policy, including typographical and grammatical changes.
5. **Reviewed** – the date documenting the annual review if the policy has no revisions necessary.

ADDITIONAL DEFINITIONS:

1. **Formulary** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. **Non-formulary products** – those medications that are not included in the Formulary.
3. **Healthcare provider** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
4. **NCQA** – National Committee for Quality Assurance.
5. **Medically Necessary or Medical Necessity** – covered services rendered by a provider that the Health Plan determines are:

- A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
- B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
- C. In accordance with current standards of medical practice;
- D. Not primarily for the convenience of the Member, or the Member's Provider; and
- E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

PROCEDURE:

An exception for coverage of acyclovir cream or Denavir, may be made for members who meet the following criteria:

For the treatment of Cold Sores:

- An exception for the coverage of **acyclovir cream** may be made for members who meet the following criteria:
 - Medical record documentation of a diagnosis of Cold Sores (Herpes Simplex 1 or Herpes Labialis) in patients 12 years of age and older **AND**
 - Medical record documentation of therapeutic failure on, intolerance to, or contraindication to:
 - Abreva (OTC), valacyclovir, **AND** famciclovir (famciclovir only if age greater than or equal to 18 years)
- An exception for the coverage of **Denavir Cream** may be made for members who meet the following criteria:
 - Medical record documentation of a diagnosis of cold sores (Herpes Simplex 1 or Herpes Labialis) in patients 12 years of age and older **AND**
 - Medical record documentation of therapeutic failure on, intolerance to, or contraindication to:
 - Abreva (OTC), acyclovir cream (prior authorization required), valacyclovir, **AND** famciclovir (famciclovir only if age greater than or equal to 18 years)

MEDISPAN AUTHORIZATION LEVEL: GPI-12, if request is for acyclovir cream include generic only.



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 223.0

**SECTION: Commercial Drug
SUBJECT: Acyclovir Cream and
Denavir**

QUANTITY LIMIT: *No QLs need to be entered within the authorization unless the requested quantity exceeds the QL.*

- **QL FOR LETTER ONLY:** 1 copay per package

If an exception is made, topical acyclovir or Denavir will be paid for under the member's prescription drug benefit.

Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.

FORMULARY ALTERNATIVES:

Cold Sores: valacyclovir, famciclovir

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE
STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND
FEDERAL REGULATORY ENTITIES.**

**THIS POLICY WILL BE REVISED AS NECESSARY AND
REVIEWED NO LESS THAN ANNUALLY.**

Signed: _____

Title: Director, Pharmacy Services

Date: March 1, 2022

Devised: 3/11
Revised: 3/1/12 – annual review, updated signature
Revised: 3/1/13 – annual review, updated logo and definitions
Reviewed: 3/1/14 – annual review
Revised: 7/22/14 – removed approval with concomitant valacyclovir, updated FA and signature
Revised: 3/1/15 – annual review, updated formatting
Reviewed: 3/1/16 – annual review
Revised: 5/1/16 – updated format, logo, & procedure
Reviewed: 3/1/17 – annual review
Revised: 8/8/17 – added note to require famciclovir only if age greater than or equal to 18 years



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 223.0

**SECTION: Commercial Drug
SUBJECT: Acyclovir Cream and
Denavir**

- Revised: 3/1/18 – annual review, updated signature, corrected typo
- Revised: 3/1/19 – annual review, renamed to generic acyclovir
- Revised: 4/9/19 – updated Zovirax to acyclovir within Denavir criteria, defined *
- Revised: 3/1/20 – annual review, added GHP Kids
- Revised: 7/29/20 – removed PA from acyclovir ointment, deleted genital herpes section of policy
- Revised: 3/1/21 – annual review, updated logo, added MediSpan approval level, updated QL statement.
- Revised: 3/1/22 – annual review, updated referenced policies & covered LOBs



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 224.0

**SECTION: Commercial Drug
SUBJECT: Naproxen/esomeprazole**

Applicable line of business:

Commercial	X	Medicaid	
Medicare		ACA	X
GHP Kids	X	Self-Insured	X

POLICY:

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for naproxen/esomeprazole for GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 487.0 Quantity Limit Exceptions

REQUIRED DEFINITIONS:

1. **Attachment** – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. **Exhibit** – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. **Devised** – the date the policy was implemented.
4. **Revised** – the date of every revision to the policy, including typographical and grammatical changes.
5. **Reviewed** – the date documenting the annual review if the policy has no revisions necessary.

ADDITIONAL DEFINITIONS:

1. **Formulary** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. **Non-formulary products** – those medications that are not included in the Formulary.
3. **Healthcare provider** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
4. **NCQA** – National Committee for Quality Assurance.
5. **Medically Necessary or Medical Necessity** – covered services rendered by a provider that the Health Plan determines are:

- A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
- B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
- C. In accordance with current standards of medical practice;
- D. Not primarily for the convenience of the Member, or the Member's Provider; and
- E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

PROCEDURE:

An exception for coverage of naproxen/esomeprazole may be made for members who meet the following criteria:

Osteoarthritis, Rheumatoid Arthritis, and Ankylosing Spondylitis

- Medical record documentation of a diagnosis of osteoarthritis, rheumatoid arthritis, or ankylosing spondylitis **AND**
- Medical record documentation of age greater than or equal to 18 years **AND**
- Medical record documentation of therapeutic failure on, intolerance to, or contraindication to naproxen and three (3) formulary PPI (proton pump inhibitor) agents used in combination

Juvenile Idiopathic Arthritis

- Medical record documentation of a diagnosis of juvenile idiopathic arthritis (JIA) **AND**
- Medical record documentation of age greater than or equal to 12 years **AND**
- Medical record documentation of weight greater than or equal to 38 kg **AND**
- Medical record documentation of therapeutic failure on, intolerance to, or contraindication to naproxen and three (3) formulary PPI (proton pump inhibitor) agents used in combination

MEDISPAN AUTHORIZATION LEVEL: GPI-12, generic only

QUANTITY LIMIT: *No QLs need to be entered within the authorization unless the requested quantity exceeds the QL.*

- **QL FOR LETTER ONLY:** 2 tablets per day, 28 day supply per fill

If an exception is made, naproxen/esomeprazole will be paid for under the member's prescription drug benefit.



POLICY NUMBER: 224.0

**POLICY AND PROCEDURE
PHARMACY
MANUAL**

**SECTION: Commercial Drug
SUBJECT: Naproxen/esomeprazole**

Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.

FORMULARY ALTERNATIVES:

naproxen, omeprazole, pantoprazole, lansoprazole, rabeprazole, esomeprazole

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE STANDARDS
OF NCQA AND ANY OTHER APPLICABLE STATE AND FEDERAL REGULATORY
ENTITIES.**

**THIS POLICY WILL BE REVISED AS NECESSARY AND
REVIEWED NO LESS THAN ANNUALLY.**

Signed: _____

Title: Director, Pharmacy Services

Date: March 1, 2022

Devised: 3/11
Revised: 3/1/12 – annual review, updated signature
Revised: 3/1/13 – annual review, updated logo and definitions
Reviewed: 3/1/14 – annual review
Revised: 3/1/15 – annual review, updated signature, added rabeprazole to alternatives
Revised: 3/1/16 – annual review, update bullet formatting
Revised: 5/1/16 – updated format, logo, & procedure
Reviewed: 3/1/17 – annual review
Revised: 11/27/17 – added indication headers, added JIA, added age & updated alt. bullet for OA, RA, and AS, added QL, updated signature
Reviewed: 3/1/18 – annual review
Revised: 3/1/19 – annual review, added QL approval note, updated FA
Revised: 3/1/20 – annual review, added GHP Kids
Revised: 3/1/21 – annual review, updated logo, added MediSpan approval level, updated QL statement, updated Vimovo to generic
Revised: 3/1/22 – annual review, updated referenced policies & covered LOBs, corrected typo



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 225.0

**SECTION: Commercial Drug
SUBJECT: Alogliptin/Metformin
and Kombiglyze XR**

Applicable line of business:

Commercial	X	Medicaid	
Medicare		ACA	X
GHP Kids	X	Self-Insured	X

POLICY:

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for alogliptin/metformin and Kombiglyze XR for GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 487.0 Quantity Limit Exceptions

REQUIRED DEFINITIONS:

1. **Attachment** – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. **Exhibit** – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. **Devised** – the date the policy was implemented.
4. **Revised** – the date of every revision to the policy, including typographical and grammatical changes.
5. **Reviewed** – the date documenting the annual review if the policy has no revisions necessary.

ADDITIONAL DEFINITIONS:

1. **Formulary** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. **Non-formulary products** – those medications that are not included in the Formulary.
3. **Healthcare provider** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
4. **NCQA** – National Committee for Quality Assurance.
5. **Medically Necessary or Medical Necessity** – covered services rendered by a provider that the Health Plan determines are:



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 225.0

**SECTION: Commercial Drug
SUBJECT: Alogliptin/Metformin
and Kombiglyze XR**

- A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
- B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
- C. In accordance with current standards of medical practice;
- D. Not primarily for the convenience of the Member, or the Member's Provider; and
- E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

PROCEDURE:

An exception for coverage of alogliptin/metformin or Kombiglyze XR may be made for members who meet the following criteria:

- Medical record documentation of therapeutic failure on, intolerance to, or contraindication to Tradjenta in combination with metformin, Jentadueto, **OR** Jentadueto XR

MEDISPAN AUTHORIZATION LEVEL: GPI-12, if request is for alogliptin/metformin include generic only.

QUANTITY LIMIT: *No QLs need to be entered within the authorization unless the requested quantity exceeds the QL.*

- **QL FOR LETTER ONLY:**
 - Kombiglyze XR 2.5-1000 mg: 2 tablets per day
 - Kombiglyze XR (all other strengths): 1 tablet per day
 - Alogliptin/metformin: 2 tablets per day

If an exception is made, alogliptin/metformin or Kombiglyze XR will be paid for under the member's prescription drug benefit.

Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.

FORMULARY ALTERNATIVES:

Tradjenta, metformin, Jentadueto, Jentadueto XR



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 225.0

**SECTION: Commercial Drug
SUBJECT: Alogliptin/Metformin
and Kombiglyze XR**

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE STANDARDS
OF NCQA AND ANY OTHER APPLICABLE STATE AND FEDERAL REGULATORY
ENTITIES.**

**THIS POLICY WILL BE REVISED AS NECESSARY AND
REVIEWED NO LESS THAN ANNUALLY.**

Signed: _____

Title: Director, Pharmacy Services

Date: March 1, 2022

Devised: 3/11
Revised: 3/1/12 – annual review, updated signature
Revised: 7/18/12 – added Jentaduo to policy, updated alternatives to include Janumet XR
Revised: 3/1/13 – annual review, updated logo and definitions
Revised: 6/24/13 – added Kazano to policy, updated formulary alternatives
Reviewed: 3/1/14 – annual review
Revised: 3/1/15 – annual review, updated signature
Revised: 3/1/16 – annual review, updated PA requirements to ST
Revised: 5/1/16 – updated format, logo, & procedure
Revised: 3/1/17 – annual review, updated Kazano to alogliptin/metformin
Revised: 11/28/17 – added failure of Tradjenta products, updated FA/signature, added QL
Revised: 2/9/18 – removed failure of sitagliptin, updated Tradjenta to combo with metformin, updated FA,
corrected typo
Reviewed: 3/1/18 – annual review
Revised: 3/1/19 – annual review, added QL approval note, removed step indicator from FA
Revised: 3/1/20 – annual review, added GHP Kids
Revised: 3/1/21 – annual review, updated logo, added MediSpan approval level, updated QL statement
Revised: 3/1/22 – annual review, updated referenced policies & covered LOBs



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 228.0

**SECTION: Commercial Drug
SUBJECT: Viibryd**

Applicable line of business:

Commercial	X	Medicaid	
Medicare		ACA	X
GHP Kids	X	Self-Insured	X

POLICY:

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for Viibryd for GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 487.0 Quantity Limit Exceptions

REQUIRED DEFINITIONS:

1. **Attachment** – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. **Exhibit** – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. **Devised** – the date the policy was implemented.
4. **Revised** – the date of every revision to the policy, including typographical and grammatical changes.
5. **Reviewed** – the date documenting the annual review if the policy has no revisions necessary.

ADDITIONAL DEFINITIONS:

1. **Formulary** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. **Non-formulary products** – those medications that are not included in the Formulary.
3. **Healthcare provider** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
4. **NCQA** – National Committee for Quality Assurance.
5. **Medically Necessary or Medical Necessity** – covered services rendered by a provider that the Health Plan determines are:

- A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
- B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
- C. In accordance with current standards of medical practice;
- D. Not primarily for the convenience of the Member, or the Member's Provider; and
- E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

PROCEDURE:

New members to the plan already established on therapy may be eligible for continuity of care coverage as long as there is medical record documentation that the safety and effectiveness of use for the prescribed indication is supported by Food and Drug Administration (FDA) approval or adequate medical and scientific evidence in the medical literature.

An exception for coverage of Viibryd may be made for members who meet the following criteria:

- Medical record documentation of age greater than or equal to 18 years **AND**
- Medical record documentation of a diagnosis of major depressive disorder **AND**
- Medical record documentation of therapeutic failure on, intolerance to, or contraindication to, at least three antidepressant classes

MEDISPAN AUTHORIZATION LEVEL: GPI-10

QUANTITY LIMIT: *No QLs need to be entered within the authorization unless the requested quantity exceeds the QL.*

- QL FOR LETTER ONLY: 1 tablet per day

If an exception is made, Viibryd will be paid for under the member's prescription drug benefit.

Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.

FORMULARY ALTERNATIVES:

SSRIs: citalopram, fluoxetine, paroxetine, sertraline, escitalopram

MAOIs: phenelzine, tranylcypromine

SNRIs: venlafaxine hcl, venlafaxine er, duloxetine

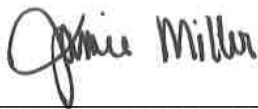
Tricyclics: amitriptyline, nortriptyline, desipramine, doxepin, imipramine

Bupropion: bupropion hcl, bupropion xl, bupropion sr

Other: trazodone, nefazodone, mirtazapine

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE
STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND
FEDERAL REGULATORY ENTITIES.**

**THIS POLICY WILL BE REVISED AS NECESSARY AND
REVIEWED NO LESS THAN ANNUALLY.**



Signed: _____

Title: Director, Pharmacy Services

Date: March 1, 2022

Devised: 6/11
Revised: 3/1/12 – annual review, updated signature
Revised: 3/1/13 – annual review, updated logo and definitions
Revised: 3/1/14 – annual review, updated formatting, added duloxetine to formulary alternatives
Revised: 3/1/15 – annual review, updated signature, added escitalopram to alternatives
Revised: 3/1/16 – annual review, updated bullet formatting
Revised: 5/1/16 – updated format, logo, & procedure
Revised: 3/1/17 – annual review, removed Unicode characters
Revised: 3/1/18 – annual review, updated signature, added grandfather language, updated age criteria & FA
Reviewed: 3/1/19 – annual review
Revised: 3/1/20 – annual review, added GHP Kids
Revised: 3/1/21 – annual review, updated logo, added MediSpan approval level
Revised: 6/4/21 – removed specific failure of bupropion, added QL
Revised: 3/1/22 – annual review, updated referenced policies & covered LOBs



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 229.0

**SECTION: Commercial Drug
SUBJECT: Caprelsa**

Applicable line of business:

Commercial	X	Medicaid	
Medicare		ACA	X
GHP Kids	X	Self-Insured	X

POLICY:

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for Caprelsa for GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 487.0 Quantity Limit Exceptions

REQUIRED DEFINITIONS:

1. **Attachment** – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. **Exhibit** – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. **Devised** – the date the policy was implemented.
4. **Revised** – the date of every revision to the policy, including typographical and grammatical changes.
5. **Reviewed** – the date documenting the annual review if the policy has no revisions necessary.

ADDITIONAL DEFINITIONS:

1. **Formulary** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. **Non-formulary products** – those medications that are not included in the Formulary.
3. **Healthcare provider** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
4. **NCQA** – National Committee for Quality Assurance.
5. **Medically Necessary or Medical Necessity** – covered services rendered by a provider that the Health Plan determines are:

- A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
- B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
- C. In accordance with current standards of medical practice;
- D. Not primarily for the convenience of the Member, or the Member's Provider; and
- E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

PROCEDURE:

New members to the plan already established on therapy may be eligible for continuity of care coverage as long as there is medical record documentation that the safety and effectiveness of use for the prescribed indication is supported by Food and Drug Administration (FDA) approval or adequate medical and scientific evidence in the medical literature.

An exception for coverage of Caprelsa may be made for members who meet the following criteria:

- Medical record documentation that Caprelsa is prescribed by an oncologist **AND**
- Medical record documentation of a diagnosis of medullary thyroid carcinoma in patients with unresectable, advanced, or metastatic disease

MEDISPAN AUTHORIZATION LEVEL: GPI-12, number of claims authorized = 1, enter for the remainder of the calendar year

QUANTITY LIMIT: *No QLs need to be entered within the authorization unless the requested quantity exceeds the QL.*

- **QL FOR LETTER ONLY:**
 - 100 mg tablet: 2 tablets per day, 30 day supply per fill
 - 300 mg tablet: 1 tablet per day, 30 day supply per fill

RE-AUTHORIZATION CRITERIA: Caprelsa is configured as a prior authorization for new starts only. Caprelsa will no longer be covered if it is identified that the member is not receiving appropriate follow-up care from the prescribing specialist or if the member has greater than or equal to a 90 day break in therapy.

- Medical record documentation that the member is receiving appropriate follow-up care from the prescribing specialist



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 229.0

**SECTION: Commercial Drug
SUBJECT: Caprelsa**

If an exception is made, Caprelsa will be paid for under the member's prescription drug benefit.

Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.

FORMULARY ALTERNATIVES:

Cometriq*

*prior authorization required

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE
STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND
FEDERAL REGULATORY ENTITIES.**

**THIS POLICY WILL BE REVISED AS NECESSARY AND
REVIEWED NO LESS THAN ANNUALLY.**

Signed: _____

Title: Director, Pharmacy Services

Date: March 1, 2022

- Devised: 6/11
- Revised: 3/1/12 – annual review, updated signature
- Revised: 3/1/13 – annual review, updated logo, policy title and definitions
- Revised: 5/4/13 – added oncologist requirement, updated alternatives
- Reviewed: 3/1/14 – annual review
- Revised: 3/1/15 – annual review, updated signature
- Revised: 3/1/16 – annual review, updated bullet formatting
- Revised: 5/1/16 – updated format, logo, & procedure
- Reviewed: 3/1/17 – annual review
- Revised: 10/10/17 – added authorization duration
- Revised: 3/1/18 – annual review, updated signature & prescribed criteria, added grandfather language
- Revised: 6/1/18 – added QL
- Revised: 3/1/19 – annual review, added QL approval note
- Revised: 3/1/20 – annual review, added GHP Kids
- Revised: 3/1/21 – annual review, updated logo, added MediSpan approval level, updated QL statement
- Revised: 11/24/21 – added one-time PA to approval crit., removed auth duration & added re-auth crit.



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 229.0

**SECTION: Commercial Drug
SUBJECT: Caprelsa**

Revised: 3/1/22 – annual review, updated referenced policies & covered LOBs



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 231.0

**SECTION: Commercial Drug
SUBJECT: Letrozole**

Applicable line of business:

Commercial	X	Medicaid	
Medicare		ACA	X
GHP Kids	X	Self-Insured	X

POLICY:

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for letrozole GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 487.0 Quantity Limit Exceptions

REQUIRED DEFINITIONS:

1. **Attachment** – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. **Exhibit** – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. **Devised** – the date the policy was implemented.
4. **Revised** – the date of every revision to the policy, including typographical and grammatical changes.
5. **Reviewed** – the date documenting the annual review if the policy has no revisions necessary.

ADDITIONAL DEFINITIONS:

1. **Formulary** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. **Non-formulary products** – those medications that are not included in the Formulary.
3. **Healthcare provider** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
4. **NCQA** – National Committee for Quality Assurance.
5. **Medically Necessary or Medical Necessity** – covered services rendered by a provider that the Health Plan determines are:



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 231.0

**SECTION: Commercial Drug
SUBJECT: Letrozole**

- A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
- B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
- C. In accordance with current standards of medical practice;
- D. Not primarily for the convenience of the Member, or the Member's Provider; and
- E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

PROCEDURE:

An exception for coverage of letrozole may be made for members who meet the following criteria:

- Medical record documentation of letrozole being used for a Food and Drug Administration (FDA) approved indication (breast cancer in postmenopausal women)

OR

- Medical record documentation that letrozole is prescribed by or in consultation with a reproductive specialist or infertility specialist **AND**
- Medical record documentation of infertility associated with polycystic ovarian syndrome (PCOS) **OR**
- Medical record documentation of use for infertility not associated with polycystic ovarian syndrome (PCOS) **AND** medical record documentation of therapeutic failure on, intolerance to, or contraindication to clomiphene

MEDISPAN AUTHORIZATION LEVEL: GPI-12, generic only

If an exception is made, letrozole will be paid for under the member's prescription drug benefit.

Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.

FORMULARY ALTERNATIVES:

Female Infertility: clomiphene



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 231.0

**SECTION: Commercial Drug
SUBJECT: Letrozole**

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE
STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND
FEDERAL REGULATORY ENTITIES.**

**THIS POLICY WILL BE REVISED AS NECESSARY AND
REVIEWED NO LESS THAN ANNUALLY.**

Signed: _____

Title: Director, Pharmacy Services

Date: March 1, 2022

- Devised: 6/11
- Revised: 3/1/12 – annual review, updated signature
- Revised: 3/1/13 – annual review, updated logo and definitions, fixed typo
- Reviewed: 3/1/14 – annual review
- Revised: 3/1/15 – annual review, updated signature, removed Femara, updated formatting
- Revised: 3/1/16 – annual review, added FDA approved indication for clarity
- Revised: 5/1/16 – updated format, logo, & procedure
- Revised: 3/1/17 – annual review, defined FDA
- Revised: 3/1/18 – annual review, updated signature
- Reviewed: 3/1/19 – annual review
- Revised: 9/20/19 – added criteria section for PCOS, updated FA
- Revised: 3/1/20 – annual review, added GHP Kids
- Revised: 3/1/21 – annual review, updated logo, added MediSpan approval level
- Revised: 3/1/22 – annual review, updated referenced policies & covered LOBs



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 236.0

**SECTION: Commercial Drug
SUBJECT: Spacers for MDI**

Applicable line of business:

Commercial	X	Medicaid	
Medicare		ACA	X
GHP Kids	X	Self-Insured	X

POLICY:

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for spacers for MDI for GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 487.0 Quantity Limit Exceptions

REQUIRED DEFINITIONS:

1. **Attachment** – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. **Exhibit** – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. **Devised** – the date the policy was implemented.
4. **Revised** – the date of every revision to the policy, including typographical and grammatical changes.
5. **Reviewed** – the date documenting the annual review if the policy has no revisions necessary.

ADDITIONAL DEFINITIONS:

1. **Formulary** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. **Non-formulary products** – those medications that are not included in the Formulary.
3. **Healthcare provider** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
4. **NCQA** – National Committee for Quality Assurance.
5. **Medically Necessary or Medical Necessity** – covered services rendered by a provider that the Health Plan determines are:



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 236.0

**SECTION: Commercial Drug
SUBJECT: Spacers for MDI**

- A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
- B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
- C. In accordance with current standards of medical practice;
- D. Not primarily for the convenience of the Member, or the Member's Provider; and
- E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

PROCEDURE:

An exception for coverage of a spacer for a metered dose inhaler (MDI) may be made for members who meet the following criteria:

- Medical record documentation of therapeutic failure on OptiChamber

NOTE: The member will be charged 1 copay per unit

MEDISPAN AUTHORIZATION LEVEL: NDC-9

QUANTITY LIMIT: Members are limited to 2 spacers/masks per calendar year

If an exception is made, a Spacer for an MDI will be paid for under the member's prescription drug benefit.

Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.

FORMULARY ALTERNATIVES:

OptiChamber

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE
STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND
FEDERAL REGULATORY ENTITIES.**

**THIS POLICY WILL BE REVISED AS NECESSARY AND
REVIEWED NO LESS THAN ANNUALLY.**



POLICY NUMBER: 236.0

**POLICY AND PROCEDURE
PHARMACY
MANUAL**

**SECTION: Commercial Drug
SUBJECT: Spacers for MDI**

Signed: _____

Title: Director, Pharmacy Services

Date: March 1, 2022

Devised: 9/11
Revised: 3/1/12 – annual review, updated signature
Revised: 3/1/13 – annual review, updated logo and definitions
Reviewed: 3/1/14 – annual review
Revised: 3/1/15 – annual review, updated signature
Reviewed: 3/1/16 – annual review
Revised: 5/1/16 – updated format, logo, & procedure, added note and auth duration indicator
Reviewed: 3/1/17 – annual review
Revised: 3/1/18 – annual review, updated signature, corrected typo, defined MDI
Revised: 3/1/19 – annual review, defined MDI
Revised: 3/1/20 – annual review, added GHP Kids
Revised: 3/1/21 – annual review, updated logo, added MediSpan approval level
Revised: 3/1/22 – annual review, updated referenced policies & covered LOBs



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 237.0

**SECTION: Commercial Drug
SUBJECT: Daliresp**

Applicable line of business:

Commercial	X	Medicaid	
Medicare		ACA	X
GHP Kids	X	Self-Insured	X

POLICY:

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for Daliresp for GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 487.0 Quantity Limit Exceptions

REQUIRED DEFINITIONS:

1. **Attachment** – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. **Exhibit** – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. **Devised** – the date the policy was implemented.
4. **Revised** – the date of every revision to the policy, including typographical and grammatical changes.
5. **Reviewed** – the date documenting the annual review if the policy has no revisions necessary.

ADDITIONAL DEFINITIONS:

1. **Formulary** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. **Non-formulary products** – those medications that are not included in the Formulary.
3. **Healthcare provider** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
4. **NCQA** – National Committee for Quality Assurance.
5. **Medically Necessary or Medical Necessity** – covered services rendered by a provider that the Health Plan determines are:

- A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
- B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
- C. In accordance with current standards of medical practice;
- D. Not primarily for the convenience of the Member, or the Member's Provider; and
- E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

PROCEDURE:

An exception for coverage of Daliresp may be made for members who meet the following criteria:

- Medical record documentation of a diagnosis of chronic obstructive pulmonary disease (COPD) associated with chronic bronchitis **AND**
- Medical record documentation of therapeutic failure on, intolerance to, or contraindication to one long acting antimuscarinic antagonist and one long acting beta agonist

MEDISPAN AUTHORIZATION LEVEL: GPI-12

If an exception is made, Daliresp will be paid for under the member's prescription drug benefit.

Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.

FORMULARY ALTERNATIVES:

Long Acting Beta Agonists: Serevent Diskus

Beta Agonist/Corticosteroid Combinations: fluticasone/salmeterol, Wixela Inhub, Breo Ellipta

Short Acting Anticholinergics: ipratropium/albuterol nebulizer, Combivent, Atrovent

Long Acting Antimuscarinic Antagonists: Spiriva, Incruse Ellipta

Anticholinergic/Beta Agonist Combinations: Anoro Ellipta

Anticholinergic/Beta Agonist/Long Acting Anticholinergic Combinations: Trelegy Ellipta



POLICY NUMBER: 237.0

**POLICY AND PROCEDURE
PHARMACY
MANUAL**

**SECTION: Commercial Drug
SUBJECT: Daliresp**

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE
STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND
FEDERAL REGULATORY ENTITIES.**

**THIS POLICY WILL BE REVISED AS NECESSARY AND
REVIEWED NO LESS THAN ANNUALLY.**

Signed: _____

Title: Director, Pharmacy Services

Date: March 1, 2022

Devised: 2/12
Revised: 3/1/12 – annual review, updated signature
Revised: 3/1/13 – annual review, updated logo and definitions
Revised: 3/1/14 – annual review, removed Symbicort from FA, added Breo Ellipta & Tudorza to FA
Revised: 3/1/15 – annual review, updated signature, remove Tudorza Pressair from alternatives
Revised: 3/1/16 – annual review, updated FA bullet formatting
Revised: 5/1/16 – updated format, logo, & procedure
Revised: 12/7/16 – removed Foradil from FA
Reviewed: 3/1/17 – annual review
Revised: 3/1/18 – annual review, updated signature, defined COPD, updated FA
Revised: 3/1/19 – annual review, updated FA
Revised: 11/21/19 – updated FA
Revised: 3/1/20 – annual review, added GHP Kids
Revised: 10/12/20 – updated from failure of Spiriva to one LAMA, updated FA
Revised: 3/1/21 – annual review, updated logo, added MediSpan approval level
Revised: 3/1/22 – annual review, updated referenced policies & covered LOBs



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 238.0

**SECTION: Commercial Drug
SUBJECT: Dutasteride/Tamsulosin**

Applicable line of business:

Commercial	X	Medicaid	
Medicare		ACA	X
GHP Kids	X	Self-Insured	X

POLICY:

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for dutasteride/tamsulosin for GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 487.0 Quantity Limit Exceptions

REQUIRED DEFINITIONS:

1. **Attachment** – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. **Exhibit** – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. **Devised** – the date the policy was implemented.
4. **Revised** – the date of every revision to the policy, including typographical and grammatical changes.
5. **Reviewed** – the date documenting the annual review if the policy has no revisions necessary.

ADDITIONAL DEFINITIONS:

1. **Formulary** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. **Non-formulary products** – those medications that are not included in the Formulary.
3. **Healthcare provider** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
4. **NCQA** – National Committee for Quality Assurance.
5. **Medically Necessary or Medical Necessity** – covered services rendered by a provider that the Health Plan determines are:



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 238.0

**SECTION: Commercial Drug
SUBJECT: Dutasteride/Tamsulosin**

- A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
- B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
- C. In accordance with current standards of medical practice;
- D. Not primarily for the convenience of the Member, or the Member's Provider; and
- E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

PROCEDURE:

An exception for coverage of dutasteride/tamsulosin may be made for members who meet the following criteria:

- Medical record documentation of a diagnosis of benign prostatic hypertrophy **AND**
- Medical record documentation of a therapeutic failure on, intolerance to, or contraindication to a 3-month trial with formulary 5-alpha reductase inhibitors in combination with formulary alpha 1A antagonists

MEDISPAN AUTHORIZATION LEVEL: GPI-12, generic only

If an exception is made, dutasteride/tamsulosin will be paid for under the member's prescription drug benefit.

Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.

FORMULARY ALTERNATIVES:

5-alpha reductase inhibitors: finasteride, dutasteride

Alpha 1A antagonists: alfuzosin, doxazosin, tamsulosin, terazosin

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE
STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND
FEDERAL REGULATORY ENTITIES.**

**THIS POLICY WILL BE REVISED AS NECESSARY AND
REVIEWED NO LESS THAN ANNUALLY.**



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 238.0

**SECTION: Commercial Drug
SUBJECT: Dutasteride/Tamsulosin**

Signed: _____

Title: Director, Pharmacy Services

Date: March 1, 2022

- Devised: 2/12
- Revised: 3/1/12 – annual review, updated signature
- Revised: 3/1/13 – annual review, updated logo and definitions
- Reviewed: 3/1/14 – annual review
- Revised: 3/1/15 – annual review, updated signature
- Revised: 3/1/16 – annual review, updated Avodart to dutasteride
- Revised: 5/1/16 – updated format, logo, & procedure
- Revised: 3/1/17 – annual review, updated Jalyn to dutasteride/Tamsulosin
- Revised: 3/1/18 – annual review, updated signature
- Reviewed: 3/1/19 – annual review
- Revised: 3/1/20 – annual review, added GHP Kids
- Revised: 3/1/21 – annual review, updated logo, added MediSpan approval level
- Revised: 3/1/22 – annual review, updated referenced policies & covered LOBs



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 239.0

**SECTION: Commercial Drug
SUBJECT: Difucid**

Applicable line of business:

Commercial	X	Medicaid	
Medicare		ACA	X
GHP Kids	X	Self-Insured	X

POLICY:

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for Difucid for GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 BrandPolicy 487.0 Quantity Limit Exceptions

REQUIRED DEFINITIONS:

1. **Attachment** – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. **Exhibit** – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. **Devised** – the date the policy was implemented.
4. **Revised** – the date of every revision to the policy, including typographical and grammatical changes.
5. **Reviewed** – the date documenting the annual review if the policy has no revisions necessary.

ADDITIONAL DEFINITIONS:

1. **Formulary** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. **Non-formulary products** – those medications that are not included in the Formulary.
3. **Healthcare provider** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
4. **NCQA** – National Committee for Quality Assurance.
5. **Medically Necessary or Medical Necessity** – covered services rendered by a provider that the Health Plan determines are:
 - A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;

- B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
- C. In accordance with current standards of medical practice;
- D. Not primarily for the convenience of the Member, or the Member's Provider; and
- E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

PROCEDURE:

An exception for coverage of Dificid may be made for members who meet the following criteria:

- Medical record documentation of a diagnosis of Clostridium difficile associated diarrhea in members greater than or equal to 6 months of age **AND**
- Medical record documentation of therapeutic failure on, intolerance to, or contraindication to vancomycin capsules. Must try at least two courses of treatment, one course must be a taper or pulsed regimen

OR

- Initiation of therapy with Dificid in the hospital

MEDISPAN AUTHORIZATION LEVEL: GPI-10

QUANTITY LIMIT: *No QLs need to be entered within the authorization unless the requested quantity exceeds the QL.*

- **QL FOR LETTER ONLY:**
 - Tablets: 20 tablets per fill
 - Suspension: 150 mL per fill

AUTHORIZATION DURATION: 10 days, RX count 1

If a formulary exception is approved, Dificid will be paid for under the member's prescription drug benefit.

Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.

FORMULARY ALTERNATIVES:

vancomycin capsules, metronidazole



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 239.0

**SECTION: Commercial Drug
SUBJECT: Difucid**

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE
STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND
FEDERAL REGULATORY ENTITIES.**

**THIS POLICY WILL BE REVISED AS NECESSARY AND
REVIEWED NO LESS THAN ANNUALLY.**

Signed: _____

Title: Director, Pharmacy Services

Date: March 1, 2022

- Devised: 3/29/12
- Revised: 3/1/13 – annual review, updated logo
- Revised: 3/1/14 – annual review, added prescriber statement
- Revised: 3/1/15 – annual review, updated signature, updated formatting
- Revised: 3/1/16 – annual review, updated bullets to include “medical record documentation,” changed Vancocin to vancomycin
- Revised: 5/1/16 – updated format, logo, & procedure, added authorization duration indicator
- Revised: 3/1/17 – annual review, removed Unicode characters
- Revised: 3/1/18 – annual review, updated signature
- Revised: 8/21/18 – removed failure of metronidazole
- Revised: 3/1/19 – annual review, added QL approval note, added RX count
- Revised: 3/1/20 – annual review, added GHP Kids
- Revised: 7/28/20 – updated age to 6 months
- Revised: 3/1/21 – annual review, updated logo, added MediSpan approval level, updated QL statement
- Revised: 3/1/22 – annual review, updated referenced policies & covered LOBs and added suspension QL



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 242.0

**SECTION: Commercial Drug
SUBJECT: Bupropion XL
(generic Forfivo XL)**

Applicable line of business:

Commercial	X	Medicaid	
Medicare		ACA	X
GHP Kids	X	Self-Insured	X

POLICY:

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for bupropion XR (generic Forfivo XL) for GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 487.0 Quantity Limit Exceptions

REQUIRED DEFINITIONS:

1. **Attachment** – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. **Exhibit** – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. **Devised** – the date the policy was implemented.
4. **Revised** – the date of every revision to the policy, including typographical and grammatical changes.
5. **Reviewed** – the date documenting the annual review if the policy has no revisions necessary.

ADDITIONAL DEFINITIONS:

1. **Formulary** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. **Non-formulary products** – those medications that are not included in the Formulary.
3. **Healthcare provider** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
4. **NCQA** – National Committee for Quality Assurance.
5. **Medically Necessary or Medical Necessity** – covered services rendered by a provider that the Health Plan determines are:

- A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
- B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
- C. In accordance with current standards of medical practice;
- D. Not primarily for the convenience of the Member, or the Member's Provider; and
- E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

PROCEDURE:

New members to the plan already established on therapy may be eligible for continuity of care coverage as long as there is medical record documentation that the safety and effectiveness of use for the prescribed indication is supported by Food and Drug Administration (FDA) approval or adequate medical and scientific evidence in the medical literature.

An exception for coverage of bupropion XL (generic Forfivo XL) may be made for members who meet the following criteria:

- Medical record documentation of diagnosis of Major Depressive Disorder **AND**
- Medical record documentation of a therapeutic failure on, intolerance to, or contraindication to bupropion xl

MEDISPAN AUTHORIZATION LEVEL: GPI-14, generic only

QUANTITY LIMIT: *No QLs need to be entered within the authorization unless the requested quantity exceeds the QL.*

- **QL FOR LETTER ONLY:** 1 tablet per day

If a formulary exception is approved bupropion XL (generic Forfivo XL) will be paid for under the member's prescription drug benefit.

Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 242.0

**SECTION: Commercial Drug
SUBJECT: Bupropion XL
(generic Forfivo XL)**

FORMULARY ALTERNATIVES:

bupropion, bupropion sr, bupropion xl

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE STANDARDS
OF NCQA AND ANY OTHER APPLICABLE STATE AND FEDERAL REGULATORY
ENTITIES.**

**THIS POLICY WILL BE REVISED AS NECESSARY AND
REVIEWED NO LESS THAN ANNUALLY.**

Signed: _____

Title: Director, Pharmacy Services

Date: March 1, 2022

Devised: 3/29/12
Revised: 3/1/13 – annual review, updated logo and definitions
Revised: 3/1/14 – annual review, updated formatting, updated title
Revised: 3/1/15 – annual review, updated signature, updated formatting
Reviewed: 3/1/16 – annual review
Revised: 5/1/16 – updated format, logo, & procedure
Reviewed: 3/1/17 – annual review
Revised: 3/1/18 – annual review, updated signature, updated QL to daily dose, added grandfather language
Revised: 3/1/19 – annual review, added QL approval note
Revised: 3/1/20 – annual review, added GHP Kids
Revised: 3/1/21 – annual review, updated logo, added MediSpan approval level, updated QL statement, updated Forfivo to generic
Revised: 3/1/22 – annual review, updated referenced policies & covered LOBs



POLICY NUMBER: 243.0

**POLICY AND PROCEDURE
PHARMACY
MANUAL**

**SECTION: Commercial Drug
SUBJECT: Livalo**

Applicable line of business:

Commercial	X	Medicaid	
Medicare		ACA	X
GHP Kids	X	Self-Insured	X

POLICY:

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for Livalo for GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 469.0 Statin Quantity Limit Exceptions
- Policy 487.0 Quantity Limit Exceptions

REQUIRED DEFINITIONS:

1. **Attachment** – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. **Exhibit** – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. **Devised** – the date the policy was implemented.
4. **Revised** – the date of every revision to the policy, including typographical and grammatical changes.
5. **Reviewed** – the date documenting the annual review if the policy has no revisions necessary.

ADDITIONAL DEFINITIONS:

1. **Formulary** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. **Non-formulary products** – those medications that are not included in the Formulary.
3. **Healthcare provider** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
4. **NCQA** – National Committee for Quality Assurance.

5. **Medically Necessary or Medical Necessity** – covered services rendered by a provider that the Health Plan determines are:
- A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
 - B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
 - C. In accordance with current standards of medical practice;
 - D. Not primarily for the convenience of the Member, or the Member's Provider; and
 - E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

PROCEDURE:

An exception for coverage of Livalo may be made for members who meet the following criteria:

- Medical record documentation of member age greater than or equal to 8 years **AND**
- *For members greater than or equal to 10 years of age:* Medical record documentation of intolerance to, contraindication to, or therapeutic failure (including up-to-date laboratory values) to reach goal low-density lipoprotein (LDL) (per NCEP guidelines) after titration to tolerated doses of simvastatin **AND** atorvastatin **AND** rosuvastatin **OR**
- *For members greater than or equal to 8 years of age to less than 10 years of age:* Medical record documentation of intolerance to, contraindication to, or therapeutic failure (including up-to-date laboratory values) to reach goal low-density lipoprotein (LDL) (per NCEP guidelines) after titration to tolerated doses of rosuvastatin

MEDISPAN AUTHORIZATION LEVEL: GPI-12

If a formulary exception is approved Livalo will be paid for under the member's prescription drug benefit.

Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.

FORMULARY ALTERNATIVES:

Greater than or equal to 8 years of age to 10 years of age: rosuvastatin, pravastatin
Greater than or equal to 10 years of age: atorvastatin, lovastatin, pravastatin, simvastatin, rosuvastatin



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 243.0

**SECTION: Commercial Drug
SUBJECT: Livalo**

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE
STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND
FEDERAL REGULATORY ENTITIES.**

**THIS POLICY WILL BE REVISED AS NECESSARY AND
REVIEWED NO LESS THAN ANNUALLY.**

Signed: _____

Title: Director, Pharmacy Services

Date: March 1, 2022

Devised: 3/29/12
Revised: 1/25/13 – indicated prior authorization required for Crestor
Revised: 3/1/13 – annual review, updated logo and definitions
Reviewed: 3/1/14 – annual review
Revised: 3/1/15 – annual review, updated signature
Reviewed: 3/1/16 – annual review
Revised: 5/1/16 – updated format, logo, & procedure
Revised: 5/27/16 – updated Crestor to rosuvastatin
Reviewed: 3/1/17 – annual review
Revised: 3/1/18 – annual review, updated signature
Revised: 3/1/19 – annual review, defined LDL
Revised: 10/1/19 – added age criteria, split FA criteria by age, updated FA
Revised: 3/1/20 – annual review, added GHP Kids
Revised: 3/1/21 – annual review, updated logo, added MediSpan approval level
Revised: 3/1/22 – annual review, updated referenced policies & covered LOBs

Geisinger

**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 244.0

**SECTION: Commercial Drug
SUBJECT: Ferriprox**

Applicable line of business:

Commercial	X	Medicaid	
Medicare		ACA	X
GHP Kids	X	Self-Insured	X

POLICY:

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for Ferriprox for GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 487.0 Quantity Limit Exceptions

REQUIRED DEFINITIONS:

1. **Attachment** – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. **Exhibit** – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. **Devised** – the date the policy was implemented.
4. **Revised** – the date of every revision to the policy, including typographical and grammatical changes.
5. **Reviewed** – the date documenting the annual review if the policy has no revisions necessary.

ADDITIONAL DEFINITIONS:

1. **Formulary** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. **Non-formulary products** – those medications that are not included in the Formulary.
3. **Healthcare provider** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
4. **NCQA** – National Committee for Quality Assurance.
5. **Medically Necessary or Medical Necessity** – covered services rendered by a provider that the Health Plan determines are:

- A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
- B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
- C. In accordance with current standards of medical practice;
- D. Not primarily for the convenience of the Member, or the Member's Provider; and
- E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

PROCEDURE:

An exception for coverage of Ferriprox may be made for members who meet the following criteria:

- Medical record documentation that Ferriprox is prescribed by a hematologist **AND**
- Medical record documentation of being used for the treatment of transfusional iron overload due to one of the following:
 - Thalassemia syndromes **OR**
 - Sickle cell disease and other anemias*

AND

- Medical record documentation of therapeutic failure on, intolerance to, or contraindication to deferasirox (generic Exjade) **AND**
- Medical record documentation of absolute neutrophil count (ANC) greater than $1.5 \times 10^9/L$

***NOTE:** Safety and effectiveness of Ferriprox have not been established for the treatment of transfusional iron overload in patients with myelodysplastic syndrome or in patients with Diamond Blackfan anemia.

MEDISPAN AUTHORIZATION LEVEL: GPI-10

AUTHORIZATION DURATION: Initial approval will be for 6 months or less if the reviewing provider feels it is medically appropriate. Subsequent approvals will be for an additional 6 months or less if the reviewing provider feels it is medically appropriate and will require medical record documentation of serum ferritin level $> 300 \text{ mcg/L}$.

If a formulary exception is approved, Ferriprox will be paid for under the member's prescription drug benefit.

Geisinger

**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 244.0

**SECTION: Commercial Drug
SUBJECT: Ferriprox**

Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.

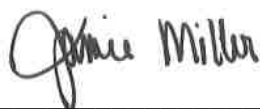
FORMULARY ALTERNATIVES:

deferasirox (generic Exjade)*

*prior authorization required

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE
STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND
FEDERAL REGULATORY ENTITIES.**

**THIS POLICY WILL BE REVISED AS NECESSARY AND
REVIEWED NO LESS THAN ANNUALLY.**



Signed: _____

Title: Director, Pharmacy Services

Date: March 1, 2022

Devised: 3/29/12
Revised: 3/1/13 – annual review, updated logo and definitions, fixed typo
Revised: 3/1/14 – annual review, indicated PA required on Exjade
Revised: 3/1/15 – annual review, updated signature
Revised: 3/1/16 – annual review, added “medical record documentation of” to Exjade bullet
Revised: 5/1/16 – updated format, logo, & procedure
Reviewed: 3/1/17 – annual review
Revised: 8/8/17 – added authorization duration
Revised: 3/1/18 – annual review, updated signature, updated prescribed criteria, defined Unicode
Revised: 3/1/19 – annual review, removed distribution information
Revised: 3/1/20 – annual review, added GHP Kids
Revised: 3/1/21 – annual review, updated logo, added MediSpan approval level, updated Exjade to generic
Revised: 11/19/21 – added indication for sickle cell disease & other anemias, added note
Revised: 3/1/22 – annual review, updated referenced policies & covered LOBs



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 245.0

**SECTION: Commercial Drug
SUBJECT: Erivedge**

Applicable line of business:

Commercial	X	Medicaid	
Medicare		ACA	X
GHP Kids	X	Self-Insured	X

POLICY:

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for Erivedge for GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 487.0 Quantity Limit Exceptions

REQUIRED DEFINITIONS:

1. **Attachment** – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. **Exhibit** – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. **Devised** – the date the policy was implemented.
4. **Revised** – the date of every revision to the policy, including typographical and grammatical changes.
5. **Reviewed** – the date documenting the annual review if the policy has no revisions necessary.

ADDITIONAL DEFINITIONS:

1. **Formulary** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. **Non-formulary products** – those medications that are not included in the Formulary.
3. **Healthcare provider** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
4. **NCQA** – National Committee for Quality Assurance.
5. **Medically Necessary or Medical Necessity** – covered services rendered by a provider that the Health Plan determines are:

- A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
- B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
- C. In accordance with current standards of medical practice;
- D. Not primarily for the convenience of the Member, or the Member's Provider; and
- E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

PROCEDURE:

New members to the plan already established on therapy may be eligible for continuity of care coverage as long as there is medical record documentation that the safety and effectiveness of use for the prescribed indication is supported by Food and Drug Administration (FDA) approval or adequate medical and scientific evidence in the medical literature.

An exception for coverage of Erivedge may be made for members who meet the following criteria:

- Medical record documentation that Erivedge is prescribed by an oncologist or dermatologist **AND**
- Medical record documentation of age greater than or equal to 18 years **AND**
- Medical record documentation of metastatic basal cell carcinoma, or locally advanced basal cell carcinoma that has recurred following surgery or for patients who are not candidates for surgery, and who are not candidates for radiation **AND**
- Medical record documentation of Erivedge treatment supported by multidisciplinary board consultation or a second dermatologist/oncologist per NCCN guidelines

MEDISPAN AUTHORIZATION LEVEL: GPI-12, number of claims authorized = 1, enter for the remainder of the calendar year

QUANTITY LIMIT: *No QLs need to be entered within the authorization unless the requested quantity exceeds the QL.*

- **QL FOR LETTER ONLY:** 1 capsule per day, 28 day supply per fill

RE-AUTHORIZATION CRITERIA: Erivedge is configured as a prior authorization for new starts only. Erivedge will no longer be covered if it is identified that the member is not receiving appropriate follow-up care from the prescribing specialist or if the member has greater than or equal to a 90 day break in therapy.

- Medical record documentation that the member is receiving appropriate follow-up care from the prescribing specialist

If a formulary exception is approved, Erivedge will be paid for under the member's prescription drug benefit.

Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.

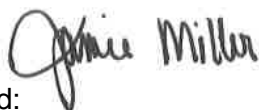
FORMULARY ALTERNATIVES:

Odomzo*

*prior authorization required

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE
STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND
FEDERAL REGULATORY ENTITIES.**

**THIS POLICY WILL BE REVISED AS NECESSARY AND
REVIEWED NO LESS THAN ANNUALLY.**



Signed: _____

Title: Director, Pharmacy Services

Date: March 1, 2022

Devised: 3/29/12
Revised: 3/1/13 – annual review, updated logo and definitions
Reviewed: 3/1/14 – annual review
Revised: 3/1/15 – annual review, updated signature, updated formatting
Revised: 11/20/15 – updated diagnosis requirements, added age requirement, updated FA
Reviewed: 3/1/16 – annual review



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 245.0

**SECTION: Commercial Drug
SUBJECT: Erivedge**

Revised: 5/1/16 – updated format, logo, & procedure, updated note to authorization duration
Revised: 3/1/17 – annual review, removed Unicode characters
Revised: 10/10/17 – increased authorization duration to 12 months
Revised: 3/1/18 – annual review, updated signature, added grandfather language, updated prescriber & age criteria, removed QL indicator, updated QL to daily dosing
Revised: 3/1/19 – annual review, added QL approval note, removed distribution information
Revised: 3/1/20 – annual review, added GHP Kids
Revised: 3/1/21 – annual review, updated logo, added MediSpan approval level, updated QL statement
Revised: 9/1/21 – updated QL to reflect package size of 28 capsules
Revised: 11/24/21 – added one-time PA to approval crit., removed auth duration & added re-auth crit.
Revised: 3/1/22 – annual review, updated referenced policies & covered LOBs



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 246.0

**SECTION: Commercial Drug
SUBJECT: Inlyta**

Applicable line of business:

Commercial	X	Medicaid	
Medicare		ACA	X
GHP Kids	X	Self-Insured	X

POLICY:

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for Inlyta for GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 487.0 Quantity Limit Exceptions

REQUIRED DEFINITIONS:

1. **Attachment** – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. **Exhibit** – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. **Devised** – the date the policy was implemented.
4. **Revised** – the date of every revision to the policy, including typographical and grammatical changes.
5. **Reviewed** – the date documenting the annual review if the policy has no revisions necessary.

ADDITIONAL DEFINITIONS:

1. **Formulary** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. **Non-formulary products** – those medications that are not included in the Formulary.
3. **Healthcare provider** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
4. **NCQA** – National Committee for Quality Assurance.
5. **Medically Necessary or Medical Necessity** – covered services rendered by a provider that the Health Plan determines are:



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 246.0

**SECTION: Commercial Drug
SUBJECT: Inlyta**

- A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
- B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
- C. In accordance with current standards of medical practice;
- D. Not primarily for the convenience of the Member, or the Member's Provider; and
- E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

PROCEDURE:

New members to the plan already established on therapy may be eligible for continuity of care coverage as long as there is medical record documentation that the safety and effectiveness of use for the prescribed indication is supported by Food and Drug Administration (FDA) approval or adequate medical and scientific evidence in the medical literature.

An exception for coverage of Inlyta may be made for members who meet the following criteria:

- Medical record documentation that Inlyta is prescribed by an oncologist **AND**
- Medical record documentation of advanced renal cell carcinoma (RCC) **AND**
- Medication record documentation of one of the following:
 - Medical record documentation of failure of one prior systemic therapy**OR**
 - Use as first-line treatment **AND**
 - Use in combination with pembrolizumab (Keytruda)**OR**
 - Use as first-line treatment **AND**
 - Used in combination with avelumab (Bavencio)

MEDISPAN AUTHORIZATION LEVEL: GPI-12, number of claims authorized = 1, enter for the remainder of the calendar year

QUANTITY LIMIT: *No QLs need to be entered within the authorization unless the requested quantity exceeds the QL.*

- **QL FOR LETTER ONLY:**
 - 1 mg tablet: 6 tablets per day, 30 day supply per fill
 - 5 mg tablet: 4 tablets per day, 30 day supply per fill



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 246.0

**SECTION: Commercial Drug
SUBJECT: Inlyta**

RE-AUTHORIZATION CRITERIA: Inlyta is configured as a prior authorization for new starts only. Inlyta will no longer be covered if it is identified that the member is not receiving appropriate follow-up care from the prescribing specialist or if the member has greater than or equal to a 90 day break in therapy.

- Medical record documentation that the member is receiving appropriate follow-up care from the prescribing specialist

If a formulary exception is approved, Inlyta will be paid for under the member's prescription drug benefit.

Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.

FORMULARY ALTERNATIVES:

Everolimus (generic Afinitor)*, Avastin*, Nexavar*, Proleukin, sunitinib*, Torisel*, Votrient*

*prior authorization required

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE
STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND
FEDERAL REGULATORY ENTITIES.**

**THIS POLICY WILL BE REVISED AS NECESSARY AND
REVIEWED NO LESS THAN ANNUALLY.**

Signed: _____

Title: Director, Pharmacy Services

Date: March 1, 2022

- Devised: 3/29/12
Revised: 3/1/13 – annual review, updated logo and definitions
Reviewed: 3/1/14 – annual review
Revised: 3/1/15 – annual review, updated signature
Revised: 3/1/16 – annual review, updated CuraScript to Accredo
Revised: 5/1/16 – updated format, logo, & procedure, added authorization duration indicator



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 246.0

**SECTION: Commercial Drug
SUBJECT: Inlyta**

- Reviewed: 3/1/17 – annual review
- Revised: 10/10/17 – increased authorization duration to 12 months
- Revised: 3/1/18 – annual review, updated signature, updated prescriber criteria, added grandfather language
- Revised: 6/1/18 – added QL
- Revised: 3/1/19 – annual review, added QL approval note, removed distribution information
- Revised: 3/1/20 – annual review, added GHP Kids
- Revised: 7/29/20 – added first line treatment with Keytruda or Bavencio
- Revised: 3/1/21 – annual review, updated logo, added MediSpan approval level, updated QL statement
- Revised: 11/24/21 – added one-time PA to approval crit., removed auth duration & added re-auth crit., updated FA
- Revised: 3/1/22 – annual review, updated referenced policies & covered LOBs, updated FA



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 247.0

**SECTION: Commercial Drug
SUBJECT: H.P. Acthar Gel**

Applicable line of business:

Commercial	X	Medicaid	
Medicare		ACA	X
GHP Kids	X	Self-Insured	X

POLICY:

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for H.P. Acthar Gel for GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 487.0 Quantity Limit Exceptions

REQUIRED DEFINITIONS:

1. **Attachment** – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. **Exhibit** – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. **Devised** – the date the policy was implemented.
4. **Revised** – the date of every revision to the policy, including typographical and grammatical changes.
5. **Reviewed** – the date documenting the annual review if the policy has no revisions necessary.

ADDITIONAL DEFINITIONS:

1. **Formulary** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. **Non-formulary products** – those medications that are not included in the Formulary.
3. **Healthcare provider** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
4. **NCQA** – National Committee for Quality Assurance.
5. **Medically Necessary or Medical Necessity** – covered services rendered by a provider that the Health Plan determines are:

- A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
- B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
- C. In accordance with current standards of medical practice;
- D. Not primarily for the convenience of the Member, or the Member's Provider; and
- E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

PROCEDURE:

An exception for coverage of H.P. Acthar Gel may be made for members who meet the following criteria:

For infantile myoclonic seizures (infantile spasms):

- Documentation that the member is less than 2 years of age **AND**
- Medical record documentation that H.P. Acthar Gel is prescribed by a neurologist **AND**
- Documentation of diagnosis confirmed by electroencephalogram (EEG)

For all other Indications:

- GHP considers H.P. Acthar Gel **not medically necessary** for diagnostic testing of adrenocortical function because it has not been shown to be superior to Cosyntropin for this test.
- GHP considers H.P. Acthar Gel **not medically necessary** for corticosteroid-responsive conditions because it has not been proven to be more effective than corticosteroids for these indications.
- GHP considers H.P. Acthar Gel **experimental and investigational** or unproven for all other indications because its effectiveness for these indications has not been established in peer-reviewed literature citing well-designed clinical trials to indicated that the member's healthcare outcome will be improved by using H.P. Acthar Gel.

MEDISPAN AUTHORIZATION LEVEL: GPI-12

AUTHORIZATION DURATION: Treatment period is defined as 28 days; a re-review is required at that time.



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 247.0

**SECTION: Commercial Drug
SUBJECT: H.P. Acthar Gel**

If a formulary exception is approved, H.P. Acthar Gel will be paid for under the member's prescription drug benefit.

Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.

FORMULARY ALTERNATIVES:

none

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE
STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND
FEDERAL REGULATORY ENTITIES.**

**THIS POLICY WILL BE REVISED AS NECESSARY AND
REVIEWED NO LESS THAN ANNUALLY.**

Signed: _____

Title: Director, Pharmacy Services

Date: March 1, 2022

Devised: 3/29/12
Revised: 12/12/12 – Removed indication specific criter. & added “criteria for all other indications”
Revised: 3/1/13 – annual review, updated logo and definitions
Revised: 3/1/14 – annual review, added exception statement, updated formatting
Revised: 3/1/15 – annual review, updated signature, updated formatting
Revised: 3/1/16 – annual review, added FA section
Revised: 5/1/16 – updated format, logo, & procedure, added authorization duration indicator
Reviewed: 3/1/17 – annual review
Revised: 3/1/18 – annual review, updated signature
Revised: 3/1/19 – annual review, updated formatting, defined EEG, removed Unicode character
Revised: 3/1/20 – annual review, added GHP Kids
Revised: 3/1/21 – annual review, updated logo, added MediSpan approval level
Revised: 3/1/22 – annual review, updated referenced policies & covered LOBs



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 249.0

**SECTION: Commercial Drug
SUBJECT: Cycloset**

Applicable line of business:

Commercial	X	Medicaid	
Medicare		ACA	X
GHP Kids	X	Self-Insured	X

POLICY:

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for Cycloset for GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 487.0 Quantity Limit Exceptions

REQUIRED DEFINITIONS:

1. **Attachment** – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. **Exhibit** – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. **Devised** – the date the policy was implemented.
4. **Revised** – the date of every revision to the policy, including typographical and grammatical changes.
5. **Reviewed** – the date documenting the annual review if the policy has no revisions necessary.

ADDITIONAL DEFINITIONS:

1. **Formulary** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. **Non-formulary products** – those medications that are not included in the Formulary.
3. **Healthcare provider** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
4. **NCQA** – National Committee for Quality Assurance.
5. **Medically Necessary or Medical Necessity** – covered services rendered by a provider that the Health Plan determines are:



POLICY NUMBER: 249.0

**POLICY AND PROCEDURE
PHARMACY
MANUAL**

**SECTION: Commercial Drug
SUBJECT: Cycloset**

- A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
- B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
- C. In accordance with current standards of medical practice;
- D. Not primarily for the convenience of the Member, or the Member's Provider; and
- E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

PROCEDURE:

An exception for coverage of Cycloset may be made for members who meet the following criteria:

- Medical record documentation of therapeutics failure on, intolerance to, or contraindication to 3 oral formulary alternatives

MEDISPAN AUTHORIZATION LEVEL: GPI-12

If a formulary exception is approved, Cycloset will be paid for under the member's prescription drug benefit.

Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.

FORMULARY ALTERNATIVES:

metformin, glyburide, glipizide, glipizide sustained-release, chlorpropamide, glimepiride, acarbose, miglitol, repaglinide, pioglitazone, Jardiance, Synjardy, Invokana, Invokamet, Tradjenta, Jentadueto, Rybelsus

*prior authorization required



POLICY NUMBER: 249.0

**POLICY AND PROCEDURE
PHARMACY
MANUAL**

**SECTION: Commercial Drug
SUBJECT: Cycloset**

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE STANDARDS OF
NCQA AND ANY OTHER APPLICABLE STATE AND FEDERAL REGULATORY
ENTITIES.**

**THIS POLICY WILL BE REVISED AS NECESSARY AND
REVIEWED NO LESS THAN ANNUALLY.**

Signed: _____

Title: Director, Pharmacy Services

Date: March 1, 2022

Devised: 6/21/12
Revised: 3/1/13 – annual review, updated logo and definitions
Revised: 3/1/14 – annual review, updated formatting, updated Prandin to generic repaglinide
Revised: 3/1/15 – annual review, updated signature, removed VII from alternatives, removed Byetta & Bydureon from alternatives, added Jardiance, Tanzeum & Victoza to alternatives, changed Actos to pioglitazone
Revised: 3/1/16 – annual review, added Toujeo, Synjardy, Invokana, & Invokamet to FA, updated PA/ST indicator
Revised: 5/1/16 – updated format, logo, & procedure
Reviewed: 3/1/17 – annual review
Revised: 3/1/18 – annual review, updated signature, updated FA
Revised: 3/1/19 – annual review, updated FA
Revised: 3/1/20 – annual review, added GHP Kids
Revised: 3/1/21 – annual review, updated logo, added MediSpan approval level
Revised: 3/1/22 – annual review, updated referenced policies & covered LOBs, updated FA



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 250.0

**SECTION: Commercial Drug
SUBJECT: Jakafi**

Applicable line of business:

Commercial	X	Medicaid	
Medicare		ACA	X
GHP Kids	X	Self-Insured	X

POLICY:

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for Jakafi for GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 487.0 Quantity Limit Exceptions

REQUIRED DEFINITIONS:

1. **Attachment** – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. **Exhibit** – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. **Devised** – the date the policy was implemented.
4. **Revised** – the date of every revision to the policy, including typographical and grammatical changes.
5. **Reviewed** – the date documenting the annual review if the policy has no revisions necessary.

ADDITIONAL DEFINITIONS:

1. **Formulary** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. **Non-formulary products** – those medications that are not included in the Formulary.
3. **Healthcare provider** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
4. **NCQA** – National Committee for Quality Assurance.
5. **Medically Necessary or Medical Necessity** – covered services rendered by a provider that the Health Plan determines are:

- A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
- B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
- C. In accordance with current standards of medical practice;
- D. Not primarily for the convenience of the Member, or the Member's Provider; and
- E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

PROCEDURE:

New members to the plan already established on therapy may be eligible for continuity of care coverage as long as there is medical record documentation that the safety and effectiveness of use for the prescribed indication is supported by Food and Drug Administration (FDA) approval or adequate medical and scientific evidence in the medical literature.

An exception for coverage of Jakafi may be made for members who meet the following criteria:

For Myelofibrosis

- Medical record documentation that Jakafi is prescribed by a hematologist/oncologist **AND**
- Medical record documentation of a diagnosis of intermediate or high-risk myelofibrosis, including primary myelofibrosis, post-polycythemia vera myelofibrosis or post-essential thrombocythemia myelofibrosis **AND**
- Medical record documentation of platelet count greater than or equal to $50 \times 10^9/L$ **AND**
- Medical record documentation of splenomegaly as measured by computed tomography (CT), magnetic resonance imaging (MRI), or ultrasound **AND**
- Medical record documentation of a baseline Total Symptom Score as measured by the modified Myelofibrosis Symptom Assessment Form (MFSAF) **AND**
- Medical record documentation that Jakafi will not be used concurrently with Inrebic

NOTE: Intermediate or High-Risk Myelofibrosis is defined by having at least 2 of the following factors:

- ✓ Age > 65 years
- ✓ WBC > $25 \times 10^9/L$
- ✓ Hemoglobin < 10 g/dL

- ✓ Blood Blasts \geq 1%
- ✓ Presence of Constitutional Symptoms (weight loss, fever, excessive sweats, etc.)
- ✓ Transfusion dependency
- ✓ Platelets less than $100 \times 10^9/L$
- ✓ Unfavorable karyotype

AUTHORIZATION DURATION: Each treatment period will be defined as six (6) months. Re-review with occur every six (6) months. Jakafi will no longer be covered if medical record documentation does not show:

- ✓ Medical record documentation of platelet count greater than or equal to $50 \times 10^9/L$ **AND**
- ✓ The member has achieved a reduction from pretreatment baseline of at least 35% in spleen volume as measured by computed tomography (CT), magnetic resonance imaging (MRI), or ultrasound **OR**
- ✓ The member has achieved a 50% or greater reduction in the Total Symptom Score from baseline as measured by the modified Myelofibrosis Symptom Assessment Form (MFSAF)

For Polycythemia Vera

- Medical record documentation of a diagnosis of polycythemia vera **AND**
- Medical record documentation that member requires phlebotomy **AND**
- Medical record documentation of splenomegaly **AND**
- Medical record documentation of an inadequate response or intolerance to hydroxyurea **AND**
- Medical record documentation of a therapeutic failure on, intolerance to, or contraindication to interferon therapy **OR** medical record documentation of post – polycythemia vera myelofibrosis with hydroxyurea-refractory symptomatic splenomegaly **OR** severe constitutional symptoms

AUTHORIZATION DURATION: Initial approval will be given for 6 months or less is the reviewing provider feels it is medically appropriate. Subsequent approvals will be for an additional 6 months or less if the reviewing provider feels it is medically appropriate and will require medical record documentation of continued disease improvement or lack of disease progression. The medication will no longer be covered if the member experiences unacceptable toxicity or worsening of disease.



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 250.0

**SECTION: Commercial Drug
SUBJECT: Jakafi**

For Graft versus Host Disease

- Medical record documentation that Jakafi is prescribed by a hematologist/oncologist or transplant specialist **AND**
- Medical record documentation of age greater than or equal to 12 years **AND**
- Medical record documentation of a diagnosis of steroid refractory graft-versus-host disease (GVHD) **OR**
- Medical record documentation of both of the following:
 - Documentation of a diagnosis of chronic graft-versus-host disease (cGVHD) **AND**
 - Documentation of therapeutic failure of one or two prior lines of systemic therapy

AUTHORIZATION DURATION: Initial approval will be given for 6 months or less if the reviewing provider feels it is medically appropriate. Subsequent approvals will be for an additional 6 months or less if the reviewing provider feels it is medically appropriate and will require medical record documentation of continued disease improvement or lack of disease progression. The medication will no longer be covered if the member experiences unacceptable toxicity or worsening of disease.

Note for GVHD: Tapering of Jakafi may be considered after 6 months of treatment in patients with response who have discontinued therapeutic doses of corticosteroids. Taper will take at least 4 months. If signs/symptoms recur during or after the taper, Jakafi can be restarted.

MEDISPAN AUTHORIZATION LEVEL: GPI-12

QUANTITY LIMIT (all indications): *No QLs need to be entered within the authorization unless the requested quantity exceeds the QL.*

- **QL FOR LETTER ONLY:** 2 tablets per day, 30 day supply per fill

If a formulary exception is approved, Jakafi will be paid for under the member's prescription drug benefit.

Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.

FORMULARY ALTERNATIVES:
none



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 250.0

**SECTION: Commercial Drug
SUBJECT: Jakafi**

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE STANDARDS OF
NCQA AND ANY OTHER APPLICABLE STATE AND FEDERAL REGULATORY
ENTITIES.**

**THIS POLICY WILL BE REVISED AS NECESSARY AND
REVIEWED NO LESS THAN ANNUALLY.**

Signed: _____

Title: Director, Pharmacy Services

Date: March 1, 2022

- Devised: 6/21/12
- Revised: 3/1/13 – annual review, updated logo and definitions
- Reviewed: 3/1/14 – annual review
- Revised: 2/9/15 – added polycythemia vera indication
- Reviewed: 3/1/15 – annual review
- Reviewed: 3/1/16 – annual review
- Revised: 5/1/16 – updated format, logo, & procedure
- Revised: 7/27/16 – updated platelet count to ≥ 50 for myelofibrosis, added transfusion dependency, platelets < 100, and unfavorable karyotype to intermediate/high risk definition, corrected refractory typo, changed SV to Accredo
- Reviewed: 3/1/17 – annual review
- Revised: 3/1/18 – annual review, updated signature, corrected 2 typos, updated prescribed criteria, added grandfather language, removed QL indicator
- Reviewed: 3/1/19 – annual review, defined abbr., removed Unicode characters, added QL approval note, removed distribution information
- Revised: 7/23/19 – added GVHD indication, indicated QL is for all indications
- Revised: 11/20/19 – added not to be used in combo with Inrebic for myelofibrosis
- Revised: 3/1/20 – annual review, added GHP Kids
- Revised: 3/1/21 – annual review, updated logo, added MediSpan approval level, updated QL statement
- Revised: 11/23/21 – added chronic GVHD indication
- Revised: 3/1/22 – annual review, updated referenced policies & covered LOBs



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 251.0

**SECTION: Commercial Drug
SUBJECT: Kalydeco**

Applicable line of business:

Commercial	X	Medicaid	
Medicare		ACA	X
GHP Kids	X	Self-Insured	X

POLICY:

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for Kalydeco for GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 487.0 Quantity Limit Exceptions

REQUIRED DEFINITIONS:

1. **Attachment** – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. **Exhibit** – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. **Devised** – the date the policy was implemented.
4. **Revised** – the date of every revision to the policy, including typographical and grammatical changes.
5. **Reviewed** – the date documenting the annual review if the policy has no revisions necessary.

ADDITIONAL DEFINITIONS:

1. **Formulary** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. **Non-formulary products** – those medications that are not included in the Formulary.
3. **Healthcare provider** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
4. **NCQA** – National Committee for Quality Assurance.
5. **Medically Necessary or Medical Necessity** – covered services rendered by a provider that the Health Plan determines are:



POLICY NUMBER: 251.0

**POLICY AND PROCEDURE
PHARMACY
MANUAL**

**SECTION: Commercial Drug
SUBJECT: Kalydeco**

- A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
- B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
- C. In accordance with current standards of medical practice;
- D. Not primarily for the convenience of the Member, or the Member's Provider; and
- E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

PROCEDURE:

An exception for coverage of Kalydeco may be made for members who meet the following criteria:

- Medical record documentation that Kalydeco is prescribed by a pulmonologist or cystic fibrosis specialist **AND**
- Medical record documentation of age greater than or equal to 4 months **AND**
- Medical record documentation of a diagnosis of cystic fibrosis **AND**
- Medical record documentation of one mutation in the cystic fibrosis transmembrane conductance regulator (CFTR) gene that is responsive to ivacaftor potentiation per product labeling as evidenced by a Food and Drug Administration (FDA) cleared cystic fibrosis mutation test **AND**
- Medical record documentation that the patient is not homozygous for the *F508del* mutation in the cystic fibrosis transmembrane conductance regulator (CFTR) gene

MEDISPAN AUTHORIZATION LEVEL: GPI-10

QUANTITY LIMIT: *No QLs need to be entered within the authorization unless the requested quantity exceeds the QL.*

- **QL FOR LETTER ONLY:** 2 tablets or granule packets per day, 30 day supply per fill

NOTE:

2789+5G→A	D110H	F1052V	G551S	R117H	S549R
3272-26A→G	D1152H	F1074L	K1060T	R347H	S945L
3849+10kbC→T	D1270N	G1069R	L206W	R352Q	S977F
711+3A→G	D579G	G1244E	P67L	R74W	
A1067T	E193K	G1349D	R1070Q	S1251N	
A455E	E56K	G178R	R1070W	S1255P	
D110E	E831X	G551D	R117C	S549N	



POLICY NUMBER: 251.0

**POLICY AND PROCEDURE
PHARMACY
MANUAL**

**SECTION: Commercial Drug
SUBJECT: Kalydeco**

AUTHORIZATION DURATION: Initial authorization period will be defined at four (4) months. Re-review will occur at this time. Additional authorization will require medical record documentation of improvement or stabilization in the signs and symptoms of cystic fibrosis.

After the initial four (4) month approval, subsequent approvals for coverage will be for a duration of one (1) year. Reevaluation of coverage will be every one (1) year requiring medical record documentation of improvement or stabilization in the signs and symptoms of cystic fibrosis.

If a formulary exception is approved, Kalydeco will be paid for under the member's prescription drug benefit.

Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.

FORMULARY ALTERNATIVES:

none

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE STANDARDS
OF NCQA AND ANY OTHER APPLICABLE STATE AND FEDERAL REGULATORY
ENTITIES.**

**THIS POLICY WILL BE REVISED AS NECESSARY AND
REVIEWED NO LESS THAN ANNUALLY.**

Signed: _____

Title: Director, Pharmacy Services

Date: March 1, 2022

- Devised: 6/21/12
- Revised: 3/1/13 – annual review, updated logo and definitions
- Revised: 7/29/13 – updated language regarding *F508del* mutation
- Reviewed: 3/1/14 – annual review
- Revised: 7/22/14 – added new gene mutations, added day supply limit, removed CuraScript as preferred



POLICY NUMBER: 251.0

**POLICY AND PROCEDURE
PHARMACY
MANUAL**

**SECTION: Commercial Drug
SUBJECT: Kalydeco**

vendor, updated signature

- Reviewed: 3/1/15 – annual review
- Revised: 4/13/15 – added *R117H* mutation to policy
- Revised: 7/22/15 – updated age to 2 years for all mutations except *R117H*
- Revised: 11/20/15 – removed duplicate section referencing *R117H*
- Reviewed: 3/1/16 – annual review
- Revised: 5/1/16 – updated format, logo, & procedure
- Revised: 3/1/17 – annual review, removed Unicode characters
- Revised: 10/3/17 – updated mutation chart
- Revised: 1/18/18 – updated format of prescriber & age criteria, increased auth duration to 4 months, updated signature, removed QL indicators

- Reviewed: 3/1/18 – annual review
- Revised: 7/27/18 – added CF specialist, added per labeling to mutation crit., moved table to note
- Revised: 2/6/19 – updated age to 12 months, added QL note to CSR
- Revised: 3/1/19 – annual review, defined abbr., removed distribution information
- Revised: 10/1/19 – updated age to 6 months
- Revised: 3/1/20 – annual review, added GHP Kids
- Revised: 3/1/21 – annual review, updated logo, added MediSpan approval level, updated QL statement
- Revised: 3/26/21 – updated age to 4 months
- Revised: 3/1/22 – annual review, updated referenced policies & covered LOBs



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 252.0

**SECTION: Commercial Drug
SUBJECT: Korlym**

Applicable line of business:

Commercial	X	Medicaid	
Medicare		ACA	X
GHP Kids	X	Self-Insured	X

POLICY:

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for Korlym for GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 487.0 Quantity Limit Exceptions

REQUIRED DEFINITIONS:

1. **Attachment** – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. **Exhibit** – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. **Devised** – the date the policy was implemented.
4. **Revised** – the date of every revision to the policy, including typographical and grammatical changes.
5. **Reviewed** – the date documenting the annual review if the policy has no revisions necessary.

ADDITIONAL DEFINITIONS:

1. **Formulary** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. **Non-formulary products** – those medications that are not included in the Formulary.
3. **Healthcare provider** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
4. **NCQA** – National Committee for Quality Assurance.
5. **Medically Necessary or Medical Necessity** – covered services rendered by a provider that the Health Plan determines are:



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 252.0

**SECTION: Commercial Drug
SUBJECT: Korlym**

- A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
- B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
- C. In accordance with current standards of medical practice;
- D. Not primarily for the convenience of the Member, or the Member's Provider; and
- E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

PROCEDURE:

An exception for coverage of Korlym may be made for members who meet the following criteria:

- Medical record documentation that Korlym is prescribed by an endocrinologist **AND**
- Medical record documentation of a negative pregnancy test within 14 days of initiating Korlym therapy in women of reproductive potential **AND**
- Medical record documentation of a diagnosis of endogenous Cushing's syndrome **AND**
- Medical record documentation of failed surgical treatment for Cushing's syndrome or that the patient is not a candidate for surgery **AND**
- Medical record documentation of therapeutic failure or, contraindication to, or intolerance to conventional therapy for hyperglycemic control

MEDISPAN AUTHORIZATION LEVEL: GPI-12

QUANTITY LIMIT: *No QLs need to be entered within the authorization unless the requested quantity exceeds the QL.*

- **QL FOR LETTER ONLY:** 4 tablets per day, 28 day supply per fill

If a formulary exception is approved, Korlym will be paid for under the member's prescription drug benefit.

Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 252.0

**SECTION: Commercial Drug
SUBJECT: Korlym**

FORMULARY ALTERNATIVES:

none

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE STANDARDS
OF NCQA AND ANY OTHER APPLICABLE STATE AND FEDERAL REGULATORY
ENTITIES.**

**THIS POLICY WILL BE REVISED AS NECESSARY AND
REVIEWED NO LESS THAN ANNUALLY.**

Signed: _____

Title: Director, Pharmacy Services

Date: March 1, 2022

Devised: 6/21/12
Revised: 3/1/13 – annual review, updated logo and definitions
Reviewed: 3/1/14 – annual review
Revised: 3/1/15 – annual review, updated signature, updated formatting
Revised: 3/1/16 – annual review, removed duplicate medical record documentation statement, updated CuraScript to Accredo
Revised: 5/1/16 – updated format, logo, & procedure
Reviewed: 3/1/17 – annual review
Revised: 3/1/18 – annual review, updated signature, removed QL indicator, added DS limit, updated prescriber criteria
Revised: 3/1/19 – annual review, added QL approval note, removed distribution information
Revised: 3/1/20 – annual review, added GHP Kids
Revised: 3/1/21 – annual review, updated logo, added MediSpan approval level, updated QL statement
Revised: 3/1/22 – annual review, updated referenced policies & covered LOBs



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 253.0

**SECTION: Commercial Drug
SUBJECT: Orenzia Subcutaneous (SC)**

Applicable line of business:

Commercial	X	Medicaid	
Medicare		ACA	X
GHP Kids	X	Self-Insured	X

POLICY:

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for Orenzia SC for GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 487.0 Quantity Limit Exceptions

REQUIRED DEFINITIONS:

1. **Attachment** – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. **Exhibit** – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. **Devised** – the date the policy was implemented.
4. **Revised** – the date of every revision to the policy, including typographical and grammatical changes.
5. **Reviewed** – the date documenting the annual review if the policy has no revisions necessary.

ADDITIONAL DEFINITIONS:

1. **Formulary** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. **Non-formulary products** – those medications that are not included in the Formulary.
3. **Healthcare provider** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
4. **NCQA** – National Committee for Quality Assurance.

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Dev. 6/21/12

Rev. 3/1/2022



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 253.0

**SECTION: Commercial Drug
SUBJECT: Orencia Subcutaneous (SC)**

5. **Medically Necessary or Medical Necessity** – covered services rendered by a provider that the Health Plan determines are:
- A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
 - B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
 - C. In accordance with current standards of medical practice;
 - D. Not primarily for the convenience of the Member, or the Member's Provider; and
 - E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

PROCEDURE:

New members to the plan already established on therapy may be eligible for continuity of care coverage as long as there is medical record documentation that the safety and effectiveness of use for the prescribed indication is supported by Food and Drug Administration (FDA) approval or adequate medical and scientific evidence in the medical literature.

For treatment of adult rheumatoid arthritis:

An exception for coverage of Orencia SC may be made for members who meet the following criteria:

- Medical record documentation that subcutaneous Orencia is prescribed by a rheumatologist **AND**
- Medical record documentation of a diagnosis of moderate to severe rheumatoid arthritis (made in accordance with the American College of Rheumatology Criteria for the Classification and Diagnosis of Rheumatoid Arthritis) **AND**
- Medical record documentation of age greater than or equal to 18 years **AND**
- Medical record documentation of therapeutic failure on, intolerance to, or contraindication to a minimum 3 month trial of Humira*, Rinvog*, OR Xeljanz* **AND**
- Medical record documentation that Orencia is not being used concurrently with a tumor necrosis factor (TNF) blocker or other biologic agent

MEDISPAN AUTHORIZATION LEVEL: GPI-12, number of claims authorized = 1, enter for the remainder of the calendar year



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 253.0

**SECTION: Commercial Drug
SUBJECT: Orencia Subcutaneous (SC)**

QUANTITY LIMIT: *No QLs need to be entered within the authorization unless the requested quantity exceeds the QL.*

- QL FOR LETTER ONLY: 4 syringes per 28 days

RE-AUTHORIZATION CRITERIA: Orencia is configured as a prior authorization for new starts only. Orencia will no longer be covered if it is identified that the member is not receiving appropriate follow-up care from the prescribing specialist or if the member has greater than or equal to a 90 day break in therapy.

- Medical record documentation that the member is receiving appropriate follow-up care from the prescribing specialist

FORMULARY ALTERNATIVES:

Humira*, Rinvoq*, Xeljanz*

*prior authorization required



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 253.0

**SECTION: Commercial Drug
SUBJECT: Orencia Subcutaneous (SC)**

For treatment of polyarticular juvenile idiopathic:

An exception for coverage of Orencia SC may be made for members who meet the following criteria:

- Medical record documentation of age greater than or equal to 2 years **AND**
- Medical record documentation of a diagnosis of moderate to severe polyarticular juvenile idiopathic arthritis or juvenile rheumatoid arthritis **AND**
- Medical record documentation that subcutaneous Orencia is prescribed by a rheumatologist **AND**
- Medical record documentation of an inadequate response to a minimum 4 month trial of one preferred tumor necrosis factor (TNF)-alpha inhibitor (Humira* **OR** Enbrel*) **AND**
- If Orencia ClickJect autoinjector is prescribed: Medical record documentation of age greater than or equal to 18 years **AND**
- Medical record documentation that Orencia is not being used concurrently with a tumor necrosis factor (TNF) blocker or other biologic agent

MEDISPAN AUTHORIZATION LEVEL: GPI-12, number of claims authorized = 1, enter for the remainder of the calendar year

QUANTITY LIMIT: *No QLs need to be entered within the authorization unless the requested quantity exceeds the QL.*

- QL FOR LETTER ONLY: 4 syringes per 28 days

RE-AUTHORIZATION CRITERIA: Orencia is configured as a prior authorization for new starts only. Orencia will no longer be covered if it is identified that the member is not receiving appropriate follow-up care from the prescribing specialist or if the member has greater than or equal to a 90 day break in therapy.

- Medical record documentation that the member is receiving appropriate follow-up care from the prescribing specialist

NOTE: The safety and efficacy of Orencia ClickJect autoinjector for subcutaneous injection has not been studied in patients under 18 years of age.

FORMULARY ALTERNATIVES:

Enbrel*, Humira*

*prior authorization required



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 253.0

**SECTION: Commercial Drug
SUBJECT: Orenzia Subcutaneous (SC)**

For treatment of psoriatic arthritis:

An exception for coverage of Orenzia SC may be made for members who meet the following criteria:

- Medical record documentation of age greater than or equal to 18 years **AND**
- Medical record documentation of a diagnosis of active psoriatic arthritis which must include the following:
 - Documentation of either active psoriatic lesions or a documented history of psoriasis **AND**
- Medical record documentation that subcutaneous Orenzia is prescribed by a rheumatologist or dermatologist **AND**
- Medical record documentation of therapeutic failure on, intolerance to, or contraindication to Cosentyx* **AND** Humira*
- Medical record documentation that Orenzia is not being used concurrently with a tumor necrosis factor (TNF) blocker or other biologic agent

MEDISPAN AUTHORIZATION LEVEL: GPI-12, number of claims authorized = 1, enter for the remainder of the calendar year

QUANTITY LIMIT: *No QLs need to be entered within the authorization unless the requested quantity exceeds the QL.*

- QL FOR LETTER ONLY: 4 syringes per 28 days

RE-AUTHORIZATION CRITERIA: Orenzia is configured as a prior authorization for new starts only. Orenzia will no longer be covered if it is identified that the member is not receiving appropriate follow-up care from the prescribing specialist or if the member has greater than or equal to a 90 day break in therapy.

- Medical record documentation that the member is receiving appropriate follow-up care from the prescribing specialist

NOTE: The safety and efficacy of Orenzia ClickJect autoinjector for subcutaneous injection has not been studied in patients under 18 years of age.

FORMULARY ALTERNATIVES:

Cosentyx*, Humira*

*prior authorization required



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 253.0

**SECTION: Commercial Drug
SUBJECT: Orencia Subcutaneous (SC)**

If a formulary exception is approved, Orencia SC** will be paid for under the member's prescription drug benefit.

Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE
STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND
FEDERAL REGULATORY ENTITIES.**

**THIS POLICY WILL BE REVISED AS NECESSARY AND
REVIEWED NO LESS THAN ANNUALLY.**

Signed: _____

Title: Director, Pharmacy Services

Date: March 1, 2022

Devised: 6/21/12
Revised: 3/1/13 – annual review, updated logo and definitions, fixed typo
Reviewed: 3/1/14 – annual review
Revised: 9/22/14 – updated diagnosis, joint count, and alternatives criteria, modified auth duration wording, updated signature and FA
Revised: 2/9/15 – updated alternatives criteria and formulary alternatives
Reviewed: 3/1/15 – annual review
Revised: 9/19/15 – removed joint count criteria from initial and renewal requirements
Revised: 3/1/16 – annual review, removed dup. medical record statement, updated formatting
Revised: 5/1/16 – updated format, logo, & procedure
Revised: 3/1/17 – annual review, removed Unicode characters
Revised: 10/9/17 – added JIA and PsA indications
Revised: 3/1/18 – annual review, updated signature, updated prescribed & age criteria, removed QL indicator, added grandfather language
Revised: 5/30/18 – added combination with other biologic agents, added history of PP for PsA, removed failure of Enbrel and added failure of Cosentyx (PsA)
Revised: 10/1/18 – removed failure of Enbrel & updated FA (RA)
Revised: 3/1/19 – annual review, added QL approval note, defined abbr.
Revised: 1/28/20 – updated RA FA and added failure of Rinvoq and Xeljanz
Revised: 3/1/20 – annual review, added GHP Kids
Revised: 3/1/21 – annual review, updated logo, added MediSpan approval level, updated QL statement

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Dev. 6/21/12

Rev. 3/1/2022



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 253.0

**SECTION: Commercial Drug
SUBJECT: Orenzia Subcutaneous (SC)**

Revised: 12/2/21 – added one-time PA to approval crit., removed auth duration & added re-auth crit.
Revised: 3/1/22 – annual review, updated referenced policies & covered LOBs



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 254.0

**SECTION: Commercial Drug
SUBJECT: Sylatron**

Applicable line of business:

Commercial	X	Medicaid	
Medicare		ACA	X
GHP Kids	X	Self-Insured	X

POLICY:

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for Sylatron for GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 487.0 Quantity Limit Exceptions

REQUIRED DEFINITIONS:

1. **Attachment** – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. **Exhibit** – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. **Devised** – the date the policy was implemented.
4. **Revised** – the date of every revision to the policy, including typographical and grammatical changes.
5. **Reviewed** – the date documenting the annual review if the policy has no revisions necessary.

ADDITIONAL DEFINITIONS:

1. **Formulary** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. **Non-formulary products** – those medications that are not included in the Formulary.
3. **Healthcare provider** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
4. **NCQA** – National Committee for Quality Assurance.
5. **Medically Necessary or Medical Necessity** – covered services rendered by a provider that the Health Plan determines are:



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 254.0

**SECTION: Commercial Drug
SUBJECT: Sylatron**

- A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
- B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
- C. In accordance with current standards of medical practice;
- D. Not primarily for the convenience of the Member, or the Member's Provider; and
- E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

PROCEDURE:

New members to the plan already established on therapy may be eligible for continuity of care coverage as long as there is medical record documentation that the safety and effectiveness of use for the prescribed indication is supported by Food and Drug Administration (FDA) approval or adequate medical and scientific evidence in the medical literature.

An exception for coverage of Sylatron may be made for members who meet the following criteria:

- Medical record documentation that Sylatron is prescribed by an oncologist or dermatologist **AND**
- Medical record documentation of a diagnosis of melanoma with microscopic or gross nodal involvement within 84 days of definitive surgical resection including complete lymphadenectomy

MEDISPAN AUTHORIZATION LEVEL: GPI-12

AUTHORIZATION DURATION: Each treatment period will be defined as twelve (12) months. Re-review will occur every twelve (12) months. Sylatron will no longer be covered if there is medical record documentation of disease progression.

If a formulary exception is approved, Sylatron will be paid for under the member's prescription drug benefit.

Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 254.0

**SECTION: Commercial Drug
SUBJECT: Sylatron**

FORMULARY ALTERNATIVES:

Intron A

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE
STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND
FEDERAL REGULATORY ENTITIES.**

**THIS POLICY WILL BE REVISED AS NECESSARY AND
REVIEWED NO LESS THAN ANNUALLY.**

Signed: _____

Title: Director, Pharmacy Services

Date: March 1, 2022

Devised: 6/21/12
Revised: 3/1/13 – annual review, updated logo and definitions
Reviewed: 3/1/14 – annual review
Revised: 3/1/15 – annual review, updated signature
Reviewed: 3/1/16 – annual review
Revised: 5/1/16 – updated format, logo, & procedure
Reviewed: 3/1/17 – annual review
Revised: 3/1/18 – annual review, updated signature, added grandfather language, updated prescriber criteria
Reviewed: 3/1/19 – annual review
Revised: 3/1/20 – annual review, added GHP Kids
Revised: 3/1/21 – annual review, updated logo, added MediSpan approval level
Revised: 3/1/22 – annual review, updated referenced policies & covered LOBs



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 255.0

**SECTION: Commercial Drug
SUBJECT: Xalkori**

Applicable line of business:

Commercial	X	Medicaid	
Medicare		ACA	X
GHP Kids	X	Self-Insured	X

POLICY:

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for Xalkori for GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 487.0 Quantity Limit Exceptions

REQUIRED DEFINITIONS:

1. **Attachment** – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. **Exhibit** – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. **Devised** – the date the policy was implemented.
4. **Revised** – the date of every revision to the policy, including typographical and grammatical changes.
5. **Reviewed** – the date documenting the annual review if the policy has no revisions necessary.

ADDITIONAL DEFINITIONS:

1. **Formulary** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. **Non-formulary products** – those medications that are not included in the Formulary.
3. **Healthcare provider** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
4. **NCQA** – National Committee for Quality Assurance.
5. **Medically Necessary or Medical Necessity** – covered services rendered by a provider that the Health Plan determines are:

- A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
- B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
- C. In accordance with current standards of medical practice;
- D. Not primarily for the convenience of the Member, or the Member's Provider; and
- E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

PROCEDURE:

New members to the plan already established on therapy may be eligible for continuity of care coverage as long as there is medical record documentation that the safety and effectiveness of use for the prescribed indication is supported by Food and Drug Administration (FDA) approval or adequate medical and scientific evidence in the medical literature.

An exception for coverage of Xalkori may be made for members who meet the following criteria:

Metastatic ALK-positive NSCLC

- Medical record documentation that Xalkori is prescribed by an oncologist **AND**
- Medical record documentation of locally advanced or metastatic non-small cell lung cancer (NSCLC) that is anaplastic lymphoma kinase (ALK) positive as detected by an FDA approved test **AND**
- Medical record documentation of therapeutic failure on, intolerance to, or contraindication to Alecensa

Metastatic ROS1-positive NSCLC

- Medical record documentation that Xalkori is prescribed by an oncologist **AND**
- Medical record documentation of a diagnosis of metastatic non-small cell lung cancer (NSCLC) that is ROS1-positive

Anaplastic Large Cell Lymphoma (ALCL)

- Medical record documentation that Xalkori is prescribed by a hematologist or oncologist **AND**
- Medical record documentation of age greater than or equal to 1 year of age **AND**
- Medical record documentation of a diagnosis of relapsed or refractory, systemic anaplastic large cell lymphoma (ALCL) that is anaplastic lymphoma kinase (ALK) positive **AND**
- Medical record documentation of at least one prior systemic treatment

NOTE: The FDA approved test is the Vysis ALK Break-Apart FISH Probe Kit

MEDISPAN AUTHORIZATION LEVEL: GPI-12, number of claims authorized = 1, enter for the remainder of the calendar year

QUANTITY LIMIT: *No QLs need to be entered within the authorization unless the requested quantity exceeds the QL.*

- **QL FOR LETTER ONLY:** 4 capsules per day, 30 day supply per fill

RE-AUTHORIZATION CRITERIA: Xalkori is configured as a prior authorization for new starts only. Xalkori will no longer be covered if it is identified that the member is not receiving appropriate follow-up care from the prescribing specialist or if the member has greater than or equal to a 90 day break in therapy.

- Medical record documentation that the member is receiving appropriate follow-up care from the prescribing specialist

If a formulary exception is approved, Xalkori will be paid for under the member's prescription drug benefit.

Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.

FORMULARY ALTERNATIVES:

Alecensa*, Zykadia*

*prior authorization required



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 255.0

**SECTION: Commercial Drug
SUBJECT: Xalkori**

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE
STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND
FEDERAL REGULATORY ENTITIES.**

**THIS POLICY WILL BE REVISED AS NECESSARY AND
REVIEWED NO LESS THAN ANNUALLY.**

Signed: _____

Title: Director, Pharmacy Services

Date: March 1, 2022

Devised: 6/21/12
Revised: 3/1/13 – annual review, updated logo and definitions
Reviewed: 3/1/14 – annual review
Revised: 3/1/15 – annual review, updated signature
Reviewed: 3/1/16 – annual review
Revised: 5/1/16 – updated format, logo, & procedure
Revised: 5/27/16 – added ROS1-positive NSCLC
Revised: 3/1/17 – annual review, updated QL to capsules
Revised: 10/10/17 – increased authorization duration to 12 months
Revised: 1/17/18 – separated indications, added failure of Alecensa for ALK+, updated prescriber criteria, updated FA, updated signature, updated QL
Revised: 3/1/18 – annual review, corrected typo, added grandfather language
Revised: 3/1/19 – annual review, added QL approval note
Revised: 3/1/20 – annual review, added GHP Kids
Revised: 3/1/21 – annual review, updated logo, added MediSpan approval level, updated QL statement
Revised: 3/26/21 – added ALCL indication, updated QL to 4 per day
Revised: 12/2/21 – added one-time PA to approval crit., removed auth duration & added re-auth crit.
Revised: 3/1/22 – annual review, updated referenced policies & covered LOBs



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 256.0

**SECTION: Commercial Drug
SUBJECT: Zelboraf**

Applicable line of business:

Commercial	X	Medicaid	
Medicare		ACA	X
GHP Kids	X	Self-Insured	X

POLICY:

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for Zelboraf for GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 487.0 Quantity Limit Exceptions

REQUIRED DEFINITIONS:

1. **Attachment** – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. **Exhibit** – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. **Devised** – the date the policy was implemented.
4. **Revised** – the date of every revision to the policy, including typographical and grammatical changes.
5. **Reviewed** – the date documenting the annual review if the policy has no revisions necessary.

ADDITIONAL DEFINITIONS:

1. **Formulary** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. **Non-formulary products** – those medications that are not included in the Formulary.
3. **Healthcare provider** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
4. **NCQA** – National Committee for Quality Assurance.
5. **Medically Necessary or Medical Necessity** – covered services rendered by a provider that the Health Plan determines are:



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 256.0

**SECTION: Commercial Drug
SUBJECT: Zelboraf**

- A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
- B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
- C. In accordance with current standards of medical practice;
- D. Not primarily for the convenience of the Member, or the Member's Provider; and
- E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

PROCEDURE:

New members to the plan already established on therapy may be eligible for continuity of care coverage as long as there is medical record documentation that the safety and effectiveness of use for the prescribed indication is supported by Food and Drug Administration (FDA) approval or adequate medical and scientific evidence in the medical literature.

An exception for coverage of Zelboraf may be made for members who meet the following criteria:

Metastatic Melanoma

- Medical record documentation that Zelboraf is prescribed by an oncologist or dermatologist **AND**
- Medical record documentation of a diagnosis of unresectable or metastatic melanoma **AND**
- Medical record documentation of a Food and Drug Administration (FDA)-approved test documenting the presence of the BRAF V600E mutation

Metastatic Melanoma

- Medical record documentation that Zelboraf is prescribed by an oncologist or dermatologist **AND**
- Medical record documentation of a diagnosis of Erdheim-Chester disease (ECD) **AND**
- Medical record documentation of a Food and Drug Administration (FDA)-approved test documenting the presence of the BRAF V600 mutation

NOTE: The FDA-approved test is the Cobas® 4800 BRAF V600 Mutation Test

MEDISPAN AUTHORIZATION LEVEL: GPI-12, number of claims authorized = 1, enter for the remainder of the calendar year



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 256.0

**SECTION: Commercial Drug
SUBJECT: Zelboraf**

QUANTITY LIMIT: *No QLs need to be entered within the authorization unless the requested quantity exceeds the QL.*

- **QL FOR LETTER ONLY:** 8 tablets per day, 30 day supply per fill

RE-AUTHORIZATION CRITERIA: Zelboraf is configured as a prior authorization for new starts only. Zelboraf will no longer be covered if it is identified that the member is not receiving appropriate follow-up care from the prescribing specialist or if the member has greater than or equal to a 90 day break in therapy.

- Medical record documentation that the member is receiving appropriate follow-up care from the prescribing specialist

If a formulary exception is approved, Zelboraf will be paid for under the member's prescription drug benefit.

Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.

FORMULARY ALTERNATIVES:

none

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE
STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND
FEDERAL REGULATORY ENTITIES.**

**THIS POLICY WILL BE REVISED AS NECESSARY AND
REVIEWED NO LESS THAN ANNUALLY.**

Signed: _____

Title: Director, Pharmacy Services

Date: March 1, 2022

Devised: 6/21/12
Revised: 3/1/13 – annual review, updated logo and definitions
Reviewed: 3/1/14 – annual review
Revised: 3/1/15 – annual review, updated signature

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Dev. 6/21/12

Rev. 3/1/22



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 256.0

**SECTION: Commercial Drug
SUBJECT: Zelboraf**

Reviewed: 3/1/16 – annual review
Revised: 5/1/16 – updated format, logo, & procedure
Reviewed: 3/1/17 – annual review
Revised: 10/10/17 – increased authorization duration to 12 months
Revised: 1/17/17 – updated prescriber criteria, separated indications, added ECD, updated QL, updated signature
Revised: 3/1/18 – annual review, corrected 2 typos, added grandfather language
Revised: 4/10/18 – defined FDA, updated ECD to BRAF V600 mutation
Revised: 3/1/19 – annual review, defined abbr., added QL approval note
Revised: 3/1/20 – annual review, added GHP Kids
Revised: 3/1/21 – annual review, updated logo, added MediSpan approval level, updated QL statement
Revised: 12/2/21 – added one-time PA to approval crit., removed auth duration & added re-auth crit.
Revised: 3/1/22 – annual review, updated referenced policies & covered LOBs



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 257.0

**SECTION: Commercial Drug
SUBJECT: Abiraterone**

Applicable line of business:

Commercial	X	Medicaid	
Medicare		ACA	X
GHP Kids	X	Self-Insured	X

POLICY:

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for abiraterone for GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 487.0 Quantity Limit Exceptions

REQUIRED DEFINITIONS:

1. **Attachment** – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. **Exhibit** – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. **Devised** – the date the policy was implemented.
4. **Revised** – the date of every revision to the policy, including typographical and grammatical changes.
5. **Reviewed** – the date documenting the annual review if the policy has no revisions necessary.

ADDITIONAL DEFINITIONS:

1. **Formulary** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. **Non-formulary products** – those medications that are not included in the Formulary.
3. **Healthcare provider** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
4. **NCQA** – National Committee for Quality Assurance.
5. **Medically Necessary or Medical Necessity** – covered services rendered by a provider that the Health Plan determines are:



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 257.0

**SECTION: Commercial Drug
SUBJECT: Abiraterone**

- A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
- B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
- C. In accordance with current standards of medical practice;
- D. Not primarily for the convenience of the Member, or the Member's Provider; and
- E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

PROCEDURE:

New members to the plan already established on therapy may be eligible for continuity of care coverage as long as there is medical record documentation that the safety and effectiveness of use for the prescribed indication is supported by Food and Drug Administration (FDA) approval or adequate medical and scientific evidence in the medical literature.

An exception for coverage of abiraterone may be made for members who meet the following criteria:

- Medical record documentation that abiraterone is prescribed by an oncologist or urologist **AND**
- Medical record documentation of a diagnosis of prostate cancer with evidence of metastatic disease **AND**
- Medical record documentation that prednisone will be administered concomitantly with abiraterone **AND**
- Medical record documentation of one of the following:
 - That the member is no longer responding to castration or is hormone resistant **OR**
 - That the member has high-risk[†], castration-sensitive disease

[†]**NOTE:** In clinical trials, patients were considered to be high risk if they had two of the following factors at baseline: a total Gleason score of greater than or equal to 8, presence of greater than or equal to 3 lesions on bone scan, and evidence of measurable visceral metastases.

MEDISPAN AUTHORIZATION LEVEL: GPI-14 (must enter 21406010200320 & 21406010200330), number of claims authorized = 1, enter for the remainder of the calendar year



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 257.0

**SECTION: Commercial Drug
SUBJECT: Abiraterone**

QUANTITY LIMIT: *No QLs need to be entered within the authorization unless the requested quantity exceeds the QL.*

- **QL FOR LETTER ONLY:**
 - 250 mg tablet: 4 tablets per day, 30 day supply per fill
 - 500 mg tablets: 2 tablets per day, 30 day supply per fill

RE-AUTHORIZATION CRITERIA: Abiraterone is configured as a prior authorization for new starts only. Abiraterone will no longer be covered if it is identified that the member is not receiving appropriate follow-up care from the prescribing specialist or if the member has greater than or equal to a 90 day break in therapy.

- Medical record documentation that the member is receiving appropriate follow-up care from the prescribing specialist

If a formulary exception is approved, abiraterone will be paid for under the member's prescription drug benefit.

Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.

FORMULARY ALTERNATIVES:

Xtandi*

*prior authorization required

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE
STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND
FEDERAL REGULATORY ENTITIES.**

**THIS POLICY WILL BE REVISED AS NECESSARY AND
REVIEWED NO LESS THAN ANNUALLY.**

Signed: _____

Title: Director, Pharmacy Services

Date: March 1, 2022

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Dev. 6/21/12

Rev. 3/1/22



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 257.0

**SECTION: Commercial Drug
SUBJECT: Abiraterone**

Devised: 6/21/12
Revised: 1/25/13 – Updated policy criteria
Revised: 3/1/13 – annual review, updated logo and definitions
Reviewed: 3/1/14 – annual review
Revised: 3/1/15 – annual review, updated signature
Reviewed: 3/1/16 – annual review
Revised: 5/1/16 – updated format, logo, & procedure
Reviewed: 3/1/17 – annual review
Revised: 10/10/17 – increased authorization duration to 12 months
Revised: 3/1/18 – annual review, updated signature, added grandfather language, updated prescribed criteria, removed QL indicator, updated FA
Revised: 6/1/18 – removed prednisone dosing, adding castration sensitive, added high risk note, updated QL
Revised: 8/7/18 – added concomitant prednisone
Revised: 3/1/19 – annual review, added QL approval note
Revised: 3/1/20 – annual review, added GHP Kids
Revised: 3/1/21 – annual review, updated logo, added MediSpan approval level, updated QL statement
Revised: 11/24/21 – updated policy to generic name, added one-time PA language to approval criteria, removed auth duration & added re-auth criteria
Revised: 3/1/22 – annual review, updated referenced policies & covered LOBs

Applicable line of business:

Commercial	X	Medicaid	
Medicare		ACA	X
GHP Kids	X	Self-Insured	X

POLICY:

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for Picato for GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 487.0 Quantity Limit Exceptions

REQUIRED DEFINITIONS:

1. **Attachment** – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. **Exhibit** – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. **Devised** – the date the policy was implemented.
4. **Revised** – the date of every revision to the policy, including typographical and grammatical changes.
5. **Reviewed** – the date documenting the annual review if the policy has no revisions necessary.

ADDITIONAL DEFINITIONS:

1. **Formulary** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. **Non-formulary products** – those medications that are not included in the Formulary.
3. **Healthcare provider** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
4. **NCQA** – National Committee for Quality Assurance.
5. **Medically Necessary or Medical Necessity** – covered services rendered by a provider that the Health Plan determines are:

- A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
- B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
- C. In accordance with current standards of medical practice;
- D. Not primarily for the convenience of the Member, or the Member's Provider; and
- E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

PROCEDURE:

An exception for coverage of Picato may be made for members who meet the following criteria:

- Medical record documentation that Picato is prescribed by a dermatologist **AND**
- Medical record documentation of greater than 4 lesions within a contiguous 25 cm² area **AND**
- Medical record documentation of a therapeutic failure on, intolerance to, or contraindication to topical fluorouracil

MEDISPAN AUTHORIZATION LEVEL: GPI-12

QUANTITY LIMIT: *No QLs need to be entered within the authorization unless the requested quantity exceeds the QL.*

- **QL FOR LETTER ONLY:** 1 package (2 or 3 tubes depending on strength) per dispensing

If an exception is made, Picato will be paid for under the member's prescription drug benefit.

Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.

FORMULARY ALTERNATIVES:

topical fluorouracil



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 258.0

**SECTION: Commercial Drug
SUBJECT: Picato**

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE
STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND
FEDERAL REGULATORY ENTITIES.**

**THIS POLICY WILL BE REVISED AS NECESSARY AND
REVIEWED NO LESS THAN ANNUALLY.**

Signed: _____

Title: Director, Pharmacy Services

Date: March 1, 2022

Devised: 7/18/12
Revised: 3/1/13 – annual review, updated logo, quantity limits, and definitions
Reviewed: 3/1/14 – annual review
Revised: 3/1/15 – annual review, updated signature
Reviewed: 3/1/16 – annual review
Revised: 5/1/16 – updated format, logo, & procedure
Reviewed: 3/1/17 – annual review
Revised: 3/1/18 – annual review, updated signature, updated prescriber criteria, removed QL indicator
Revised: 3/1/19 – annual review, added QL approval note
Revised: 3/1/20 – annual review, added GHP Kids
Revised: 3/1/21 – annual review, updated logo, added MediSpan approval level, updated QL statement
Revised: 3/1/22 – annual review, updated referenced policies & covered LOBs



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 259.0

**SECTION: Commercial Drug
SUBJECT: Pancreaze, Pertzye,
Viokace, and Zenpep**

Applicable line of business:

Commercial	X	Medicaid	
Medicare		ACA	X
GHP Kids	X	Self-Insured	X

POLICY:

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for Pancreaze, Pertzye, Viokace, and Zenpep for GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 487.0 Quantity Limit Exceptions

REQUIRED DEFINITIONS:

1. **Attachment** – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. **Exhibit** – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. **Devised** – the date the policy was implemented.
4. **Revised** – the date of every revision to the policy, including typographical and grammatical changes.
5. **Reviewed** – the date documenting the annual review if the policy has no revisions necessary.

ADDITIONAL DEFINITIONS:

1. **Formulary** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. **Non-formulary products** – those medications that are not included in the Formulary.
3. **Healthcare provider** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
4. **NCQA** – National Committee for Quality Assurance.
5. **Medically Necessary or Medical Necessity** – covered services rendered by a provider that the Health Plan determines are:



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 259.0

**SECTION: Commercial Drug
SUBJECT: Pancreaze, Pertzye,
Viokace, and Zenpep**

- A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
- B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
- C. In accordance with current standards of medical practice;
- D. Not primarily for the convenience of the Member, or the Member's Provider; and
- E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

PROCEDURE:

An exception for coverage of **Viokace** may be made for members who meet the following criteria:

- Medical record documentation of exocrine pancreatic insufficiency due to chronic pancreatitis or pancreatectomy **AND**
- Medical record documentation of age greater than or equal to 18 years **AND**
- Medical record documentation that Viokace is being prescribed in conjunction with a proton pump inhibitor **AND**
- Medical record documentation of therapeutic failure on, contraindication to, or intolerance to Creon

An exception for coverage of **Pancreaze, Pertzye, and Zenpep** may be made for members who meet the following criteria:

- Medical record documentation of exocrine pancreatic insufficiency **AND**
- Medical record documentation of therapeutic failure on, contraindication to, or intolerance to Creon

MEDISPAN AUTHORIZATION LEVEL: GPI-12

If an exception is made, Pancreaze, Pertzye, Viokace, or Zenpep will be paid for under the member's prescription drug benefit.

Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 259.0

**SECTION: Commercial Drug
SUBJECT: Pancreaze, Pertzye,
Viokace, and Zenpep**

FORMULARY ALTERNATIVES:
pancrelipase, Creon

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE
STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND
FEDERAL REGULATORY ENTITIES.**

**THIS POLICY WILL BE REVISED AS NECESSARY AND
REVIEWED NO LESS THAN ANNUALLY.**

Signed: _____

Title: Director, Pharmacy Services

Date: March 1, 2022

Devised: 7/18/12
Revised: 3/1/13 – annual review, updated logo and definitions
Reviewed: 3/1/14 – annual review
Revised: 3/1/15 – annual review, updated signature
Reviewed: 3/1/16 – annual review
Revised: 5/1/16 – updated format, logo, & procedure
Revised: 3/1/17 – annual review, removed Unicode characters, removed Ultresa (D/C by man.)
Revised: 3/1/18 – annual review, updated signature, updated age criteria
Reviewed: 3/1/19 – annual review
Revised: 3/1/20 – annual review, added GHP Kids
Revised: 10/12/20 – added Pancreaze & Zenpep to policy, removed failure of Zenpep
Revised: 3/1/21 – annual review, updated logo, added MediSpan approval level
Revised: 3/1/22 – annual review, updated referenced policies & covered LOBs



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 262.0

**SECTION: Commercial Drug
SUBJECT: Xtandi**

Applicable line of business:

Commercial	X	Medicaid	
Medicare		ACA	X
GHP Kids	X	Self-Insured	X

POLICY:

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for Xtandi for GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 487.0 Quantity Limit Exceptions

REQUIRED DEFINITIONS:

1. **Attachment** – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. **Exhibit** – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. **Devised** – the date the policy was implemented.
4. **Revised** – the date of every revision to the policy, including typographical and grammatical changes.
5. **Reviewed** – the date documenting the annual review if the policy has no revisions necessary.

ADDITIONAL DEFINITIONS:

1. **Formulary** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. **Non-formulary products** – those medications that are not included in the Formulary.
3. **Healthcare provider** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
4. **NCQA** – National Committee for Quality Assurance.
5. **Medically Necessary or Medical Necessity** – covered services rendered by a provider that the Health Plan determines are:



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 262.0

**SECTION: Commercial Drug
SUBJECT: Xtandi**

- A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
- B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
- C. In accordance with current standards of medical practice;
- D. Not primarily for the convenience of the Member, or the Member's Provider; and
- E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

PROCEDURE:

New members to the plan already established on therapy may be eligible for continuity of care coverage as long as there is medical record documentation that the safety and effectiveness of use for the prescribed indication is supported by Food and Drug Administration (FDA) approval or adequate medical and scientific evidence in the medical literature.

An exception for coverage of Xtandi may be made for members who meet the following criteria:

- Medical record documentation that Xtandi is prescribed by a hematologist, oncologist, or urologist **AND**
- Medical record documentation of a diagnosis of prostate cancer **AND**
- Medical record documentation of one of the following:
 - That the member is no longer responding to castration or is hormone resistant **OR**
 - That the member has metastatic castration-sensitive prostate cancer

AND

- Medical record documentation that a gonadotropin-releasing hormone (GnRH) analog will be used concurrently **OR** member has had bilateral orchiectomy

MEDISPAN AUTHORIZATION LEVEL: GPI-12, number of claims authorized = 1, enter for the remainder of the calendar year

QUANTITY LIMIT: *No QLs need to be entered within the authorization unless the requested quantity exceeds the QL.*

- **QL FOR LETTER ONLY:**
 - 40 mg capsules: 4 capsules per day, 30 day supply per fill
 - 40 mg tablets: 4 tablets per day, 30 day supply per fill
 - 80 mg tablets: 2 tablets per day, 30 day supply per fill



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 262.0

**SECTION: Commercial Drug
SUBJECT: Xtandi**

RE-AUTHORIZATION CRITERIA: Xtandi is configured as a prior authorization for new starts only. Xtandi will no longer be covered if it is identified that the member is not receiving appropriate follow-up care from the prescribing specialist or if the member has greater than or equal to a 90 day break in therapy.

- Medical record documentation that the member is receiving appropriate follow-up care from the prescribing specialist

If an exception is made, Xtandi will be paid for under the member's prescription drug benefit.

Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.

FORMULARY ALTERNATIVES:

abiraterone acetate*, Yonsa*, Zytiga*

*prior authorization required

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE
STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND
FEDERAL REGULATORY ENTITIES.**

**THIS POLICY WILL BE REVISED AS NECESSARY AND
REVIEWED NO LESS THAN ANNUALLY.**

Signed: _____

Title: Director, Pharmacy Services

Date: March 1, 2022

Devised: 11/7/12
Revised: 1/25/13 – Added authorization duration
Revised: 3/1/13 – annual review, updated logo and definitions
Revised: 2/1/14 – updated criteria to require failure on Zytiga
Reviewed: 3/1/14 – annual review
Revised: 12/1/14 – removed failure of docetaxel from criteria, updated signature
Revised: 3/1/15 – annual review, added PA indicator to Zytiga
Reviewed: 3/1/16 – annual review
Revised: 5/1/16 – updated format, logo, & procedure

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Dev. 11/7/12

Rev. 3/1/22



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 262.0

**SECTION: Commercial Drug
SUBJECT: Xtandi**

- Reviewed: 3/1/17 – annual review
- Revised: 10/10/17 – increased authorization duration to 12 months
- Revised: 3/1/18 – annual review, updated signature, updated prescriber criteria, added grandfather language, removed QL indicator, updated QL to daily dose
- Revised: 4/10/18 – removed failure of Zytiga
- Revised: 10/8/18 – removed metastatic requirement, defined castration resistant, added concurrent GnRH analog or orchiectomy
- Revised: 3/1/19 – annual review, added QL approval note, updated FA
- Revised: 1/28/20 – added indication for metastatic castration-sensitive prostate cancer
- Revised: 3/1/20 – annual review, added GHP Kids
- Revised: 3/1/21 – annual review, updated logo, added MediSpan approval level, updated QL statement, corrected abiraterone typo
- Revised: 6/7/21 – added QL for tablets
- Revised: 12/2/21 – added one-time PA to approval crit., removed auth duration & added re-auth crit.
- Revised: 3/1/22 – annual review, updated referenced policies & covered LOBs



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 263.0

**SECTION: Commercial Drug
SUBJECT: Bosulif**

Applicable line of business:

Commercial	X	Medicaid	
Medicare		ACA	X
GHP Kids	X	Self-Insured	X

POLICY:

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for Bosulif for GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 487.0 Quantity Limit Exceptions

REQUIRED DEFINITIONS:

1. **Attachment** – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. **Exhibit** – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. **Devised** – the date the policy was implemented.
4. **Revised** – the date of every revision to the policy, including typographical and grammatical changes.
5. **Reviewed** – the date documenting the annual review if the policy has no revisions necessary.

ADDITIONAL DEFINITIONS:

1. **Formulary** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. **Non-formulary products** – those medications that are not included in the Formulary.
3. **Healthcare provider** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
4. **NCQA** – National Committee for Quality Assurance.
5. **Medically Necessary or Medical Necessity** – covered services rendered by a provider that the Health Plan determines are:



POLICY NUMBER: 263.0

**POLICY AND PROCEDURE
PHARMACY
MANUAL**

**SECTION: Commercial Drug
SUBJECT: Bosulif**

- A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
- B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
- C. In accordance with current standards of medical practice;
- D. Not primarily for the convenience of the Member, or the Member's Provider; and
- E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

PROCEDURE:

New members to the plan already established on therapy may be eligible for continuity of care coverage as long as there is medical record documentation that the safety and effectiveness of use for the prescribed indication is supported by Food and Drug Administration (FDA) approval or adequate medical and scientific evidence in the medical literature.

An exception for coverage of Bosulif may be made for members who meet the following criteria:

Newly-diagnosed chronic phase Ph+ CML

- Medical record documentation that Bosulif is prescribed by a hematologist/oncologist **AND**
- Medical record documentation of newly-diagnosed chronic phase Philadelphia chromosome-positive (Ph+) chronic myelogenous leukemia (CML)

Chronic, accelerated, or blast phase Ph+ CML resistant or intolerant of prior therapy

- Medical record documentation that Bosulif is prescribed by a hematologist/oncologist **AND**
- Medical record documentation of chronic, accelerated, or blast phase Philadelphia chromosome-positive (Ph+) chronic myelogenous leukemia (CML) **AND**
- Medical record documentation of therapeutic failure on, intolerance to, or contraindication to one prior therapy (imatinib, Sprycel*, or Tasigna*)

MEDISPAN AUTHORIZATION LEVEL: GPI-12, number of claims authorized = 1, enter for the remainder of the calendar year



POLICY NUMBER: 263.0

**POLICY AND PROCEDURE
PHARMACY
MANUAL**

**SECTION: Commercial Drug
SUBJECT: Bosulif**

QUANTITY LIMIT: *No QLs need to be entered within the authorization unless the requested quantity exceeds the QL.*

- **QL FOR LETTER ONLY:**
 - 100 mg tablets: 3 tablets per day, 30 day supply per fill
 - 400 mg tablets: 1 tablet per day, 30 day supply per fill
 - 500 mg tablets: 1 tablet per day, 30 day supply per fill

RE-AUTHORIZATION CRITERIA: Bosulif is configured as a prior authorization for new starts only. Bosulif will no longer be covered if it is identified that the member is not receiving appropriate follow-up care from the prescribing specialist or if the member has greater than or equal to a 90 day break in therapy.

- Medical record documentation that the member is receiving appropriate follow-up care from the prescribing specialist

If an exception is made, Bosulif will be paid for under the member's prescription drug benefit.

Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.

FORMULARY ALTERNATIVES:

imatinib, Sprycel*, Tasigna*

*prior authorization required

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE
STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND
FEDERAL REGULATORY ENTITIES.**

**THIS POLICY WILL BE REVISED AS NECESSARY AND
REVIEWED NO LESS THAN ANNUALLY.**

Signed: _____

Title: Director, Pharmacy Services

Date: March 1, 2022

HPRX02

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Dev. 11/7/12

Rev. 3/1/22



POLICY NUMBER: 263.0

**POLICY AND PROCEDURE
PHARMACY
MANUAL**

**SECTION: Commercial Drug
SUBJECT: Bosulif**

Devised: 11/7/12
Revised: 1/25/13 – Added quantity limit and authorization duration
Revised: 3/1/13 – annual review, updated logo, quantity limits, and definitions
Reviewed: 3/1/14 – annual review
Revised: 3/1/15 – annual review, updated signature
Reviewed: 3/1/16 – annual review
Revised: 5/1/16 – updated format, logo, & procedure
Revised: 3/1/17 – annual review, updated Gleevec to imatinib
Revised: 10/10/17 – increased authorization duration to 12 months
Revised: 1/17/18 – updated to separate indications, updated prescriber criteria, added newly diagnosed, updated QL, defined abbreviations, updated signature
Revised: 3/1/18 – annual review, added grandfather language
Revised: 3/1/19 – annual review, added QL approval note
Revised: 3/1/20 – annual review, added GHP Kids
Revised: 3/1/21 – annual review, updated logo, added MediSpan approval level, updated QL statement
Revised: 11/24/21 – added one-time PA to approval crit., removed auth duration & added re-auth crit.
Revised: 3/1/22 – annual review, updated referenced policies & covered LOBs



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 264.0

**SECTION: Commercial Drug
SUBJECT: Azelastine/Fluticasone
Nasal Suspension**

Applicable line of business:

Commercial	X	Medicaid	
Medicare		ACA	X
GHP Kids	X	Self-Insured	X

POLICY:

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for azelastine/fluticasone nasal spray for GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 487.0 Quantity Limit Exceptions

REQUIRED DEFINITIONS:

1. **Attachment** – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. **Exhibit** – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. **Devised** – the date the policy was implemented.
4. **Revised** – the date of every revision to the policy, including typographical and grammatical changes.
5. **Reviewed** – the date documenting the annual review if the policy has no revisions necessary.

ADDITIONAL DEFINITIONS:

1. **Formulary** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. **Non-formulary products** – those medications that are not included in the Formulary.
3. **Healthcare provider** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
4. **NCQA** – National Committee for Quality Assurance.
5. **Medically Necessary or Medical Necessity** – covered services rendered by a provider that the Health Plan determines are:



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 264.0

**SECTION: Commercial Drug
SUBJECT: Azelastine/Fluticasone
Nasal Suspension**

- A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
- B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
- C. In accordance with current standards of medical practice;
- D. Not primarily for the convenience of the Member, or the Member's Provider; and
- E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

PROCEDURE:

An exception for coverage of azelastine/fluticasone nasal suspension may be made for members who meet the following criteria:

- Medical record documentation of age greater than or equal to 6 years **AND**
- Medical record documentation of therapeutic failure on, intolerance to, or contraindication to azelastine in combination with fluticasone

MEDISPAN AUTHORIZATION LEVEL: GPI-12, generic only

If an exception is made, azelastine/fluticasone nasal suspension will be paid for under the member's prescription drug benefit.

Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.

FORMULARY ALTERNATIVES:

azelastine nasal spray in combination with fluticasone nasal spray

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE
STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND
FEDERAL REGULATORY ENTITIES.**

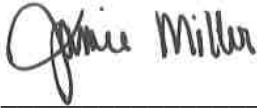
**THIS POLICY WILL BE REVISED AS NECESSARY AND
REVIEWED NO LESS THAN ANNUALLY.**

Geisinger

**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 264.0

**SECTION: Commercial Drug
SUBJECT: Azelastine/Fluticasone
Nasal Suspension**



Signed: _____

Title: Director, Pharmacy Services

Date: March 1, 2022

Devised: 11/7/12
Revised: 3/1/13 – annual review, updated logo and definitions
Reviewed: 3/1/14 – annual review
Revised: 3/1/15 – annual review, updated signature, updated alternatives
Revised: 7/22/15 – added age requirement
Reviewed: 3/1/16 – annual review
Revised: 5/1/16 – updated format, logo, & procedure
Revised: 3/1/17 – annual review, removed Unicode characters
Revised: 3/1/18 – annual review, updated signature
Reviewed: 3/1/19 – annual review
Revised: 3/1/20 – annual review, added GHP Kids
Revised: 3/1/21 – annual review, updated logo, added MediSpan approval level, updated to Dymista to generic
Revised: 3/1/22 – annual review, updated referenced policies & covered LOBs



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 265.0

**SECTION: Commercial Drug
SUBJECT: Albendazole**

Applicable line of business:

Commercial	X	Medicaid	
Medicare		ACA	X
GHP Kids	X	Self-Insured	X

POLICY:

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for albendazole for GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 487.0 Quantity Limit Exceptions

REQUIRED DEFINITIONS:

1. **Attachment** – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. **Exhibit** – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. **Devised** – the date the policy was implemented.
4. **Revised** – the date of every revision to the policy, including typographical and grammatical changes.
5. **Reviewed** – the date documenting the annual review if the policy has no revisions necessary.

ADDITIONAL DEFINITIONS:

1. **Formulary** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. **Non-formulary products** – those medications that are not included in the Formulary.
3. **Healthcare provider** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
4. **NCQA** – National Committee for Quality Assurance.
5. **Medically Necessary or Medical Necessity** – covered services rendered by a provider that the Health Plan determines are:



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 265.0

**SECTION: Commercial Drug
SUBJECT: Albendazole**

- A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
- B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
- C. In accordance with current standards of medical practice;
- D. Not primarily for the convenience of the Member, or the Member's Provider; and
- E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

PROCEDURE:

An exception for coverage of albendazole may be made for members who meet the following criteria:

- Medical record documentation of use for a Food and Drug Administration (FDA) approved indication (hydatid disease or neurocysticercosis)

MEDISPAN AUTHORIZATION LEVEL: GPI-12, generic only

If an exception is made, albendazole will be paid for under the member's prescription drug benefit.

Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.

FORMULARY ALTERNATIVES:

none

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE
STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND
FEDERAL REGULATORY ENTITIES.**

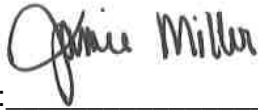
**THIS POLICY WILL BE REVISED AS NECESSARY AND
REVIEWED NO LESS THAN ANNUALLY.**

Geisinger

**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 265.0

**SECTION: Commercial Drug
SUBJECT: Albendazole**



Signed: _____

Title: Director, Pharmacy Services

Date: March 1, 2022

Devised: 11/7/12
Revised: 3/1/13 – annual review, updated logo and definitions
Reviewed: 3/1/14 – annual review
Revised: 3/1/15 – annual review, updated signature
Reviewed: 3/1/16 – annual review
Revised: 5/1/16 – updated format, logo, & procedure
Reviewed: 3/1/17 – annual review
Revised: 3/1/18 – annual review, updated signature, defined FDA
Reviewed: 3/1/19 – annual review
Revised: 11/21/19 – updated Albenza to generic albendazole
Revised: 3/1/20 – annual review, added GHP Kids
Revised: 3/1/21 – annual review, updated logo, added MediSpan approval level
Revised: 3/1/22 – annual review, updated referenced policies & covered LOBs



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 267.0

**SECTION: Commercial Drug
SUBJECT: Ivermectin Lotion
(generic Sklice)**

Applicable line of business:

Commercial	X	Medicaid	
Medicare		ACA	X
GHP Kids	X	Self-Insured	X

POLICY:

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for ivermectin lotion (generic Sklice) for GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 487.0 Quantity Limit Exceptions

REQUIRED DEFINITIONS:

1. **Attachment** – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. **Exhibit** – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. **Devised** – the date the policy was implemented.
4. **Revised** – the date of every revision to the policy, including typographical and grammatical changes.
5. **Reviewed** – the date documenting the annual review if the policy has no revisions necessary.

ADDITIONAL DEFINITIONS:

1. **Formulary** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. **Non-formulary products** – those medications that are not included in the Formulary.
3. **Healthcare provider** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
4. **NCQA** – National Committee for Quality Assurance.
5. **Medically Necessary or Medical Necessity** – covered services rendered by a provider that the Health Plan determines are:



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 267.0

**SECTION: Commercial Drug
SUBJECT: Ivermectin Lotion
(generic Sklice)**

- A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
- B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
- C. In accordance with current standards of medical practice;
- D. Not primarily for the convenience of the Member, or the Member's Provider; and
- E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

PROCEDURE:

An exception for coverage of ivermectin lotion (generic Sklice) may be made for members who meet the following criteria:

- Medical record documentation of age less than or equal to 2 years **AND** therapeutic failure on, intolerance to, or contraindication to over the counter (OTC) permethrin **OR**
- Medical record documentation of age greater than or equal to 2 years **AND** therapeutic failure on, intolerance to, or contraindication to over the counter (OTC) permethrin **AND** over the counter (OTC) pyrethrins

MEDISPAN AUTHORIZATION LEVEL: GPI-12, generic only

If an exception is made, ivermectin lotion (generic Sklice) will be paid for under the member's prescription drug benefit.

Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.

FORMULARY ALTERNATIVES:

lindane shampoo, malathion, spinosad



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 267.0

**SECTION: Commercial Drug
SUBJECT: Ivermectin Lotion
(generic Sklice)**

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE
STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND
FEDERAL REGULATORY ENTITIES.**

**THIS POLICY WILL BE REVISED AS NECESSARY AND
REVIEWED NO LESS THAN ANNUALLY.**

Signed: _____

Title: Director, Pharmacy Services

Date: March 1, 2022

Devised: 11/7/12
Revised: 3/1/13 – annual review, updated logo and definitions
Reviewed: 3/1/14 – annual review
Revised: 3/1/15 – annual review, updated signature
Reviewed: 3/1/16 – annual review
Revised: 5/1/16 – updated format, logo, & procedure
Revised: 3/1/17 – annual review, removed Unicode characters
Revised: 3/1/18 – annual review, updated signature
Revised: 3/1/19 – annual review, defined abbr.
Revised: 3/1/20 – annual review, added GHP Kids
Revised: 3/1/21 – annual review, updated logo, added MediSpan approval level, updated Sklice to generic
Revised: 3/1/22 – annual review, updated referenced policies & covered LOBs



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 268.0

**SECTION: Commercial Drug
SUBJECT: Tadalafil 2.5 mg and 5 mg**

Applicable line of business:

Commercial	X	Medicaid	
Medicare		ACA	X
GHP Kids	X	Self-Insured	X

POLICY:

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for tadalafil 2.5 mg and 5 mg for GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 487.0 Quantity Limit Exceptions

REQUIRED DEFINITIONS:

1. **Attachment** – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. **Exhibit** – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. **Devised** – the date the policy was implemented.
4. **Revised** – the date of every revision to the policy, including typographical and grammatical changes.
5. **Reviewed** – the date documenting the annual review if the policy has no revisions necessary.

ADDITIONAL DEFINITIONS:

1. **Formulary** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. **Non-formulary products** – those medications that are not included in the Formulary.
3. **Healthcare provider** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).

4. **NCQA** – National Committee for Quality Assurance.
5. **Medically Necessary or Medical Necessity** – covered services rendered by a provider that the Health Plan determines are:
 - A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
 - B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
 - C. In accordance with current standards of medical practice;
 - D. Not primarily for the convenience of the Member, or the Member's Provider; and
 - E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

PROCEDURE:

An exception for coverage of tadalafil 2.5 mg or 5 mg may be made for members who meet the following criteria:

- Medical record documentation of use to treat the signs and symptoms of benign prostatic hyperplasia **AND**
- Medical record documentation of therapeutic failure on, intolerance to, or contraindication to finasteride, dutasteride, alfuzosin, **AND** tamsulosin

MEDISPAN AUTHORIZATION LEVEL: GPI-14, generic only

If an exception is made, tadalafil 2.5 mg or 5 mg will be paid for under the member's prescription drug benefit.

Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.

FORMULARY ALTERNATIVES:

finasteride, alfuzosin, tamsulosin, dutasteride



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 268.0

**SECTION: Commercial Drug
SUBJECT: Tadalafil 2.5 mg and 5 mg**

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE
STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND
FEDERAL REGULATORY ENTITIES.**

**THIS POLICY WILL BE REVISED AS NECESSARY AND
REVIEWED NO LESS THAN ANNUALLY.**

Signed: _____

Title: Director, Pharmacy Services

Date: March 1, 2022

- Devised: 11/7/12
- Revised: 3/1/13 – annual review, updated logo and definitions
- Reviewed: 3/1/14 – annual review
- Revised: 3/1/15 – annual review, updated signature
- Revised: 3/1/16 – annual review, changed Avodart to dutasteride
- Revised: 5/1/16 – updated format, logo, & procedure
- Revised: 3/1/17 – annual review, clarified that policy only applies to 5 mg strength
- Revised: 3/1/18 – annual review, updated signature
- Revised: 3/1/19 – annual review, updated to generic name, added note
- Revised: 3/1/20 – annual review, added GHP Kids
- Revised: 3/1/21 – annual review, updated logo, added MediSpan approval level, deleted GPID note, added 2.5 mg dose to policy
- Revised: 3/1/22 – annual review, updated referenced policies & covered LOBs



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 269.0

**SECTION: Commercial Drug
SUBJECT: Stivarga**

Applicable line of business:

Commercial	X	Medicaid	
Medicare		ACA	X
GHP Kids	X	Self-Insured	X

POLICY:

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for Stivarga for GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 487.0 Quantity Limit Exceptions

REQUIRED DEFINITIONS:

1. **Attachment** – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. **Exhibit** – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. **Devised** – the date the policy was implemented.
4. **Revised** – the date of every revision to the policy, including typographical and grammatical changes.
5. **Reviewed** – the date documenting the annual review if the policy has no revisions necessary.

ADDITIONAL DEFINITIONS:

1. **Formulary** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. **Non-formulary products** – those medications that are not included in the Formulary.
3. **Healthcare provider** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
4. **NCQA** – National Committee for Quality Assurance.
5. **Medically Necessary or Medical Necessity** – covered services rendered by a provider that the Health Plan determines are:

- A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
- B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
- C. In accordance with current standards of medical practice;
- D. Not primarily for the convenience of the Member, or the Member's Provider; and
- E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

PROCEDURE:

New members to the plan already established on therapy may be eligible for continuity of care coverage as long as there is medical record documentation that the safety and effectiveness of use for the prescribed indication is supported by Food and Drug Administration (FDA) approval or adequate medical and scientific evidence in the medical literature.

An exception for coverage of Stivarga may be made for members who meet the following criteria:

Colorectal Cancer (CRC)

- Medical record documentation that Stivarga is prescribed by a hematologist or oncologist **AND**
- Medical record documentation of metastatic colorectal cancer (CRC) **AND**
- Medical record documentation of therapeutic failure on, intolerance to, or contraindication to three prior failures which must include treatment with the following drugs:
 - fluoropyrimidine (examples are capecitabine, floxuridine, or fluorouracil (5-FU)) – based chemotherapy
 - oxaliplatin – based chemotherapy
 - irinotecan – based chemotherapy
 - an anti – VEGF therapy (bevacizumab)
 - *if* KRAS wild type, an anti-EGFR therapy (cetuximab or panitumumab)

Gastrointestinal Stromal Tumor (GIST)

- Medical record documentation that Stivarga is prescribed by a hematologist or oncologist **AND**
- Medical record documentation of locally advanced, unresectable, or metastatic gastrointestinal stromal tumor (GIST) **AND**

- Medical record documentation of therapeutic failure on, intolerance to, or contraindication to imatinib mesylate (Gleevec) and sunitinib malate (Sutent*)

Hepatocellular Carcinoma

- Medical record documentation that Stivarga is prescribed by a hematologist or oncologist **AND**
- Medical record documentation of hepatocellular carcinoma **AND**
- Medical record documentation of therapeutic failure on, intolerance to, or contraindication to sorafenib (Nexavar)*

MEDISPAN AUTHORIZATION LEVEL: GPI-12, number of claims authorized = 1, enter for the remainder of the calendar year

QUANTITY LIMIT: *No QLs need to be entered within the authorization unless the requested quantity exceeds the QL.*

- **QL FOR LETTER ONLY:** 84 tablets per 28 days (4 tablets per day for 21 days of 28 day cycle)

RE-AUTHORIZATION CRITERIA: Stivarga is configured as a prior authorization for new starts only. Stivarga will no longer be covered if it is identified that the member is not receiving appropriate follow-up care from the prescribing specialist or if the member has greater than or equal to a 90 day break in therapy.

- Medical record documentation that the member is receiving appropriate follow-up care from the prescribing specialist

If an exception is made, Stivarga will be paid for under the member's prescription drug benefit.

Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.

FORMULARY ALTERNATIVES:

Metastatic Colorectal Cancer: capecitabine

Metastatic Gastrointestinal Stromal Tumor: imatinib, sunitinib*

Hepatocellular Carcinoma: Nexavar*

*prior authorization required



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 269.0

**SECTION: Commercial Drug
SUBJECT: Stivarga**

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE
STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND
FEDERAL REGULATORY ENTITIES.**

**THIS POLICY WILL BE REVISED AS NECESSARY AND
REVIEWED NO LESS THAN ANNUALLY.**

Signed: _____

Title: Director, Pharmacy Services

Date: March 1, 2022

Devised: 11/7/12
Revised: 1/25/13 – added authorization duration
Revised: 3/1/13 – annual review, updated logo and definitions, fixed typo
Revised: 6/24/13 – added GIST indication, updated formulary alternatives
Reviewed: 3/1/14 – annual review
Revised: 3/1/15 – annual review, updated signature
Revised: 3/1/16 – annual review, updated bullet format, changed Xeloda to capecitabine
Revised: 5/1/16 – updated format, logo, & procedure
Revised: 3/1/17 – annual review, updated Gleeevec to imatinib
Revised: 8/8/17 – added indication headers, added hepatocellular carcinoma, updated QL & FA
Revised: 10/10/17 – increased authorization duration to 12 months
Revised: 3/1/18 – annual review, updated signature, updated prescriber criteria, added grandfather language
Revised: 3/1/19 – annual review, added QL approval note
Revised: 3/1/20 – annual review, added GHP Kids
Revised: 3/1/21 – annual review, updated logo, added MediSpan approval level, updated QL statement
Revised: 12/1/21 – added one-time PA to approval crit., removed auth duration & added re-auth crit.
Revised: 1/5/22 – updated QL to reflect appropriate dosing
Revised: 3/1/22 – annual review, updated referenced policies & covered LOBs, updated FA



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 271.0

**SECTION: Commercial Drug
SUBJECT: Binosto**

Applicable line of business:

Commercial	X	Medicaid	
Medicare		ACA	X
GHP Kids	X	Self-Insured	X

POLICY:

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for Binosto for GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 487.0 Quantity Limit Exceptions

REQUIRED DEFINITIONS:

1. **Attachment** – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. **Exhibit** – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. **Devised** – the date the policy was implemented.
4. **Revised** – the date of every revision to the policy, including typographical and grammatical changes.
5. **Reviewed** – the date documenting the annual review if the policy has no revisions necessary.

ADDITIONAL DEFINITIONS:

1. **Formulary** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. **Non-formulary products** – those medications that are not included in the Formulary.
3. **Healthcare provider** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
4. **NCQA** – National Committee for Quality Assurance.
5. **Medically Necessary or Medical Necessity** – covered services rendered by a provider that the Health Plan determines are:



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 271.0

**SECTION: Commercial Drug
SUBJECT: Binosto**

- A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
- B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
- C. In accordance with current standards of medical practice;
- D. Not primarily for the convenience of the Member, or the Member's Provider; and
- E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

PROCEDURE:

An exception for coverage of Binosto may be made for members who meet the following criteria:

- Medical record documentation of treatment of osteoporosis in postmenopausal women **OR** treatment to increase bone mass in men with osteoporosis **AND**
- Medical record documentation of therapeutic failure on, intolerance to, or contraindication to generic alternatives in tablet form: ibandronate **AND** alendronate **AND** risedronate

MEDISPAN AUTHORIZATION LEVEL: GPI-12

If an exception is made, Binosto will be paid for under the member's prescription drug benefit.

Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.

FORMULARY ALTERNATIVES:

alendronate, ibandronate, risedronate

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE
STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND
FEDERAL REGULATORY ENTITIES.**

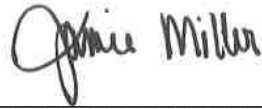
**THIS POLICY WILL BE REVISED AS NECESSARY AND
REVIEWED NO LESS THAN ANNUALLY.**

Geisinger

**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 271.0

**SECTION: Commercial Drug
SUBJECT: Binosto**



Signed: _____

Title: Director, Pharmacy Services

Date: March 1, 2022

Devised: 1/25/13
Revised: 3/1/13 – annual review, updated logo and definitions
Reviewed: 3/1/14 – annual review
Revised: 3/1/15 – annual review, updated signature
Revised: 3/1/16 – annual review, added risedronate to formulary alternatives
Revised: 5/1/16 – updated format, logo, & procedure
Reviewed: 3/1/17 – annual review
Revised: 3/27/17 – failure of risedronate
Revised: 3/1/18 – annual review, updated signature
Reviewed: 3/1/19 – annual review
Revised: 3/1/20 – annual review, added GHP Kids
Revised: 3/1/21 – annual review, updated logo, added MediSpan approval level
Revised: 3/1/22 – annual review, updated referenced policies & covered LOBs



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 272.0

**SECTION: Commercial Drug
SUBJECT: Latuda**

Applicable line of business:

Commercial	X	Medicaid	
Medicare		ACA	X
GHP Kids	X	Self-Insured	X

POLICY:

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for Latuda for GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 487.0 Quantity Limit Exceptions

REQUIRED DEFINITIONS:

1. **Attachment** – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. **Exhibit** – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. **Devised** – the date the policy was implemented.
4. **Revised** – the date of every revision to the policy, including typographical and grammatical changes.
5. **Reviewed** – the date documenting the annual review if the policy has no revisions necessary.

ADDITIONAL DEFINITIONS:

1. **Formulary** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. **Non-formulary products** – those medications that are not included in the Formulary.
3. **Healthcare provider** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
4. **NCQA** – National Committee for Quality Assurance.
5. **Medically Necessary or Medical Necessity** – covered services rendered by a provider that the Health Plan determines are:

- A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
- B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
- C. In accordance with current standards of medical practice;
- D. Not primarily for the convenience of the Member, or the Member's Provider; and
- E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

PROCEDURE:

New members to the plan already established on therapy may be eligible for continuity of care coverage as long as there is medical record documentation that the safety and effectiveness of use for the prescribed indication is supported by Food and Drug Administration (FDA) approval or adequate medical and scientific evidence in the medical literature.

An exception for coverage of Latuda may be made for members who meet the following criteria:

- Medical record documentation of a diagnosis of schizophrenia **AND**
- Medical record documentation of therapeutic failure on, intolerance to, or contraindication to three formulary atypical antipsychotics (olanzapine, risperidone, quetiapine, ziprasidone, aripiprazole) **OR**
- Medical record documentation of therapeutic failure on, intolerance to, or contraindication to ziprasidone and aripiprazole for members with metabolic syndrome

OR

- Medical record documentation of a diagnosis of depressive episodes associated with Bipolar I Disorder (bipolar depression) **AND**
- **For members 18 years of age or older:** Medical record documentation of therapeutic failure on, intolerance to, or contraindication to quetiapine

MEDISPAN AUTHORIZATION LEVEL: GPI-12



POLICY NUMBER: 272.0

**POLICY AND PROCEDURE
PHARMACY
MANUAL**

**SECTION: Commercial Drug
SUBJECT: Latuda**

If an exception is made, Latuda will be paid for under the member's prescription drug benefit.

Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.

FORMULARY ALTERNATIVES:

Schizophrenia: olanzapine, risperidone, quetiapine, ziprasidone, aripiprazole
Bipolar Depression: quetiapine

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE
STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND
FEDERAL REGULATORY ENTITIES.**

**THIS POLICY WILL BE REVISED AS NECESSARY AND
REVIEWED NO LESS THAN ANNUALLY.**

Signed: _____

Title: Director, Pharmacy Services

Date: March 1, 2022

Devised: 1/25/13
Revised: 3/1/13 – annual review, updated logo and definitions
Revised: 11/15/13 – added bipolar depression indication, updated formulary alternatives
Reviewed: 3/1/14 – annual review
Revised: 3/1/15 – annual review, updated signature
Revised: 3/1/16 – annual review, changed Abilify to aripiprazole
Revised: 5/1/16 – updated format, logo, & procedure
Reviewed: 3/1/17 – annual review
Revised: 3/1/18 – annual review, updated signature, added grandfather language
Revised: 5/30/18 – updated failure of quetiapine to only if over 18 for bipolar
Reviewed: 3/1/19 – annual review
Revised: 3/1/20 – annual review, added GHP Kids
Revised: 3/1/21 – annual review, updated logo, added MediSpan approval level
Revised: 3/1/22 – annual review, updated referenced policies & covered LOBs



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 273.0

**SECTION: Commercial Drug
SUBJECT: Xeljanz and Xeljanz XR**

Applicable line of business:

Commercial	X	Medicaid	
Medicare		ACA	X
GHP Kids	X	Self-Insured	X

POLICY:

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for Xeljanz and Xeljanz XR for GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 487.0 Quantity Limit Exceptions

REQUIRED DEFINITIONS:

1. **Attachment** – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. **Exhibit** – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. **Devised** – the date the policy was implemented.
4. **Revised** – the date of every revision to the policy, including typographical and grammatical changes.
5. **Reviewed** – the date documenting the annual review if the policy has no revisions necessary.

ADDITIONAL DEFINITIONS:

1. **Formulary** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. **Non-formulary products** – those medications that are not included in the Formulary.
3. **Healthcare provider** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
4. **NCQA** – National Committee for Quality Assurance.
5. **Medically Necessary or Medical Necessity** – covered services rendered by a provider that the Health Plan determines are:

- A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
- B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
- C. In accordance with current standards of medical practice;
- D. Not primarily for the convenience of the Member, or the Member's Provider; and
- E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

6. **DMARD** – *disease modifying anti-rheumatic drug*

PROCEDURE:

New members to the plan already established on therapy may be eligible for continuity of care coverage as long as there is medical record documentation that the safety and effectiveness of use for the prescribed indication is supported by Food and Drug Administration (FDA) approval or adequate medical and scientific evidence in the medical literature.

For treatment of rheumatoid arthritis

An exception for coverage of Xeljanz or Xeljanz XR may be made for members who meet the following criteria:

- Medical record documentation of a diagnosis of moderate to severe rheumatoid arthritis (made in accordance with the American College of Rheumatology Criteria for the Classification and Diagnosis of Rheumatoid Arthritis) **AND**
- Medical record documentation that Xeljanz or Xeljanz XR is prescribed by a rheumatologist **AND**
- Medical record documentation of age greater than or equal to 18 years **AND**
- Medical record documentation of therapeutic failure on, intolerance to, or contraindication to a minimum 3 month trial of Humira **AND**
- Medical record documentation that Xeljanz or Xeljanz XR is not being used concurrently with a tumor necrosis factor (TNF) blocker or other biologic agent **AND**
- Medical record documentation that Xeljanz or Xeljanz XR is being dosed consistent with Food and Drug Administration (FDA)-approved labeling

NOTE: Xeljanz 10 mg twice daily and Xeljanz XR 22 mg once daily are only indicated for the treatment of ulcerative colitis induction treatment and in cases of loss of response to maintenance treatment. The maximum recommended dosage for rheumatoid arthritis and psoriatic arthritis are Xeljanz 5 mg twice daily or Xeljanz XR 11 mg once daily.



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 273.0

**SECTION: Commercial Drug
SUBJECT: Xeljanz and Xeljanz XR**

MEDISPAN AUTHORIZATION LEVEL: GPI-14, number of claims authorized = 1, enter for the remainder of the calendar year

QUANTITY LIMIT: *No QLs need to be entered within the authorization unless the requested quantity exceeds the QL.*

- **QL FOR LETTER ONLY:**
 - Xeljanz 5 mg: 2 tablets per day, 30 day supply per fill
 - Xeljanz XR 11 mg: 1 tablet per day, 30 day supply per fill

RE-AUTHORIZATION CRITERIA: Xeljanz is configured as a prior authorization for new starts only. Xeljanz will no longer be covered if it is identified that the member is not receiving appropriate follow-up care from the prescribing specialist or if the member has greater than or equal to a 90 day break in therapy.

- Medical record documentation that the member is receiving appropriate follow-up care from the prescribing specialist

FORMULARY ALTERNATIVES:

azathioprine, cyclosporine, hydroxychloroquine, methotrexate, sulfasalazine, leflunomide, Depen, Ridaura

For treatment of psoriatic arthritis

An exception for coverage of Xeljanz or Xeljanz XR may be made for members who meet the following criteria:

- Medical record documentation of a diagnosis of moderately to severely active psoriatic arthritis which must include the following:
 - Documentation of either active psoriatic lesions or a documented history of psoriasis **AND**
- Medical record documentation of an inadequate response to or intolerance to a 3-month trial of methotrexate or another disease-modifying antirheumatic drug (DMARD) **AND**
- Medical record documentation that Xeljanz or Xeljanz XR is prescribed by a rheumatologist or dermatologist **AND**
- Medical record documentation that Xeljanz or Xeljanz XR is being prescribed in combination with non-biologic disease modifying antirheumatic drug (DMARD) therapy (including but not limited to methotrexate, sulfasalazine, and/or leflunomide) **AND**
- Medical record documentation of age greater than or equal to 18 years **AND**
- Medical record documentation of intolerance to, contraindication to, or therapeutic failure on a minimum 3 month trial of Humira* **AND** Cosentyx* **AND**
- Medical record documentation that Xeljanz or Xeljanz XR is not being used concurrently with a tumor necrosis factor (TNF) blocker or other biologic agent **AND**
- Medical record documentation that Xeljanz or Xeljanz XR is being dosed consistent with Food and Drug Administration (FDA)-approved labeling

NOTE: Xeljanz 10 mg twice daily and Xeljanz XR 22 mg once daily are only indicated for the treatment of ulcerative colitis induction treatment and in cases of loss of response to maintenance treatment. The maximum recommended dosage for rheumatoid arthritis and psoriatic arthritis are Xeljanz 5 mg twice daily or Xeljanz XR 11 mg once daily.

MEDISPAN AUTHORIZATION LEVEL: GPI-14, number of claims authorized = 1, enter for the remainder of the calendar year

QUANTITY LIMIT: *No QLs need to be entered within the authorization unless the requested quantity exceeds the QL.*

- **QL FOR LETTER ONLY:**
 - Xeljanz 5 mg: 2 tablets per day, 30 day supply per fill
 - Xeljanz XR 11 mg: 1 tablet per day, 30 day supply per fill



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 273.0

**SECTION: Commercial Drug
SUBJECT: Xeljanz and Xeljanz XR**

RE-AUTHORIZATION CRITERIA: Xeljanz is configured as a prior authorization for new starts only. Xeljanz will no longer be covered if it is identified that the member is not receiving appropriate follow-up care from the prescribing specialist or if the member has greater than or equal to a 90 day break in therapy.

- Medical record documentation that the member is receiving appropriate follow-up care from the prescribing specialist

FORMULARY ALTERNATIVES:

Cosentyx*, Humira*

*prior authorization required



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 273.0

**SECTION: Commercial Drug
SUBJECT: Xeljanz and Xeljanz XR**

For treatment of ulcerative colitis

An exception for coverage of Xeljanz may be made for members who meet the following criteria:

- Medical record documentation of a diagnosis of moderate to severe ulcerative colitis **AND**
- Medical record documentation that Xeljanz or Xeljanz XR is prescribed by a gastroenterologist **AND**
- Medical record documentation of age greater than or equal to 18 years **AND**
- Medical record documentation of intolerance to, contraindication to, or therapeutic failure on a minimum 3 month trial of Humira* **AND**
- Medical record documentation that Xeljanz is not being used concurrently with a tumor necrosis factor (TNF) blocker, potent immunosuppressant (e.g., azathioprine and cyclosporine), or other biologic agent

MEDISPAN AUTHORIZATION LEVEL: GPI-10, number of claims authorized = 1, enter for the remainder of the calendar year

QUANTITY LIMIT: *No QLs need to be entered within the authorization unless the requested quantity exceeds the QL.*

- **QL FOR LETTER ONLY:**
 - Xeljanz 5 mg or 10 mg*: 2 tablets per day, 30 day supply per fill.
 - Xeljanz XR 11 mg or 22 mg*: 1 tablet per day, 30 day supply per fill

RE-AUTHORIZATION CRITERIA: Xeljanz is configured as a prior authorization for new starts only. Xeljanz will no longer be covered if it is identified that the member is not receiving appropriate follow-up care from the prescribing specialist or if the member has greater than or equal to a 90 day break in therapy.

- Medical record documentation that the member is receiving appropriate follow-up care from the prescribing specialist

***NOTE:** Xeljanz 10 mg twice daily and Xeljanz XR 22 mg once daily are only indicated for the treatment of ulcerative colitis induction treatment and in cases of loss of response to maintenance treatment. These dosages are not recommended for the treatment of rheumatoid arthritis and psoriatic arthritis.

FORMULARY ALTERNATIVES:

Humira*

*prior authorization required



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 273.0

**SECTION: Commercial Drug
SUBJECT: Xeljanz and Xeljanz XR**

For treatment of polyarticular course juvenile idiopathic arthritis

An exception for coverage of Xeljanz may be made for members who meet the following criteria:

- Medical record documentation of a diagnosis of active polyarticular course juvenile idiopathic arthritis **AND**
- Medical record documentation of age greater than or equal to 2 years **AND**
- Medical record documentation that Xeljanz is prescribed by a rheumatologist **AND**
- Medical record documentation of an inadequate response to a minimum 3 month trial of Humira* **AND**
- Medical record documentation that Xeljanz is not being used concurrently with a tumor necrosis factor (TNF) blocker or other biologic agent **AND**
- Medical record documentation that Xeljanz or Xeljanz oral solution is being dosed consistent with Food and Drug Administration (FDA)-approved labeling

MEDISPAN AUTHORIZATION LEVEL: GPI-14, number of claims authorized = 1, enter for the remainder of the calendar year

NOTE: Xeljanz XR is not indicated for the treatment of pcJIA. The maximum dose for pcJIA is 5 mg (tablet or solution) twice daily. Xeljanz 10 mg twice daily and Xeljanz XR 22 mg once daily are only indicated for the treatment of ulcerative colitis induction treatment and in cases of loss of response to maintenance treatment.

QUANTITY LIMIT: *No QLs need to be entered within the authorization unless the requested quantity exceeds the QL.*

- **QL FOR LETTER ONLY:**
 - Xeljanz 5 mg: 2 tablets per day, 30 day supply per fill.
 - Xeljanz oral solution: 10 mL per day, 30 day supply per fill

RE-AUTHORIZATION CRITERIA: Xeljanz is configured as a prior authorization for new starts only. Xeljanz will no longer be covered if it is identified that the member is not receiving appropriate follow-up care from the prescribing specialist or if the member has greater than or equal to a 90 day break in therapy.

- Medical record documentation that the member is receiving appropriate follow-up care from the prescribing specialist

FORMULARY ALTERNATIVES:

Humira*

*prior authorization required



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 273.0

**SECTION: Commercial Drug
SUBJECT: Xeljanz and Xeljanz XR**

If an exception is made, Xeljanz or Xeljanz XR will be paid for under the member's prescription drug benefit.

Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE
STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND
FEDERAL REGULATORY ENTITIES.**

**THIS POLICY WILL BE REVISED AS NECESSARY AND
REVIEWED NO LESS THAN ANNUALLY.**

Signed: _____

Title: Director, Pharmacy Services

Date: June 7, 2022

- Devised: 1/25/13
- Revised: 3/1/13 – annual review, updated logo and definitions
- Reviewed: 3/1/14 – annual review
- Revised: 9/22/14 – updated diagnosis, joint count, and alternatives criteria, modified auth duration wording, updated signature and FA
- Revised: 2/9/15 – updated alternatives criteria and formulary alternatives
- Reviewed: 3/1/15 – annual review
- Revised: 9/19/15 – removed joint count criteria from initial and renewal requirements
- Reviewed: 3/1/16 – annual review
- Revised: 5/1/16 – updated format, logo, & procedure
- Revised: 7/27/16 – updated existing QL, added Xeljanz XR QL
- Revised: 3/1/17 – annual review, added Xeljanz XR
- Revised: 3/1/18 – annual review, updated signature, added grandfather language, updated prescriber criteria
- Revised: 4/10/18 – added indication headers, RA (added no other biologic language), added PsA, updated FA
- Revised: 5/31/18 – added DMARD failure to RA, moved FA
- Revised: 10/1/18 – removed failure of Enbrel & updated FA (RA)
- Revised: 11/28/18 – added UC indication, added QL note to RA & PsA
- Revised: 3/1/19 – annual review, defined abbr.
- Revised: 01/28/20 – removed failure of Humira, added prior biologic failure, updated FA (RA)
- Revised: 3/1/20 – annual review, added GHP Kids
- Revised: 6/4/20 – updated QL for RA/PsA to GPID, added Xeljanz XR for UC, updated UC QL & note
- Revised: 7/29/20 – added dosing criteria and note to RA AND PsA
- Revised: 3/1/21 – annual review, updated logo, added MediSpan approval level, updated QL statement,

Geisinger

**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 273.0

**SECTION: Commercial Drug
SUBJECT: Xeljanz and Xeljanz XR**

corrected typo in note

Revised: 3/26/21 – added pcJIA indication
Revised: 12/2/21 – added one-time PA to approval crit., removed auth duration & added re-auth crit.
Revised: 3/1/22 – annual review, updated referenced policies & covered LOBs
Revised: 6/7/22 – added failure of Humira & removed failure of MTX/other biologic for RA



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 274.0

**SECTION: Commercial Drug
SUBJECT: Omeclamox**

Applicable line of business:

Commercial	X	Medicaid	
Medicare		ACA	X
GHP Kids	X	Self-Insured	X

POLICY:

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for Omeclamox for GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 487.0 Quantity Limit Exceptions

REQUIRED DEFINITIONS:

1. **Attachment** – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. **Exhibit** – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. **Devised** – the date the policy was implemented.
4. **Revised** – the date of every revision to the policy, including typographical and grammatical changes.
5. **Reviewed** – the date documenting the annual review if the policy has no revisions necessary.

ADDITIONAL DEFINITIONS:

1. **Formulary** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. **Non-formulary products** – those medications that are not included in the Formulary.
3. **Healthcare provider** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
4. **NCQA** – National Committee for Quality Assurance.
5. **Medically Necessary or Medical Necessity** – covered services rendered by a provider that the Health Plan determines are:



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 274.0

**SECTION: Commercial Drug
SUBJECT: Omeclamox**

- A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
- B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
- C. In accordance with current standards of medical practice;
- D. Not primarily for the convenience of the Member, or the Member's Provider; and
- E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

PROCEDURE:

An exception for coverage of Omeclamox may be made for members who meet the following criteria:

- Medical record documentation of a confirmed *Helicobacter pylori* infection **AND**
- Medical record documentation of therapeutic failure on, intolerance to, or contraindication to a formulary proton pump inhibitor (omeprazole, pantoprazole, lansoprazole, rabeprazole) + amoxicillin + clarithromycin

MEDISPAN AUTHORIZATION LEVEL: GPI-12

If an exception is made, Omeclamox will be paid for under the member's prescription drug benefit.

Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.

FORMULARY ALTERNATIVES:

omeprazole, pantoprazole, lansoprazole, rabeprazole, esomeprazole, amoxicillin, clarithromycin

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE
STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND
FEDERAL REGULATORY ENTITIES.**

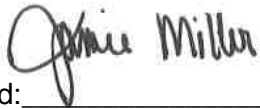
**THIS POLICY WILL BE REVISED AS NECESSARY AND
REVIEWED NO LESS THAN ANNUALLY.**

Geisinger

**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 274.0

**SECTION: Commercial Drug
SUBJECT: Omeclamox**



Signed: _____

Title: Director, Pharmacy Services

Date: March 1, 2022

Devised: 1/25/13
Revised: 3/1/13 – annual review, updated logo and definitions
Reviewed: 3/1/14 – annual review
Revised: 3/1/15 – annual review, updated signature, added rabeprazole to alternatives
Revised: 3/1/16 – annual review, removed DMARD definition
Revised: 5/1/16 – updated format, logo, & procedure
Reviewed: 3/1/17 – annual review
Revised: 3/1/18 – annual review, updated signature
Revised: 3/1/19 – annual review, updated FA
Revised: 3/1/20 – annual review, added GHP Kids
Revised: 3/1/21 – annual review, updated logo, added MediSpan approval level
Revised: 3/1/22 – annual review, updated referenced policies & covered LOBs



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 275.0

**SECTION: Commercial Drug
SUBJECT: Aubagio 7 mg**

Applicable line of business:

Commercial	X	Medicaid	
Medicare		ACA	X
GHP Kids	X	Self-Insured	X

POLICY:

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for Aubagio 7 mg for GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 487.0 Quantity Limit Exceptions

REQUIRED DEFINITIONS:

1. **Attachment** – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. **Exhibit** – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. **Devised** – the date the policy was implemented.
4. **Revised** – the date of every revision to the policy, including typographical and grammatical changes.
5. **Reviewed** – the date documenting the annual review if the policy has no revisions necessary.

ADDITIONAL DEFINITIONS:

1. **Formulary** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. **Non-formulary products** – those medications that are not included in the Formulary.
3. **Healthcare provider** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
4. **NCQA** – National Committee for Quality Assurance.
5. **Medically Necessary or Medical Necessity** – covered services rendered by a provider that the Health Plan determines are:

- A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
- B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
- C. In accordance with current standards of medical practice;
- D. Not primarily for the convenience of the Member, or the Member's Provider; and
- E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

PROCEDURE:

New members to the plan already established on therapy may be eligible for continuity of care coverage as long as there is medical record documentation that the safety and effectiveness of use for the prescribed indication is supported by Food and Drug Administration (FDA) approval or adequate medical and scientific evidence in the medical literature.

An exception for coverage of Aubagio 7 mg may be made for members who meet the following criteria:

- Medical record documentation of why patient is unable to utilize Aubagio 14 mg tablet once daily

MEDISPAN AUTHORIZATION LEVEL: GPI-14

QUANTITY LIMIT: *No QLs need to be entered within the authorization unless the requested quantity exceeds the QL.*

- **QL FOR LETTER ONLY:** 1 tablet per day, 28 day supply per fill

If an exception is made, Aubagio 7 mg will be paid for under the member's prescription drug benefit.

Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.

FORMULARY ALTERNATIVES:

Aubagio 14 mg, Avonex, Betaseron, glatiramer acetate, Extavia, Gilenya, Mayzent, Plegridy, Rebif, dimethyl fumarate



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 275.0

**SECTION: Commercial Drug
SUBJECT: Aubagio 7 mg**

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE
STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND
FEDERAL REGULATORY ENTITIES.**

**THIS POLICY WILL BE REVISED AS NECESSARY AND
REVIEWED NO LESS THAN ANNUALLY.**

Signed: _____

Title: Director, Pharmacy Services

Date: March 1, 2022

Devised: 1/25/13
Revised: 3/1/13 – annual review, updated logo and definitions
Revised: 3/1/14 – annual review, remove DMARD definition from policy
Revised: 4/1/14 – updated criteria to require Gilenya & Tecfidera in addition to Copaxone & Betaseron, updated alternatives
Revised: 12/1/14 – added grandfather provision, updated signature
Reviewed: 3/1/15 – annual review
Revised: 3/1/16 – annual review, update formatting of policy bullets
Revised: 5/1/16 – updated format, logo, & procedure
Revised: 1/25/17 – updated title to include 7 mg only, updated criteria for 7 mg only, added QL
Reviewed: 3/1/17 – annual review
Revised: 3/1/18 – annual review, updated signature, removed note & added grandfather criteria
Revised: 3/1/19 – annual review, added QL approval note, updated FA
Revised: 3/1/20 – annual review, added GHP Kids
Revised: 3/1/21 – annual review, updated logo, added MediSpan approval level, updated QL statement & FA
Revised: 3/1/22 – annual review, updated referenced policies & covered LOBs



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 276.0

**SECTION: Commercial Drug
SUBJECT: Absorica**

Applicable line of business:

Commercial	X	Medicaid	
Medicare		ACA	X
GHP Kids	X	Self-Insured	X

POLICY:

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for Absorica for GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 487.0 Quantity Limit Exceptions

REQUIRED DEFINITIONS:

1. **Attachment** – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. **Exhibit** – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. **Devised** – the date the policy was implemented.
4. **Revised** – the date of every revision to the policy, including typographical and grammatical changes.
5. **Reviewed** – the date documenting the annual review if the policy has no revisions necessary.

ADDITIONAL DEFINITIONS:

1. **Formulary** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. **Non-formulary products** – those medications that are not included in the Formulary.
3. **Healthcare provider** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
4. **NCQA** – National Committee for Quality Assurance.
5. **Medically Necessary or Medical Necessity** – covered services rendered by a provider that the Health Plan determines are:



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 276.0

**SECTION: Commercial Drug
SUBJECT: Absorica**

- A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
- B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
- C. In accordance with current standards of medical practice;
- D. Not primarily for the convenience of the Member, or the Member's Provider; and
- E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

PROCEDURE:

An exception for coverage of Absorica may be made for members who meet the following criteria:

- Medical record documentation a diagnosis of severe nodular acne **AND**
- Medical record documentation of therapeutic failure on, intolerance to, or contraindication to conventional therapy (includes systemic antibiotics and topicals) **AND**
- Medical record documentation of therapeutic failure on, intolerance to, or contraindication to Claravis **AND** Myorisan

MEDISPAN AUTHORIZATION LEVEL: GPI-12

If an exception is made, Absorica will be paid for under the member's prescription drug benefit.

Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.

FORMULARY ALTERNATIVES:

Topical Therapies

adapalene, benzoyl peroxide, topical clindamycin, clindamycin/benzoyl peroxide, topical erythromycin, erythromycin/benzoyl peroxide, isotretinoin, sulfur, topical tretinoin

Oral Therapies

doxycycline, minocycline, erythromycin, trimethoprim/sulfamethoxazole, azithromycin, Claravis, Myorisan, Zenatane, Amnesteem



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 276.0

**SECTION: Commercial Drug
SUBJECT: Absorica**

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE
STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND
FEDERAL REGULATORY ENTITIES.**

**THIS POLICY WILL BE REVISED AS NECESSARY AND
REVIEWED NO LESS THAN ANNUALLY.**

Signed: _____

Title: Director, Pharmacy Services

Date: March 1, 2022

Devised: 5/04/13
Reviewed: 3/1/14 – annual review
Revised: 3/1/15 – annual review, updated signature
Reviewed: 3/1/16 – annual review
Revised: 5/1/16 – updated format, logo, & procedure
Revised: 7/27/16 – removed failure of Amnesteem, updated FA
Revised: 3/1/17 – annual review, updated FA
Revised: 3/1/18 – annual review, updated signature, updated FA
Revised: 3/1/19 – annual review, updated FA
Revised: 3/1/20 – annual review, added GHP Kids
Revised: 3/1/21 – annual review, updated logo, added MediSpan approval level
Revised: 3/1/22 – annual review, updated referenced policies & covered LOBs



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 277.0

**SECTION: Commercial Drug
SUBJECT: Cometriq**

Applicable line of business:

Commercial	X	Medicaid	
Medicare		ACA	X
GHP Kids	X	Self-Insured	X

POLICY:

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for Cometriq for GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 487.0 Quantity Limit Exceptions

REQUIRED DEFINITIONS:

1. **Attachment** – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. **Exhibit** – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. **Devised** – the date the policy was implemented.
4. **Revised** – the date of every revision to the policy, including typographical and grammatical changes.
5. **Reviewed** – the date documenting the annual review if the policy has no revisions necessary.

ADDITIONAL DEFINITIONS:

1. **Formulary** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. **Non-formulary products** – those medications that are not included in the Formulary.
3. **Healthcare provider** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
4. **NCQA** – National Committee for Quality Assurance.
5. **Medically Necessary or Medical Necessity** – covered services rendered by a provider that the Health Plan determines are:



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 277.0

**SECTION: Commercial Drug
SUBJECT: Cometriq**

- A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
- B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
- C. In accordance with current standards of medical practice;
- D. Not primarily for the convenience of the Member, or the Member's Provider; and
- E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

PROCEDURE:

New members to the plan already established on therapy may be eligible for continuity of care coverage as long as there is medical record documentation that the safety and effectiveness of use for the prescribed indication is supported by Food and Drug Administration (FDA) approval or adequate medical and scientific evidence in the medical literature.

An exception for coverage of Cometriq may be made for members who meet the following criteria:

- Medical record documentation that Cometriq is prescribed by an oncologist **AND**
- Medical record documentation a diagnosis of progressive metastatic medullary thyroid cancer

MEDISPAN AUTHORIZATION LEVEL: GPI-12, number of claims authorized = 1, enter for the remainder of the calendar year

QUANTITY LIMIT: *No QLs need to be entered within the authorization unless the requested quantity exceeds the QL.*

- **QL FOR LETTER ONLY:**
 - 60 mg daily dose: 3 capsules per day, 28 day supply per fill
 - 100 mg daily dose: 2 capsules per day, 28 day supply per fill
 - 140 mg daily dose: 4 capsules per day, 28 day supply per fill

RE-AUTHORIZATION CRITERIA: Cometriq is configured as a prior authorization for new starts only. Cometriq will no longer be covered if it is identified that the member is not receiving appropriate follow-up care from the prescribing specialist or if the member has greater than or equal to a 90 day break in therapy.

- Medical record documentation that the member is receiving appropriate follow-up care from the prescribing specialist



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 277.0

**SECTION: Commercial Drug
SUBJECT: Cometriq**

If an exception is made, Cometriq will be paid for under the member's prescription drug benefit.

Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.

FORMULARY ALTERNATIVES:

Caprelsa*

*prior authorization required

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE
STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND
FEDERAL REGULATORY ENTITIES.**

**THIS POLICY WILL BE REVISED AS NECESSARY AND
REVIEWED NO LESS THAN ANNUALLY.**

Signed: _____

Title: Director, Pharmacy Services

Date: March 1, 2022

Devised: 5/4/13
Reviewed: 3/1/14 – annual review
Revised: 3/1/15 – annual review, updated signature
Reviewed: 3/1/16 – annual review
Revised: 5/1/16 – updated format, logo, & procedure
Reviewed: 3/1/17 – annual review
Revised: 10/10/17 – added authorization duration
Revised: 3/1/18 – annual review, updated signature, added grandfather language, updated prescriber criteria
Revised: 6/1/18 – added QL
Revised: 3/1/19 – annual review, added QL approval note
Revised: 3/1/20 – annual review, added GHP Kids
Revised: 3/1/21 – annual review, updated logo, added MediSpan approval level, updated QL statement
Revised: 11/24/21 – added one-time PA to approval crit., removed auth duration & added re-auth crit.
Revised: 3/1/22 – annual review, updated referenced policies & covered LOBs



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 278.0

**SECTION: Commercial Drug
SUBJECT: Iclusig**

Applicable line of business:

Commercial	X	Medicaid	
Medicare		ACA	X
GHP Kids	X	Self-Insured	X

POLICY:

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for Iclusig for GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 487.0 Quantity Limit Exceptions

REQUIRED DEFINITIONS:

1. **Attachment** – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. **Exhibit** – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. **Devised** – the date the policy was implemented.
4. **Revised** – the date of every revision to the policy, including typographical and grammatical changes.
5. **Reviewed** – the date documenting the annual review if the policy has no revisions necessary.

ADDITIONAL DEFINITIONS:

1. **Formulary** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. **Non-formulary products** – those medications that are not included in the Formulary.
3. **Healthcare provider** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
4. **NCQA** – National Committee for Quality Assurance.
5. **Medically Necessary or Medical Necessity** – covered services rendered by a provider that the Health Plan determines are:

- A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
- B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
- C. In accordance with current standards of medical practice;
- D. Not primarily for the convenience of the Member, or the Member's Provider; and
- E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

PROCEDURE:

New members to the plan already established on therapy may be eligible for continuity of care coverage as long as there is medical record documentation that the safety and effectiveness of use for the prescribed indication is supported by Food and Drug Administration (FDA) approval or adequate medical and scientific evidence in the medical literature.

An exception for coverage of Iclusig may be made for members who meet the following criteria:

- Medical record documentation that Iclusig is prescribed by a hematologist or oncologist **AND**
- Medical record documentation of age greater than or equal to 18 years **AND**
- Medical record documentation of one of the following:
 - Medical record documentation of T315I mutation positive chronic myeloid leukemia (CML) or Philadelphia chromosome positive acute lymphoblastic leukemia (Ph+ ALL)**OR**
 - Medical record documentation of a diagnosis of accelerated or blast phase chronic myeloid leukemia (CML) **OR** Philadelphia chromosome positive acute lymphoblastic leukemia (Ph+ ALL) **AND**
 - Medical record documentation of resistance or intolerance to all other indicated tyrosine kinase inhibitors, including but not limited to bosutinib, dasatinib, imatinib, and nilotinib**OR**
 - Medical record documentation of a diagnosis of chronic phase chronic myeloid leukemia (CML) **AND**
 - Medical record documentation of resistance or intolerance to at least two prior tyrosine kinase inhibitors



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 278.0

**SECTION: Commercial Drug
SUBJECT: Iclusig**

MEDISPAN AUTHORIZATION LEVEL: GPI-12, number of claims authorized = 1, enter for the remainder of the calendar year

QUANTITY LIMIT: *No QLs need to be entered within the authorization unless the requested quantity exceeds the QL.*

- QL FOR LETTER ONLY: 1 tablet per day, 30 day supply per fill

RE-AUTHORIZATION CRITERIA: Iclusig is configured as a prior authorization for new starts only. Iclusig will no longer be covered if it is identified that the member is not receiving appropriate follow-up care from the prescribing specialist or if the member has greater than or equal to a 90 day break in therapy.

- Medical record documentation that the member is receiving appropriate follow-up care from the prescribing specialist

If an exception is made, Iclusig will be paid for under the member's prescription drug benefit.

Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.

FORMULARY ALTERNATIVES:

imatinib, Sprycel*, Tasigna*, Bosulif*

*prior authorization required

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE
STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND
FEDERAL REGULATORY ENTITIES.**

**THIS POLICY WILL BE REVISED AS NECESSARY AND
REVIEWED NO LESS THAN ANNUALLY.**

Signed: 

Title: Director, Pharmacy Services

Date: March 1, 2022



POLICY NUMBER: 278.0

**POLICY AND PROCEDURE
PHARMACY
MANUAL**

**SECTION: Commercial Drug
SUBJECT: Iclusig**

Devised: 5/4/13
Reviewed: 3/1/14 – annual review
Revised: 3/1/15 – annual review, updated signature
Revised: 3/1/16 – annual review, updated formatting of authorization duration
Revised: 5/1/16 – updated format, logo, & procedure, updated Gleevec to imatinib
Reviewed: 3/1/17 – annual review
Revised: 10/10/17 – increased authorization duration to 12 months
Revised: 3/1/18 – annual review, updated signature, added grandfather language, updated prescriber criteria
Revised: 6/1/18 – added QL
Revised: 8/21/18 – removed CML from T315I mutation
Revised: 3/1/19 – annual review, added QL approval note
Revised: 3/1/20 – annual review, added GHP Kids
Revised: 3/1/21 – annual review, updated logo, added MediSpan approval level, updated QL statement
Revised: 3/26/21 – split indication to AP/BP CML & ALL after failure of all TKI; T315I positive; CP CML after failure of 2 TKI, updated QL
Revised: 11/24/21 – added one-time PA to approval crit., removed auth duration & added re-auth crit.
Revised: 3/1/22 – annual review, updated referenced policies & covered LOBs



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 279.0

**SECTION: Commercial Drug
SUBJECT: Linzess**

Applicable line of business:

Commercial	X	Medicaid	
Medicare		ACA	X
GHP Kids	X	Self-Insured	X

POLICY:

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for Linzess for GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 487.0 Quantity Limit Exceptions

REQUIRED DEFINITIONS:

1. **Attachment** – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. **Exhibit** – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. **Devised** – the date the policy was implemented.
4. **Revised** – the date of every revision to the policy, including typographical and grammatical changes.
5. **Reviewed** – the date documenting the annual review if the policy has no revisions necessary.

ADDITIONAL DEFINITIONS:

1. **Formulary** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. **Non-formulary products** – those medications that are not included in the Formulary.
3. **Healthcare provider** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
4. **NCQA** – National Committee for Quality Assurance.
5. **Medically Necessary or Medical Necessity** – covered services rendered by a provider that the Health Plan determines are:



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 279.0

**SECTION: Commercial Drug
SUBJECT: Linzess**

- A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
- B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
- C. In accordance with current standards of medical practice;
- D. Not primarily for the convenience of the Member, or the Member's Provider; and
- E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

PROCEDURE:

An exception for coverage of Linzess may be made for members who meet the following criteria:

- Medical record documentation of a diagnosis of irritable bowel syndrome with constipation or chronic idiopathic constipation **AND**
- Medical record documentation of age greater than or equal to 6 years **AND**
- Medical record documentation of therapeutic failure on, contraindication to, or intolerance to three alternative bowel therapies

MEDISPAN AUTHORIZATION LEVEL: GPI-12

If an exception is made, Linzess will be paid for under the member's prescription drug benefit.

Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.

FORMULARY ALTERNATIVES:

lactulose, polyethylene glycol

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE
STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND
FEDERAL REGULATORY ENTITIES.**

**THIS POLICY WILL BE REVISED AS NECESSARY AND
REVIEWED NO LESS THAN ANNUALLY.**



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 279.0

**SECTION: Commercial Drug
SUBJECT: Linzess**

Signed: _____

Title: Director, Pharmacy Services

Date: March 1, 2022

- Devised: 5/4/13
- Reviewed: 3/1/14 – annual review
- Revised: 3/1/15 – annual review, updated signature
- Revised: 3/1/16 – annual review
- Revised: 5/1/16 – updated format, logo, & procedure
- Revised: 3/1/17 – annual review, removed Unicode characters
- Revised: 3/1/18 – annual review, updated signature
- Reviewed: 3/1/19 – annual review
- Revised: 3/1/20 – annual review, added GHP Kids
- Revised: 3/1/21 – annual review, updated logo, added MediSpan approval level
- Revised: 3/1/22 – annual review, updated referenced policies & covered LOBs



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 280.0

**SECTION: Commercial Drug
SUBJECT: Alogliptin/Pioglitazone**

Applicable line of business:

Commercial	X	Medicaid	
Medicare		ACA	X
GHP Kids	X	Self-Insured	X

POLICY:

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for alogliptin/pioglitazone for GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 487.0 Quantity Limit Exceptions

REQUIRED DEFINITIONS:

1. **Attachment** – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. **Exhibit** – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. **Devised** – the date the policy was implemented.
4. **Revised** – the date of every revision to the policy, including typographical and grammatical changes.
5. **Reviewed** – the date documenting the annual review if the policy has no revisions necessary.

ADDITIONAL DEFINITIONS:

1. **Formulary** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. **Non-formulary products** – those medications that are not included in the Formulary.
3. **Healthcare provider** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
4. **NCQA** – National Committee for Quality Assurance.
5. **Medically Necessary or Medical Necessity** – covered services rendered by a provider that the Health Plan determines are:

- A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
- B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
- C. In accordance with current standards of medical practice;
- D. Not primarily for the convenience of the Member, or the Member's Provider; and
- E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

PROCEDURE:

An exception for coverage of alogliptin/pioglitazone may be made for members who meet the following criteria:

- Medical record documentation of therapeutic failure on, intolerance to, or contraindication to Tradjenta + pioglitazone

MEDISPAN AUTHORIZATION LEVEL: GPI-12, generic only

QUANTITY LIMIT: *No QLs need to be entered within the authorization unless the requested quantity exceeds the QL.*

- **QL FOR LETTER ONLY:** 1 tablet per day

If an exception is made, alogliptin/pioglitazone will be paid for under the member's prescription drug benefit.

Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.

FORMULARY ALTERNATIVES:

pioglitazone, metformin, Tradjenta, Jentaduetto, Jentaduetto XR



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 280.0

**SECTION: Commercial Drug
SUBJECT: Alogliptin/Pioglitazone**

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE
STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND
FEDERAL REGULATORY ENTITIES.**

**THIS POLICY WILL BE REVISED AS NECESSARY AND
REVIEWED NO LESS THAN ANNUALLY.**

Signed: _____

Title: Director, Pharmacy Services

Date: March 1, 2022

- Devised: 6/24/13
- Reviewed: 3/1/14 – annual review
- Revised: 3/1/15 – annual review, updated signature
- Revised: 3/1/16 – annual review, updated PA requirements to ST
- Revised: 5/1/16 – updated format, logo, & procedure
- Revised: 3/1/17 – annual review, updated Oseni to alogliptin/pioglitazone
- Revised: 11/28/17 – removed indication, added failure of Tradjenta & QL, updated FA/signature
- Revised: 2/9/18 – removed failure of sitagliptin, updated FA
- Reviewed: 3/1/18 – annual review
- Revised: 3/1/19 – annual review, added QL approval note, removed ST indicator from FA
- Revised: 3/1/20 – annual review, added GHP Kids
- Revised: 3/1/21 – annual review, updated logo, added MediSpan approval level, updated QL statement
- Revised: 3/1/22 – annual review, updated referenced policies & covered LOBs



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 281.0

**SECTION: Commercial Drug
SUBJECT: Pomalyst**

Applicable line of business:

Commercial	X	Medicaid	
Medicare		ACA	X
GHP Kids	X	Self-Insured	X

POLICY:

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for Pomalyst for GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 487.0 Quantity Limit Exceptions

REQUIRED DEFINITIONS:

1. **Attachment** – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. **Exhibit** – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. **Devised** – the date the policy was implemented.
4. **Revised** – the date of every revision to the policy, including typographical and grammatical changes.
5. **Reviewed** – the date documenting the annual review if the policy has no revisions necessary.

ADDITIONAL DEFINITIONS:

1. **Formulary** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. **Non-formulary products** – those medications that are not included in the Formulary.
3. **Healthcare provider** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
4. **NCQA** – National Committee for Quality Assurance.
5. **Medically Necessary or Medical Necessity** – covered services rendered by a provider that the Health Plan determines are:

- A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
- B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
- C. In accordance with current standards of medical practice;
- D. Not primarily for the convenience of the Member, or the Member's Provider; and
- E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

PROCEDURE:

New members to the plan already established on therapy may be eligible for continuity of care coverage as long as there is medical record documentation that the safety and effectiveness of use for the prescribed indication is supported by Food and Drug Administration (FDA) approval or adequate medical and scientific evidence in the medical literature.

An exception for coverage of Pomalyst may be made for members who meet the following criteria:

Multiple Myeloma

- Medical record documentation that Pomalyst is prescribed by a hematologist or oncologist **AND**
- Medical record documentation of multiple myeloma **AND**
- Medical record documentation of therapeutic failure on, intolerance to, or contraindication to two prior therapies: bortezomib (Velcade*) and lenalidomide (Revlimid*) **AND**
- Medical record documentation that Pomalyst is being prescribed in combination with dexamethasone **OR** medical record documentation that the patient is steroid-intolerant

Kaposi Sarcoma

- Medical record documentation that Pomalyst is prescribed by a hematologist or oncologist **AND**
- Medical record documentation of age greater than or equal to 18 years **AND**
- Medical record documentation of Kaposi sarcoma **AND**
- Medical record documentation of one of the following:
 - Medical record documentation of AIDS-related Kaposi sarcoma **AND**



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 281.0

**SECTION: Commercial Drug
SUBJECT: Pomalyst**

- Medical record documentation of progression of Kaposi sarcoma despite the use of antiretroviral therapy **AND**
- Medical record documentation that antiretroviral therapy will be continued **OR**
- Medical record documentation that the member is HIV-negative

MEDISPAN AUTHORIZATION LEVEL: GPI-12, number of claims authorized = 1, enter for the remainder of the calendar year

QUANTITY LIMIT: *No QLs need to be entered within the authorization unless the requested quantity exceeds the QL.*

- QL FOR LETTER ONLY: 21 tablets per 28 days

RE-AUTHORIZATION CRITERIA: Pomalyst is configured as a prior authorization for new starts only. Pomalyst will no longer be covered if it is identified that the member is not receiving appropriate follow-up care from the prescribing specialist or if the member has greater than or equal to a 90 day break in therapy.

- Medical record documentation that the member is receiving appropriate follow-up care from the prescribing specialist

If an exception is made, Pomalyst will be paid for under the member's prescription drug benefit.

Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.

FORMULARY ALTERNATIVES:

Revlimid*

*prior authorization required

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE
STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND
FEDERAL REGULATORY ENTITIES.**

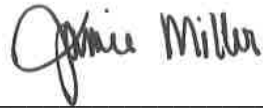
**THIS POLICY WILL BE REVISED AS NECESSARY AND
REVIEWED NO LESS THAN ANNUALLY.**

Geisinger

**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 281.0

**SECTION: Commercial Drug
SUBJECT: Pomalyst**



Signed: _____

Title: Director, Pharmacy Services

Date: March 1, 2022

Devised: 6/24/13
Reviewed: 3/1/14 – annual review
Revised: 3/1/15 – annual review, updated signature
Revised: 7/22/15 – added steroid requirement
Reviewed: 3/1/16 – annual review
Revised: 5/1/16 – updated format, logo, & procedure
Reviewed: 3/1/17 – annual review
Revised: 10/10/17 – increased authorization duration to 12 months
Revised: 3/1/18 – annual review, updated signature, added grandfather language, updated prescriber criteria, removed QL indicator
Revised: 3/1/19 – annual review, added QL approval note
Revised: 3/1/20 – annual review, added GHP Kids
Revised: 7/29/20 – added Kaposi sarcoma indication
Revised: 3/1/21 – annual review, updated logo, added MediSpan approval level, updated QL statement
Revised: 11/30/21 – added one-time PA to approval crit., removed auth duration & added re-auth crit.
Revised: 3/1/22 – annual review, updated referenced policies & covered LOBs



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 283.0

**SECTION: Commercial Drug
SUBJECT: Zortress**

Applicable line of business:

Commercial	X	Medicaid	
Medicare		ACA	X
GHP Kids	X	Self-Insured	X

POLICY:

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for Zortress for GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 487.0 Quantity Limit Exceptions

REQUIRED DEFINITIONS:

1. **Attachment** – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. **Exhibit** – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. **Devised** – the date the policy was implemented.
4. **Revised** – the date of every revision to the policy, including typographical and grammatical changes.
5. **Reviewed** – the date documenting the annual review if the policy has no revisions necessary.

ADDITIONAL DEFINITIONS:

1. **Formulary** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. **Non-formulary products** – those medications that are not included in the Formulary.
3. **Healthcare provider** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
4. **NCQA** – National Committee for Quality Assurance.
5. **Medically Necessary or Medical Necessity** – covered services rendered by a provider that the Health Plan determines are:

- A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
- B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
- C. In accordance with current standards of medical practice;
- D. Not primarily for the convenience of the Member, or the Member's Provider; and
- E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

PROCEDURE:

New members to the plan already established on therapy may be eligible for continuity of care coverage as long as there is medical record documentation that the safety and effectiveness of use for the prescribed indication is supported by Food and Drug Administration (FDA) approval or adequate medical and scientific evidence in the medical literature.

An exception for coverage of Zortress may be made for members who meet the following criteria:

Kidney Transplant

- Medical record documentation that Zortress is prescribed by a physician experienced in immunosuppressive therapy and management of transplant patients **AND**
- Medical record documentation that member received a kidney transplant **AND**
- Medical record documentation of age greater than or equal to 18 years **AND**
- Medical record documentation of one of the following:
 - Zortress is being administered in combination with basiliximab (Simulect) induction and concurrently with reduced doses of cyclosporine and corticosteroids **OR**
 - Medical record documentation that member has had a prior therapeutic failure on, intolerance to, or contraindication to calcineurin inhibitors

OR

Liver Transplant

- Medical record documentation that Zortress is prescribed by a physician experienced in immunosuppressive therapy and management of transplant patients **AND**
- Medical record documentation that member received a liver transplant **AND**
- Medical record documentation of age greater than or equal to 18 years **AND**

- Medical record documentation that Zortress is being administered no earlier than 30 days post-transplant **AND**
- Medical record documentation of one of the following:
 - Zortress is being administered in combination with low-dose tacrolimus and corticosteroids **OR**
 - Medical record documentation that member has had a prior therapeutic failure on, intolerance to, or contraindication to calcineurin inhibitors

NOTE:

- Zortress (and other mTOR inhibitors) should not be administered any sooner than 30 days after liver transplant due to risk of hepatic artery thrombosis in the early post-transplantation period.
- The use of corticosteroids beyond the first week post-transplant is controversial and varies between treatment centers. The 2009 KDIGO guidelines recommend for kidney transplant patients at low immunogenic risk and who receive induction therapy, to discontinue prednisone during the first week post-transplant.

MEDISPAN AUTHORIZATION LEVEL: GPI-12

If an exception is made, Zortress will be paid for under the member's prescription drug benefit.

Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.

FORMULARY ALTERNATIVES:

Renal Transplant: azathioprine, mycophenolate mofetil, cyclosporine, tacrolimus, sirolimus solution*, sirolimus tablets*

Liver Transplant: cyclosporine, mycophenolate mofetil, tacrolimus

*prior authorization required

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE
STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND
FEDERAL REGULATORY ENTITIES.**

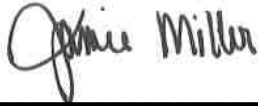
**THIS POLICY WILL BE REVISED AS NECESSARY AND
REVIEWED NO LESS THAN ANNUALLY.**

Geisinger

**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 283.0

**SECTION: Commercial Drug
SUBJECT: Zortress**



Signed: _____

Title: Director, Pharmacy Services

Date: March 1, 2022

Devised: 6/24/13
Reviewed: 3/1/14 – annual review
Revised: 3/1/15 – annual review, updated signature, added Rapamune Solution & sirolimus tabs
Reviewed: 3/1/16 – annual review
Revised: 5/1/16 – updated format, logo, & procedure
Reviewed: 3/1/17 – annual review
Revised: 3/1/18 – annual review, updated signature, added grandfather language, updated format of prescriber, age, and diagnosis criteria
Reviewed: 3/1/19 – annual review
Revised: 3/21/19 – added failure of calcineurin inhibitors, added note
Revised: 3/1/20 – annual review, added GHP Kids
Revised: 3/1/21 – annual review, updated logo, added MediSpan approval level
Revised: 3/1/22 – annual review, updated referenced policies & covered LOBs, updated FA



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 284.0

**SECTION: Commercial Drug
SUBJECT: Deferasirox**

Applicable line of business:

Commercial	X	Medicaid	
Medicare		ACA	X
GHP Kids	X	Self-Insured	X

POLICY:

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for deferasirox for GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 487.0 Quantity Limit Exceptions

REQUIRED DEFINITIONS:

1. **Attachment** – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. **Exhibit** – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. **Devised** – the date the policy was implemented.
4. **Revised** – the date of every revision to the policy, including typographical and grammatical changes.
5. **Reviewed** – the date documenting the annual review if the policy has no revisions necessary.

ADDITIONAL DEFINITIONS:

1. **Formulary** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. **Non-formulary products** – those medications that are not included in the Formulary.
3. **Healthcare provider** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
4. **NCQA** – National Committee for Quality Assurance.
5. **Medically Necessary or Medical Necessity** – covered services rendered by a provider that the Health Plan determines are:

- A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
- B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
- C. In accordance with current standards of medical practice;
- D. Not primarily for the convenience of the Member, or the Member's Provider; and
- E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

PROCEDURE:

An exception for coverage of deferasirox may be made for members who meet the following criteria:

Chronic Iron Overload caused by Transfusion-Dependent Thalassemia

- Medical record documentation of a diagnosis of chronic iron overload caused by transfusion dependent thalassemia **AND**
- Medical record documentation of age greater than or equal to 2 years **AND**
- Medical record documentation of a serum ferritin level greater than 1,000 mcg/L

Chronic Iron Overload caused by Non-Transfusion Dependent Thalassemia

- Medical record documentation of a diagnosis of chronic iron overload caused by non-transfusion dependent thalassemia **AND**
- Medical record documentation of age greater than or equal to 10 years **AND**
- Medical record documentation of liver iron concentration (LIC) greater than 5 mg Fe/g dw **AND**
- Medical record documentation of serum ferritin greater than 300 mcg/L

MEDISPAN AUTHORIZATION LEVEL: GPI-10, generic only

AUTHORIZATION DURATION: If approved, initial approval will be for 6 months or less if the reviewing provider feels it is medically appropriate. Subsequent approvals will be for an additional 6 months or less if the reviewing provider feels it is medically appropriate and will require medical record documentation of serum ferritin level greater than 300 mcg/L.

If an exception is made, deferasirox will be paid for under the member's prescription drug benefit.



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 284.0

**SECTION: Commercial Drug
SUBJECT: Deferasirox**

Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.

FORMULARY ALTERNATIVES:

none

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE
STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND
FEDERAL REGULATORY ENTITIES.**

**THIS POLICY WILL BE REVISED AS NECESSARY AND
REVIEWED NO LESS THAN ANNUALLY.**

Signed: _____

Title: Director, Pharmacy Services

Date: March 1, 2022

Devised: 6/24/13
Reviewed: 3/1/14 – annual review
Revised: 3/1/15 – annual review, updated signature
Revised: 3/1/16 – annual review, updated authorization duration format
Revised: 5/1/16 – updated format, logo, & procedure
Reviewed: 3/1/17 – annual review
Revised: 6/2/17 – added Jadenu to policy, auth duration to 6 months, reauth ferritin to >300
Revised: 3/1/18 – annual review, updated signature, updated age criteria
Revised: 10/8/18 – removed caused by Transfusion-Dependent Thalassemia from chronic iron overload indication and updated re-auth to ferritin > 500
Reviewed: 3/1/19 – annual review
Revised: 11/21/19 – updated Exjade to generic deferasirox
Revised: 3/1/20 – annual review, added GHP Kids
Revised: 3/1/21 – annual review, updated logo, added MediSpan approval level, updated Jadenu to generic
Revised: 3/1/22 – annual review, updated referenced policies & covered LOBs



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 285.0

**SECTION: Commercial Drug
SUBJECT: Icatibant**

Applicable line of business:

Commercial	X	Medicaid	
Medicare		ACA	X
GHP Kids	X	Self-Insured	X

POLICY:

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for icatibant for GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 487.0 Quantity Limit Exceptions

REQUIRED DEFINITIONS:

1. **Attachment** – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. **Exhibit** – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. **Devised** – the date the policy was implemented.
4. **Revised** – the date of every revision to the policy, including typographical and grammatical changes.
5. **Reviewed** – the date documenting the annual review if the policy has no revisions necessary.

ADDITIONAL DEFINITIONS:

1. **Formulary** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. **Non-formulary products** – those medications that are not included in the Formulary.
3. **Healthcare provider** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
4. **NCQA** – National Committee for Quality Assurance.
5. **Medically Necessary or Medical Necessity** – covered services rendered by a provider that the Health Plan determines are:

- A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
- B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
- C. In accordance with current standards of medical practice;
- D. Not primarily for the convenience of the Member, or the Member's Provider; and
- E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

PROCEDURE:

An exception for coverage of icatibant may be made for members who meet the following criteria:

- Medical record documentation of age greater than or equal to 18 years **AND**
- Medical record documentation that icatibant is prescribed by an allergist, immunologist, hematologist, or dermatologist **AND**
- Medical record documentation of hereditary angioedema supported by physician documentation of
 - Recurrent, self-limiting non-inflammatory subcutaneous angioedema without urticarial, lasting more than 12 hours **OR**
 - Laryngeal edema **OR**
 - Recurrent, self-remitting abdominal pain lasting more than 6 hours, without clear organic etiology **AND**
 - The presence of specific abnormalities in complement proteins, in the setting of a suggestive clinical history or episodic angioedema without urticarial **AND**
- Medication is being used as a treatment of acute hereditary angioedema attack **AND**
- Physician provided documentation of concurrent use of failure on, intolerance to, or contraindication to prophylactic therapy (androgen)

MEDISPAN AUTHORIZATION LEVEL: GPI-12, generic only

QUANTITY LIMIT: *No QLs need to be entered within the authorization unless the requested quantity exceeds the QL. Quantities requested above limits will be reviewed for necessity. Exceptions will be allowed for patients maximizing prophylactic therapies and medical record documentation of acute attacks requiring more than 3 syringes monthly.*

- **QL FOR LETTER ONLY:** 3 syringes (9 mL) per 30 days.



POLICY NUMBER: 285.0

**POLICY AND PROCEDURE
PHARMACY
MANUAL**

**SECTION: Commercial Drug
SUBJECT: Icatibant**

AUTHORIZATION DURATION: Initial authorization will be for 6 months, with annual review thereafter. Firazyr will no longer be covered if patient is no longer using prophylactic therapy and does not have medical record documentation of contraindication or intolerance to all prophylactic therapy options.

If an exception is made, icatibant will be paid for under the member's prescription drug benefit.

Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.

FORMULARY ALTERNATIVES:

none

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE
STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND
FEDERAL REGULATORY ENTITIES.**

**THIS POLICY WILL BE REVISED AS NECESSARY AND
REVIEWED NO LESS THAN ANNUALLY.**

Signed: _____

Title: Director, Pharmacy Services

Date: March 1, 2022

Devised: 7/29/13
Reviewed: 3/1/14 – annual review
Revised: 3/1/15 – annual review, updated signature
Reviewed: 3/1/16 – annual review
Revised: 5/1/16 – updated format, logo, & procedure, corrected typo in authorization duration
Reviewed: 3/1/17 – annual review
Revised: 3/1/18 – annual review, updated signature, updated age & prescriber criteria, removed QL indicator
Reviewed: 3/1/19 – annual review
Revised: 11/21/19 – updated Firazyr to generic icatibant
Revised: 3/1/20 – annual review, added GHP Kids
Revised: 3/1/21 – annual review, updated logo, added MediSpan approval level, updated QL statement

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Dev. 7/29/13

Rev. 3/1/22



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 285.0

**SECTION: Commercial Drug
SUBJECT: Icatibant**

Revised: 3/1/22 – annual review, updated referenced policies & covered LOBs



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 286.0

**SECTION: Commercial Drug
SUBJECT: Gattex**

Applicable line of business:

Commercial	X	Medicaid	
Medicare		ACA	X
GHP Kids	X	Self-Insured	X

POLICY:

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for Gattex for GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 487.0 Quantity Limit Exceptions

REQUIRED DEFINITIONS:

1. **Attachment** – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. **Exhibit** – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. **Devised** – the date the policy was implemented.
4. **Revised** – the date of every revision to the policy, including typographical and grammatical changes.
5. **Reviewed** – the date documenting the annual review if the policy has no revisions necessary.

ADDITIONAL DEFINITIONS:

1. **Formulary** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. **Non-formulary products** – those medications that are not included in the Formulary.
3. **Healthcare provider** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
4. **NCQA** – National Committee for Quality Assurance.
5. **Medically Necessary or Medical Necessity** – covered services rendered by a provider that the Health Plan determines are:

- A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
- B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
- C. In accordance with current standards of medical practice;
- D. Not primarily for the convenience of the Member, or the Member's Provider; and
- E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

PROCEDURE:

An exception for coverage of Gattex may be made for members who meet the following criteria:

- Medical record documentation that Gattex is prescribed by a gastroenterologist **AND**
- Medical record documentation of age greater than or equal to 1 year **AND**
- Medical record documentation of a diagnosis of short bowel syndrome **AND**
- If age 1 to 17 years:
 - Medical record documentation that the member is dependent on parenteral nutrition/intravenous support at least 3 times per week
- If age greater than or equal to 18 years:
 - Medical record documentation that the member has been dependent on parenteral nutrition/intravenous support for a minimum of 12 consecutive months continuously **AND**
 - Medical record documentation that the member requires concurrent parenteral nutrition at least three days per week

MEDISPAN AUTHORIZATION LEVEL: GPI-12

QUANTITY LIMIT: *No QLs need to be entered within the authorization unless the requested quantity exceeds the QL.*

- **QL FOR LETTER ONLY:** One (1) vial per day, 30 day supply limit per fill

AUTHORIZATION DURATION: If approved, approval will be for an initial duration of six (6) months. For continuation of coverage, medical record documentation of a decrease of at least 20% volume of parenteral nutrition/intravenous support from baseline is required.



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 286.0

**SECTION: Commercial Drug
SUBJECT: Gattex**

After the initial six (6) month approval, subsequent approvals for coverage will be for a duration of one (1) year. Reevaluation of coverage will be every one (1) year requiring medical record documentation of sustained improvements in the volume of parenteral nutrition/intravenous support that the member requires while on Gattex therapy.

If an exception is made, Gattex will be paid for under the member's prescription drug benefit.

Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.

FORMULARY ALTERNATIVES:

none

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE
STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND
FEDERAL REGULATORY ENTITIES.**

**THIS POLICY WILL BE REVISED AS NECESSARY AND
REVIEWED NO LESS THAN ANNUALLY.**

Signed: _____

Title: Director, Pharmacy Services

Date: March 1, 2022

Devised: 7/29/13
Reviewed: 3/1/14 – annual review
Revised: 3/1/15 – annual review, updated signature
Revised: 3/1/16 – annual review, corrected typo in authorization
Revised: 5/1/16 – updated format, logo, & procedure
Reviewed: 3/1/17 – annual review
Revised: 3/1/18 – annual review, updated signature, updated age & prescriber criteria, removed QL indicator
Reviewed: 3/1/19 – annual review, added QL approval note, updated QL to match package size
Revised: 10/1/19 – updated age to 1 year
Revised: 11/20/19 – revised parenteral nutrition requirements and separated by age
Revised: 3/1/20 – annual review, added GHP Kids
Revised: 3/1/21 – annual review, updated logo, added MediSpan approval level, updated QL statement

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Dev. 7/29/13

Rev. 3/1/22

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**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 286.0

**SECTION: Commercial Drug
SUBJECT: Gattex**

Revised: 3/1/22 – annual review, updated referenced policies & covered LOBs



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 287.0

**SECTION: Commercial Drug
SUBJECT: Mytesi**

Applicable line of business:

Commercial	X	Medicaid	
Medicare		ACA	X
GHP Kids	X	Self-Insured	X

POLICY:

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for Mytesi for GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 487.0 Quantity Limit Exceptions

REQUIRED DEFINITIONS:

1. **Attachment** – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. **Exhibit** – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. **Devised** – the date the policy was implemented.
4. **Revised** – the date of every revision to the policy, including typographical and grammatical changes.
5. **Reviewed** – the date documenting the annual review if the policy has no revisions necessary.

ADDITIONAL DEFINITIONS:

1. **Formulary** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. **Non-formulary products** – those medications that are not included in the Formulary.
3. **Healthcare provider** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
4. **NCQA** – National Committee for Quality Assurance.
5. **Medically Necessary or Medical Necessity** – covered services rendered by a provider that the Health Plan determines are:



POLICY NUMBER: 287.0

**POLICY AND PROCEDURE
PHARMACY
MANUAL**

**SECTION: Commercial Drug
SUBJECT: Mytesi**

- A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
- B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
- C. In accordance with current standards of medical practice;
- D. Not primarily for the convenience of the Member, or the Member's Provider; and
- E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

PROCEDURE:

An exception for coverage of Mytesi may be made for members who meet the following criteria:

- Medical record documentation of a diagnosis of human immunodeficiency virus (HIV) or acquired immune deficiency syndrome (AIDS) **AND**
- Medical record documentation of antiretroviral therapy for at least four (4) week duration **AND**
- Medical record documentation of contraindication to, intolerance to, or therapeutic failure on loperamide **AND** diphenoxylate-atropine

MEDISPAN AUTHORIZATION LEVEL: GPI-12

If an exception is made, Mytesi will be paid for under the member's prescription drug benefit.

Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.

FORMULARY ALTERNATIVES:

loperamide, diphenoxylate-atropine

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE
STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND
FEDERAL REGULATORY ENTITIES.**

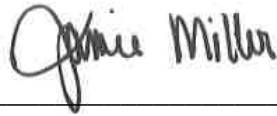
**THIS POLICY WILL BE REVISED AS NECESSARY AND
REVIEWED NO LESS THAN ANNUALLY.**

Geisinger

**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 287.0

**SECTION: Commercial Drug
SUBJECT: Mytesi**



Signed: _____

Title: Director, Pharmacy Services

Date: March 1, 2022

Devised: 7/29/13
Reviewed: 3/1/14 – annual review
Revised: 3/1/15 – annual review, updated signature
Revised: 3/1/16 – annual review, added loperamide and diphenoxylate-atropine to FA
Revised: 5/1/16 – updated format, logo, & procedure
Revised: 3/1/17 – annual review, corrected typo
Revised: 11/29/17 – updated drug name to Mytesi, updated signature
Revised: 3/1/18 – annual review, removed QL indicator, defined HIV/AIDS, updated Fulyzaq to Mytesi, corrected typo
Reviewed: 3/1/19 – annual review
Revised: 3/1/20 – annual review, added GHP Kids
Revised: 3/1/21 – annual review, updated logo, added MediSpan approval level
Revised: 3/1/22 – annual review, updated referenced policies & covered LOBs



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 288.0

**SECTION: Commercial Drug
SUBJECT: Signifor**

Applicable line of business:

Commercial	X	Medicaid	
Medicare		ACA	X
GHP Kids	X	Self-Insured	X

POLICY:

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for Signifor for GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 487.0 Quantity Limit Exceptions

REQUIRED DEFINITIONS:

1. **Attachment** – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. **Exhibit** – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. **Devised** – the date the policy was implemented.
4. **Revised** – the date of every revision to the policy, including typographical and grammatical changes.
5. **Reviewed** – the date documenting the annual review if the policy has no revisions necessary.

ADDITIONAL DEFINITIONS:

1. **Formulary** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. **Non-formulary products** – those medications that are not included in the Formulary.
3. **Healthcare provider** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
4. **NCQA** – National Committee for Quality Assurance.
5. **Medically Necessary or Medical Necessity** – covered services rendered by a provider that the Health Plan determines are:



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 288.0

**SECTION: Commercial Drug
SUBJECT: Signifor**

- A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
- B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
- C. In accordance with current standards of medical practice;
- D. Not primarily for the convenience of the Member, or the Member's Provider; and
- E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

PROCEDURE:

An exception for coverage of Signifor may be made for members who meet the following criteria:

- Medical record documentation that Signifor is prescribed by endocrinology **AND**
- Medical record documentation of a diagnosis of Cushing's disease **AND**
- Medical record documentation that pituitary surgery is not an option or has not been curative **AND**
- Medical record documentation of therapeutic failure on, intolerance to, or contraindication to ketoconazole **AND** metyrapone*

MEDISPAN AUTHORIZATION LEVEL: GPI-12

QUANTITY LIMIT: *No QLs need to be entered within the authorization unless the requested quantity exceeds the QL.*

- **QL FOR LETTER ONLY:** 60 ampules per month, for each strength

AUTHORIZATION DURATION: If approved, approval will be given for a period of six (6) months. Re-authorization will require medical record documentation that urinary free cortisol levels are within normal limits.

If an exception is made, Signifor will be paid for under the member's prescription drug benefit.

Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.

Geisinger

**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 288.0

**SECTION: Commercial Drug
SUBJECT: Signifor**

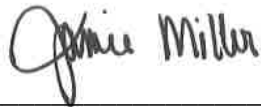
FORMULARY ALTERNATIVES:

ketoconazole, metyrapone*

*prior authorization required

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE
STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND
FEDERAL REGULATORY ENTITIES.**

**THIS POLICY WILL BE REVISED AS NECESSARY AND
REVIEWED NO LESS THAN ANNUALLY.**



Signed: _____

Title: Director, Pharmacy Services

Date: March 1, 2022

Devised: 7/29/13
Reviewed: 3/1/14 – annual review
Revised: 3/1/15 – annual review
Reviewed: 3/1/16 – annual review
Revised: 5/1/16 – updated format, logo, & procedure, corrected typo in authorization duration
Reviewed: 3/1/17 – annual review
Revised: 3/1/18 – annual review, updated signature, updated prescriber/diagnosis criteria, removed QL indicator
Revised: 3/1/19 – annual review, added QL approval note
Revised: 3/1/20 – annual review, added GHP Kids
Revised: 3/1/21 – annual review, updated logo, added MediSpan approval level, updated QL statement
Revised: 3/1/22 – annual review, updated referenced policies & covered LOBs



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 289.0

**SECTION: Commercial Drug
SUBJECT: Kynamro**

Applicable line of business:

Commercial	X	Medicaid	
Medicare		ACA	X
GHP Kids	X	Self-Insured	X

POLICY:

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for Kynamro for GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 487.0 Quantity Limit Exceptions

REQUIRED DEFINITIONS:

1. **Attachment** – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. **Exhibit** – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. **Devised** – the date the policy was implemented.
4. **Revised** – the date of every revision to the policy, including typographical and grammatical changes.
5. **Reviewed** – the date documenting the annual review if the policy has no revisions necessary.

ADDITIONAL DEFINITIONS:

1. **Formulary** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. **Non-formulary products** – those medications that are not included in the Formulary.
3. **Healthcare provider** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
4. **NCQA** – National Committee for Quality Assurance.
5. **Medically Necessary or Medical Necessity** – covered services rendered by a provider that the Health Plan determines are:

- A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
- B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
- C. In accordance with current standards of medical practice;
- D. Not primarily for the convenience of the Member, or the Member's Provider; and
- E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

PROCEDURE:

An exception for coverage of Kynamro may be made for members who meet the following criteria:

- Medical record documentation of a diagnosis of homozygous familial hypercholesterolemia that is caused by mutations of the low density lipoprotein (LDL) receptor (LDLr) gene **AND**
 - Medical record documentation that Kynamro is prescribed by a hepatologist, lipidologist, or cardiologist registered with the Kynamro risk evaluation and mitigation strategies (REMS) program **AND**
 - Medical record documentation of age greater than or equal to 18 years **AND**
 - Medical record documentation of failure to adequately control low density lipoprotein (LDL) levels with combination of maximum tolerated statin dose and low density lipoprotein (LDL) apheresis treatment defined as:
 - Greater than or equal to 200 mg/dL in patients without cardiovascular disease
 - Greater than or equal to 160 mg/dL in patients with established cardiovascular disease
- AND**
- Medical record documentation of Kynamro to be used in adjunct with maximum tolerated statin dose **AND**
 - Medical record documentation that Kynamro will not be used in conjunction with low density lipoprotein (LDL) apheresis **AND**
 - Medical record documentation of therapeutic failure on, intolerance to, or contraindication to Repatha

MEDISPAN AUTHORIZATION LEVEL: GPI-12



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 289.0

**SECTION: Commercial Drug
SUBJECT: Kynamro**

QUANTITY LIMIT: *No QLs need to be entered within the authorization unless the requested quantity exceeds the QL.*

- **QL FOR LETTER ONLY:** Four (4) vials per 28 days

AUTHORIZATION DURATION: Initial approval will be granted for a period of six (6) months. A new prior authorization may be submitted at that time for continuation of therapy. Subsequent approval will be for one (1) year and will require medical record documentation that current medical necessity criteria are met and that therapy has been effective.

If an exception is made, Kynamro will be paid for under the member's prescription drug benefit.

Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.

FORMULARY ALTERNATIVES:

atorvastatin, simvastatin, ezetimibe, rosuvastatin, Repatha*, Praluent*

*prior authorization required

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE
STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND
FEDERAL REGULATORY ENTITIES.**

**THIS POLICY WILL BE REVISED AS NECESSARY AND
REVIEWED NO LESS THAN ANNUALLY.**

Signed: _____

Title: Director, Pharmacy Services

Date: March 1, 2022

Devised: 7/29/13

Reviewed: 3/1/14 – annual review

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Dev. 7/29/13

Rev. 3/1/22



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 289.0

**SECTION: Commercial Drug
SUBJECT: Kynamro**

- Revised: 3/1/15 – annual review, updated signature
- Revised: 3/1/16 – annual review, corrected typo in authorization duration, added failure of Repatha, added Repatha to FA
- Revised: 5/1/16 – updated format, logo, & procedure
- Revised: 5/27/16 – updated Crestor to rosuvastatin
- Revised: 3/1/17 – annual review, updated FA
- Revised: 3/1/18 – annual review, updated signature, updated prescriber & age criteria, removed QL indicator, updated FA
- Revised: 3/1/19 – annual review, defined abbr., added QL approval note
- Revised: 3/1/20 – annual review, added GHP Kids
- Revised: 3/1/21 – annual review, updated logo, added MediSpan approval level, updated QL statement
- Revised: 3/1/22 – annual review, updated referenced policies & covered LOBs



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 290.0

**SECTION: Commercial Drug
SUBJECT: Ravicti**

Applicable line of business:

Commercial	X	Medicaid	
Medicare		ACA	X
GHP Kids	X	Self-Insured	X

POLICY:

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for Ravicti for GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 487.0 Quantity Limit Exceptions

REQUIRED DEFINITIONS:

1. **Attachment** – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. **Exhibit** – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. **Devised** – the date the policy was implemented.
4. **Revised** – the date of every revision to the policy, including typographical and grammatical changes.
5. **Reviewed** – the date documenting the annual review if the policy has no revisions necessary.

ADDITIONAL DEFINITIONS:

1. **Formulary** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. **Non-formulary products** – those medications that are not included in the Formulary.
3. **Healthcare provider** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
4. **NCQA** – National Committee for Quality Assurance.
5. **Medically Necessary or Medical Necessity** – covered services rendered by a provider that the Health Plan determines are:



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 290.0

**SECTION: Commercial Drug
SUBJECT: Ravicti**

- A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
- B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
- C. In accordance with current standards of medical practice;
- D. Not primarily for the convenience of the Member, or the Member's Provider; and
- E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

PROCEDURE:

An exception for coverage of Ravicti may be made for members who meet the following criteria:

- Medical record documentation of a urea cycle disorder **AND**
- Medical record documentation of a protein-restricted diet **AND**
- Medical record documentation of increased blood ammonia levels **AND**
- Medical record documentation of contraindication to, intolerance to, or therapeutic failure on sodium phenylbutyrate powder* or Buphenyl powder* **AND** Buphenyl tablet*

MEDISPAN AUTHORIZATION LEVEL: GPI-12

QUANTITY LIMIT: *No QLs need to be entered within the authorization unless the requested quantity exceeds the QL.*

- QL FOR LETTER ONLY: 19 gm (17.3 mL) per day

AUTHORIZATION DURATION: Initial authorization will be for 6 months of therapy. Re-review will be annually thereafter. Ravicti will no longer be covered if the patient does not show improvement in either fasting ammonia levels, 24-hour AUC, or number of hyperammonemic crises.

If an exception is made, Ravicti will be paid for under the member's prescription drug benefit.

Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 290.0

**SECTION: Commercial Drug
SUBJECT: Ravicti**

FORMULARY ALTERNATIVES:

sodium phenylbutyrate powder*, Buphenyl Tablet*

*prior authorization required

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE
STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND
FEDERAL REGULATORY ENTITIES.**

**THIS POLICY WILL BE REVISED AS NECESSARY AND
REVIEWED NO LESS THAN ANNUALLY.**

Signed: _____

Title: Director, Pharmacy Services

Date: March 1, 2022

Devised: 7/29/13
Reviewed: 3/1/14 – annual review
Revised: 3/1/15 – annual review, updated signature
Revised: 3/1/16 – annual review, corrected typo in authorization duration
Revised: 5/1/16 – updated format, logo, & procedure
Reviewed: 3/1/17 – annual review
Revised: 10/3/17 – updated age from 2 years to 2 months
Revised: 3/1/18 – annual review, updated signature, updated age criteria, corrected typo
Revised: 3/1/19 – annual review, added QL approval note
Revised: 5/24/19 – removed age requirement
Revised: 3/1/20 – annual review, added GHP Kids
Revised: 3/1/21 – annual review, updated logo, added MediSpan approval level, updated QL statement
Revised: 3/1/22 – annual review, updated referenced policies & covered LOBs



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 292.0

**SECTION: Commercial Drug
SUBJECT: Erlotinib**

Applicable line of business:

Commercial	X	Medicaid	
Medicare		ACA	X
GHP Kids	X	Self-Insured	X

POLICY:

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for erlotinib for GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 487.0 Quantity Limit Exceptions

REQUIRED DEFINITIONS:

1. **Attachment** – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. **Exhibit** – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. **Devised** – the date the policy was implemented.
4. **Revised** – the date of every revision to the policy, including typographical and grammatical changes.
5. **Reviewed** – the date documenting the annual review if the policy has no revisions necessary.

ADDITIONAL DEFINITIONS:

1. **Formulary** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. **Non-formulary products** – those medications that are not included in the Formulary.
3. **Healthcare provider** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
4. **NCQA** – National Committee for Quality Assurance.
5. **Medically Necessary or Medical Necessity** – covered services rendered by a provider that the Health Plan determines are:

- A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
- B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
- C. In accordance with current standards of medical practice;
- D. Not primarily for the convenience of the Member, or the Member's Provider; and
- E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

PROCEDURE:

New members to the plan already established on therapy may be eligible for continuity of care coverage as long as there is medical record documentation that the safety and effectiveness of use for the prescribed indication is supported by Food and Drug Administration (FDA) approval or adequate medical and scientific evidence in the medical literature.

An exception for coverage of erlotinib may be made for members who meet the following criteria:

Non-Small Cell Lung Cancer

- Medical record documentation that erlotinib is prescribed by a hematologist or oncologist **AND**
- Medical record documentation of a diagnosis of metastatic non-small cell lung cancer **AND**
- Medical record documentation that erlotinib is being used as first line treatment **OR** maintenance treatment **OR** second line or greater treatment after progression on at least one prior chemotherapy regimen **AND**
- Medical record documentation of one of the following epidermal growth factor receptor (EGFR) mutations as detected by a Food and Drug Administration (FDA) approved test
 - Exon 19 deletion
 - Exon 21 (L858R) substitution

Pancreatic Cancer

- Medical record documentation that erlotinib is prescribed by a hematologist or oncologist **AND**
- Medical record documentation of locally advanced, unresectable, or metastatic pancreatic cancer **AND**



POLICY NUMBER: 292.0

**POLICY AND PROCEDURE
PHARMACY
MANUAL**

**SECTION: Commercial Drug
SUBJECT: Erlotinib**

- Medical record documentation of erlotinib being prescribed in combination with gemcitabine

MEDISPAN AUTHORIZATION LEVEL: GPI-12, generic only, number of claims authorized = 1, enter for the remainder of the calendar year

QUANTITY LIMIT: *No QLs need to be entered within the authorization unless the requested quantity exceeds the QL.*

- **QL FOR LETTER ONLY:**
 - 100 mg and 150 mg tablets: 1 tablet per day, 30 day supply per fill
 - 25 mg tablets: 3 tablets per day, 30 day supply per fill

RE-AUTHORIZATION CRITERIA: Erlotinib is configured as a prior authorization for new starts only. Erlotinib will no longer be covered if it is identified that the member is not receiving appropriate follow-up care from the prescribing specialist or if the member has greater than or equal to a 90 day break in therapy.

- Medical record documentation that the member is receiving appropriate follow-up care from the prescribing specialist

If an exception is made, erlotinib will be paid for under the member's prescription drug benefit.

Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.

FORMULARY ALTERNATIVES:

none

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE
STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND
FEDERAL REGULATORY ENTITIES.**

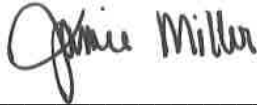
**THIS POLICY WILL BE REVISED AS NECESSARY AND
REVIEWED NO LESS THAN ANNUALLY.**

Geisinger

**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 292.0

**SECTION: Commercial Drug
SUBJECT: Erlotinib**



Signed: _____

Title: Director, Pharmacy Services

Date: March 1, 2022

Devised: 7/29/13
Reviewed: 3/1/14 – annual review
Revised: 3/1/15 – annual review, updated signature
Revised: 3/1/16 – annual review, corrected typo in authorization duration
Revised: 5/1/16 – updated format, logo, & procedure
Revised: 3/1/17 – annual review, defined abbreviations
Revised: 3/27/17 – updated NSCLC indication, increased auth duration to 12 months
Revised: 3/1/18 – annual review, updated signature, corrected 2 typos, updated prescriber criteria, added grandfather language, updated format/added DS limit
Revised: 3/1/19 – annual review, added QL approval note
Revised: 11/21/19 – updated Tarceva to generic erlotinib
Revised: 3/1/20 – annual review, added GHP Kids
Revised: 3/1/21 – annual review, updated logo, added MediSpan approval level, updated QL statement
Revised: 11/24/21 – added one-time PA to approval crit., removed auth duration & added re-auth crit.
Revised: 3/1/22 – annual review, updated referenced policies & covered LOBs



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 293.0

**SECTION: Commercial Drug
SUBJECT: Juxtapid**

Applicable line of business:

Commercial	X	Medicaid	
Medicare		ACA	X
GHP Kids	X	Self-Insured	X

POLICY:

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for Juxtapid for GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 487.0 Quantity Limit Exceptions

REQUIRED DEFINITIONS:

1. **Attachment** – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. **Exhibit** – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. **Devised** – the date the policy was implemented.
4. **Revised** – the date of every revision to the policy, including typographical and grammatical changes.
5. **Reviewed** – the date documenting the annual review if the policy has no revisions necessary.

ADDITIONAL DEFINITIONS:

1. **Formulary** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. **Non-formulary products** – those medications that are not included in the Formulary.
3. **Healthcare provider** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
4. **NCQA** – National Committee for Quality Assurance.
5. **Medically Necessary or Medical Necessity** – covered services rendered by a provider that the Health Plan determines are:

- A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
- B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
- C. In accordance with current standards of medical practice;
- D. Not primarily for the convenience of the Member, or the Member's Provider; and
- E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

PROCEDURE:

An exception for coverage of Juxtapid may be made for members who meet the following criteria:

- Medical record documentation of a diagnosis of homozygous familial hypercholesterolemia (HoFH) **AND** either
 - Genetic testing to confirm diagnosis showing a mutation in the low-density lipoprotein (LDL) receptor (LDLR) gene, apolipoprotein B (ApoB) gene, proprotein convertase subtilisin/kexin type 9 (PCSK9) gene, or LDL protein receptor adaptor 1 (LDLRAP1) gene **OR**
 - Diagnosis made based on history of an untreated low-density lipoprotein cholesterol (LDL-C) greater than 500 mg/dL **AND** either xanthoma before 10 years of age **OR** evidence of heterozygous familial hypercholesterolemia (HeFH) in both parents
- AND**
- Medical record documentation that Juxtapid is prescribed by a hepatologist, lipidologist, or cardiologist registered with the Juxtapid risk evaluation and mitigation strategies (REMS) program **AND**
- Medical record documentation of age greater than or equal to 18 years **AND**
- Medical record documentation of failure to adequately control low-density lipoprotein (LDL) levels with combination of maximum tolerated statin dose and ezetimibe defined as:
 - Greater than or equal to 100 mg/dL in patients without cardiovascular disease
 - Greater than or equal to 70 mg/dL in patients with established cardiovascular disease
- AND**
- Medical record documentation of Juxtapid to be used in adjunct with maximum tolerated statin dose **AND** low density lipoprotein (LDL) apheresis **AND**

- Medical record documentation of therapeutic failure on, intolerance to, or contraindication to one formulary proprotein convertase subtilisin kexin type 9 (PCSK9) inhibitor **AND**
- If the request is for use in combination with Evkeeza: Medical record documentation of failure to adequately control low-density lipoprotein (LDL) levels with a minimum 3-month trial of Evkeeza without the concomitant use of Juxtapid

MEDISPAN AUTHORIZATION LEVEL: GPI-12

QUANTITY LIMIT: *No QLs need to be entered within the authorization unless the requested quantity exceeds the QL.*

- **QL FOR LETTER ONLY:**
 - 5 mg and 10 mg capsules: 1 capsule per day, 28 day supply per fill
 - 20 mg and 30 mg capsules: 2 capsules per day, 28 day supply per fill

AUTHORIZATION DURATION: Initial approval will be granted for a period of six (6) months. A new prior authorization may be submitted at that time for continuation of therapy. Subsequent approval will be for one (1) year and will require medical record documentation that current medical necessity criteria are met and that therapy has been effective.

If an exception is made, Juxtapid will be paid for under the member's prescription drug benefit.

Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.

FORMULARY ALTERNATIVES:

atorvastatin, simvastatin, ezetimibe, rosuvastatin, Repatha*, Praluent*

*prior authorization required

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE
STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND
FEDERAL REGULATORY ENTITIES.**

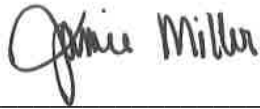
**THIS POLICY WILL BE REVISED AS NECESSARY AND
REVIEWED NO LESS THAN ANNUALLY.**

Geisinger

**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 293.0

**SECTION: Commercial Drug
SUBJECT: Juxtapid**



Signed: _____

Title: Director, Pharmacy Services

Date: April 6, 2022

Devised: 7/29/13
Reviewed: 3/1/14 – annual review
Revised: 3/1/15 – annual review, updated signature, updated procedure to Juxtapid
Revised: 7/22/15 – updated QL
Revised: 3/1/16 – annual review, corrected typo in authorization duration, added failure of Repatha, added Repatha to FA
Revised: 5/1/16 – updated format, logo, & procedure
Revised: 5/27/16 – updated Crestor to rosuvastatin
Revised: 3/1/17 – annual review, updated FA
Revised: 3/1/18 – annual review, updated signature, updated prescriber/age criteria, removed QL indicator, updated FA, corrected typo
Revised: 3/1/19 – annual review, added QL approval note, defined abbr.
Revised: 3/1/20 – annual review, added GHP Kids
Revised: 3/1/21 – annual review, updated logo, added MediSpan approval level, updated QL statement
Revised: 9/1/21 – updated LDL failure levels, removed failure of Kynamro, updated Repatha criteria to allow any PCSK9, added Evkeeza criteria, updated QL, updated FA
Revised: 3/1/22 – annual review, updated referenced policies & covered LOBs
Revised: 4/6/22 – updated diag. reqs., removed failure of apheresis & Repatha, added failure of ezetimibe



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 294.0

**SECTION: Commercial Drug
SUBJECT: Zolmitriptan Nasal Spray**

Applicable line of business:

Commercial	X	Medicaid	
Medicare		ACA	X
GHP Kids	X	Self-Insured	X

POLICY:

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for zolmitriptan nasal spray for GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 296.0 Triptan Quantity Limit Exceptions
- Policy 487.0 Quantity Limit Exceptions

REQUIRED DEFINITIONS:

1. **Attachment** – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. **Exhibit** – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. **Devised** – the date the policy was implemented.
4. **Revised** – the date of every revision to the policy, including typographical and grammatical changes.
5. **Reviewed** – the date documenting the annual review if the policy has no revisions necessary.

ADDITIONAL DEFINITIONS:

1. **Formulary** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. **Non-formulary products** – those medications that are not included in the Formulary.
3. **Healthcare provider** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
4. **NCQA** – National Committee for Quality Assurance.

5. **Medically Necessary or Medical Necessity** – covered services rendered by a provider that the Health Plan determines are:
- A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
 - B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
 - C. In accordance with current standards of medical practice;
 - D. Not primarily for the convenience of the Member, or the Member's Provider; and
 - E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

PROCEDURE:

An exception for coverage of zolmitriptan nasal spray may be made for members who meet the following criteria:

- Medical record documentation of a Food and Drug Administration (FDA) approved indication **AND**
- Medical record documentation the member is not using concurrent opioid or barbiturate therapy for migraine treatment **AND**
- Medical record documentation of a therapeutic failure on, intolerance to, or contraindication to sumatriptan nasal spray for patients 18 years of age and older **OR**
- Medical record documentation of a therapeutic failure on, intolerance to, or contraindication to rizatriptan **AND** almotriptan for patients 12 to 18 years or age

MEDISPAN AUTHORIZATION LEVEL: GPI-12, generic only

QUANTITY LIMIT: *No QLs need to be entered within the authorization unless the requested quantity exceeds the QL.*

- **QL FOR LETTER ONLY:** 16 units per 28 days (The quantity limit of 16 units per 28 days applies to each individual nasal or injectable product however applies *across all triptan oral tablet products.*) (1 unit = 1 tablet = 1 injection = 1 nasal spray)

If an exception is made zolmitriptan nasal spray will be paid for under the member's prescription drug benefit.

Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.



POLICY NUMBER: 294.0

**POLICY AND PROCEDURE
PHARMACY
MANUAL**

**SECTION: Commercial Drug
SUBJECT: Zolmitriptan Nasal Spray**

FORMULARY ALTERNATIVES:

sumatriptan**, Cafergot, rizatriptan**, rizatriptan tablet dispersible**, Migranal, DHE 45, naratriptan**

** quantity limits apply

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE
STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND
FEDERAL REGULATORY ENTITIES.**

**THIS POLICY WILL BE REVISED AS NECESSARY AND
REVIEWED NO LESS THAN ANNUALLY.**

Signed: _____

Title: Director, Pharmacy Services

Date: March 1, 2022

Devised: 9/25/13
Revised: 3/1/14 – annual review, corrected typo
Revised: 3/1/15 – annual review, updated signature
Revised: 1/20/15 – added age indicator to alternatives, added ages 12-18
Reviewed: 3/1/16 – annual review
Revised: 5/1/16 – updated format, logo, & procedure
Reviewed: 3/1/17 – annual review
Revised: 3/1/18 – annual review, updated signature, defined FDA, removed QL indicator
Reviewed: 3/1/19 – annual review
Revised: 3/1/20 – annual review, added GHP Kids
Revised: 3/1/21 – annual review, updated logo, added MediSpan approval level, updated Zomig to generic, updated QL statement
Revised: 3/1/22 – annual review, updated referenced policies & covered LOBs



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 295.0

**SECTION: Commercial Drug
SUBJECT: Almotriptan, Eletriptan,
and Frovatriptan**

Applicable line of business:

Commercial	X	Medicaid	
Medicare		ACA	X
GHP Kids	X	Self-Insured	X

POLICY:

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for almotriptan, eletriptan, and frovatriptan for GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 296.0 Triptan Quantity Limit Exceptions
- Policy 487.0 Quantity Limit Exceptions

REQUIRED DEFINITIONS:

1. **Attachment** – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. **Exhibit** – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. **Devised** – the date the policy was implemented.
4. **Revised** – the date of every revision to the policy, including typographical and grammatical changes.
5. **Reviewed** – the date documenting the annual review if the policy has no revisions necessary.

ADDITIONAL DEFINITIONS:

1. **Formulary** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. **Non-formulary products** – those medications that are not included in the Formulary.
3. **Healthcare provider** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
4. **NCQA** – National Committee for Quality Assurance.



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 295.0

**SECTION: Commercial Drug
SUBJECT: Almotriptan, Eletriptan,
and Frovatriptan**

5. **Medically Necessary or Medical Necessity** – covered services rendered by a provider that the Health Plan determines are:
- A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
 - B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
 - C. In accordance with current standards of medical practice;
 - D. Not primarily for the convenience of the Member, or the Member's Provider; and
 - E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

PROCEDURE:

An exception for coverage of almotriptan, eletriptan, or frovatriptan may be made for members who meet the following criteria:

- Medical record documentation of a medically accepted indication:
 - Almotriptan, eletriptan, frovatriptan: migraine
 - Frovatriptan: short term menstrual related migraines

AND

- Medical record documentation the member is not using concurrent opioid or barbiturate therapy for migraine treatment

AND

- Based on indication:
 - **For migraine indication:** Medical record documentation of a therapeutic failure on, intolerance to, or contraindication to sumatriptan, naratriptan, and rizatriptan **OR**
 - **For short term menstrual related migraines:** Medical record documentation of a therapeutic failure on, intolerance to, or contraindication naratriptan **OR**
 - **For members 12-17 years with migraines (almotriptan only):** medical record documentation of therapeutic failure, intolerance to, or contraindication to rizatriptan and sumatriptan

MEDISPAN AUTHORIZATION LEVEL: GPI-12

QUANTITY LIMIT: *No QLs need to be entered within the authorization unless the requested quantity exceeds the QL.*

- **QL FOR LETTER ONLY:** 16 doses per 28 days (Dose limit applies across all oral triptan products.)



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 295.0

**SECTION: Commercial Drug
SUBJECT: Almotriptan, Eletriptan,
and Frovatriptan**

If an exception is made, almotriptan, eletriptan or frovatriptan will be paid for under the member's prescription drug benefit.

Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.

FORMULARY ALTERNATIVES:

sumatriptan**, Cafergot, rizatriptan**, Migranal, DHE 45, naratriptan**

** Quantity Limits apply

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE
STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND
FEDERAL REGULATORY ENTITIES.**

**THIS POLICY WILL BE REVISED AS NECESSARY AND
REVIEWED NO LESS THAN ANNUALLY.**

Signed: _____

Title: Director, Pharmacy Services

Date: March 1, 2022

Devised: 9/25/13
Reviewed: 3/1/14 – annual review
Revised: 3/1/15 – annual review, updated signature
Reviewed: 3/1/16 – annual review
Revised: 5/1/16 – updated format, logo, & procedure
Revised: 3/1/17 – annual review, updated Axert & Frova to almotriptan & frovatriptan
Revised: 3/1/18 – annual review, updated signature & Relpax to generic, removed QL indicator
Reviewed: 3/1/19 – annual review
Revised: 3/1/20 – annual review, added GHP Kids
Revised: 3/1/21 – annual review, updated logo, added MediSpan approval level, updated QL statement
Revised: 3/1/22 – annual review, updated referenced policies & covered LOBs



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 296.0

**SECTION: Commercial Drug
SUBJECT: Triptan Quantity Limit
Exception**

Applicable line of business:

Commercial	X	Medicaid	
Medicare		ACA	X
GHP Kids	X	Self-Insured	X

POLICY:

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for triptan quantity limit exceptions for GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 487.0 Quantity Limit Exceptions

REQUIRED DEFINITIONS:

1. **Attachment** – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. **Exhibit** – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. **Devised** – the date the policy was implemented.
4. **Revised** – the date of every revision to the policy, including typographical and grammatical changes.
5. **Reviewed** – the date documenting the annual review if the policy has no revisions necessary.

ADDITIONAL DEFINITIONS:

1. **Formulary** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. **Non-formulary products** – those medications that are not included in the Formulary.
3. **Healthcare provider** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
4. **NCQA** – National Committee for Quality Assurance.
5. **Medically Necessary or Medical Necessity** – covered services rendered by a provider that the Health Plan determines are:



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 296.0

**SECTION: Commercial Drug
SUBJECT: Triptan Quantity Limit
Exception**

- A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
- B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
- C. In accordance with current standards of medical practice;
- D. Not primarily for the convenience of the Member, or the Member's Provider; and
- E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

PROCEDURE:

An exception for the quantity limit of 16 units in 28 days of a triptan product may be made for members who meet the following criteria. (NOTE: Dose limit applies across all ORAL triptan products):

- Medical record documentation that requested medication is prescribed by a neurologist **AND**
- The greater than 16 dose per month prescription is being used for a medically accepted indication, including:
 - Cluster Headaches
 - Headache Bridging
 - Menstrual Migraine

AND

- Member is not using concurrent opioid or barbiturate therapy for migraine treatment **AND**
- Medical record documentation of current use of prophylaxis therapy or therapeutic failure, contraindication, or intolerance to **ALL** of the following:
 - Beta blocker (metoprolol, propranolol, atenolol, nadolol or timolol)
 - Topiramate
 - Amitriptyline
 - Divalproex or Sodium Valproate
 - Venlafaxine

If the QL exception is made for headache bridging therapy only a one month prior authorization override will be provided. Future need for a triptan headache bridge will require additional prior authorization.

*1 unit = 1 tablet = 1 injection = 1 nasal spray. The quantity limit of 16 units per 28 days applies to each individual nasal or injectable product but applies across all triptan oral tablet products.



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 296.0

**SECTION: Commercial Drug
SUBJECT: Triptan Quantity Limit
Exception**

MEDISPAN AUTHORIZATION LEVEL: GPI-14

If an exception is made, the triptan quantity limit exception will be paid for under the member's prescription drug benefit.

Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.

FORMULARY ALTERNATIVES:

none

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE
STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND
FEDERAL REGULATORY ENTITIES.**

**THIS POLICY WILL BE REVISED AS NECESSARY AND
REVIEWED NO LESS THAN ANNUALLY.**

Signed: _____

Title: Director, Pharmacy Services

Date: March 1, 2022

Devised: 9/25/13
Reviewed: 3/1/14 – annual review
Revised: 3/1/15 – annual review, updated signature
Reviewed: 3/1/16 – annual review
Revised: 5/1/16 – updated format, logo, & procedure
Reviewed: 3/1/17 – annual review
Revised: 3/1/18 – annual review, updated signature & prescriber criteria, removed Unicode
Reviewed: 3/1/19 – annual review
Revised: 3/1/20 – annual review, added GHP Kids
Revised: 3/1/21 – annual review, updated logo, added MediSpan approval level
Revised: 3/1/22 – annual review, updated referenced policies & covered LOBs



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 297.0

**SECTION: Commercial Drug
SUBJECT: Sirturo**

Applicable line of business:

Commercial	X	Medicaid	
Medicare		ACA	X
GHP Kids	X	Self-Insured	X

POLICY:

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for Sirturo for GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 487.0 Quantity Limit Exceptions

REQUIRED DEFINITIONS:

1. **Attachment** – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. **Exhibit** – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. **Devised** – the date the policy was implemented.
4. **Revised** – the date of every revision to the policy, including typographical and grammatical changes.
5. **Reviewed** – the date documenting the annual review if the policy has no revisions necessary.

ADDITIONAL DEFINITIONS:

1. **Formulary** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. **Non-formulary products** – those medications that are not included in the Formulary.
3. **Healthcare provider** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
4. **NCQA** – National Committee for Quality Assurance.
5. **Medically Necessary or Medical Necessity** – covered services rendered by a provider that the Health Plan determines are:



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 297.0

**SECTION: Commercial Drug
SUBJECT: Sirturo**

- A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
- B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
- C. In accordance with current standards of medical practice;
- D. Not primarily for the convenience of the Member, or the Member's Provider; and
- E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

PROCEDURE:

An exception for coverage of Sirturo may be made for members who meet the following criteria:

- Medical record documentation Sirturo is prescribed by a physician specializing in infectious disease **AND**
- Medical record documentation of one of the following:
 - Age greater than or equal to 18 years **OR**
 - Age greater than or equal to 5 years, weighing at least 15 kg **AND**
- Medical record documentation of resistance to isoniazid **AND** rifampin **AND**
- Medical record documentation that an effective treatment regimen cannot be attained with other available treatment options **AND**
- Medical record documentation of one of the following:
 - Sirturo is being prescribed in combination with at least 3 other drugs to which the patient's multi-drug resistant tuberculosis (MDR-TB) isolate has been shown to be susceptible to in vitro **OR**
 - If in vitro testing results are unavailable, Sirturo is being prescribed in combination with at least 4 other drugs to which the patient's MDR-TB isolate is likely to be susceptible

MEDISPAN AUTHORIZATION LEVEL: GPI-12

QUANTITY LIMIT: *QLs must be entered within the authorization.*

- 100 mg tablets: First Fill – 56 tablets, Subsequent Fills – 24 tablets
- 20 mg tablets: First Fill – 280 tablets, Subsequent Fills – 120 tablets

AUTHORIZATION DURATION: 24 weeks



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 297.0

**SECTION: Commercial Drug
SUBJECT: Sirturo**

If an exception is made, Sirturo will be paid for under the member's prescription drug benefit.

Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.

FORMULARY ALTERNATIVES:

amoxicillin-clavulanic acid, clarithromycin, ethambutol, isoniazid, levofloxacin, pyrazinamide, rifampin, moxifloxacin

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE
STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND
FEDERAL REGULATORY ENTITIES.**

**THIS POLICY WILL BE REVISED AS NECESSARY AND
REVIEWED NO LESS THAN ANNUALLY.**

Signed: _____

Title: Director, Pharmacy Services

Date: March 1, 2022

Devised: 10/7/13
Reviewed: 3/1/14 – annual review
Revised: 3/1/15 – annual review, updated signature
Revised: 3/1/16 – annual review, corrected typo in auth duration, changed Avelox to moxifloxacin
Revised: 5/1/16 – updated format, logo, & procedure
Revised: 3/1/17 – annual review, removed Unicode characters
Revised: 3/1/18 – annual review, updated signature, updated prescriber criteria
Revised: 3/1/19 – annual review, defined MDR-TB
Revised: 1/28/20 – updated for new indication in patients 12 to less than 18 years weighing at least 30 kg and added criteria for when in vitro testing results are unavailable
Revised: 3/1/20 – annual review, added GHP Kids
Revised: 11/18/20 – Changed age from 12 years/30 kg to 5 years/15 kg, added 20 mg tablet QL
Revised: 3/1/21 – annual review, updated logo, added MediSpan approval level, updated QL statement
Revised: 3/1/22 – annual review, updated referenced policies & covered LOBs



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 298.0

**SECTION: Commercial Drug
SUBJECT: Osphena**

Applicable line of business:

Commercial	X	Medicaid	
Medicare		ACA	X
GHP Kids	X	Self-Insured	X

POLICY:

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for Osphena for GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 487.0 Quantity Limit Exceptions

REQUIRED DEFINITIONS:

1. **Attachment** – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. **Exhibit** – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. **Devised** – the date the policy was implemented.
4. **Revised** – the date of every revision to the policy, including typographical and grammatical changes.
5. **Reviewed** – the date documenting the annual review if the policy has no revisions necessary.

ADDITIONAL DEFINITIONS:

1. **Formulary** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. **Non-formulary products** – those medications that are not included in the Formulary.
3. **Healthcare provider** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
4. **NCQA** – National Committee for Quality Assurance.
5. **Medically Necessary or Medical Necessity** – covered services rendered by a provider that the Health Plan determines are:



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 298.0

**SECTION: Commercial Drug
SUBJECT: Osphena**

- A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
- B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
- C. In accordance with current standards of medical practice;
- D. Not primarily for the convenience of the Member, or the Member's Provider; and
- E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

PROCEDURE:

An exception for coverage of Osphena may be made for members who meet the following criteria:

Severe Vaginal Dryness

- Medical record documentation of a diagnosis of menopause **AND**
- Medical record documentation that the member is experiencing moderate to severe vaginal dryness, a symptom of vulvar vaginal atrophy, due to menopause **AND**
- Medical record documentation of therapeutic failure on, intolerance to, or contraindication to an over-the-counter (OTC) vaginal moisturizer and/or lubricant **AND**
- Medical record documentation of therapeutic failure on, intolerance to, or contraindication to two (2) formulary topical estradiol/ conjugated estrogen products (e.g., cream, tablet, ring)

NOTE: Treatment of moderate to severe dyspareunia, a symptom of vulvar and vaginal atrophy, due to menopause is excluded from coverage, except for certain clients that request this benefit (treatment of female sexual dysfunction).

Dyspareunia

- Medical record documentation of a diagnosis of menopause **AND**
- Medical record documentation that the member is experiencing at least one of the following symptoms of vulvar and vaginal atrophy:
 - Moderate to severe dyspareunia
 - Moderate to severe vaginal dryness **AND**
- Medical record documentation of therapeutic failure on, intolerance to, or contraindication to an OTC vaginal moisturizer and/or lubricant **AND**



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 298.0

**SECTION: Commercial Drug
SUBJECT: Osphe**

- Medical record documentation of therapeutic failure on, intolerance to, or contraindication to two (2) formulary topical estradiol/ conjugated estrogen products (e.g., cream, tablet, ring)

QUANTITY LIMIT: 1 tablet per day

If an exception is made, Osphe will be paid for under the member's prescription drug benefit.

Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.

FORMULARY ALTERNATIVES:

Premarin Vaginal Cream, Estring, estradiol vaginal cream, Yuvaferm

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE
STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND
FEDERAL REGULATORY ENTITIES.**

**THIS POLICY WILL BE REVISED AS NECESSARY AND
REVIEWED NO LESS THAN ANNUALLY.**

Signed: _____

Title: Director, Pharmacy Services

Date: March 1, 2022

Devised: 10/07/13
Reviewed: 3/1/14 – annual review
Revised: 3/1/15 – annual review, updated signature
Reviewed: 3/1/16 – annual review
Revised: 5/1/16 – updated format, logo, & procedure
Revised: 3/1/17 – annual review, updated Vagifem to Yuvaferm
Retired: 2/20/18
Reinstated: 7/23/19
Revised: 8/1/19 – removed duplicate criteria, corrected typo
Revised: 3/1/20 – annual review, added GHP Kids
Revised: 3/1/21 – annual review, updated logo, added MediSpan approval level

Geisinger

**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 298.0

**SECTION: Commercial Drug
SUBJECT: Osphena**

Revised: 3/1/22 – annual review, updated referenced policies & covered LOBs, removed TPA reference from exclusions



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 304.0

**SECTION: Commercial Drug
SUBJECT: Tafenlar and Mekinist**

Applicable line of business:

Commercial	X	Medicaid	
Medicare		ACA	X
GHP Kids	X	Self-Insured	X

POLICY:

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for Tafenlar and Mekinist for GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 487.0 Quantity Limit Exceptions

REQUIRED DEFINITIONS:

1. **Attachment** – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. **Exhibit** – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. **Devised** – the date the policy was implemented.
4. **Revised** – the date of every revision to the policy, including typographical and grammatical changes.
5. **Reviewed** – the date documenting the annual review if the policy has no revisions necessary.

ADDITIONAL DEFINITIONS:

1. **Formulary** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. **Non-formulary products** – those medications that are not included in the Formulary.
3. **Healthcare provider** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
4. **NCQA** – National Committee for Quality Assurance.
5. **Medically Necessary or Medical Necessity** – covered services rendered by a provider that the Health Plan determines are:

- A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
- B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
- C. In accordance with current standards of medical practice;
- D. Not primarily for the convenience of the Member, or the Member's Provider; and
- E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

PROCEDURE:

New members to the plan already established on therapy may be eligible for continuity of care coverage as long as there is medical record documentation that the safety and effectiveness of use for the prescribed indication is supported by Food and Drug Administration (FDA) approval or adequate medical and scientific evidence in the medical literature.

An exception for coverage of Tafinlar or Mekinist may be made for members who meet the following criteria:

Unresectable or Metastatic Melanoma

- Medical record documentation that Tafinlar or Mekinist is prescribed by a hematologist, oncologist, or dermatologist **AND**
- Medical record documentation of unresectable or metastatic melanoma **AND**
- Medical record documentation of BRAF V600E or V600K mutations as detected by a Food and Drug Administration (FDA)-approved test **AND**
- One of the following:
 - Medical record documentation that the requested medication is being used as a single agent **AND**
 - If the request is for Mekinist as a single agent: Medical record documentation of no prior therapeutic failure with a BRAF inhibitor therapy (e.g., Zelboraf, Tafinlar, or Braftovi)**OR**
 - Medical record documentation that Mekinist and Tafinlar will be used in combination

Metastatic Non-Small Cell Lung Cancer

- Medical record documentation that Tafinlar and Mekinist are prescribed by a hematologist or oncologist **AND**
- Medical record documentation of metastatic non-small cell lung cancer **AND**
- Medical record documentation that Mekinist and Tafinlar will be used in combination **AND**
- Medical record documentation of BRAF V600E mutation as detected by a Food and Drug Administration (FDA)-approved test

Adjuvant Treatment of Melanoma

- Medical record documentation that Tafinlar and Mekinist are prescribed by a dermatologist, hematologist, or oncologist **AND**
- Medical record documentation of melanoma with involvement of lymph node(s) **AND**
- Medical record documentation that Mekinist and Tafinlar will be used in combination **AND**
- Medical record documentation of BRAF V600E or V600K mutation as detected by a Food and Drug Administration (FDA)-approved test **AND**
- Medical record documentation that Mekinist and Tafinlar will be used as adjuvant treatment following complete resection

Anaplastic Thyroid Cancer

- Medical record documentation that Tafinlar and Mekinist are prescribed by a hematologist or oncologist **AND**
- Medical record documentation of locally advanced or metastatic anaplastic thyroid cancer **AND**
- Medical record documentation that Mekinist and Tafinlar will be used in combination **AND**
- Medical record documentation of BRAF V600E mutation as detected by a Food and Drug Administration (FDA)-approved test

MEDISPAN AUTHORIZATION LEVEL: GPI-12

QUANTITY LIMIT: *No QLs need to be entered within the authorization unless the requested quantity exceeds the QL.*

- **QL FOR LETTER ONLY:**
 - Tafinlar: 4 capsules per day, 30 day supply per fill
 - Mekinist 1 mg and 2 mg: 1 tablet per day, 30 day supply per fill
 - Mekinist 0.5 mg: 3 tablets per day, 30 day supply per fill

NOTE TO CSR:

- If the request is for metastatic non-small cell lung cancer, adjuvant treatment of melanoma, or anaplastic thyroid carcinoma, enter two (2) authorizations, one (1) for Mekinist and one (1) for Tafinlar with appropriate authorization durations and quantity limits.
- If the request is for unresectable or metastatic melanoma as combination therapy (Mekinist and Tafinlar), enter two (2) authorizations, one (1) for Mekinist and one (1) for Tafinlar with appropriate authorization durations and quantity limits.
- If the request is for unresectable or metastatic melanoma as a single agent, enter an authorization for the requested medication with appropriate authorization duration and quantity limits.

AUTHORIZATION DURATION (for Adjuvant Treatment of Melanoma): Approval will be for 12 months or less if the reviewing provider feels it is medically appropriate. The FDA-approved treatment duration is for 12 months only. For requests exceeding the above limit, medical record documentation of the following is required:

- Peer-reviewed literature citing well-designed clinical trials to indicate that the member's healthcare outcome will be improved by dosing beyond the FDA-approved treatment duration

AUTHORIZATION DURATION (for all other indications): Each treatment period will be defined as 12 months. Re-review will occur every 12 months. Tafinlar will no longer be covered if there is medical record documentation of disease progression.

If an exception is made, Tafinlar and/or Mekinist will be paid for under the member's prescription drug benefit.

Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.

FORMULARY ALTERNATIVES:

Unresectable or Metastatic Melanoma: Zelboraf*, Braftovi*

*prior authorization required



POLICY NUMBER: 304.0

**POLICY AND PROCEDURE
PHARMACY
MANUAL**

**SECTION: Commercial Drug
SUBJECT: Tafinlar and Mekinist**

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE
STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND
FEDERAL REGULATORY ENTITIES.**

**THIS POLICY WILL BE REVISED AS NECESSARY AND
REVIEWED NO LESS THAN ANNUALLY.**

Signed: _____

Title: Director, Pharmacy Services

Date: March 1, 2022

- Devised: 10/7/13
- Revised: 3/1/14 – annual review, added PA indicator for Zelboraf
- Revised: 3/20/14 – added criteria regarding concomitant use with Mekinist
- Revised: 3/1/15 – annual review, updated signature
- Reviewed: 3/1/16 – annual review
- Revised: 5/1/16 – updated format, logo, & procedure
- Reviewed: 3/1/17 – annual review
- Revised: 10/9/17 – removed no prior therapy from melanoma, added NSCLC, auth to 12 months
- Revised: 3/1/18 – annual review, updated signature, added grandfather language, updated prescriber criteria, removed QL indicator
- Revised: 8/21/18 – combined Mekinist/Tafinlar policies for unresectable or metastatic melanoma and metastatic NSCLC, added adjuvant treatment of melanoma and thyroid cancer indications, added note to CSR, updated FA
- Revised: 3/1/19 – annual review, added QL approval note
- Revised: 3/1/20 – annual review, added GHP Kids
- Revised: 3/1/21 – annual review, updated logo, added MediSpan approval level, updated QL statement
- Revised: 3/1/22 – annual review, updated referenced policies & covered LOBs



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 305.0

**SECTION: Commercial Drug
SUBJECT: Trokendi XR**

Applicable line of business:

Commercial	X	Medicaid	
Medicare		ACA	X
GHP Kids	X	Self-Insured	X

POLICY:

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for Trokendi XR for GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 487.0 Quantity Limit Exceptions

REQUIRED DEFINITIONS:

1. **Attachment** – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. **Exhibit** – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. **Devised** – the date the policy was implemented.
4. **Revised** – the date of every revision to the policy, including typographical and grammatical changes.
5. **Reviewed** – the date documenting the annual review if the policy has no revisions necessary.

ADDITIONAL DEFINITIONS:

1. **Formulary** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. **Non-formulary products** – those medications that are not included in the Formulary.
3. **Healthcare provider** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
4. **NCQA** – National Committee for Quality Assurance.
5. **Medically Necessary or Medical Necessity** – covered services rendered by a provider that the Health Plan determines are:

- A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
- B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
- C. In accordance with current standards of medical practice;
- D. Not primarily for the convenience of the Member, or the Member's Provider; and
- E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

PROCEDURE:

New members to the plan already established on therapy may be eligible for continuity of care coverage as long as there is medical record documentation that the safety and effectiveness of use for the prescribed indication is supported by Food and Drug Administration (FDA) approval or adequate medical and scientific evidence in the medical literature.

An exception for coverage of Trokendi XR may be made for members who meet the following criteria:

Seizure Disorders

- Medical record documentation of a diagnosis of partial onset seizures, primary generalized tonic-clonic seizures, or Lennox Gastaut Syndrome **AND**
- Medical record documentation of age greater than or equal to 6 years **AND**
- Medical record documentation of therapeutic failure on, intolerance to, or contraindication to topiramate extended release*

Migraine Headache Prophylaxis

- Medical record documentation of use for prophylaxis of migraine headaches **AND**
- Medical record documentation of age greater than or equal to 12 years **AND**
- Medical record documentation of therapeutic failure on, intolerance to, or contraindication to topiramate extended release*

MEDISPAN AUTHORIZATION LEVEL: GPI-12

If an exception is made, Trokendi XR will be paid for under the member's prescription drug benefit.

Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.

FORMULARY ALTERNATIVES:

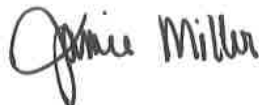
Seizure Disorders: carbamazepine, divalproex, felbamate, valproic acid, topiramate immediate release, topiramate extended release*, lamotrigine, levetiracetam, oxcarbazepine, phenytoin, zonisamide, gabapentin, tiagabine, phenobarbital, Lyrica

Migraine Prophylaxis: topiramate immediate release, topiramate extended release*, propranolol, timolol, divalproex delayed release, divalproex extended release, amitriptyline, atenolol, metoprolol, nadolol, venlafaxine, sodium valproate

*prior authorization required

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE
STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND
FEDERAL REGULATORY ENTITIES.**

**THIS POLICY WILL BE REVISED AS NECESSARY AND
REVIEWED NO LESS THAN ANNUALLY.**



Signed: _____

Title: Director, Pharmacy Services

Date: March 1, 2022

Devised: 11/15/13
Reviewed: 3/1/14 – annual review
Revised: 3/1/15 – annual review, updated signature
Revised: 4/13/15 – added indication and age requirements
Reviewed: 3/1/16 – annual review
Revised: 5/1/16 – updated format, logo, & procedure
Revised: 11/22/16 – updated FA
Reviewed: 3/1/17 – annual review
Revised: 6/2/17 – added migraine, updated seizures to trial of topiramate ER, updated FA
Revised: 3/1/18 – annual review, updated signature, added grandfather language
Reviewed: 3/1/19 – annual review
Revised: 3/1/20 – annual review, added GHP Kids
Revised: 3/1/21 – annual review, updated logo, added MediSpan approval level



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 305.0

**SECTION: Commercial Drug
SUBJECT: Trokendi XR**

Revised: 3/1/22 – annual review, updated referenced policies & covered LOBs



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 306.0

**SECTION: Commercial Drug
SUBJECT: Procysbi**

Applicable line of business:

Commercial	X	Medicaid	
Medicare		ACA	X
GHP Kids	X	Self-Insured	X

POLICY:

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for Procysbi for GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 487.0 Quantity Limit Exceptions

REQUIRED DEFINITIONS:

1. **Attachment** – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. **Exhibit** – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. **Devised** – the date the policy was implemented.
4. **Revised** – the date of every revision to the policy, including typographical and grammatical changes.
5. **Reviewed** – the date documenting the annual review if the policy has no revisions necessary.

ADDITIONAL DEFINITIONS:

1. **Formulary** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. **Non-formulary products** – those medications that are not included in the Formulary.
3. **Healthcare provider** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
4. **NCQA** – National Committee for Quality Assurance.
5. **Medically Necessary or Medical Necessity** – covered services rendered by a provider that the Health Plan determines are:



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 306.0

**SECTION: Commercial Drug
SUBJECT: Procysbi**

- A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
- B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
- C. In accordance with current standards of medical practice;
- D. Not primarily for the convenience of the Member, or the Member's Provider; and
- E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

PROCEDURE:

An exception for coverage of Procysbi may be made for members who meet the following criteria:

- Medical record documentation of a diagnosis of nephropathic cystinosis **AND**
- Medical record documentation of age greater than or equal to 1 year **AND**
- Medical record documentation that Procysbi is prescribed by a nephrologist **AND**
- Medical record documentation of one of the following:
 - Medical record documentation of intolerance to Cystagon and one of the following:
 - If intolerance is gastrointestinal-related, medical record documentation of therapeutic failure on 4 months of Cystagon and a proton-pump inhibitor (e.g. omeprazole, esomeprazole) **OR**
 - If intolerance is not gastrointestinal-related, justification supported by peer-review literature citing well-designed clinical trials that the member's intolerance will be improved by switching therapy to Procysbi
 - OR**
 - Medical record documentation of therapeutic failure on Cystagon as defined by all of the following:
 - Medical record documentation of failure to achieve white blood cell (WBC) cystine levels less than 1 nmol half-cystine/mg protein on maximally tolerated dose of Cystagon **AND**
 - Claims history or attestation from the provider that the patient is adherent to Cystagon at an every 6 hour dosing interval

MEDISPAN AUTHORIZATION LEVEL: GPI-12

DAY SUPPLY LIMIT: 34 day supply per fill



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 306.0

**SECTION: Commercial Drug
SUBJECT: Procysbi**

If an exception is made, Procysbi will be paid for under the member's prescription drug benefit.

Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.

FORMULARY ALTERNATIVES:

Cystagon

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE
STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND
FEDERAL REGULATORY ENTITIES.**

**THIS POLICY WILL BE REVISED AS NECESSARY AND
REVIEWED NO LESS THAN ANNUALLY.**

Signed: _____

Title: Director, Pharmacy Services

Date: March 1, 2022

Devised: 11/15/13
Reviewed: 3/1/14 – annual review
Revised: 3/1/15 – annual review, updated signature
Revised: 1/29/16 – updated age from 6 years to 2 years
Reviewed: 3/1/16 – annual review
Revised: 5/1/16 – updated format, logo, & procedure
Reviewed: 3/1/17 – annual review
Revised: 3/1/18 – annual review, updated signature & prescriber criteria, removed QL indicator
Revised: 5/30/18 – updated age to 1 year
Reviewed: 3/1/19 – annual review
Revised: 3/1/20 – annual review, added GHP Kids
Revised: 7/29/20 – defined intolerance and failure to Cystagon
Revised: 3/1/21 – annual review, updated logo, added MediSpan approval level
Revised: 3/1/22 – annual review, updated referenced policies & covered LOBs



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 307.0

**SECTION: Commercial Drug
SUBJECT: Gilotrif**

Applicable line of business:

Commercial	X	Medicaid	
Medicare		ACA	X
GHP Kids	X	Self-Insured	X

POLICY:

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for Gilotrif for GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 487.0 Quantity Limit Exceptions

REQUIRED DEFINITIONS:

1. **Attachment** – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. **Exhibit** – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. **Devised** – the date the policy was implemented.
4. **Revised** – the date of every revision to the policy, including typographical and grammatical changes.
5. **Reviewed** – the date documenting the annual review if the policy has no revisions necessary.

ADDITIONAL DEFINITIONS:

1. **Formulary** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. **Non-formulary products** – those medications that are not included in the Formulary.
3. **Healthcare provider** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
4. **NCQA** – National Committee for Quality Assurance.
5. **Medically Necessary or Medical Necessity** – covered services rendered by a provider that the Health Plan determines are:



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 307.0

**SECTION: Commercial Drug
SUBJECT: Gilotrif**

- A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
- B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
- C. In accordance with current standards of medical practice;
- D. Not primarily for the convenience of the Member, or the Member's Provider; and
- E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

PROCEDURE:

New members to the plan already established on therapy may be eligible for continuity of care coverage as long as there is medical record documentation that the safety and effectiveness of use for the prescribed indication is supported by Food and Drug Administration (FDA) approval or adequate medical and scientific evidence in the medical literature.

An exception for coverage of Gilotrif may be made for members who meet the following criteria:

- Medical record documentation that Gilotrif is prescribed by a hematologist or oncologist **AND**
- Medical record documentation of first line treatment for metastatic non-small cell lung cancer (NSCLC) with tumors that have non-resistant epidermal growth factor receptor (EGFR) mutations as detected by a Food and Drug Administration (FDA) approved test **OR**
- Medical record documentation of a diagnosis of metastatic, squamous non-small cell lung cancer (NSCLC) which has progressed after platinum-based chemotherapy

MEDISPAN AUTHORIZATION LEVEL: GPI-12, number of claims authorized = 1, enter for the remainder of the calendar year

QUANTITY LIMIT: *No QLs need to be entered within the authorization unless the requested quantity exceeds the QL.*

- QL FOR LETTER ONLY: 1 tablet per day, 30 day supply per fill for each strength

RE-AUTHORIZATION CRITERIA: Gilotrif is configured as a prior authorization for new starts only. Gilotrif will no longer be covered if it is identified that the member is not



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 307.0

**SECTION: Commercial Drug
SUBJECT: Gilotrif**

receiving appropriate follow-up care from the prescribing specialist or if the member has greater than or equal to a 90 day break in therapy.

- Medical record documentation that the member is receiving appropriate follow-up care from the prescribing specialist

If an exception is made, Gilotrif will be paid for under the member's prescription drug benefit.

Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.

FORMULARY ALTERNATIVES:

erlotinib*

*prior authorization required

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE
STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND
FEDERAL REGULATORY ENTITIES.**

**THIS POLICY WILL BE REVISED AS NECESSARY AND
REVIEWED NO LESS THAN ANNUALLY.**

Signed: _____

Title: Director, Pharmacy Services

Date: March 1, 2022

Devised: 11/15/13
Reviewed: 3/1/14 – annual review
Revised: 3/1/15 – annual review, updated signature
Reviewed: 3/1/16 – annual review
Revised: 5/1/16 – updated format, logo, & procedure
Revised: 5/27/16 – added metastatic NSCLC which has progressed after platinum based therapy
Reviewed: 3/1/17 – annual review
Revised: 3/1/18 – annual review, updated signature, added grandfather language, updated prescriber criteria, removed QL indicator
Revised: 4/6/18 – removed second line treatment and updated EGFR requirements
Revised: 3/1/19 – annual review, added QL approval note

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Dev. 11/15/13

Rev. 3/1/22



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 307.0

**SECTION: Commercial Drug
SUBJECT: Gilotrif**

Revised: 3/1/20 – annual review, added GHP Kids
Revised: 3/1/21 – annual review, updated logo, added MediSpan approval level, updated Tarceva to generic
Revised: 11/24/21 – added one-time PA to approval crit., removed auth duration & added re-auth crit.
Revised: 3/1/22 – annual review, updated referenced policies & covered LOBs



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 309.0

**SECTION: Commercial Drug
SUBJECT: Trintellix**

Applicable line of business:

Commercial	X	Medicaid	
Medicare		ACA	X
GHP Kids	X	Self-Insured	X

POLICY:

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for Trintellix for GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 487.0 Quantity Limit Exceptions

REQUIRED DEFINITIONS:

1. **Attachment** – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. **Exhibit** – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. **Devised** – the date the policy was implemented.
4. **Revised** – the date of every revision to the policy, including typographical and grammatical changes.
5. **Reviewed** – the date documenting the annual review if the policy has no revisions necessary.

ADDITIONAL DEFINITIONS:

1. **Formulary** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. **Non-formulary products** – those medications that are not included in the Formulary.
3. **Healthcare provider** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
4. **NCQA** – National Committee for Quality Assurance.
5. **Medically Necessary or Medical Necessity** – covered services rendered by a provider that the Health Plan determines are:



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 309.0

**SECTION: Commercial Drug
SUBJECT: Trintellix**

- A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
- B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
- C. In accordance with current standards of medical practice;
- D. Not primarily for the convenience of the Member, or the Member's Provider; and
- E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

PROCEDURE:

New members to the plan already established on therapy may be eligible for continuity of care coverage as long as there is medical record documentation that the safety and effectiveness of use for the prescribed indication is supported by Food and Drug Administration (FDA) approval or adequate medical and scientific evidence in the medical literature.

An exception for coverage of Trintellix may be made for members who meet the following criteria:

- Medical record documentation of age greater than or equal to 18 years **AND**
- Medical record documentation of a diagnosis of Major Depressive Disorder **AND**
- Medical record documentation of therapeutic failure on, intolerance to, or contraindication to at least three (3) antidepressant classes

MEDISPAN AUTHORIZATION LEVEL: GPI-12

If an exception is made, Trintellix will be paid for under the member's prescription drug benefit.

Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.



POLICY NUMBER: 309.0

**POLICY AND PROCEDURE
PHARMACY
MANUAL**

**SECTION: Commercial Drug
SUBJECT: Trintellix**

FORMULARY ALTERNATIVES:

SSRIs: citalopram, fluoxetine, paroxetine, sertraline, escitalopram

MAOIs: phenelzine, tranylcypromine

SNRIs: venlafaxine hcl, venlafaxine er, duloxetine, desvenlafaxine ER (generic Pristiq)

Tricyclics: amitriptyline, nortriptyline, desipramine, doxepin, imipramine

Bupropion: bupropion hcl, bupropion xl, bupropion sr

Other: trazodone, nefazodone, mirtazapine

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE
STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND
FEDERAL REGULATORY ENTITIES.**

**THIS POLICY WILL BE REVISED AS NECESSARY AND
REVIEWED NO LESS THAN ANNUALLY.**

Signed: _____

Title: Director, Pharmacy Services

Date: March 1, 2022

Devised: 11/15/13

Revised: 3/1/14 – annual review, added duloxetine to formulary alternatives

Revised: 3/1/15 – annual review, updated signature, added escitalopram to alternatives

Reviewed: 3/1/16 – annual review

Revised: 5/1/16 – updated format, logo, & procedure

Revised: 7/27/16 – updated name to Trintellix

Reviewed: 3/1/17 – annual review

Revised: 3/1/18 – annual review, updated signature & FA, added grandfather language

Reviewed: 3/1/19 – annual review

Revised: 3/1/20 – annual review, added GHP Kids

Revised: 3/1/21 – annual review, updated logo, added MediSpan approval level

Revised: 3/1/22 – annual review, updated referenced policies & covered LOBs, updated FA



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 310.0

**SECTION: Commercial Drug
SUBJECT: Rivastigmine Patch**

Applicable line of business:

Commercial	X	Medicaid	
Medicare		ACA	X
GHP Kids	X	Self-Insured	X

POLICY:

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for rivastigmine patch for GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 487.0 Quantity Limit Exceptions

REQUIRED DEFINITIONS:

1. **Attachment** – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. **Exhibit** – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. **Devised** – the date the policy was implemented.
4. **Revised** – the date of every revision to the policy, including typographical and grammatical changes.
5. **Reviewed** – the date documenting the annual review if the policy has no revisions necessary.

ADDITIONAL DEFINITIONS:

1. **Formulary** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. **Non-formulary products** – those medications that are not included in the Formulary.
3. **Healthcare provider** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
4. **NCQA** – National Committee for Quality Assurance.
5. **Medically Necessary or Medical Necessity** – covered services rendered by a provider that the Health Plan determines are:



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 310.0

**SECTION: Commercial Drug
SUBJECT: Rivastigmine Patch**

- A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
- B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
- C. In accordance with current standards of medical practice;
- D. Not primarily for the convenience of the Member, or the Member's Provider; and
- E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

PROCEDURE:

An exception for coverage of rivastigmine patch may be made for members who meet the following criteria:

- Medical record documentation of a diagnosis of mild to moderate dementia of the Alzheimer's type **AND**
- Medical record documentation of therapeutic failure on, intolerance to, or contraindication to rivastigmine capsules, donepezil tablets, **AND** galantamine tablets

OR

- Medical record documentation of a diagnosis of severe dementia of the Alzheimer's type **AND**
- Medical record documentation of therapeutic failure on, intolerance to, or contraindication to donepezil tablets

OR

- Medical record documentation of a diagnosis of mild to moderate dementia associated with Parkinson's disease **AND**
- Medical record documentation of therapeutic failure on, intolerance to, or contraindication to rivastigmine capsules

MEDISPAN AUTHORIZATION LEVEL: GPI-12, generic only

If an exception is made, rivastigmine patch will be paid for under the member's prescription drug benefit.



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 310.0

**SECTION: Commercial Drug
SUBJECT: Rivastigmine Patch**

Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.

FORMULARY ALTERNATIVES:

Mild to Moderate Dementia of the Alzheimer's Type: rivastigmine capsules, donepezil tablets, galantamine tablets

Severe Dementia of the Alzheimer's Type: donepezil tablets

Mild to Moderate Dementia associated with Parkinson's disease: rivastigmine capsules

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE
STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND
FEDERAL REGULATORY ENTITIES.**

**THIS POLICY WILL BE REVISED AS NECESSARY AND
REVIEWED NO LESS THAN ANNUALLY.**

Signed: _____

Title: Director, Pharmacy Services

Date: March 1, 2022

Devised: 11/15/13
Reviewed: 3/1/14 – annual review
Revised: 3/1/15 – annual review, updated signature
Reviewed: 3/1/16 – annual review
Revised: 5/1/16 – updated format, logo, & procedure
Revised: 3/1/17 – annual review, updated Exelon to rivastigmine
Revised: 3/1/18 – annual review, updated signature
Reviewed: 3/1/19 – annual review
Revised: 3/1/20 – annual review, added GHP Kids
Revised: 3/1/21 – annual review, updated logo, added MediSpan approval level
Revised: 3/1/22 – annual review, updated referenced policies & covered LOBs



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 311.0

**SECTION: Commercial Drug
SUBJECT: Sucraid**

Applicable line of business:

Commercial	X	Medicaid	
Medicare		ACA	X
GHP Kids	X	Self-Insured	X

POLICY:

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for Sucraid for GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 487.0 Quantity Limit Exceptions

REQUIRED DEFINITIONS:

1. **Attachment** – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. **Exhibit** – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. **Devised** – the date the policy was implemented.
4. **Revised** – the date of every revision to the policy, including typographical and grammatical changes.
5. **Reviewed** – the date documenting the annual review if the policy has no revisions necessary.

ADDITIONAL DEFINITIONS:

1. **Formulary** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. **Non-formulary products** – those medications that are not included in the Formulary.
3. **Healthcare provider** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
4. **NCQA** – National Committee for Quality Assurance.
5. **Medically Necessary or Medical Necessity** – covered services rendered by a provider that the Health Plan determines are:



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 311.0

**SECTION: Commercial Drug
SUBJECT: Sucraid**

- A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
- B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
- C. In accordance with current standards of medical practice;
- D. Not primarily for the convenience of the Member, or the Member's Provider; and
- E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

PROCEDURE:

An exception for coverage of Sucraid may be made for members who meet the following criteria:

- Medical record documentation that Sucraid is prescribed by a gastroenterologist, endocrinologist, or genetic specialist **AND**
- Medical record documentation of a diagnosis of congenital sucrose-isomaltase deficiency characterized by stool pH less than 6 **AND**
- Medical record documentation of an increase in breath hydrogen of greater than 10 ppm when challenged with sucrose after fasting **AND**
- Medical record documentation of a negative lactose breath test **OR**
- Medical record documentation of a diagnosis of congenital sucrose-isomaltase deficiency characterized by low sucrose activity on duodenal biopsy **AND**
- Other disaccharidases normal on same duodenal biopsy

MEDISPAN AUTHORIZATION LEVEL: GPI-12

QUANTITY LIMIT: *No QLs need to be entered within the authorization unless the requested quantity exceeds the QL.*

- **QL FOR LETTER ONLY:** 1 box (two 118 mL bottles) per fill

If an exception is made, Sucraid will be paid for under the member's prescription drug benefit.

Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 311.0

**SECTION: Commercial Drug
SUBJECT: Sucraid**

FORMULARY ALTERNATIVES:

none

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE
STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND
FEDERAL REGULATORY ENTITIES.**

**THIS POLICY WILL BE REVISED AS NECESSARY AND
REVIEWED NO LESS THAN ANNUALLY.**

Signed: _____

Title: Director, Pharmacy Services

Date: March 1, 2022

Devised: 2/01/14
Reviewed: 3/1/14 – annual review
Revised: 12/9/14 – changed AND in 4th bullet to OR as per P&T approved minutes, updated sig.
Reviewed: 3/1/15 – annual review
Reviewed: 3/1/16 – annual review
Revised: 5/1/16 – updated format, logo, & procedure
Reviewed: 3/1/17 – annual review
Revised: 3/1/18 – annual review, updated signature & prescriber criteria, removed QL indicator
Revised: 3/1/19 – annual review, added QL approval note, removed distribution information
Revised: 3/1/20 – annual review, added GHP Kids
Revised: 3/1/21 – annual review, updated logo, added MediSpan approval level, updated QL statement
Revised: 3/1/22 – annual review, updated referenced policies & covered LOBs



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 312.0

**SECTION: Commercial Drug
SUBJECT: Mirvaso**

Applicable line of business:

Commercial	X	Medicaid	
Medicare		ACA	X
GHP Kids	X	Self-Insured	X

POLICY:

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for Mirvaso for GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 487.0 Quantity Limit Exceptions

REQUIRED DEFINITIONS:

1. **Attachment** – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. **Exhibit** – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. **Devised** – the date the policy was implemented.
4. **Revised** – the date of every revision to the policy, including typographical and grammatical changes.
5. **Reviewed** – the date documenting the annual review if the policy has no revisions necessary.

ADDITIONAL DEFINITIONS:

1. **Formulary** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. **Non-formulary products** – those medications that are not included in the Formulary.
3. **Healthcare provider** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
4. **NCQA** – National Committee for Quality Assurance.
5. **Medically Necessary or Medical Necessity** – covered services rendered by a provider that the Health Plan determines are:



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 312.0

**SECTION: Commercial Drug
SUBJECT: Mirvaso**

- A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
- B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
- C. In accordance with current standards of medical practice;
- D. Not primarily for the convenience of the Member, or the Member's Provider; and
- E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

PROCEDURE:

An exception for coverage of Mirvaso may be made for members who meet the following criteria:

- Medical record documentation of a diagnosis of persistent (non-transient) facial erythema of rosacea **AND**
- Medical record documentation of age greater than or equal to 18 years

MEDISPAN AUTHORIZATION LEVEL: GPI-12

QUANTITY LIMIT: *No QLs need to be entered within the authorization unless the requested quantity exceeds the QL.*

- **QL FOR LETTER ONLY:** One (30 gram) tube per fill

If an exception is made, Mirvaso will be paid for under the member's prescription drug benefit.

Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.

FORMULARY ALTERNATIVES:

metronidazole cream, metronidazole gel, metronidazole lotion



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 312.0

**SECTION: Commercial Drug
SUBJECT: Mirvaso**

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE
STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND
FEDERAL REGULATORY ENTITIES.**

**THIS POLICY WILL BE REVISED AS NECESSARY AND
REVIEWED NO LESS THAN ANNUALLY.**

Signed: _____

Title: Director, Pharmacy Services

Date: March 1, 2022

Devised: 2/1/14
Reviewed: 3/1/14 – annual review
Revised: 3/1/15 – annual review, updated signature
Reviewed: 3/1/16 – annual review
Revised: 5/1/16 – updated format, logo, & procedure
Reviewed: 3/1/17 – annual review
Revised: 3/1/18 – annual review, updated signature, removed QL indicator
Revised: 3/1/19 – annual review, added QL approval note
Revised: 3/1/20 – annual review, added GHP Kids
Revised: 3/1/21 – annual review, updated logo, added MediSpan approval level, updated QL statement
Revised: 6/8/21 – removed failure of metronidazole, updated indication
Revised: 3/1/22 – annual review, updated referenced policies & covered LOBs



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 313.0

**SECTION: Commercial Drug
SUBJECT: Fabior Foam**

Applicable line of business:

Commercial	X	Medicaid	
Medicare		ACA	X
GHP Kids	X	Self-Insured	X

POLICY:

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for Fabior foam for GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 487.0 Quantity Limit Exceptions

REQUIRED DEFINITIONS:

1. **Attachment** – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. **Exhibit** – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. **Devised** – the date the policy was implemented.
4. **Revised** – the date of every revision to the policy, including typographical and grammatical changes.
5. **Reviewed** – the date documenting the annual review if the policy has no revisions necessary.

ADDITIONAL DEFINITIONS:

1. **Formulary** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. **Non-formulary products** – those medications that are not included in the Formulary.
3. **Healthcare provider** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
4. **NCQA** – National Committee for Quality Assurance.
5. **Medically Necessary or Medical Necessity** – covered services rendered by a provider that the Health Plan determines are:



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 313.0

**SECTION: Commercial Drug
SUBJECT: Fabior Foam**

- A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
- B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
- C. In accordance with current standards of medical practice;
- D. Not primarily for the convenience of the Member, or the Member's Provider; and
- E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

PROCEDURE:

An exception for coverage of Fabior Foam may be made for members who meet the following criteria:

- Medical record documentation of a diagnosis of acne, acne vulgaris, or adult onset acne **AND**
- Medical record documentation of age greater than or equal to 12 years **AND**
- Medical record documentation of therapeutic failure on, intolerance to, or contraindication to four formulary alternatives, one of which must be adapalene

MEDISPAN AUTHORIZATION LEVEL: GPI-12

If an exception is made, Fabior Foam will be paid for under the member's prescription drug benefit.

Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.

FORMULARY ALTERNATIVES:

adapalene, benzoyl peroxide, topical clindamycin, clindamycin/benzoyl peroxide, oral doxycycline, topical erythromycin, erythromycin/benzoyl peroxide, isotretinoin, oral minocycline, sulfacetamide/sulfur, topical tretinoin



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 313.0

**SECTION: Commercial Drug
SUBJECT: Fabior Foam**

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE
STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND
FEDERAL REGULATORY ENTITIES.**

**THIS POLICY WILL BE REVISED AS NECESSARY AND
REVIEWED NO LESS THAN ANNUALLY.**

Signed: _____

Title: Director, Pharmacy Services

Date: March 1, 2022

Devised: 2/1/14
Reviewed: 3/1/14 – annual review
Revised: 3/1/15 – annual review, updated signature
Revised: 3/1/16 – annual review, removed Differin 0.3% gel from FA, added tretinoin microsphere gel to FA,
removed 0.1% from adapalene FA
Revised: 5/1/16 – updated format, logo, & procedure
Revised: 3/1/17 – annual review, updated FA
Revised: 3/1/18 – annual review, updated signature
Reviewed: 3/1/19 – annual review
Revised: 3/1/20 – annual review, added GHP Kids
Revised: 3/1/21 – annual review, updated logo, added MediSpan approval level
Revised: 3/1/22 – annual review, updated referenced policies & covered LOBs



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 314.0

**SECTION: Commercial Drug
SUBJECT: Tobramycin Inhalation
Solution (generic Bethkis)**

Applicable line of business:

Commercial	X	Medicaid	
Medicare		ACA	X
GHP Kids	X	Self-Insured	X

POLICY:

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined tobramycin inhalation solution (generic Bethkis) for GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 487.0 Quantity Limit Exceptions

REQUIRED DEFINITIONS:

1. **Attachment** – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. **Exhibit** – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. **Devised** – the date the policy was implemented.
4. **Revised** – the date of every revision to the policy, including typographical and grammatical changes.
5. **Reviewed** – the date documenting the annual review if the policy has no revisions necessary.

ADDITIONAL DEFINITIONS:

1. **Formulary** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. **Non-formulary products** – those medications that are not included in the Formulary.
3. **Healthcare provider** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
4. **NCQA** – National Committee for Quality Assurance.
5. **Medically Necessary or Medical Necessity** – covered services rendered by a provider that the Health Plan determines are:



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 314.0

**SECTION: Commercial Drug
SUBJECT: Tobramycin Inhalation
Solution (generic Bethkis)**

- A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
- B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
- C. In accordance with current standards of medical practice;
- D. Not primarily for the convenience of the Member, or the Member's Provider; and
- E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

PROCEDURE:

An exception for coverage of tobramycin inhalation solution (generic Bethkis) may be made for members who meet the following criteria:

- Medical record documentation of a diagnosis of cystic fibrosis **AND**
- Medical record documentation that tobramycin inhalation solution (generic Bethkis) is prescribed by a pulmonologist

MEDISPAN AUTHORIZATION LEVEL: GPI-14

QUANTITY LIMIT: *No QLs need to be entered within the authorization unless the requested quantity exceeds the QL.*

- **QL FOR LETTER ONLY:** 224 mL per 56 days

If an exception is made, tobramycin inhalation solution (generic Bethkis) will be paid for under the member's prescription drug benefit.

Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.

FORMULARY ALTERNATIVES:

tobramycin inhalation solution*, Tobi inhalation solution*, Tobi PodHaler*

*prior authorization required



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 314.0

**SECTION: Commercial Drug
SUBJECT: Tobramycin Inhalation
Solution (generic Bethkis)**

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE
STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND
FEDERAL REGULATORY ENTITIES.**

**THIS POLICY WILL BE REVISED AS NECESSARY AND
REVIEWED NO LESS THAN ANNUALLY.**

Signed: _____

Title: Director, Pharmacy Services

Date: March 1, 2022

Devised: 2/1/14
Reviewed: 3/1/14 – annual review
Revised: 3/1/15 – annual review, updated signature
Revised: 11/20/15 – removed failure of tobramycin nebulas
Reviewed: 3/1/16 – annual review
Revised: 5/1/16 – updated format, logo, & procedure, removed AND from last bullet
Reviewed: 3/1/17 – annual review
Revised: 3/1/18 – annual review, updated signature & prescriber criteria, removed QL indicator
Revised: 3/1/19 – annual review, added QL approval note, added PA indicator to FA
Revised: 6/4/19 – removed CSR QL note, added authorization parameters
Revised: 3/1/20 – annual review, added GHP Kids
Revised: 3/1/21 – annual review, updated logo, added MediSpan approval level, updated Bethkis to generic, updated QL/auth parameter statements
Revised: 3/1/22 – annual review, updated referenced policies & covered LOBs



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 315.0

**SECTION: Commercial Drug
SUBJECT: Imbruvica**

Applicable line of business:

Commercial	X	Medicaid	
Medicare		ACA	X
GHP Kids	X	Self-Insured	X

POLICY:

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for Imbruvica for GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 487.0 Quantity Limit Exceptions

REQUIRED DEFINITIONS:

1. **Attachment** – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. **Exhibit** – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. **Devised** – the date the policy was implemented.
4. **Revised** – the date of every revision to the policy, including typographical and grammatical changes.
5. **Reviewed** – the date documenting the annual review if the policy has no revisions necessary.

ADDITIONAL DEFINITIONS:

1. **Formulary** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. **Non-formulary products** – those medications that are not included in the Formulary.
3. **Healthcare provider** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
4. **NCQA** – National Committee for Quality Assurance.
5. **Medically Necessary or Medical Necessity** – covered services rendered by a provider that the Health Plan determines are:

- A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
- B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
- C. In accordance with current standards of medical practice;
- D. Not primarily for the convenience of the Member, or the Member's Provider; and
- E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

PROCEDURE:

New members to the plan already established on therapy may be eligible for continuity of care coverage as long as there is medical record documentation that the safety and effectiveness of use for the prescribed indication is supported by Food and Drug Administration (FDA) approval or adequate medical and scientific evidence in the medical literature.

An exception for coverage of Imbruvica may be made for members who meet the following criteria:

Mantle Cell Lymphoma

- Medical record documentation that Imbruvica is prescribed by a hematologist or oncologist **AND**
- Medical record documentation of mantle cell lymphoma (MCL) **AND**
- Medical record documentation of therapeutic failure on, intolerance to, or contraindication to one prior therapy

Chronic Lymphocytic Leukemia/Small Lymphocytic Lymphoma

- Medical record documentation that Imbruvica is prescribed by a hematologist or oncologist **AND**
- Medical record documentation of chronic lymphocytic leukemia (CLL) **OR** small lymphocytic lymphoma (SLL)

Chronic Lymphocytic Leukemia/Small Lymphocytic Lymphoma with 17p deletion

- Medical record documentation that Imbruvica is prescribed by a hematologist or oncologist **AND**
- Medical record documentation of chronic lymphocytic leukemia (CLL) with 17p deletion **OR** small lymphocytic lymphoma with 17p deletion

Waldenström's macroglobulinemia

- Medical record documentation that Imbruvica is prescribed by a hematologist or oncologist **AND**
- Medical record documentation of a diagnosis of Waldenström's macroglobulinemia

Marginal Zone Lymphoma

- Medical record documentation that Imbruvica is prescribed by a hematologist or oncologist **AND**
- Medical record documentation of marginal zone lymphoma **AND**
- Medical record documentation of therapeutic failure on, intolerance to, or contraindication to at least one prior anti-CD20-based therapy

Chronic Graft Versus Host Disease (cGVHD)

- Medical record documentation that Imbruvica is prescribed by a hematologist or oncologist **AND**
- Medical record documentation of chronic graft versus host disease **AND**
- Medical record documentation of therapeutic failure on one or more lines of systemic therapy

MEDISPAN AUTHORIZATION LEVEL: GPI-10, number of claims authorized = 1, enter for the remainder of the calendar year

QUANTITY LIMIT: *No QLs need to be entered within the authorization unless the requested quantity exceeds the QL.*

- **QL FOR LETTER ONLY:** 1 tablet or capsule per day, 28 day supply per fill

RE-AUTHORIZATION CRITERIA: Imbruvica is configured as a prior authorization for new starts only. Imbruvica will no longer be covered if it is identified that the member is not receiving appropriate follow-up care from the prescribing specialist or if the member has greater than or equal to a 90 day break in therapy.

- Medical record documentation that the member is receiving appropriate follow-up care from the prescribing specialist

If an exception is made, Imbruvica will be paid for under the member's prescription drug benefit.

Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.



POLICY NUMBER: 315.0

**POLICY AND PROCEDURE
PHARMACY
MANUAL**

**SECTION: Commercial Drug
SUBJECT: Imbruvica**

FORMULARY ALTERNATIVES:

Mantle Cell Lymphoma: Brukinsa*, Calquence*, Revlimid*

Chronic Lymphocytic Leukemia/Small Lymphocytic Lymphoma: Calquence*, Venclexta*

Chronic Graft Versus Host Disease: prednisone, cyclosporine, tacrolimus, mycophenolate mofetil, sirolimus, Jakafi*, imatinib

*prior authorization required

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE
STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND
FEDERAL REGULATORY ENTITIES.**

**THIS POLICY WILL BE REVISED AS NECESSARY AND
REVIEWED NO LESS THAN ANNUALLY.**

Signed: _____

Title: Director, Pharmacy Services

Date: March 1, 2022

Devised: 2/1/14
Reviewed: 3/1/14 – annual review
Revised: 3/20/14 – added CLL indication
Revised: 9/22/14 – added CLL 17p deletion indication, clarified that Revlimid is alter. for MCL
Reviewed: 3/1/15 – annual review
Revised: 4/13/15 – added Waldenström’s macroglobulinemia, added indication headers
Reviewed: 3/1/16 – annual review
Revised: 5/1/16 – updated format, logo, & procedure
Revised: 7/22/16 – added SLL indication, removed failure of prior therapy for CLL/SLL
Reviewed: 3/1/17 – annual review
Revised: 3/6/17 – corrected typo in lymphocytic
Revised: 3/27/17 – added marginal zone lymphoma, increased auth duration to 12 months
Revised: 10/10/17 – added cGVHD, updated FA
Revised: 3/1/18 – annual review, updated signature & prescriber language, added grandfather language, updated format of indication headers, removed QL indicator
Revised: 4/6/18 – updated all QL to 1 per day, 28 day supply per fill
Revised: 3/1/19 – annual review, added QL approval note
Revised: 2/04/20 – updated FA
Revised: 3/1/20 – annual review, added GHP Kids
Revised: 3/1/21 – annual review, updated logo, added MediSpan approval level, updated QL statement
Revised: 11/24/21 – added one-time PA to approval crit., removed auth duration & added re-auth crit.

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Dev. 2/1/14

Rev. 3/1/22



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 315.0

**SECTION: Commercial Drug
SUBJECT: Imbruvica**

Revised: 3/1/22 – annual review, updated referenced policies & covered LOBs



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 316.0

**SECTION: Commercial Drug
SUBJECT: Fetzima**

Applicable line of business:

Commercial	X	Medicaid	
Medicare		ACA	X
GHP Kids	X	Self-Insured	X

POLICY:

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for Fetzima for GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 487.0 Quantity Limit Exceptions

REQUIRED DEFINITIONS:

1. **Attachment** – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. **Exhibit** – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. **Devised** – the date the policy was implemented.
4. **Revised** – the date of every revision to the policy, including typographical and grammatical changes.
5. **Reviewed** – the date documenting the annual review if the policy has no revisions necessary.

ADDITIONAL DEFINITIONS:

1. **Formulary** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. **Non-formulary products** – those medications that are not included in the Formulary.
3. **Healthcare provider** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
4. **NCQA** – National Committee for Quality Assurance.
5. **Medically Necessary or Medical Necessity** – covered services rendered by a provider that the Health Plan determines are:



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 316.0

**SECTION: Commercial Drug
SUBJECT: Fetzima**

- A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
- B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
- C. In accordance with current standards of medical practice;
- D. Not primarily for the convenience of the Member, or the Member's Provider; and
- E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

PROCEDURE:

New members to the plan already established on therapy may be eligible for continuity of care coverage as long as there is medical record documentation that the safety and effectiveness of use for the prescribed indication is supported by Food and Drug Administration (FDA) approval or adequate medical and scientific evidence in the medical literature.

An exception for coverage of Fetzima may be made for members who meet the following criteria:

- Medical record documentation of age greater than or equal to 18 years **AND**
- Medical record documentation of a diagnosis of major depressive disorder **AND**
- Medical record documentation of therapeutic failure on, intolerance to, or contraindication to at least three antidepressant classes, one of which must be a generic serotonin and norepinephrine reuptake inhibitor (SNRI)

MEDISPAN AUTHORIZATION LEVEL: GPI-10

If an exception is made, Fetzima will be paid for under the member's prescription drug benefit.

Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 316.0

**SECTION: Commercial Drug
SUBJECT: Fetzima**

FORMULARY ALTERNATIVES:

Selective Serotonin Reuptake Inhibitors (SSRIs): citalopram, fluoxetine, paroxetine, sertraline, escitalopram

Monoamine Oxidase Inhibitors (MAOIs): phenelzine, tranylcypromine

Serotonin and Norepinephrine Reuptake Inhibitors (SNRIs): duloxetine, venlafaxine hcl, venlafaxine er, desvenlafaxine ER (generic Pristiq)

Tricyclics: amitriptyline, nortriptyline, desipramine, doxepin, imipramine

Bupropion: bupropion hcl, bupropion xl, bupropion sr

Other: trazodone, nefazodone, mirtazapine

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE
STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND
FEDERAL REGULATORY ENTITIES.**

**THIS POLICY WILL BE REVISED AS NECESSARY AND
REVIEWED NO LESS THAN ANNUALLY.**

Signed: _____

Title: Director, Pharmacy Services

Date: March 1, 2022

Devised: 2/1/14

Reviewed: 3/1/14 – annual review

Revised: 7/22/14 – corrected typo, updated signature

Revised: 3/1/15 – annual review, added escitalopram to alternatives

Reviewed: 3/1/16 – annual review

Revised: 5/1/16 – updated format, logo, & procedure

Revised: 3/1/17 – annual review, defined abbreviations

Revised: 3/1/18 – annual review, updated signature & FA, added grandfather language

Reviewed: 3/1/19 – annual review

Revised: 3/1/20 – annual review, added GHP Kids

Revised: 3/1/21 – annual review, updated logo, added MediSpan approval level

Revised: 3/1/22 – annual review, updated referenced policies & covered LOBs, updated FA



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 317.0

**SECTION: Commercial Drug
SUBJECT: Valchlor**

Applicable line of business:

Commercial	X	Medicaid	
Medicare		ACA	X
GHP Kids	X	Self-Insured	X

POLICY:

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for Valchlor for GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 487.0 Quantity Limit Exceptions

REQUIRED DEFINITIONS:

1. **Attachment** – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. **Exhibit** – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. **Devised** – the date the policy was implemented.
4. **Revised** – the date of every revision to the policy, including typographical and grammatical changes.
5. **Reviewed** – the date documenting the annual review if the policy has no revisions necessary.

ADDITIONAL DEFINITIONS:

1. **Formulary** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. **Non-formulary products** – those medications that are not included in the Formulary.
3. **Healthcare provider** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
4. **NCQA** – National Committee for Quality Assurance.
5. **Medically Necessary or Medical Necessity** – covered services rendered by a provider that the Health Plan determines are:



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 317.0

**SECTION: Commercial Drug
SUBJECT: Valchlor**

- A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
- B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
- C. In accordance with current standards of medical practice;
- D. Not primarily for the convenience of the Member, or the Member's Provider; and
- E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

PROCEDURE:

New members to the plan already established on therapy may be eligible for continuity of care coverage as long as there is medical record documentation that the safety and effectiveness of use for the prescribed indication is supported by Food and Drug Administration (FDA) approval or adequate medical and scientific evidence in the medical literature.

An exception for coverage of Valchlor may be made for members who meet the following criteria:

- Medical record documentation that Valchlor is prescribed by a dermatologist or oncologist **AND**
- Medical record documentation of first a diagnosis of Stage IA or IB mycosis fungoides-type cutaneous T-cell lymphoma **AND**
- Medical record documentation of therapeutic failure on, intolerance to, or contraindication to one of the following skin-directed therapies: topical corticosteroid, topical retinoid, topical nitrogen mustard, phototherapy

MEDISPAN AUTHORIZATION LEVEL: GPI-12

AUTHORIZATION DURATION: Each authorization will be for 12 months. Re-review will occur every 12 months. Valchlor will no longer be covered if there is medical record documentation of disease progression.

If an exception is made, Valchlor will be paid for under the member's prescription drug benefit.

Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.

FORMULARY ALTERNATIVES:

Low-potency topical corticosteroids: acclometasone dipropionate 0.5% cream and ointment (Aclovate); fluocinolone acetonide 0.01% soln. (Synalar); hydrocortisone 2.5% cream, ointment, and lotion (Hytone)

Medium-potency topical corticosteroids: betamethasone valerate 0.1% cream (Valisone); fluocinolone acetonide 0.025% cream and ointment (Synalar); fluticasone propionate 0.05% cream, ointment, and lotion (Cutivate); triamcinolone 0.1% cream, ointment and lotion (Kenalog); triamcinolone acetonide 0.025% cream, ointment and lotion (Kenalog); triamcinolone acetonide 0.147 mg/g aerosol (Kenalog Spray)

High-potency topical corticosteroids: augmented betamethasone dipropionate 0.05% cream (Diprolene AF); betamethasone valerate 0.1% ointment (Valisone); triamcinolone 0.5% cream (Kenalog); fluocinonide 0.05% cream, ointment and gel (Lidex)

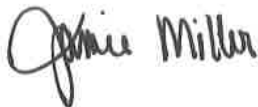
Very high-potency topical corticosteroids: augmented betamethasone dipropionate 0.05% ointment, gel and lotion (Diprolene); clobetasol 0.05% cream, ointment, and scalp lotion (Temovate) diflorasone diacetate 0.05% cream and ointment (ApexiCon/Psorcon)

Topical Retinoids: Targretin*

*prior authorization required

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE
STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND
FEDERAL REGULATORY ENTITIES.**

**THIS POLICY WILL BE REVISED AS NECESSARY AND
REVIEWED NO LESS THAN ANNUALLY.**



Signed: _____

Title: Director, Pharmacy Services

Date: March 1, 2022

Devised: 2/1/14
Revised: 3/1/14 – annual review, corrected typo
Revised: 3/1/15 – annual review, updated signature
Reviewed: 3/1/16 – annual review
Revised: 5/1/16 – updated format, logo, & procedure
Revised: 3/1/17 – annual review, updated FA
Revised: 10/10/17 – increased authorization duration to 12 months



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 317.0

**SECTION: Commercial Drug
SUBJECT: Valchlor**

- Revised: 3/1/18 – annual review, updated signature & prescriber criteria, added grandfather language
- Revised: 3/1/19 – annual review, removed distribution information
- Revised: 3/1/20 – annual review, added GHP Kids
- Revised: 3/1/21 – annual review, updated logo, added MediSpan approval level
- Revised: 3/1/22 – annual review, updated referenced policies & covered LOBs



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 318.0

**SECTION: Commercial Drug
SUBJECT: Stelara**

Applicable line of business:

Commercial	X	Medicaid	
Medicare		ACA	X
GHP Kids	X	Self-Insured	X

POLICY:

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for Stelara for GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 487.0 Quantity Limit Exceptions

REQUIRED DEFINITIONS:

1. **Attachment** – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. **Exhibit** – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
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4. **Revised** – the date of every revision to the policy, including typographical and grammatical changes.
5. **Reviewed** – the date documenting the annual review if the policy has no revisions necessary.

ADDITIONAL DEFINITIONS:

1. **Formulary** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. **Non-formulary products** – those medications that are not included in the Formulary.
3. **Healthcare provider** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
4. **NCQA** – National Committee for Quality Assurance.
5. **Medically Necessary or Medical Necessity** – covered services rendered by a provider that the Health Plan determines are:

- A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
- B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
- C. In accordance with current standards of medical practice;
- D. Not primarily for the convenience of the Member, or the Member's Provider; and
- E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

PROCEDURE:

New members to the plan already established on therapy may be eligible for continuity of care coverage as long as there is medical record documentation that the safety and effectiveness of use for the prescribed indication is supported by Food and Drug Administration (FDA) approval or adequate medical and scientific evidence in the medical literature.

An exception for coverage of Stelara may be made for members who meet the following criteria:

Psoriasis

- Medical record documentation that Stelara is prescribed by a dermatologist **AND**
- Medical record documentation of age greater than or equal to 18 years **AND**
- Medical record documentation of a diagnosis of moderate to severe plaque psoriasis characterized by greater than or equal to 5% of body surface area involved or disease affecting crucial body areas such as hands, feet, face or genitals **AND**
- Medical record documentation of an intolerance to, contraindication to or therapeutic failure on a minimum 3 month trial of Cosentyx* **AND** Humira* **AND**
- Medical record documentation that the prescribed dosing is appropriate for patient's weight **AND**
- Medical record documentation that Stelara is not being used concurrently with a tumor necrosis factor (TNF) blocker or other biologic agent

RE-AUTHORIZATION CRITERIA: Stelara is configured as a prior authorization for new starts only. Stelara will no longer be covered if it is identified that the member is not receiving appropriate follow-up care from the prescribing specialist or if the member has greater than or equal to a 90 day break in therapy.

- Medical record documentation that the member is receiving appropriate follow-up care from the prescribing specialist



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 318.0

**SECTION: Commercial Drug
SUBJECT: Stelara**

NOTE:

- Patients weighing over 100 kg should receive 90 mg every 12 weeks
- Patients weighing less than 100 kg should receive 45 mg every 12 weeks

MEDISPAN AUTHORIZATION LEVEL: GPI-14

QUANTITY LIMIT – *Two authorizations must be entered.*

- Stelara 45 mg syringe (less than 100 kg)
 1. In PA Hub: Add PA, OQL, DS, max quantity dispensed 0.5, min day supply 28, max day supply 28, number of claims authorized 1, with a duration of 3 weeks.
 2. In Darwin: Add DS, min day supply 84, max day supply 84, with an end date of 12/31/2099. Start date of this authorization is 3 weeks after initial approval date.
 - QL FOR LETTER: Loading dose: 0.5 mL per 28 days;
Maintenance dose: 0.5 mL per 84 days
- Stelara 90 mg syringe (greater than or equal to 100 kg)
 1. In PA Hub: Add PA, OQL, DS, max quantity dispensed 1, min day supply 28, max day supply 28, number of claims authorized 1, with a duration of 3 weeks.
 2. In Darwin: Add DS, min day supply 84, max day supply 84, with an end date of 12/31/2099. Start date of this authorization is 3 weeks after initial approval date.
 - QL FOR LETTER: Loading dose: 1 mL per 28 days;
Maintenance dose: 1 mL per 84 days

FORMULARY ALTERNATIVES:

Cosentyx*, Humira*

*prior authorization required

Pediatric Plaque Psoriasis

- Medical record documentation that Stelara is prescribed by a dermatologist **AND**
- Medical record documentation of age greater than or equal to 6 years **AND**
- Medical record documentation of a diagnosis of moderate to severe plaque psoriasis characterized by greater than or equal to 5% of body surface area involved or disease affecting crucial body areas such as hands, feet, face or genitals **AND**
- Medical record documentation of therapeutic failure on, intolerance to, or contraindication to at least two topical corticosteroids **AND**
- Medical record documentation that the prescribed dosing is appropriate for patient's weight **AND**
- Medical record documentation that Stelara is not being used concurrently with a tumor necrosis factor (TNF) blocker or other biologic agent

RE-AUTHORIZATION CRITERIA: Stelara is configured as a prior authorization for new starts only. Stelara will no longer be covered if it is identified that the member is not receiving appropriate follow-up care from the prescribing specialist or if the member has greater than or equal to a 90 day break in therapy.

- Medical record documentation that the member is receiving appropriate follow-up care from the prescribing specialist

NOTE:

- Patients weighing over 100kg should receive 90 mg every 12 weeks
- Patients weighing ≥ 60 kg to < 100 kg should receive 45 mg every 12 weeks
- Patients weighing less than 60kg should receive 0.75mg/kg every 12 weeks

MEDISPAN AUTHORIZATION LEVEL: GPI-14

QUANTITY LIMIT – *Two authorizations must be entered.*

- Stelara 45 mg vial (less than 60 kg)
 1. In PA Hub: Add PA, DS, min day supply 28, max day supply 28, max quantity dispensed 1, and number of claims authorized 1, with a duration of 3 weeks.
 2. In Darwin: Add DS, min day supply 84, max day supply 84, with an end date of 12/31/2099. Start date of this authorization is 3 weeks after initial approval date.
 - QL FOR LETTER: Loading dose: 1 vial per 28 days;
Maintenance dose: 1 vial per 84 days
- Stelara 45 mg syringe (less than 100 kg)
 1. In PA Hub: Add PA, OQL, DS, max quantity dispensed 0.5, min day supply 28, max day supply 28, number of claims authorized 1, with a duration of 3 weeks.

2. In Darwin: Add DS, min day supply 84, max day supply 84, with an end date of 12/31/2099. Start date of this authorization is 3 weeks after initial approval date.
 - QL FOR LETTER: Loading dose: 0.5 mL per 28 days;
Maintenance dose: 0.5 mL per 84 days
- Stelara 90 mg syringe (greater than or equal to 100 kg)
 1. In PA Hub: Add PA, OQL, DS, max quantity dispensed 1, min day supply 28, max day supply 28, number of claims authorized 1, with a duration of 3 weeks.
 2. In Darwin: Add DS, min day supply 84, max day supply 84, with an end date of 12/31/2099. Start date of this authorization is 3 weeks after initial approval date.
 - QL FOR LETTER: Loading dose: 1 mL per 28 days;
Maintenance dose: 1 mL per 84 days

FORMULARY ALTERNATIVES:

Low-potency topical corticosteroids: acclometasone dipropionate 0.5% cream and ointment (Aclovate); fluocinolone acetonide 0.01% soln. (Synalar); hydrocortisone 2.5% cream, ointment, and lotion (Hytone)

Medium-potency topical corticosteroids: betamethasone valerate 0.1% cream (Valisone); fluocinolone acetonide 0.025% cream and ointment (Synalar); fluticasone propionate 0.05% cream, ointment, and lotion (Cutivate); triamcinolone 0.1% cream, ointment and lotion (Kenalog); triamcinolone acetonide 0.025% cream, ointment and lotion (Kenalog); triamcinolone acetonide 0.147 mg/g aerosol (Kenalog Spray)

High-potency topical corticosteroids: augmented betamethasone dipropionate 0.05% cream (Diprolene AF); betamethasone valerate 0.1% ointment (Valisone); triamcinolone 0.5% cream (Kenalog); fluocinonide 0.05% cream, ointment and gel (Lidex)

Very high-potency topical corticosteroids: augmented betamethasone dipropionate 0.05% ointment, gel and lotion (Diprolene); clobetasol 0.05% cream, ointment, and scalp lotion (Temovate) diflorasone diacetate 0.05% cream and ointment (ApexiCon/Psorcon)

Psoriatic Arthritis

- Medical record documentation that Stelara is prescribed by a rheumatologist or dermatologist **AND**
- Medical record documentation of age greater than or equal to 18 years **AND**
- Medical record documentation of a diagnosis of moderately to severely active psoriatic arthritis which must include the following:
 - Documentation of either active psoriatic lesions or a documented history of psoriasis **AND**
- Medical record documentation of an intolerance to, contraindication to or therapeutic failure on a minimum 3 month trial of Cosentyx* **AND** Humira* **AND**
- Medical record documentation that the patient is going to receive a dose of 45 mg every 12 weeks **OR** medical record documentation that the patients has a co-existing diagnosis of moderate-to-severe plaque psoriasis and weight greater than 100 kg **AND**
- Medical record documentation that Stelara is not being used concurrently with a tumor necrosis factor (TNF) blocker or other biologic agent

RE-AUTHORIZATION CRITERIA: Stelara is configured as a prior authorization for new starts only. Stelara will no longer be covered if it is identified that the member is not receiving appropriate follow-up care from the prescribing specialist or if the member has greater than or equal to a 90 day break in therapy.

- Medical record documentation that the member is receiving appropriate follow-up care from the prescribing specialist

NOTE:

- 45 mg every 12 weeks
- For patients with co-existent moderate-to-severe plaque psoriasis weighing greater than 100 kg, the recommended dose is 90 mg every 12 weeks.

MEDISPAN AUTHORIZATION LEVEL: GPI-14

QUANTITY LIMIT – *Two authorizations must be entered.*

- Stelara 45 mg syringe (less than 100 kg)
 1. In PA Hub: Add PA, OQL, DS, max quantity dispensed 0.5, min day supply 28, max day supply 28, number of claims authorized 1, with a duration of 3 weeks.
 2. In Darwin: Add DS, min day supply 84, max day supply 84, with an end date of 12/31/2099. Start date of this authorization is 3 weeks after initial approval date.



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 318.0

**SECTION: Commercial Drug
SUBJECT: Stelara**

- QL FOR LETTER: Loading dose: 0.5 mL per 28 days;
Maintenance dose: 0.5 mL per 84 days
- Stelara 90 mg syringe (greater than or equal to 100 kg)
 1. In PA Hub: Add PA, OQL, DS, max quantity dispensed 1, min day supply 28, max day supply 28, number of claims authorized 1, with a duration of 3 weeks.
 2. In Darwin: Add DS, min day supply 84, max day supply 84, with an end date of 12/31/2099. Start date of this authorization is 3 weeks after initial approval date.
 - QL FOR LETTER: Loading dose: 1 mL per 28 days;
Maintenance dose: 1 mL per 84 days

FORMULARY ALTERNATIVES:

Cosentyx*, Humira*

*prior authorization required

Crohn's Disease

- Medical record documentation that Stelara is prescribed by a gastroenterologist **AND**
- Medical record documentation of age greater than or equal to 18 years **AND**
- Medical record documentation of a diagnosis of moderately to severely active Crohn's disease **AND**
- Medical record documentation of an intolerance to, contraindication to, or therapeutic failure on a minimum 3 month trial of three (3) of the following medications: Humira*, Cimzia*, Entyvio*, infliximab*, or Tysabri* **AND**
- Medical record documentation of Stelara 130 mg vials as IV infusion (for induction therapy) **OR** Stelara 90 mg syringes (for maintenance therapy) being prescribed **AND**
- Medical record documentation that Stelara is not being used concurrently with a tumor necrosis factor (TNF) blocker or other biologic agent

RE-AUTHORIZATION CRITERIA: Stelara is configured as a prior authorization for new starts only. Stelara will no longer be covered if it is identified that the member is not receiving appropriate follow-up care from the prescribing specialist or if the member has greater than or equal to a 90 day break in therapy.

- Medical record documentation that the member is receiving appropriate follow-up care from the prescribing specialist

MEDISPAN AUTHORIZATION LEVEL: GPI-14

QUANTITY LIMIT:

- **Initial Approval – Two authorizations must be entered.**
 1. In PA Hub: Add PA, number of claims authorized 1, enter for the remainder of the calendar year
 2. In Darwin: Add DS, min day supply 56, max day supply 56, with an end date of 12/31/2099
 - QL FOR LETTER: 1 mL per 56 days

NOTE: Stelara 45 mg syringe is not indicated for use in Crohn's disease.

NOTE: If the initial infusion will be billed through the pharmacy benefit (i.e., specialty pharmacy trying to process the 130 mg/26 mL intravenous solution), in Darwin enter PA, OQL, DS only by GPI 52504070002020, enter 1 in the max number of claims authorized, max quantity 104, min and max day supply 56) with a duration of 1 month. This will be in addition to the authorization above. Also, you will need to update the QL for the letter to the following:

- QL FOR LETTER: Intravenous loading dose: 104 mL per 56 days; 90 mg Syringe maintenance dose: 1 mL per 56 days

Geisinger

**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 318.0

**SECTION: Commercial Drug
SUBJECT: Stelara**

FORMULARY ALTERNATIVES:

Humira*, Cimzia*, Entyvio*, infliximab*, Tysabri*

*prior authorization required

Ulcerative Colitis

- Medical record documentation that Stelara is prescribed by a gastroenterologist **AND**
- Medical record documentation of age greater than or equal to 18 years **AND**
- Medical record documentation of a diagnosis of moderately to severely active ulcerative colitis **AND**
- Medical record documentation of an intolerance to, contraindication to, or therapeutic failure on a minimum 3 month trial of Humira* **AND** Entyvio* **AND** infliximab* **AND**
- Medical record documentation of Stelara 130 mg vials as IV infusion (for induction therapy) **OR** Stelara 90 mg syringes (for maintenance therapy) being prescribed **AND**
- Medical record documentation that Stelara is not being used concurrently with a tumor necrosis factor (TNF) blocker or other biologic agent

RE-AUTHORIZATION CRITERIA: Stelara is configured as a prior authorization for new starts only. Stelara will no longer be covered if it is identified that the member is not receiving appropriate follow-up care from the prescribing specialist or if the member has greater than or equal to a 90 day break in therapy.

- Medical record documentation that the member is receiving appropriate follow-up care from the prescribing specialist

MEDISPAN AUTHORIZATION LEVEL: GPI-14

QUANTITY LIMIT:

- **Initial Approval** – *Two authorizations must be entered.*
 1. In PA Hub: Add PA, number of claims authorized 1, enter for the remainder of the calendar year
 2. In Darwin: Add DS, min day supply 56, max day supply 56, with an end date of 12/31/2099
 - QL FOR LETTER: 1 mL per 56 days

NOTE: Stelara 45 mg syringe is not indicated for use in ulcerative colitis.

NOTE: If the initial infusion will be billed through the pharmacy benefit (i.e., specialty pharmacy trying to process the 130 mg/26 mL intravenous solution), in Darwin enter PA, OQL, DS only by GPI 52504070002020, enter 1 in the max number of claims authorized, max quantity 104, min and max day supply 56) with a duration of 1 month. This will be in addition to the authorization above. Also, you will need to update the QL for the letter to the following:

- QL FOR LETTER: Intravenous loading dose: 104 mL per 56 days; 90 mg Syringe maintenance dose: 1 mL per 56 days



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 318.0

**SECTION: Commercial Drug
SUBJECT: Stelara**

FORMULARY ALTERNATIVES:

Humira*, Entyvio*, infliximab*

*prior authorization required

If an exception is made, Stelara will be paid for under the member's prescription drug benefit.

Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE
STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND
FEDERAL REGULATORY ENTITIES.**

**THIS POLICY WILL BE REVISED AS NECESSARY AND
REVIEWED NO LESS THAN ANNUALLY.**

Signed: _____

Title: Director, Pharmacy Services

Date: April 6, 2022

Devised: 2/1/14
Reviewed: 3/1/14 – annual review
Revised: 9/22/14 – updated alternatives criteria and auth duration for both indications, updated FA and signature, and added “at least” to age criteria for both indications
Revised: 2/9/15 – updated alternatives criteria & FA for both indications, updated prescriber criteria for PsA
Reviewed: 3/1/15 – annual review
Revised: 9/19/15 – removed joint count criteria from initial and renewal requirements
Reviewed: 3/1/16 – annual review
Revised: 5/1/16 – updated format, logo, & procedure
Revised: 7/27/16 – added dosing requirement for both indications, added dosing note
Reviewed: 3/1/17 – annual review
Revised: 3/27/17 – added Crohn's, moved notes to indication in policy
Revised: 6/2/17 – removed Unicode characters, corrected typo in Crohn's note
Revised: 9/15/17 – updated Crohn's to failure of 3 agents, added induction/maintenance bullet to match P&T approved policy
Revised: 3/1/18 – annual review, updated signature, updated prescriber & age criteria, added grandfather language



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 318.0

**SECTION: Commercial Drug
SUBJECT: Stelara**

- Revised: 5/30/18 – added pediatric psoriasis, moved FA, added no use with other biologics, removed failure of Enbrel and added failure of Cosentyx (PP, PsA), added QL (PP, PsA), updated GPID note
- Revised: 3/1/19 – annual review, defined TNF
- Revised: 6/4/19 – updated QL, removed RX counts, added authorization parameters
- Revised: 3/1/20 – annual review, added GHP Kids
- Revised: 4/21/20 – updated CD QL, removed reference to Remicade/Inflectra, added UC indication
- Revised: 1/25/21 – updated pedPP to age 6 & auth duration/QL language, added MediSpan approval level
- Revised: 3/1/21 – annual review, updated logo, updated QL statements, add FA to CD & UC
- Revised: 12/2/21 – added one-time PA to approval crit., removed auth duration & added re-auth crit., updated QL auth entry to account for PA NSO
- Reviewed: 1/5/22 – added OUP to all auths, updated GPI for CD 7 UC
- Revised: 3/1/22 – annual review, updated referenced policies & covered LOBs, updated how QL's are entered
- Revised: 4/6/22 – updated vial QL for ped. PsO, added IV loading dose note to CD & UC



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 319.0

**SECTION: Commercial Drug
SUBJECT: Budesonide/Formoterol**

Applicable line of business:

Commercial	X	Medicaid	
Medicare		ACA	X
GHP Kids	X	Self-Insured	X

POLICY:

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for budesonide/formoterol for GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 487.0 Quantity Limit Exceptions

REQUIRED DEFINITIONS:

1. **Attachment** – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. **Exhibit** – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. **Devised** – the date the policy was implemented.
4. **Revised** – the date of every revision to the policy, including typographical and grammatical changes.
5. **Reviewed** – the date documenting the annual review if the policy has no revisions necessary.

ADDITIONAL DEFINITIONS:

1. **Formulary** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. **Non-formulary products** – those medications that are not included in the Formulary.
3. **Healthcare provider** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
4. **NCQA** – National Committee for Quality Assurance.
5. **Medically Necessary or Medical Necessity** – covered services rendered by a provider that the Health Plan determines are:



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 319.0

**SECTION: Commercial Drug
SUBJECT: Budesonide/Formoterol**

- A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
- B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
- C. In accordance with current standards of medical practice;
- D. Not primarily for the convenience of the Member, or the Member's Provider; and
- E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

PROCEDURE:

An exception for coverage of budesonide/formoterol may be made for members who meet the following criteria:

Asthma

- Medical record documentation of age greater than or equal to 6 years **AND**
- Medical record documentation of a diagnosis of asthma **AND**
- For ages 6 to less than 12 years, medical record documentation of therapeutic failure on, intolerance to, or contraindication to fluticasone/salmeterol* **OR**
- For ages greater than 12 years, medical record documentation of therapeutic failure on, intolerance to, or contraindication to fluticasone/salmeterol **AND** Dulera

OR

COPD

- Medical record documentation of a diagnosis of chronic obstructive pulmonary disease (COPD) **AND**
- Medical record documentation of therapeutic failure on, intolerance to, or contraindication to fluticasone/salmeterol **AND** Breo Ellipta

***Note:** Fluticasone/salmeterol 100/50 is the only approved dose for patients 4 to 11 years old. The other formulations of fluticasone/salmeterol are approved for 12 years and older.

MEDISPAN AUTHORIZATION LEVEL: GPI-12, generic only



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 319.0

**SECTION: Commercial Drug
SUBJECT: Budesonide/Formoterol**

If an exception is made, budesonide/formoterol will be paid for under the member's prescription drug benefit.

Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.

FORMULARY ALTERNATIVES:

Asthma: fluticasone/salmeterol, Dulera, Breo Ellipta
COPD: fluticasone/salmeterol, Breo Ellipta

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE
STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND
FEDERAL REGULATORY ENTITIES.**

**THIS POLICY WILL BE REVISED AS NECESSARY AND
REVIEWED NO LESS THAN ANNUALLY.**

Signed: _____

Title: Director, Pharmacy Services

Date: March 1, 2022

Devised: 2/1/14
Reviewed: 3/1/14 – annual review
Revised: 3/1/15 – annual review, updated signature
Reviewed: 3/1/16 – annual review
Revised: 5/1/16 – updated format, logo, & procedure, added Breo Ellipta to asthma FA
Reviewed: 3/1/17 – annual review
Revised: 8/8/17 – added indication criteria, added age to asthma, updated FA for asthma
Revised: 3/1/18 – annual review, updated signature, defined COPD
Reviewed: 3/1/19 – annual review
Revised: 3/1/20 – annual review, added GHP Kids
Revised: 3/1/21 – annual review, updated logo, added MediSpan approval level, updated Symbicort & Advair to generic
Revised: 3/1/22 – annual review, updated referenced policies & covered LOBs



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 321.0

**SECTION: Commercial Drug
SUBJECT: Actemra Self-Injectable**

Applicable line of business:

Commercial	X	Medicaid	
Medicare		ACA	X
GHP Kids	X	Self-Insured	X

POLICY:

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for Actemra self-injectable for GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 487.0 Quantity Limit Exceptions

REQUIRED DEFINITIONS:

1. **Attachment** – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. **Exhibit** – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. **Devised** – the date the policy was implemented.
4. **Revised** – the date of every revision to the policy, including typographical and grammatical changes.
5. **Reviewed** – the date documenting the annual review if the policy has no revisions necessary.

ADDITIONAL DEFINITIONS:

1. **Formulary** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. **Non-formulary products** – those medications that are not included in the Formulary.
3. **Healthcare provider** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
4. **NCQA** – National Committee for Quality Assurance.
5. **Medically Necessary or Medical Necessity** – covered services rendered by a provider that the Health Plan determines are:

- A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
- B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
- C. In accordance with current standards of medical practice;
- D. Not primarily for the convenience of the Member, or the Member's Provider; and
- E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

PROCEDURE:

New members to the plan already established on therapy may be eligible for continuity of care coverage as long as there is medical record documentation that the safety and effectiveness of use for the prescribed indication is supported by Food and Drug Administration (FDA) approval or adequate medical and scientific evidence in the medical literature.

An exception for coverage of Actemra Self Injectable may be made for members who meet the following criteria:

Rheumatoid Arthritis

- Medical record documentation that Actemra Self Injectable is prescribed by a rheumatologist **AND**
- Medical record documentation of a diagnosis of moderate to severe rheumatoid arthritis (made in accordance with the American College of Rheumatology Criteria for the Classification and Diagnosis of Rheumatoid Arthritis **AND**
- Medical record documentation of age greater than or equal to 18 years **AND**
- Medical record documentation of therapeutic failure on, intolerance to, or contraindication to a minimum 3 month trial of Humira*, Rinvoq*, **OR** Xeljanz* **AND**
- Medical record documentation that Actemra is not being used concurrently with a tumor necrosis factor (TNF) blocker or other biologic agent

MEDISPAN AUTHORIZATION LEVEL: GPI-14, number of claims authorized = 1, enter for the remainder of the calendar year

QUANTITY LIMIT: *No QLs need to be entered within the authorization unless the requested quantity exceeds the QL.*

- **QL FOR LETTER ONLY:** 3.6 mL per 28 days



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 321.0

**SECTION: Commercial Drug
SUBJECT: Actemra Self-Injectable**

RE-AUTHORIZATION CRITERIA: Actemra self-injectable is configured as a prior authorization for new starts only. Actemra self-injectable will no longer be covered if it is identified that the member is not receiving appropriate follow-up care from the prescribing specialist or if the member has greater than or equal to a 90 day break in therapy.

- Medical record documentation that the member is receiving appropriate follow-up care from the prescribing specialist

FORMULARY ALTERNATIVES:

Humira*, Rinvoq*, Xeljanz*

*prior authorization required

Active polyarticular juvenile idiopathic arthritis (PJIA)

- Medical record documentation that Actemra Self Injectable is prescribed by a rheumatologist **AND**
- Medical record documentation of a diagnosis of active polyarticular juvenile idiopathic arthritis or juvenile rheumatoid arthritis **AND**
- Medical record documentation of age greater than or equal to 2 years **AND**
- Medical record documentation of an intolerance to, contraindication to, or therapeutic failure on a minimum 3 month trial of Humira* **AND**
- Medical record documentation that Actemra is not being used concurrently with a tumor necrosis factor (TNF) blocker or other biologic agent

MEDISPAN AUTHORIZATION LEVEL: GPI-14, number of claims authorized = 1, enter for the remainder of the calendar year

QUANTITY LIMIT: *No QLs need to be entered within the authorization unless the requested quantity exceeds the QL.*

- QL FOR LETTER ONLY: 3.6 mL per 28 days

RE-AUTHORIZATION CRITERIA: Actemra self-injectable is configured as a prior authorization for new starts only. Actemra self-injectable will no longer be covered if it is identified that the member is not receiving appropriate follow-up care from the prescribing specialist or if the member has greater than or equal to a 90 day break in therapy.

- Medical record documentation that the member is receiving appropriate follow-up care from the prescribing specialist

FORMULARY ALTERNATIVES:

Humira*

*prior authorization required

Active systemic juvenile idiopathic arthritis (SJIA)

- Medical record documentation that Actemra Self Injectable is prescribed by a rheumatologist **AND**
- Medical record documentation of a diagnosis of active systemic juvenile idiopathic arthritis **AND**
- Medical record documentation of age greater than or equal to 2 years **AND**
- Medical record documentation that Actemra is not being used concurrently with a tumor necrosis factor (TNF) or other biologic agent

MEDISPAN AUTHORIZATION LEVEL: GPI-14, number of claims authorized = 1, enter for the remainder of the calendar year

QUANTITY LIMIT: *No QLs need to be entered within the authorization unless the requested quantity exceeds the QL.*

- QL FOR LETTER ONLY: 3.6 mL per 28 days

RE-AUTHORIZATION CRITERIA: Actemra self-injectable is configured as a prior authorization for new starts only. Actemra self-injectable will no longer be covered if it is identified that the member is not receiving appropriate follow-up care from the prescribing specialist or if the member has greater than or equal to a 90 day break in therapy.

- Medical record documentation that the member is receiving appropriate follow-up care from the prescribing specialist

FORMULARY ALTERNATIVES:

none

Giant Cell Arteritis

- Medical record documentation that Actemra Self Injectable is prescribed by a rheumatologist **AND**
- Medical record documentation of a diagnosis of giant cell arteritis **AND**
- Medical record documentation that Actemra is being prescribed in combination with oral glucocorticoids **AND**
- Medical record documentation that Actemra is not being used concurrently with a tumor necrosis factor (TNF) blocker or other biologic agent

MEDISPAN AUTHORIZATION LEVEL: GPI-14, number of claims authorized = 1, enter for the remainder of the calendar year

QUANTITY LIMIT: *No QLs need to be entered within the authorization unless the requested quantity exceeds the QL.*

- QL FOR LETTER ONLY: 3.6 mL per 28 days

RE-AUTHORIZATION CRITERIA: Actemra self-injectable is configured as a prior authorization for new starts only. Actemra self-injectable will no longer be covered if it is identified that the member is not receiving appropriate follow-up care from the prescribing specialist or if the member has greater than or equal to a 90 day break in therapy.

- Medical record documentation that the member is receiving appropriate follow-up care from the prescribing specialist

NOTE: Although traditionally the erythrocyte sedimentation rate and/or C-reactive protein are high in giant cell arteritis, the range of values for both test is broad and non-specific.

FORMULARY ALTERNATIVES:

none

Systemic Sclerosis-Associated Interstitial Lung Disease (SSc-ILD)

- Medical record documentation that Actemra Self Injectable is prescribed by or in consultation with a pulmonologist and/or rheumatologist **AND**
- Medical record documentation of age greater than or equal to 18 years **AND**
- Medical record documentation of a diagnosis of systemic sclerosis according to American College of Rheumatology (ACR) and European League Against Rheumatism (EULAR) **AND**
- Medical record documentation that Actemra is not being used concurrently with a tumor necrosis factor (TNF) blocker or other biologic agent
- Medical record documentation of systemic sclerosis related to interstitial lung disease confirmed by all of the following:
 - $\geq 10\%$ fibrosis on a chest high resolution computer tomography **AND**
 - FVC $\geq 40\%$ of predicted normal **AND**
 - DLCO (diffusion capacity of the lung for carbon monoxide) 30-89% of predicted normal

***NOTE:** ACR/EULAR Diagnostic Criteria for Systemic Sclerosis:

Item	Sub-item(s)	Weight/score†
Skin thickening of the fingers of both hands extending proximal to the metacarpophalangeal joints (<i>sufficient criterion</i>)	-	9
Skin thickening of the fingers (<i>only count the higher score</i>)	Puffy fingers	2
	Sclerodactyly of the fingers (distal to the metacarpophalangeal joints but proximal to the proximal interphalangeal joints)	4
Fingertip lesions (<i>only count the higher score</i>)	Digital tip ulcers	2
	Fingertip pitting scars	3
Telangiectasia	-	2
Abnormal nailfold capillaries	-	2
Pulmonary arterial hypertension and/or interstitial lung disease (<i>maximum score is 2</i>)	Pulmonary arterial hypertension	2
	Interstitial lung disease	2
Raynaud's phenomenon	-	3
SSc-related autoantibodies (anticentromere, anti-topoisomerase I [anti-Scl-70], anti-RNA polymerase III) (<i>maximum score is 3</i>)	Anticentromere	3
	Anti-topoisomerase I	
	Anti-RNA polymerase III	

* These criteria are applicable to any patient considered for inclusion in an SSc study. The criteria are not applicable to patients with skin thickening sparing the fingers or to patients who have a scleroderma-like disorder that better explains their manifestations (e.g., nephrogenic sclerosing fibrosis, generalized morphea, eosinophilic fasciitis, scleredema diabeticorum, scleromyxedema, erythromyalgia, porphyria, lichen sclerosis, graft-versus-host disease, diabetic cheiroarthropathy).

† The total score is determined by adding the maximum weight (score) in each category. Patients with a total score of ≥ 9 are classified as having definite SSc.

MEDISPAN AUTHORIZATION LEVEL: GPI-14, number of claims authorized = 1, enter for the remainder of the calendar year



POLICY NUMBER: 321.0

**POLICY AND PROCEDURE
PHARMACY
MANUAL**

**SECTION: Commercial Drug
SUBJECT: Actemra Self-Injectable**

QUANTITY LIMIT: *No QLs need to be entered within the authorization unless the requested quantity exceeds the QL.*

- QL FOR LETTER ONLY: 3.6 mL per 28 days

RE-AUTHORIZATION CRITERIA: Actemra self-injectable is configured as a prior authorization for new starts only. Actemra self-injectable will no longer be covered if it is identified that the member is not receiving appropriate follow-up care from the prescribing specialist or if the member has greater than or equal to a 90 day break in therapy.

- Medical record documentation that the member is receiving appropriate follow-up care from the prescribing specialist

FORMULARY ALTERNATIVES:

none



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 321.0

**SECTION: Commercial Drug
SUBJECT: Actemra Self-Injectable**

COVID-19

If Actemra is being prescribed for COVID-19, see the FDA website for Emergency Use Authorizations at <https://www.fda.gov/emergency-preparedness-and-response/mcm-legal-regulatory-and-policy-framework/emergency-use-authorization#coviddrugs> for current FDA authorized use. At this time, Actemra is authorized for inpatient use only for COVID-19 and would not be covered for outpatient use.



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 321.0

**SECTION: Commercial Drug
SUBJECT: Actemra Self-Injectable**

If an exception is made, Actemra Self Injectable will be paid for under the member's prescription drug benefit.

Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE
STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND
FEDERAL REGULATORY ENTITIES.**

**THIS POLICY WILL BE REVISED AS NECESSARY AND
REVIEWED NO LESS THAN ANNUALLY.**

Signed: _____

Title: Director, Pharmacy Services

Date: March 1, 2022

Devised: 3/20/14
Revised: 9/22/14 – updated joint count and alternatives criteria, added Cimzia and removed Enbrel from FA, changed auth. duration wording, and updated signature
Revised: 2/9/15 – updated alternatives criteria and added Enbrel and removed Cimzia from FA
Reviewed: 3/1/15 – annual review
Revised: 9/19/15 – removed joint count criteria from initial and renewal requirements
Reviewed: 3/1/16 – annual review
Revised: 5/1/16 – updated format, logo, & procedure
Revised: 3/1/17 – annual review, removed Unicode Characters
Revised: 10/9/17 – added GCA
Revised: 3/1/18 – annual review, updated signature, added grandfather language, updated age and prescriber criteria
Revised: 10/1/18 – removed failure on Enbrel, updated RA FA, added PJIA indication
Revised: 3/1/19 – annual review, added QL approval note, defined TNF
Revised: 3/21/19 – added SJIA indication, added other biologic criteria to PJIA/GCA, updated QL's to mL
Revised: 1/28/20 – updated RA FA and added failure of Rinvoq and Xeljanz
Revised: 3/1/20 – annual review, added GHP Kids
Revised: 3/1/21 – annual review, updated logo, added MediSpan approval level, updated QL statement
Revised: 9/1/21 – added SSc-ILD indication
Revised: 12/2/21 – added one-time PA to approval crit., removed auth duration & added re-auth crit.
Revised: 3/1/22 – annual review, updated referenced policies & covered LOBs, added COVID-19



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 322.0

**SECTION: Commercial Drug
SUBJECT: Fycompa**

Applicable line of business:

Commercial	X	Medicaid	
Medicare		ACA	X
GHP Kids	X	Self-Insured	X

POLICY:

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for Fycompa for GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 487.0 Quantity Limit Exceptions

REQUIRED DEFINITIONS:

1. **Attachment** – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. **Exhibit** – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. **Devised** – the date the policy was implemented.
4. **Revised** – the date of every revision to the policy, including typographical and grammatical changes.
5. **Reviewed** – the date documenting the annual review if the policy has no revisions necessary.

ADDITIONAL DEFINITIONS:

1. **Formulary** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. **Non-formulary products** – those medications that are not included in the Formulary.
3. **Healthcare provider** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
4. **NCQA** – National Committee for Quality Assurance.
5. **Medically Necessary or Medical Necessity** – covered services rendered by a provider that the Health Plan determines are:



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 322.0

**SECTION: Commercial Drug
SUBJECT: Fycompa**

- A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
- B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
- C. In accordance with current standards of medical practice;
- D. Not primarily for the convenience of the Member, or the Member's Provider; and
- E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

PROCEDURE:

New members to the plan already established on therapy may be eligible for continuity of care coverage as long as there is medical record documentation that the safety and effectiveness of use for the prescribed indication is supported by Food and Drug Administration (FDA) approval or adequate medical and scientific evidence in the medical literature.

An exception for coverage of Fycompa may be made for members who meet the following criteria:

Partial Onset Seizures

- Medical record documentation of a diagnosis of partial onset seizures **AND**
- Medical record documentation of age greater than or equal to 4 years **AND**
- Medical record documentation of therapeutic failure on, intolerance to, or contraindication to three (3) formulary alternatives

Primary Generalized Tonic-Clonic Seizures

- Medical record documentation of a diagnosis of primary generalized tonic-clonic seizures **AND**
- Medical record documentation of age greater than or equal to 12 years **AND**
- Medical record documentation of therapeutic failure on, intolerance to, or contraindication to three (3) formulary alternatives **AND**
- Medical record documentation that Fycompa is being used concomitantly with at least one (1) other formulary antiepileptic drug

MEDISPAN AUTHORIZATION LEVEL: GPI-10

Geisinger

**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 322.0

**SECTION: Commercial Drug
SUBJECT: Fycompa**

QUANTITY LIMIT: *No QLs need to be entered within the authorization unless the requested quantity exceeds the QL.*

- **QL FOR LETTER ONLY:** 1 tablet per day

If an exception is made, Fycompa will be paid for under the member's prescription drug benefit.

Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.

FORMULARY ALTERNATIVES:

Partial Onset Seizures:

For patients > 4 years of age: carbamazepine, gabapentin, lamotrigine IR, levetiracetam IR, oxcarbazepine, phenobarbital, phenytoin, pregabalin, topiramate IR, topiramate ER*

Additional formulary alternatives for patients over certain ages:

divalproex (10+), levetiracetam ER (12+), tiagabine (12+), lamotrigine ER (13+), felbamate (14+), and zonisamide (16+)

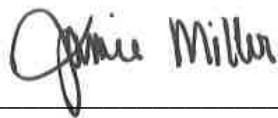
Primary Generalized Tonic-Clonic Seizures: carbamazepine, lamotrigine, levetiracetam, phenytoin, primidone, topiramate

*prior authorization required

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE
STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND
FEDERAL REGULATORY ENTITIES.**

**THIS POLICY WILL BE REVISED AS NECESSARY AND
REVIEWED NO LESS THAN ANNUALLY.**

Signed: _____



Title: Director, Pharmacy Services

Date: March 1, 2022

HPRX02

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Dev. 3/20/14

Rev. 3/1/22



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 322.0

**SECTION: Commercial Drug
SUBJECT: Fycompa**

Devised: 3/20/14
Revised: 3/1/15 – annual review, updated signature
Revised: 9/19/15 – added primary generalized tonic-clonic seizures, updated FA
Reviewed: 3/1/16 – annual review
Revised: 5/1/16 – updated format, logo, & procedure
Reviewed: 3/1/17 – annual review
Revised: 11/27/17 – separated indications, removed adjunct. from partial onset, updated age formatting, updated signature
Revised: 3/1/18 – annual review, added grandfather language
Revised: 12/27/18 – updated partial-onset seizure age and FA
Revised: 3/1/19 – annual review, added QL approval note
Revised: 11/15/19 – updated FA
Revised: 3/1/20 – annual review, added GHP Kids
Revised: 3/1/21 – annual review, updated logo, added MediSpan approval level, updated QL statement
Revised: 3/1/22 – annual review, updated referenced policies & covered LOBs, updated FA



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 323.0

**SECTION: Commercial Drug
SUBJECT: Opsumit**

Applicable line of business:

Commercial	X	Medicaid	
Medicare		ACA	X
GHP Kids	X	Self-Insured	X

POLICY:

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for Opsumit for GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 487.0 Quantity Limit Exceptions

REQUIRED DEFINITIONS:

1. **Attachment** – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. **Exhibit** – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. **Devised** – the date the policy was implemented.
4. **Revised** – the date of every revision to the policy, including typographical and grammatical changes.
5. **Reviewed** – the date documenting the annual review if the policy has no revisions necessary.

ADDITIONAL DEFINITIONS:

1. **Formulary** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. **Non-formulary products** – those medications that are not included in the Formulary.
3. **Healthcare provider** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
4. **NCQA** – National Committee for Quality Assurance.
5. **Medically Necessary or Medical Necessity** – covered services rendered by a provider that the Health Plan determines are:

- A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
- B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
- C. In accordance with current standards of medical practice;
- D. Not primarily for the convenience of the Member, or the Member's Provider; and
- E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

PROCEDURE:

An exception for coverage of Opsumit may be made for members who meet the following criteria:

- Medical record documentation that Opsumit is prescribed by a cardiologist or pulmonologist **AND**
- Medical record documentation of World Health Organization (WHO) functional class II, III, or IV pulmonary arterial hypertension **AND**
- Medical record documentation of a negative pregnancy test in females of childbearing potential **AND**
- Medical record documentation that Opsumit will be used in combination with (or therapeutic failure on, intolerance to, or contraindication to) sildenafil*

MEDISPAN AUTHORIZATION LEVEL: GPI-12

QUANTITY LIMIT: *No QLs need to be entered within the authorization unless the requested quantity exceeds the QL.*

- **QL FOR LETTER ONLY:** 1 tablet per day, 30 day supply per fill

If an exception is made, Opsumit will be paid for under the member's prescription drug benefit.

Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.



POLICY NUMBER: 323.0

**POLICY AND PROCEDURE
PHARMACY
MANUAL**

**SECTION: Commercial Drug
SUBJECT: Opsumit**

FORMULARY ALTERNATIVES:

Uptravi*, Orenitram*, treprostinil* (generic Remodulin), Tyvaso*, Ventavis*, Adempas*, bosentan*, ambrisentan*, tadalafil* (generic Adcirca), sildenafil* (generic Revatio)

*prior authorization required

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE
STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND
FEDERAL REGULATORY ENTITIES.**

**THIS POLICY WILL BE REVISED AS NECESSARY AND
REVIEWED NO LESS THAN ANNUALLY.**

Signed: _____

Title: Director, Pharmacy Services

Date: March 1, 2022

Devised: 3/20/14

Revised: 9/22/2014 – removed failure of Tracleer & added failure of Letairis, removed Tracleer from FA, updated signature

Reviewed: 3/1/15 – annual review

Reviewed: 3/1/16 – annual review

Revised: 5/1/16 – updated format, logo, & procedure

Revised: 7/22/16 – removed failure of Letairis, updated FA

Revised: 3/1/17 – annual review, defined abbreviations

Revised: 3/1/18 – annual review, updated signature & prescriber criteria, corrected typo

Revised: 3/1/19 – annual review, added QL approval note, updated QL to match package size

Revised: 3/1/21 – annual review, updated logo, added MediSpan approval level, updated QL statement, updated FA

Revised: 3/1/22 – annual review, updated referenced policies & covered LOBs



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 326.0

**SECTION: Commercial Drug
SUBJECT: Sovaldi**

Applicable line of business:

Commercial	X	Medicaid	
Medicare		ACA	X
GHP Kids	X	Self-Insured	X

POLICY:

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for Sovaldi for GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 487.0 Quantity Limit Exceptions

REQUIRED DEFINITIONS:

1. **Attachment** – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. **Exhibit** – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. **Devised** – the date the policy was implemented.
4. **Revised** – the date of every revision to the policy, including typographical and grammatical changes.
5. **Reviewed** – the date documenting the annual review if the policy has no revisions necessary.

ADDITIONAL DEFINITIONS:

1. **Formulary** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. **Non-formulary products** – those medications that are not included in the Formulary.
3. **Healthcare provider** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
4. **NCQA** – National Committee for Quality Assurance.
5. **Medically Necessary or Medical Necessity** – covered services rendered by a provider that the Health Plan determines are:

- A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
 - B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
 - C. In accordance with current standards of medical practice;
 - D. Not primarily for the convenience of the Member, or the Member's Provider; and
 - E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.
6. **HCV** – Hepatitis C Virus
 7. **FDA** – Food and Drug Administration
 8. **HIV** – Human Immunodeficiency Virus
 9. **HBV** – Hepatitis B Virus

PROCEDURE:

An exception for coverage of Sovaldi may be made for members who meet the following criteria:

- Medical record documentation of age greater than or equal to 3 years using weight-based dosing **AND**
- Medical record documentation of a diagnosis of hepatitis C infection **AND**
- Medical record documentation of the member's hepatitis C genotype **AND**
- Medical record documentation of a diagnosis of Hepatitis C Virus (HCV) genotype 1, 2, 3, or 4 infection in adults **OR** HCV genotype 2 or 3 in pediatric patients \geq 3 years of age in combination with ribavirin **AND**
- Medical record documentation of METAVIR liver scoring **AND**
- Medical record documentation of a hepatocellular carcinoma screening in those with cirrhosis (METAVIR score F4) **AND**
- Medical record documentation of the member receiving a Food and Drug Administration (FDA) approved medication regimen that is inside the parameters of use approved by the FDA or supported in the widely used compendia available **AND**
- Medical record documentation of appropriate duration of treatment **AND**
- Medical record documentation of previous treatment and treatment response **AND**
- Medical record documentation of concurrent therapy with appropriate dose and duration of ribavirin (weight-based dosing of ribavirin 1200 mg per day if greater than or equal to 75 kg, or 1000 mg per day if less than 75 kg, or 15 mg/kg in pediatric patients less than 47 kg), if indicated **AND**
- Medical record documentation of any potential drug interactions addressed by the prescriber (such as discontinuation of the interacting drug, dose reduction of the

interacting drug, or counseling of the recipient of the risks associated with the use of both medications when they interact) **AND**

- Medical record documentation of receiving the following with the past 3 months:
 - Hepatic function panel
 - Complete blood count including differential
 - Basic metabolic panel
 - Baseline Hepatitis C Virus (HCV) RNA viral load **AND**
- Medical record documentation that member does not have severe renal impairment (estimated glomerular filtration rate less than 30 mL/min/1.73 m²) or end stage renal disease requiring hemodialysis **AND**
- Medical record documentation of a negative pregnancy test if member is female of childbearing potential and receiving ribavirin **AND**
- When concurrent ribavirin therapy is indicated and prescribed, medical record documentation for male members that female partner is not pregnant **AND**
- If the member or their partner are of childbearing potential, medical record documentation that the member was instructed to practice effective contraception during therapy with ribavirin and for 6 months following discontinuation of ribavirin therapy **AND**
- If actively abusing alcohol or intravenous (IV) drugs, or has a history of abuse, has documentation of prescriber counseling regarding the risks of alcohol or IV drug abuse, and an offer of a referral for substance use disorder treatment **AND**
- Medical record documentation that member received pre-treatment readiness education about hepatitis C treatment expectations by a health care provider **AND**
- Medical record documentation that the member commits to the documented planned course of treatment including anticipated blood tests and visits, during and after treatment **AND**
- Medical record documentation that member does not have a limited life expectancy of less than 12 months due to non-liver-related co-morbid conditions **AND**
- Medical record documentation of completed:
 - Hepatitis B immunization series **OR**
 - Hepatitis B screening (sAb/sAg and cAb/cAg) **AND** Quantitative hepatitis B virus (HBV) DNA if positive for hepatitis B sAg or cAb or cAg **AND**
 - If there is detectable hepatitis B virus (HBV) DNA, will be treated for Hepatitis B **OR**
 - If negative for hepatitis B sAb, is being vaccinated against Hepatitis B **AND**
- Medical record documentation of human immunodeficiency virus (HIV) screening (HIV Ag/Ab) and if confirmed positive by HIV-1/HIV-2 differentiation immunoassay:
 - Is being treated for human immunodeficiency virus (HIV) **OR**

- If not being treated for human immunodeficiency virus (HIV), the medical record documents the rationale for the beneficiary not being treated **AND**
- Medical record documentation of therapeutic failure on, intolerance to, or contraindication to Mavyret, if clinically appropriate **AND**
- Medical record documentation that member has been evaluated and treated by a contracted Center of Excellence in hepatitis C management

OR

- Medical record documentation of a hepatitis C negative recipient receiving a transplant from a hepatitis C positive donor **AND**
- Medical record documentation of therapeutic failure on, intolerance to, or contraindication to Mavyret, if clinically appropriate

NOTE: Center of Excellence (COE) requirements do not apply to strategic partner TPA plans (i.e., Northern Light Health).

TREATMENT DURATION: Consistent with AASLD/ISDA Guidelines

MEDISPAN AUTHORIZATION LEVEL: GPI-10

QUANTITY LIMIT: *No QLs need to be entered within the authorization unless the requested quantity exceeds the QL.*

- **QL FOR LETTER ONLY:**
 - 200 mg and 400 mg tablets: 1 tablet per day, 28 day supply per fill
 - 200 mg pellets: 2 packets per day, 28 day supply per fill
 - 400 mg pellets: 1 packet per day, 28 day supply per fill

If an exception is made, Sovaldi will be paid for under the member's prescription drug benefit.

Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.

FORMULARY ALTERNATIVES (if applicable):

Mavyret*

*prior authorization required



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 326.0

**SECTION: Commercial Drug
SUBJECT: Sovaldi**

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE
STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND
FEDERAL REGULATORY ENTITIES.**

**THIS POLICY WILL BE REVISED AS NECESSARY AND
REVIEWED NO LESS THAN ANNUALLY.**

Signed: _____

Title: Director, Pharmacy Services

Date: March 1, 2022

- Devised: 5/28/14
- Revised: 9/22/14 – Updated the following: F3/F4 fibrosis for all genotypes, abstinence from alcohol and illegal substances for all members, removed verbal commitment to therapy, life expectancy
- Revised: 12/1/14 – Updated life expectancy criteria to include “due to non-liver-related co-morbid conditions”
- Revised: 2/9/15 – added METAVIR scoring, no S/S of decompensated liver disease, UDS, renal function
- Revised: 2/16/15 – removed duplicate renal function criteria
- Reviewed: 3/1/15 – annual review
- Revised: 1/29/16 – added HBV/HIV to definitions, added hepatocellular screening criterion, added severe extrahepatic manifestations of hep C criterion, removed in writing from member commitment
- Reviewed: 3/1/16 – annual review
- Revised: 3/24/16 – removed no S/S of decompensated liver disease
- Revised: 5/1/16 – updated format, logo, & procedure
- Revised: 5/27/16 – updated reauthorization criteria, added “if cirrhotic” for G3, added Daklinza and noncirrhotic for G3
- Revised: 11/22/16 – Added F2 fibrosis, referral to substance use treatment. Removed 6 months abstinence, substance use treatment compliance, UDS/fill history, GHP representative. Update FA, added if applicable.
- Revised: 3/1/17 – annual review, defined abbreviations, removed Unicode characters
- Revised: 3/27/17 – G3: removed peginterferon, added w/ Daklinza for post transplant
- Revised: 6/2/17 – removed fibrosis/liver manifestations requirement, added METAVIR scoring, updated diagnosis (removed HCC and HIV co-infection), removed peginterferon references for G1 therapy, added regimen supported by compendia, removed failure of same DAA
- Revised: 8/8/17 – updated age to include 12 or older OR weight greater than 35 kg for G2 & G3, added concurrent therapy with peg/rib for G1 & concurrent therapy with rib for G3
- Revised: 11/27/17 – added failure of Mavyret, updated FA, updated signature
- Revised: 1/19/18 – corrected typo, removed prescriber, added Hep B & HIV criteria, updated FA
- Revised: 3/1/18 – annual review, updated Hep B/HIV criteria to match DHS, corrected typo

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Dev. 5/28/14

Rev. 3/1/22



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 326.0

**SECTION: Commercial Drug
SUBJECT: Sovaldi**

- Revised: 12/28/18 – added HCV positive transplant indication/FA criteria, added COE
- Revised: 3/1/19 – annual review, added QL approval note, defined abbr., removed Olysio references (D/C)
- Revised: 7/23/19 – added TPA COE exclusion
- Revised: 01/28/20 – updated age to 3 and weight based dosing, updated genotypes, removed concurrent peginterferon criteria, updated treatment duration to consistent with AASLD/ISDA guidelines and removed subsequent authorization criteria
- Revised: 3/1/20 – annual review, added GHP Kids
- Revised: 7/29/20 – added QL for pellets
- Revised: 3/1/21 – annual review, updated logo, added MediSpan approval level, updated QL statement
- Revised: 3/1/22 – annual review, updated referenced policies & covered LOBs, removed St. Lukes & Atlanticare from COE note



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 327.0

**SECTION: Commercial Drug
SUBJECT: Aptiom**

Applicable line of business:

Commercial	X	Medicaid	
Medicare		ACA	X
GHP Kids	X	Self-Insured	X

POLICY:

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for Aptiom for GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 487.0 Quantity Limit Exceptions

REQUIRED DEFINITIONS:

1. **Attachment** – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. **Exhibit** – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. **Devised** – the date the policy was implemented.
4. **Revised** – the date of every revision to the policy, including typographical and grammatical changes.
5. **Reviewed** – the date documenting the annual review if the policy has no revisions necessary.

ADDITIONAL DEFINITIONS:

1. **Formulary** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. **Non-formulary products** – those medications that are not included in the Formulary.
3. **Healthcare provider** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
4. **NCQA** – National Committee for Quality Assurance.
5. **Medically Necessary or Medical Necessity** – covered services rendered by a provider that the Health Plan determines are:



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 327.0

**SECTION: Commercial Drug
SUBJECT: Aptiom**

- A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
- B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
- C. In accordance with current standards of medical practice;
- D. Not primarily for the convenience of the Member, or the Member's Provider; and
- E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

PROCEDURE:

New members to the plan already established on therapy may be eligible for continuity of care coverage as long as there is medical record documentation that the safety and effectiveness of use for the prescribed indication is supported by Food and Drug Administration (FDA) approval or adequate medical and scientific evidence in the medical literature.

An exception for coverage of Aptiom may be made for members who meet the following criteria:

- Medical record documentation that Aptiom is prescribed by a neurologist **AND**
- Medical record documentation of age greater than or equal to 4 years **AND**
- Medical record documentation of a diagnosis of partial-onset seizures **AND**
- Medical record documentation of contraindication to, therapeutic failure on, or intolerance to 3 formulary alternatives, one of which must be oxcarbazepine

MEDISPAN AUTHORIZATION LEVEL: GPI-12

QUANTITY LIMIT: *No QLs need to be entered within the authorization unless the requested quantity exceeds the QL.*

- **QL FOR LETTER ONLY:**
 - 600 mg or 800 mg tablet: 2 tablets per day
 - 200 mg or 400 mg: 1 tablet per day

If an exception is made, Aptiom will be paid for under the member's prescription drug benefit.

Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.



POLICY NUMBER: 327.0

**POLICY AND PROCEDURE
PHARMACY
MANUAL**

**SECTION: Commercial Drug
SUBJECT: Aptiom**

FORMULARY ALTERNATIVES:

For patients > 4 years of age: carbamazepine, gabapentin, lamotrigine IR, levetiracetam IR, oxcarbazepine, phenobarbital, phenytoin, pregabalin, topiramate IR, topiramate ER*

Additional formulary alternatives for patients over certain ages:

divalproex (10+), levetiracetam ER (12+), tiagabine (12+), lamotrigine ER (13+), felbamate (14+), and zonisamide (16+)

*prior authorization required

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE
STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND
FEDERAL REGULATORY ENTITIES.**

**THIS POLICY WILL BE REVISED AS NECESSARY AND
REVIEWED NO LESS THAN ANNUALLY.**

Signed: _____

Title: Director, Pharmacy Services

Date: March 1, 2022

Devised: 5/28/14
Revised: 7/22/14 – removed HCV and FDA definitions
Reviewed: 3/1/15 – annual review
Revised: 11/20/15 – removed adjunctive therapy requirement
Reviewed: 3/1/16 – annual review
Revised: 5/1/16 – updated format, logo, & procedure
Revised: 11/22/16 – updated 800 mg QL to 2/day
Reviewed: 3/1/17 – annual review
Revised: 11/27/17 – revised prescriber bullet, updated to age 4, added failure of oxcarbazepine, updated signature
Revised: 3/1/18 – annual review, added grandfather language
Revised: 8/7/18 – updated FA
Revised: 3/1/19 – annual review, added QL approval note
Revised: 11/15/19 – updated FA
Revised: 3/1/20 – annual review, added GHP Kids
Revised: 3/1/21 – annual review, updated logo, added MediSpan approval level, updated QL statement
Revised: 3/1/22 – annual review, updated referenced policies & covered LOBs, updated FA



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 328.0

**SECTION: Commercial Drug
SUBJECT: Farxiga**

Applicable line of business:

Commercial	X	Medicaid	
Medicare		ACA	X
GHP Kids	X	Self-Insured	X

POLICY:

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for Farxiga for GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 487.0 Quantity Limit Exceptions

REQUIRED DEFINITIONS:

1. **Attachment** – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. **Exhibit** – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. **Devised** – the date the policy was implemented.
4. **Revised** – the date of every revision to the policy, including typographical and grammatical changes.
5. **Reviewed** – the date documenting the annual review if the policy has no revisions necessary.

ADDITIONAL DEFINITIONS:

1. **Formulary** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. **Non-formulary products** – those medications that are not included in the Formulary.
3. **Healthcare provider** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
4. **NCQA** – National Committee for Quality Assurance.
5. **Medically Necessary or Medical Necessity** – covered services rendered by a provider that the Health Plan determines are:



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 328.0

**SECTION: Commercial Drug
SUBJECT: Farxiga**

- A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
- B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
- C. In accordance with current standards of medical practice;
- D. Not primarily for the convenience of the Member, or the Member's Provider; and
- E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

PROCEDURE:

An exception for coverage of Farxiga may be made for members who meet the following criteria:

Diabetes

- Medical record documentation of a diagnosis of type II diabetes mellitus **AND**
- Medical record documentation of age greater than or equal to 18 years **AND**
- Medical record documentation of therapeutic failure on, intolerance to, or contraindication to Invokana **AND** Jardiance

Heart Failure

- Medical record documentation of a diagnosis of New York Heart Association (NYHA) class II-IV heart failure **AND**
- Medical record documentation of age greater than or equal to 18 years **AND**
- Medical record documentation of reduced ejection fraction (left ventricular ejection fraction (LVEF) of less than or equal to 40%) **AND**
- Medical record documentation that the member is on optimized pharmacological therapy (e.g. combination of renin-angiotensin system inhibitor (ACEi/ARB/angiotensin receptor-neprilysin inhibitor), evidence based beta-blocker (metoprolol succinate/carvedilol/bisoprolol), and a mineralocorticoid receptor antagonist, diuretic) unless contraindication or not tolerated **AND**
- Medical record documentation of therapeutic failure on, intolerance to, or contraindication to Jardiance

Chronic Kidney Disease:

- Medical record documentation of age greater than or equal to 18 years of age **AND**
- Medical record documentation of a diagnosis of chronic kidney disease **AND**



POLICY NUMBER: 328.0

**POLICY AND PROCEDURE
PHARMACY
MANUAL**

**SECTION: Commercial Drug
SUBJECT: Farxiga**

- Medical record documentation that Farxiga will be used in combination with angiotensin-converting enzyme/ angiotensin II receptor blocker (ACEi/ARB) unless contraindicated or not tolerated

MEDISPAN AUTHORIZATION LEVEL: GPI-12

QUANTITY LIMIT: *No QLs need to be entered within the authorization unless the requested quantity exceeds the QL.*

- QL FOR LETTER ONLY: 1 tablet per day

If an exception is made, Farxiga will be paid for under the member's prescription drug benefit.

Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.

FORMULARY ALTERNATIVES:

Diabetes: Jardiance, Synjardy, Invokana, Invokamet
Heart Failure: Jardiance

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE
STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND
FEDERAL REGULATORY ENTITIES.**

**THIS POLICY WILL BE REVISED AS NECESSARY AND
REVIEWED NO LESS THAN ANNUALLY.**

Signed: _____

Title: Director, Pharmacy Services

Date: 3/1/22

Devised: 7/22/14

Revised: 12/1/14 – added failure of Farxiga

Reviewed: 3/1/15 – annual review

Revised: 3/1/16 – annual review, added Synjardy, Invokamet, and Toujeo to FA, updated PA/ST requirement indicator

HPRX02

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Dev. 7/22/14

Rev. 3/1/22

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**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 328.0

**SECTION: Commercial Drug
SUBJECT: Farxiga**

Revised: 5/1/16 – updated format, logo, & procedure
Revised: 3/1/17 – annual review, removed Unicode characters
Revised: 3/1/18 – annual review, updated signature, updated FA
Revised: 5/2/18 – removed failure of metformin & EGFR requirement per 9/17 class review
Revised: 3/1/19 – annual review, added QL approval note, updated FA
Revised: 3/1/20 – annual review, added GHP Kids
Revised: 11/18/20 – added HF indication
Revised: 3/1/21 – annual review, updated logo, added MediSpan approval level, updated QL statement
Revised: 11/19/21 – added CKD indication, updated FA
Revised: 1/21/22 – added failure of Jardiance for HF, updated FA
Revised: 3/1/22 – annual review, updated referenced policies & covered LOBs



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 329.0

**SECTION: Commercial Drug
SUBJECT: Hetlioz**

Applicable line of business:

Commercial	X	Medicaid	
Medicare		ACA	X
GHP Kids	X	Self-Insured	X

POLICY:

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for Hetlioz for GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 487.0 Quantity Limit Exceptions

REQUIRED DEFINITIONS:

1. **Attachment** – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. **Exhibit** – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. **Devised** – the date the policy was implemented.
4. **Revised** – the date of every revision to the policy, including typographical and grammatical changes.
5. **Reviewed** – the date documenting the annual review if the policy has no revisions necessary.

ADDITIONAL DEFINITIONS:

1. **Formulary** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. **Non-formulary products** – those medications that are not included in the Formulary.
3. **Healthcare provider** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
4. **NCQA** – National Committee for Quality Assurance.
5. **Medically Necessary or Medical Necessity** – covered services rendered by a provider that the Health Plan determines are:

- A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
- B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
- C. In accordance with current standards of medical practice;
- D. Not primarily for the convenience of the Member, or the Member's Provider; and
- E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

PROCEDURE:

An exception for coverage of Hetlioz may be made for members who meet the following criteria:

Non-24-Hour Sleep-Wake Disorder (Free-Running Disorder)

- Medical record documentation of a diagnosis of Non-24-Hour Sleep-Wake Disorder (Free-Running Disorder) **AND**
- Medical record documentation that the member is totally blind with no perception of light **AND**
- Medical record documentation of age greater than or equal to 18 years **AND**
- Medical record documentation of a therapeutic failure on, intolerance to, or contraindication to at least 6 months of melatonin therapy

Smith-Magenis Syndrome (SMS)

- Medical record documentation of a diagnosis of nighttime sleep disturbances in Smith-Magenis Syndrome (SMS) **AND**
- Medical record documentation of age greater than or equal to 3 years

MEDISPAN AUTHORIZATION LEVEL: GPI-10

QUANTITY LIMIT: *No QLs need to be entered within the authorization unless the requested quantity exceeds the QL.*

- **QL FOR LETTER ONLY:**
 - Capsule: 1 capsule per day, 30 day supply per fill
 - Suspension: 5 mL per day, 30 day supply per fill



POLICY NUMBER: 329.0

**POLICY AND PROCEDURE
PHARMACY
MANUAL**

**SECTION: Commercial Drug
SUBJECT: Hetlioz**

If an exception is made, Hetlioz will be paid for under the member's prescription drug benefit.

Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.

FORMULARY ALTERNATIVES:

none

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE
STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND
FEDERAL REGULATORY ENTITIES.**

**THIS POLICY WILL BE REVISED AS NECESSARY AND
REVIEWED NO LESS THAN ANNUALLY.**

Signed: _____

Title: Director, Pharmacy Services

Date: March 1, 2022

Devised: 7/22/14
Reviewed: 3/1/15 – annual review
Reviewed: 3/1/16 – annual review
Revised: 5/1/16 – updated format, logo, & procedure
Revised: 3/1/17 – annual review, removed Unicode characters
Revised: 3/1/18 – annual review, updated signature, updated QL to match package size
Revised: 3/1/19 – annual review, added QL approval note
Revised: 3/1/20 – annual review, added GHP Kids
Revised: 3/1/21 – annual review, updated logo, added MediSpan approval level, updated QL statement
Revised: 6/7/21 – added SMS indication, added suspension QL
Revised: 3/1/22 – annual review, updated referenced policies & covered LOBs



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 330.0

**SECTION: Commercial Drug
SUBJECT: Zykadia**

Applicable line of business:

Commercial	X	Medicaid	
Medicare		ACA	X
GHP Kids	X	Self-Insured	X

POLICY:

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for Zykadia for GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 487.0 Quantity Limit Exceptions

REQUIRED DEFINITIONS:

1. **Attachment** – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. **Exhibit** – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. **Devised** – the date the policy was implemented.
4. **Revised** – the date of every revision to the policy, including typographical and grammatical changes.
5. **Reviewed** – the date documenting the annual review if the policy has no revisions necessary.

ADDITIONAL DEFINITIONS:

1. **Formulary** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. **Non-formulary products** – those medications that are not included in the Formulary.
3. **Healthcare provider** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
4. **NCQA** – National Committee for Quality Assurance.
5. **Medically Necessary or Medical Necessity** – covered services rendered by a provider that the Health Plan determines are:



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 330.0

**SECTION: Commercial Drug
SUBJECT: Zykadia**

- A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
- B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
- C. In accordance with current standards of medical practice;
- D. Not primarily for the convenience of the Member, or the Member's Provider; and
- E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

PROCEDURE:

New members to the plan already established on therapy may be eligible for continuity of care coverage as long as there is medical record documentation that the safety and effectiveness of use for the prescribed indication is supported by Food and Drug Administration (FDA) approval or adequate medical and scientific evidence in the medical literature.

An exception for coverage of Zykadia may be made for members who meet the following criteria:

- Medical record documentation that Zykadia is prescribed by an oncologist **AND**
- Medical record documentation of locally advanced or metastatic non-small cell lung cancer (NSCLC) that is anaplastic lymphoma kinase (ALK) positive as detected by a Food and Drug Administration (FDA) approved test **AND**
- Medical record documentation of therapeutic failure on, intolerance to, or contraindication to Alecensa*

NOTE: The FDA approved test is the Vysis ALK Break-Apart FISH probe Kit

MEDISPAN AUTHORIZATION LEVEL: GPI-12, number of claims authorized = 1, enter for the remainder of the calendar year

QUANTITY LIMIT: *No QLs need to be entered within the authorization unless the requested quantity exceeds the QL.*

- QL FOR LETTER ONLY: 3 tablets per day, 28 day supply per fill



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 330.0

**SECTION: Commercial Drug
SUBJECT: Zykadia**

RE-AUTHORIZATION CRITERIA: Zykadia is configured as a prior authorization for new starts only. Zykadia will no longer be covered if it is identified that the member is not receiving appropriate follow-up care from the prescribing specialist or if the member has greater than or equal to a 90 day break in therapy.

- Medical record documentation that the member is receiving appropriate follow-up care from the prescribing specialist

If an exception is made, Zykadia will be paid for under the member's prescription drug benefit.

Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.

FORMULARY ALTERNATIVES:

Alecensa*, Xalkori*, Alunbrig*

*prior authorization and quantity limits apply

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE
STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND
FEDERAL REGULATORY ENTITIES.**

**THIS POLICY WILL BE REVISED AS NECESSARY AND
REVIEWED NO LESS THAN ANNUALLY.**

Signed: _____

Title: Director, Pharmacy Services

Date: March 1, 2022

Devised: 7/22/14
Reviewed: 3/1/15 – annual review
Reviewed: 3/1/16 – annual review
Revised: 5/1/16 – updated format, logo, & procedure
Reviewed: 3/1/17 – annual review
Revised: 8/8/17 – removed failure of Xalkori, updated FA



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 330.0

**SECTION: Commercial Drug
SUBJECT: Zykadia**

- Revised: 10/10/17 – increased authorization duration to 12 months
- Revised: 1/17/18 – updated presc. criteria, updated QL, added failure of Alecensa, updated sig
- Revised: 3/1/18– annual review, added grandfather language, defined FDA
- Revised: 4/10/18 – updated QL
- Revised: 3/1/19 – annual review, added QL approval note
- Revised: 3/1/20 – annual review, added GHP Kids
- Revised: 3/1/21 – annual review, updated logo, added MediSpan approval level, updated QL statement, updated from capsules to tablets
- Revised: 3/1/21 – annual review, updated logo, added MediSpan approval level, updated QL statement
- Revised: 3/1/22 – annual review, updated referenced policies & covered LOBs



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 331.0

**SECTION: Commercial Drug
SUBJECT: Duavee**

Applicable line of business:

Commercial	X	Medicaid	
Medicare		ACA	X
GHP Kids	X	Self-Insured	X

POLICY:

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for Duavee for GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 487.0 Quantity Limit Exceptions

REQUIRED DEFINITIONS:

1. **Attachment** – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. **Exhibit** – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. **Devised** – the date the policy was implemented.
4. **Revised** – the date of every revision to the policy, including typographical and grammatical changes.
5. **Reviewed** – the date documenting the annual review if the policy has no revisions necessary.

ADDITIONAL DEFINITIONS:

1. **Formulary** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. **Non-formulary products** – those medications that are not included in the Formulary.
3. **Healthcare provider** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
4. **NCQA** – National Committee for Quality Assurance.
5. **Medically Necessary or Medical Necessity** – covered services rendered by a provider that the Health Plan determines are:



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 331.0

**SECTION: Commercial Drug
SUBJECT: Duavee**

- A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
- B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
- C. In accordance with current standards of medical practice;
- D. Not primarily for the convenience of the Member, or the Member's Provider; and
- E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

PROCEDURE:

An exception for coverage of Duavee may be made for members who meet the following criteria:

- Medical record documentation of use for abnormal vasomotor function **OR** for prevention of postmenopausal osteoporosis **AND**
- Medical record documentation of age less than 75 years
- Medical record documentation of an intact uterus **AND**
- Medical record documentation of therapeutic failure on, intolerance to, or contraindication to three formulary alternatives

MEDISPAN AUTHORIZATION LEVEL: GPI-12

If an exception is made, Duavee will be paid for under the member's prescription drug benefit.

Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.

FORMULARY ALTERNATIVES:

clomiphene citrate, estradiol, estradiol norethindrone acetate, estropipate, norethindrone acetate/ethinyl estradiol, Combipatch, Estring, Premarin, Premphase, Prempro, estradiol patch, raloxifene, alendronate, ibandronate, risedronate



POLICY NUMBER: 331.0

**POLICY AND PROCEDURE
PHARMACY
MANUAL**

**SECTION: Commercial Drug
SUBJECT: Duavee**

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE
STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND
FEDERAL REGULATORY ENTITIES.**

**THIS POLICY WILL BE REVISED AS NECESSARY AND
REVIEWED NO LESS THAN ANNUALLY.**

Signed: _____

Title: Director, Pharmacy Services

Date: March 1, 2022

Devised: 7/22/14
Reviewed: 3/1/15 – annual review
Reviewed: 3/1/16 – annual review
Revised: 5/1/16 – updated format, logo, & procedure
Reviewed: 3/1/17 – annual review
Revised: 3/1/18 – annual review, updated signature, age criteria, and FA
Reviewed: 3/1/19 – annual review
Revised: 3/1/20 – annual review, added GHP Kids
Revised: 3/1/21 – annual review, updated logo, added MediSpan approval level
Revised: 3/1/22 – annual review, updated referenced policies & covered LOBs



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 332.0

**SECTION: Commercial Drug
SUBJECT: Adempas**

Applicable line of business:

Commercial	X	Medicaid	
Medicare		ACA	X
GHP Kids	X	Self-Insured	X

POLICY:

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for Adempas for GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 487.0 Quantity Limit Exceptions

REQUIRED DEFINITIONS:

1. **Attachment** – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. **Exhibit** – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. **Devised** – the date the policy was implemented.
4. **Revised** – the date of every revision to the policy, including typographical and grammatical changes.
5. **Reviewed** – the date documenting the annual review if the policy has no revisions necessary.

ADDITIONAL DEFINITIONS:

1. **Formulary** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. **Non-formulary products** – those medications that are not included in the Formulary.
3. **Healthcare provider** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
4. **NCQA** – National Committee for Quality Assurance.
5. **Medically Necessary or Medical Necessity** – covered services rendered by a provider that the Health Plan determines are:

- A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
- B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
- C. In accordance with current standards of medical practice;
- D. Not primarily for the convenience of the Member, or the Member's Provider; and
- E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

PROCEDURE:

An exception for coverage of Adempas may be made for members who meet the following criteria:

- Medical record documentation that Adempas is prescribed by a cardiologist or pulmonologist **AND**
- Medical record documentation of a baseline 6-minute walking distance **AND**
- Medical record documentation of World Health Organization (WHO) functional class II, III, or IV symptoms **AND**
- Medical record documentation of one of the following:
 - Medical record documentation of chronic thromboembolic pulmonary hypertension (CTEPH) (World Health Organization Group 4), which is inoperable or previously treated surgically **OR**
 - All of the following:
 - Medical record documentation of a diagnosis of World Health Organization (WHO) Group I pulmonary arterial hypertension **AND**
 - Medical record documentation of therapeutic failure on, intolerance to, or contraindication to, or use in combination with bosentan*

MEDISPAN AUTHORIZATION LEVEL: GPI-12

QUANTITY LIMIT: *No QLs need to be entered within the authorization unless the requested quantity exceeds the QL.*

- **QL FOR LETTER ONLY:** 3 tablets per day, 30 day supply per fill

If an exception is made, Adempas will be paid for under the member's prescription drug benefit.



POLICY NUMBER: 332.0

**POLICY AND PROCEDURE
PHARMACY
MANUAL**

**SECTION: Commercial Drug
SUBJECT: Adempas**

Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.

FORMULARY ALTERNATIVES:

Uptravi*, Orenitram*, treprostini* (generic Remodulin), Tyvaso*, Ventavis*, Opsumit*, ambrisentan*, tadalafil* (generic Adcirca), sildenafil* (generic Revatio), bosentan*

*prior authorization required

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE
STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND
FEDERAL REGULATORY ENTITIES.**

**THIS POLICY WILL BE REVISED AS NECESSARY AND
REVIEWED NO LESS THAN ANNUALLY.**

Signed: _____

Title: Director, Pharmacy Services

Date: March 1, 2022

- Devised: 7/22/14
- Revised: 9/22/14 – removed failure of Tracleer, removed Tracleer from formulary alternatives
- Reviewed: 3/1/15 – annual review
- Reviewed: 3/1/16 – annual review
- Revised: 5/1/16 – updated format, logo, & procedure
- Revised: 7/27/16 – revised criteria to include separate criteria for WHO group I, updated FA
- Revised: 3/1/17 – annual review, defined abbreviations
- Revised: 3/1/18 – annual review, updated signature, updated prescribed criteria, corrected typo, updated QL to match package size
- Revised: 3/1/19 – annual review, added QL approval note
- Revised: 3/1/20 – annual review, added GHP Kids
- Revised: 3/1/21 – annual review, updated logo, added MediSpan approval level, updated QL statement, updated FA
- Revised: 3/1/22 – annual review, updated referenced policies & covered LOBs, updated format, updated Tracleer to bosentan in criteria



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 333.0

**SECTION: Commercial Drug
SUBJECT: Xerese**

Applicable line of business:

Commercial	X	Medicaid	
Medicare		ACA	X
GHP Kids	X	Self-Insured	X

POLICY:

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for Xerese for GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 487.0 Quantity Limit Exceptions

REQUIRED DEFINITIONS:

1. **Attachment** – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. **Exhibit** – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. **Devised** – the date the policy was implemented.
4. **Revised** – the date of every revision to the policy, including typographical and grammatical changes.
5. **Reviewed** – the date documenting the annual review if the policy has no revisions necessary.

ADDITIONAL DEFINITIONS:

1. **Formulary** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. **Non-formulary products** – those medications that are not included in the Formulary.
3. **Healthcare provider** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
4. **NCQA** – National Committee for Quality Assurance.
5. **Medically Necessary or Medical Necessity** – covered services rendered by a provider that the Health Plan determines are:



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 333.0

**SECTION: Commercial Drug
SUBJECT: Xerese**

- A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
- B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
- C. In accordance with current standards of medical practice;
- D. Not primarily for the convenience of the Member, or the Member's Provider; and
- E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

PROCEDURE:

An exception for coverage of Xerese may be made for members who meet the following criteria:

Members 12 Years of Age and Older

- Medical record documentation of a diagnosis of cold sores (Herpes Simplex 1 or Herpes Labialis) **AND**
- Medical record documentation of age greater than or equal to 12 years **AND**
- Medical record documentation of therapeutic failure on, intolerance to, or contraindication to Abreva (OTC), acyclovir cream*, Denavir Cream*, famciclovir **AND** valacyclovir

Members Aged 6 to Less Than 12 Years

- Medical record documentation of a diagnosis of cold sores (Herpes Simplex 1 or Herpes Labialis) **AND**
- Medical record documentation of age greater than or equal to 6 years and less than 12 years

MEDISPAN AUTHORIZATION LEVEL: GPI-12

If an exception is made, Xerese will be paid for under the member's prescription drug benefit.

Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.

Geisinger

**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 333.0

**SECTION: Commercial Drug
SUBJECT: Xerese**

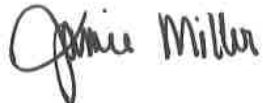
FORMULARY ALTERNATIVES:

acyclovir cream*, Denavir Cream*, famciclovir, valacyclovir

*prior authorization required

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE
STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND
FEDERAL REGULATORY ENTITIES.**

**THIS POLICY WILL BE REVISED AS NECESSARY AND
REVIEWED NO LESS THAN ANNUALLY.**



Signed: _____

Title: Director, Pharmacy Services

Date: March 1, 2022

Devised: 7/22/14
Reviewed: 3/1/15 – annual review
Reviewed: 3/1/16 – annual review
Revised: 5/1/16 – updated format, logo, & procedure
Reviewed: 3/1/17 – annual review
Revised: 3/1/18 – annual review, updated signature, updated format of diagnosis/age criteria
Revised: 3/1/19 – annual review, updated Zovirax to acyclovir
Revised: 3/1/20 – annual review, added GHP Kids
Revised: 3/1/21 – annual review, updated logo, added MediSpan approval level
Revised: 3/1/22 – annual review, updated referenced policies & covered LOBs, updated age headers



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 334.0

**SECTION: Commercial Drug
SUBJECT: Luliconazole**

Applicable line of business:

Commercial	X	Medicaid	
Medicare		ACA	X
GHP Kids	X	Self-Insured	X

POLICY:

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for luliconazole for GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 487.0 Quantity Limit Exceptions

REQUIRED DEFINITIONS:

1. **Attachment** – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. **Exhibit** – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. **Devised** – the date the policy was implemented.
4. **Revised** – the date of every revision to the policy, including typographical and grammatical changes.
5. **Reviewed** – the date documenting the annual review if the policy has no revisions necessary.

ADDITIONAL DEFINITIONS:

1. **Formulary** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. **Non-formulary products** – those medications that are not included in the Formulary.
3. **Healthcare provider** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
4. **NCQA** – National Committee for Quality Assurance.
5. **Medically Necessary or Medical Necessity** – covered services rendered by a provider that the Health Plan determines are:



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 334.0

**SECTION: Commercial Drug
SUBJECT: Luliconazole**

- A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
- B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
- C. In accordance with current standards of medical practice;
- D. Not primarily for the convenience of the Member, or the Member's Provider; and
- E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

PROCEDURE:

An exception for coverage of luliconazole may be made for members who meet the following criteria:

- Medical record documentation of a diagnosis of tinea pedis, tinea cruris, or tinea corporis **AND**
- Medical record documentation of age greater than or equal to 12 years **AND**
- Medical record documentation of therapeutic failure on, intolerance to, or contraindication to clotrimazole, econazole, ketoconazole, over the counter terbinafine, over the counter tolnaftate, **AND** over the counter miconazole **OR**
- If member is between the ages of 12 and less than 18 years: Medical record documentation of therapeutic failure on, intolerance to, or contraindication to clotrimazole, over the counter terbinafine, over the counter tolnaftate, **AND** over the counter miconazole

MEDISPAN AUTHORIZATION LEVEL: GPI-12, generic only

AUTHORIZATION DURATION: 2 weeks

If an exception is made, luliconazole will be paid for under the member's prescription drug benefit.

Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.

FORMULARY ALTERNATIVES:

topical clotrimazole, topical econazole, topical ketoconazole



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 334.0

**SECTION: Commercial Drug
SUBJECT: Luliconazole**

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE
STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND
FEDERAL REGULATORY ENTITIES.**

**THIS POLICY WILL BE REVISED AS NECESSARY AND
REVIEWED NO LESS THAN ANNUALLY.**

Signed: _____

Title: Director, Pharmacy Services

Date: March 1, 2022

Devised: 7/22/14
Reviewed: 3/1/15 – annual review
Reviewed: 3/1/16 – annual review
Revised: 5/1/16 – updated format, logo, & procedure
Revised: 3/1/17 – annual review, defined abbreviations
Revised: 3/1/18 – annual review, updated signature
Revised: 8/7/18 – updated age to 12 years, added FA for 12-18 years, added auth duration
Reviewed: 3/1/19 – annual review
Revised: 3/28/19 – updated from Luzu to generic luliconazole
Revised: 3/1/20 – annual review, added GHP Kids
Revised: 3/1/21 – annual review, updated logo, added MediSpan approval level
Revised: 3/1/22 – annual review, updated referenced policies & covered LOBs



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 335.0

**SECTION: Commercial Drug
SUBJECT: Orenitram**

Applicable line of business:

Commercial	X	Medicaid	
Medicare		ACA	X
GHP Kids	X	Self-Insured	X

POLICY:

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for Orenitram for GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 487.0 Quantity Limit Exceptions

REQUIRED DEFINITIONS:

1. **Attachment** – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. **Exhibit** – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. **Devised** – the date the policy was implemented.
4. **Revised** – the date of every revision to the policy, including typographical and grammatical changes.
5. **Reviewed** – the date documenting the annual review if the policy has no revisions necessary.

ADDITIONAL DEFINITIONS:

1. **Formulary** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. **Non-formulary products** – those medications that are not included in the Formulary.
3. **Healthcare provider** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
4. **NCQA** – National Committee for Quality Assurance.
5. **Medically Necessary or Medical Necessity** – covered services rendered by a provider that the Health Plan determines are:



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 335.0

**SECTION: Commercial Drug
SUBJECT: Orenitram**

- A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
- B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
- C. In accordance with current standards of medical practice;
- D. Not primarily for the convenience of the Member, or the Member's Provider; and
- E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

PROCEDURE:

An exception for coverage of Orenitram may be made for members who meet the following criteria:

- Medical record documentation that Orenitram is prescribed by a cardiologist or pulmonologist **AND**
- Medical record documentation of age greater than or equal to 18 years **AND**
- Medical record documentation of World Health Organization (WHO) Group 1 pulmonary arterial hypertension **AND**
- Medical record documentation of World Health Organization (WHO) functional class II or III symptoms **AND**
- Medical record documentation of a baseline 6-minute walking distance **AND**
- Medical record documentation of therapeutic failure on, intolerance to, or contraindication to Uptravi

MEDISPAN AUTHORIZATION LEVEL: GPI-12

QUANTITY LIMIT: 34 day supply per fill

AUTHORIZATION DURATION: If approved, Orenitram will require reauthorization every 6 months. At that point, the following criteria should apply:

- Medical record documentation of a 6-minute walking distance improved from baseline



POLICY NUMBER: 335.0

**POLICY AND PROCEDURE
PHARMACY
MANUAL**

**SECTION: Commercial Drug
SUBJECT: Orenitram**

If an exception is made, Orenitram will be paid for under the member's prescription drug benefit.

Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.

FORMULARY ALTERNATIVES:

Upravi*, bosentan*, treprostinil injection*, Tyvaso*, Ventavis*, Adempas*, Opsumit*, ambrisentan*, tadalafil*, sildenafil*

*prior authorization required

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE
STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND
FEDERAL REGULATORY ENTITIES.**

**THIS POLICY WILL BE REVISED AS NECESSARY AND
REVIEWED NO LESS THAN ANNUALLY.**

Signed: _____

Title: Director, Pharmacy Services

Date: March 1, 2022

- Devised: 7/22/14
- Reviewed: 3/1/15 – annual review
- Reviewed: 3/1/16 – annual review
- Revised: 5/1/16 – updated format, logo, & procedure
- Revised: 7/27/16 – added failure of Upravi, updated FA
- Revised: 3/1/17 – annual review, defined abbreviations, corrected typo
- Revised: 3/1/18 – annual review, updated signature, updated prescriber criteria, corrected typo, moved failure of Upravi from re-auth to initial review
- Reviewed: 3/1/19 – annual review
- Revised: 3/1/20 – annual review, added GHP Kids
- Revised: 4/21/20 – removed not in use with endothelin receptor antagonist criteria, updated FA to generics
- Revised: 3/1/21 – annual review, updated logo, added MediSpan approval level
- Revised: 3/1/22 – annual review, updated referenced policies & covered LOBs



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 336.0

**SECTION: Commercial Drug
SUBJECT: Otezla**

Applicable line of business:

Commercial	X	Medicaid	
Medicare		ACA	X
GHP Kids	X	Self-Insured	X

POLICY:

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for Otezla for GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 487.0 Quantity Limit Exceptions

REQUIRED DEFINITIONS:

1. **Attachment** – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. **Exhibit** – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. **Devised** – the date the policy was implemented.
4. **Revised** – the date of every revision to the policy, including typographical and grammatical changes.
5. **Reviewed** – the date documenting the annual review if the policy has no revisions necessary.

ADDITIONAL DEFINITIONS:

1. **Formulary** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. **Non-formulary products** – those medications that are not included in the Formulary.
3. **Healthcare provider** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
4. **NCQA** – National Committee for Quality Assurance.
5. **Medically Necessary or Medical Necessity** – covered services rendered by a provider that the Health Plan determines are:



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 336.0

**SECTION: Commercial Drug
SUBJECT: Otezla**

- A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
- B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
- C. In accordance with current standards of medical practice;
- D. Not primarily for the convenience of the Member, or the Member's Provider; and
- E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

PROCEDURE:

New members to the plan already established on therapy may be eligible for continuity of care coverage as long as there is medical record documentation that the safety and effectiveness of use for the prescribed indication is supported by Food and Drug Administration (FDA) approval or adequate medical and scientific evidence in the medical literature.

An exception for coverage of Otezla may be made for members who meet **ALL** of the following criteria:

For Psoriatic Arthritis:

- Medical record documentation that Otezla is prescribed by a rheumatologist or dermatologist **AND**
- Medical record documentation of age greater than or equal to 18 years **AND**
- Medical record documentation of active psoriatic arthritis which must include the following:
 - Documentation of either active psoriatic lesions or a documented history of psoriasis
- Medical record documentation of a therapeutic failure on, intolerance to, or contraindication to at least 3 months of therapy with Cosentyx* **AND** Humira*

MEDISPAN AUTHORIZATION LEVEL: GPI-10, number of claims authorized = 1, enter for the remainder of the calendar year

QUANTITY LIMIT: *No QLs need to be entered within the authorization unless the requested quantity exceeds the QL.*

- **QL FOR LETTER ONLY:** 2 tablets per day, 30 day supply per fill



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 336.0

**SECTION: Commercial Drug
SUBJECT: Otezla**

RE-AUTHORIZATION CRITERIA: Otezla is configured as a prior authorization for new starts only. Otezla will no longer be covered if it is identified that the member is not receiving appropriate follow-up care from the prescribing specialist or if the member has greater than or equal to a 90 day break in therapy.

- Medical record documentation that the member is receiving appropriate follow-up care from the prescribing specialist

FORMULARY ALTERNATIVES:

Cosentyx*, Humira*

*prior authorization required



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 336.0

**SECTION: Commercial Drug
SUBJECT: Otezla**

For Plaque Psoriasis:

- Medical record documentation that Otezla is prescribed by a dermatologist **AND**
- Medical record documentation of age greater than or equal to 18 years **AND**
- For mild disease:
 - Medical record documentation of a diagnosis of mild to moderate plaque psoriasis characterized by less than 5% of body surface area involved **AND**
 - Medical record documentation of an intolerance to, contraindication to, or therapeutic failure of 2 topical therapies (one of which is a corticosteroid of at least medium potency) **AND**
 - Medical record documentation of an intolerance to, contraindication to, or therapeutic failure of phototherapy
- For moderate-severe disease:
 - Medical record documentation of a diagnosis of moderate to severe plaque psoriasis characterized by greater than 5% of body surface area involved or disease involving crucial body areas such as the hands, feet, face, or genitals **AND**
 - Medical record documentation of an intolerance to, contraindication to, or therapeutic failure on a minimum 3 month trial of Cosentyx* **AND** Humira*

MEDISPAN AUTHORIZATION LEVEL: GPI-10, number of claims authorized = 1, enter for the remainder of the calendar year

QUANTITY LIMIT: *No QLs need to be entered within the authorization unless the requested quantity exceeds the QL.*

- QL FOR LETTER ONLY: 2 tablets per day, 30 day supply per fill

RE-AUTHORIZATION CRITERIA: Otezla is configured as a prior authorization for new starts only. Otezla will no longer be covered if it is identified that the member is not receiving appropriate follow-up care from the prescribing specialist or if the member has greater than or equal to a 90 day break in therapy.

- Medical record documentation that the member is receiving appropriate follow-up care from the prescribing specialist

FORMULARY ALTERNATIVES:

Cosentyx*, Humira*

*prior authorization required

For Behçet's Disease

- Medical record documentation of age greater than or equal to 18 years **AND**
- Medical record documentation of oral ulcers associated with Behçet's Disease

NOTE: The International Clinical Criteria for Behçet's Disease diagnostic criteria:

- Recurrent oral ulcerations (aphthous or herpetiform) at least three times in one year.
- Additionally, patients must present with two of the following:
 - Recurrent genital ulcerations
 - Eye lesions (uveitis and retinal vasculitis) observed by an ophthalmologist
 - Skin lesions (erythema nodosum, pseudofolliculitis, papulopustular lesions, acneiform nodules) found in adult patients not being treated with corticosteroids
 - Positive "pathergy test" read by a physician within 24-48 hours of testing

MEDISPAN AUTHORIZATION LEVEL: GPI-10, number of claims authorized = 1, enter for the remainder of the calendar year

QUANTITY LIMIT: *No QLs need to be entered within the authorization unless the requested quantity exceeds the QL.*

- **QL FOR LETTER ONLY:** 2 tablets per day, 30 day supply per fill

RE-AUTHORIZATION CRITERIA: Otezla is configured as a prior authorization for new starts only. Otezla will no longer be covered if it is identified that the member is not receiving appropriate follow-up care from the prescribing specialist or if the member has greater than or equal to a 90 day break in therapy.

- Medical record documentation that the member is receiving appropriate follow-up care from the prescribing specialist

FORMULARY ALTERNATIVES:

none

If an exception is made, Otezla will be paid for under the member's prescription drug benefit.

Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 336.0

**SECTION: Commercial Drug
SUBJECT: Otezla**

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE
STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND
FEDERAL REGULATORY ENTITIES.**

**THIS POLICY WILL BE REVISED AS NECESSARY AND
REVIEWED NO LESS THAN ANNUALLY.**

Signed: _____

Title: Director, Pharmacy Services

Date: June 7, 2022

- Devised: 9/22/14
- Revised: 11/21/14 – Added criteria for PsO, updated formulary alternatives
- Revised: 2/9/15 – Updated alternat. criteria & FA for both indications, prescriber criteria for PsA
- Reviewed: 3/1/15 – annual review
- Revised: 9/19/15 – removed joint count criteria from initial requirements
- Reviewed: 3/1/16 – annual review
- Revised: 5/1/16 – updated format, logo, & procedure
- Revised: 3/1/17 – annual review, removed Unicode characters
- Revised: 3/1/18 – annual review, updated signature, updated prescribed & age criteria, added grandfather language, updated QL to daily dose/package size
- Revised: 5/30/18 – removed failure of Enbrel, added failure of Cosentyx, updated FA
- Revised: 3/1/19 – annual review, added QL approval note
- Revised: 11/20/19 – added Behçet's Disease indication to policy
- Revised: 3/1/20 – annual review, added GHP Kids
- Revised: 3/1/21 – annual review, updated logo, added MediSpan approval level, updated QL statement & added QL to PsA indication
- Revised: 12/2/21 – added one-time PA to approval crit., removed auth duration & added re-auth crit.
- Revised: 3/1/22 – annual review, updated referenced policies & covered LOBs, added FA for PsO
- Revised: 6/7/22 – added mild PsO criteria



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 337.0

**SECTION: Commercial Drug
SUBJECT: Aved**

Applicable line of business:

Commercial	X	Medicaid	
Medicare		ACA	X
GHP Kids	X	Self-Insured	X

POLICY:

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for Aved for GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 487.0 Quantity Limit Exceptions

REQUIRED DEFINITIONS:

1. **Attachment** – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. **Exhibit** – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. **Devised** – the date the policy was implemented.
4. **Revised** – the date of every revision to the policy, including typographical and grammatical changes.
5. **Reviewed** – the date documenting the annual review if the policy has no revisions necessary.

ADDITIONAL DEFINITIONS:

1. **Formulary** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. **Non-formulary products** – those medications that are not included in the Formulary.
3. **Healthcare provider** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
4. **NCQA** – National Committee for Quality Assurance.
5. **Medically Necessary or Medical Necessity** – covered services rendered by a provider that the Health Plan determines are:



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 337.0

**SECTION: Commercial Drug
SUBJECT: Aved**

- A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
- B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
- C. In accordance with current standards of medical practice;
- D. Not primarily for the convenience of the Member, or the Member's Provider; and
- E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

PROCEDURE:

An exception for coverage of Aved may be made for members who meet **ALL** of the following criteria:

- Medical record documentation of use for testosterone replacement therapy in adult males for conditions associated with a deficiency or absence of endogenous testosterone:
 - Primary hypogonadism (congenital or acquired)
 - Hypogonadotropic hypogonadism (congenital or acquired) **AND**
- Medical record documentation of therapeutic failure on, intolerance to, or contraindication to testosterone cypionate **AND** testosterone enanthate

MEDISPAN AUTHORIZATION LEVEL: GPI-12

If an exception is made, Aved will be paid for under the member's prescription drug benefit.

Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.

FORMULARY ALTERNATIVES:

testosterone cypionate, testosterone enanthate



POLICY NUMBER: 337.0

**POLICY AND PROCEDURE
PHARMACY
MANUAL**

**SECTION: Commercial Drug
SUBJECT: Aved**

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE
STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND
FEDERAL REGULATORY ENTITIES.**

**THIS POLICY WILL BE REVISED AS NECESSARY AND
REVIEWED NO LESS THAN ANNUALLY.**

Signed: _____

Title: Director, Pharmacy Services

Date: March 1, 2022

Devised: 9/22/14
Reviewed: 3/1/15 – annual review
Reviewed: 3/1/16 – annual review
Revised: 5/1/16 – updated format, logo, & procedure
Reviewed: 3/1/17 – annual review
Revised: 3/1/18 – annual review, updated signature
Reviewed: 3/1/19 – annual review
Revised: 3/1/20 – annual review, added GHP Kids
Revised: 3/1/21 – annual review, updated logo, added MediSpan approval level
Revised: 3/1/22 – annual review, updated referenced policies & covered LOBs



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 338.0

**SECTION: Commercial Drug
SUBJECT: Myalept**

Applicable line of business:

Commercial	X	Medicaid	
Medicare		ACA	X
GHP Kids	X	Self-Insured	X

POLICY:

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for Myalept for GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 487.0 Quantity Limit Exceptions

REQUIRED DEFINITIONS:

1. **Attachment** – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. **Exhibit** – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. **Devised** – the date the policy was implemented.
4. **Revised** – the date of every revision to the policy, including typographical and grammatical changes.
5. **Reviewed** – the date documenting the annual review if the policy has no revisions necessary.

ADDITIONAL DEFINITIONS:

1. **Formulary** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. **Non-formulary products** – those medications that are not included in the Formulary.
3. **Healthcare provider** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
4. **NCQA** – National Committee for Quality Assurance.
5. **Medically Necessary or Medical Necessity** – covered services rendered by a provider that the Health Plan determines are:

- A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
- B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
- C. In accordance with current standards of medical practice;
- D. Not primarily for the convenience of the Member, or the Member's Provider; and
- E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

PROCEDURE:

An exception for coverage of Myalept may be made for members who meet **ALL** of the following criteria:

- Medical record documentation that Myalept is prescribed by an endocrinologist **AND**
- Medical record documentation of laboratory confirmed leptin deficiency* associated with congenital or acquired generalized lipodystrophy **AND**
- For congenital generalized lipodystrophy only: Medical record documentation of genetic testing to confirm the diagnosis of congenital generalized lipodystrophy **AND**
- No medical record documentation of human immunodeficiency virus (HIV) or congenital or acquired partial lipodystrophy **AND**
- Medical record documentation of an insufficient response to at least 6 months on a physician supervised diet program **AND**
- Medical record documentation that Myalept will be reconstituted with bacteriostatic water for injection in members 18 years of age and older **AND**
- Medical record documentation of one or both of the following:
 - A diagnosis of diabetes (including baseline hemoglobin A1C (HbA1C) value) **AND** failure (defined by HbA1C greater than or equal to 8.5% on maximum recommended dose) on, intolerance to, or contraindication to at least one formulary antidiabetic agent from three classes, one of which must be insulin;
 - A diagnosis of hypertriglyceridemia (including baseline triglyceride level greater than or equal to 500 mg/dL) associated with the above diagnosis **AND** failure on, intolerance to, or contraindication to at least one formulary antihyperlipidemic agent from three classes, one of which must be fenofibrate **AND** patient managed by a cardiologist



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 338.0

**SECTION: Commercial Drug
SUBJECT: Myalept**

*Leptin reference ranges:

Pediatric male and female

5-9.9 Years 0.6-16.8 ng/mL

10-13.9 Years 1.4-16.5 ng/mL

14-17.9 Years 0.6-24.9 ng/mL

Adult Lean Subjects (18-71 Years) with BMI range of 18-25

Male 0.3-13.4 ng/mL

Female 4.7-23.7 ng/mL

Adult Subjects (19-60 Years) with BMI range of 25-30

Male 1.8-19.9 ng/mL

Female 8.0-38.9 ng/mL

MEDISPAN AUTHORIZATION LEVEL: GPI-12

AUTHORIZATION DURATION: Initial authorization will be for 6 months. For continuation of coverage, medical record documentation of improvement in objective measures associated with the complications related to congenital or acquired generalized lipodystrophy (i.e.: hemoglobin A1c (HbA1c), fasting blood sugar, triglycerides) is required. Subsequent approvals will be for 6 months.

If an exception is made, Myalept will be paid for under the member's prescription drug benefit.

Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.

FORMULARY ALTERNATIVES:

none

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE
STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND
FEDERAL REGULATORY ENTITIES.**

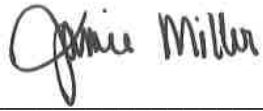
**THIS POLICY WILL BE REVISED AS NECESSARY AND
REVIEWED NO LESS THAN ANNUALLY.**

Geisinger

**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 338.0

**SECTION: Commercial Drug
SUBJECT: Myalept**



Signed: _____

Title: Director, Pharmacy Services

Date: March 1, 2022

Devised: 9/22/14
Reviewed: 3/1/15 – annual review
Reviewed: 3/1/16 – annual review
Revised: 5/1/16 – updated format, logo, & procedure
Revised: 3/1/17 – annual review, defined abbreviations, removed Unicode characters
Revised: 3/1/18 – annual review, updated signature & prescribed criteria, corrected 2 typos
Reviewed: 3/1/19 – annual review
Revised: 3/1/20 – annual review, added GHP Kids
Revised: 3/1/21 – annual review, updated logo, added MediSpan approval level
Revised: 3/1/22 – annual review, updated referenced policies & covered LOBs



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 339.0

**SECTION: Commercial Drug
SUBJECT: Zontivity**

Applicable line of business:

Commercial	X	Medicaid	
Medicare		ACA	X
GHP Kids	X	Self-Insured	X

POLICY:

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for Zontivity for GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 487.0 Quantity Limit Exceptions

REQUIRED DEFINITIONS:

1. **Attachment** – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. **Exhibit** – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. **Devised** – the date the policy was implemented.
4. **Revised** – the date of every revision to the policy, including typographical and grammatical changes.
5. **Reviewed** – the date documenting the annual review if the policy has no revisions necessary.

ADDITIONAL DEFINITIONS:

1. **Formulary** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. **Non-formulary products** – those medications that are not included in the Formulary.
3. **Healthcare provider** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
4. **NCQA** – National Committee for Quality Assurance.
5. **Medically Necessary or Medical Necessity** – covered services rendered by a provider that the Health Plan determines are:



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 339.0

**SECTION: Commercial Drug
SUBJECT: Zontivity**

- A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
- B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
- C. In accordance with current standards of medical practice;
- D. Not primarily for the convenience of the Member, or the Member's Provider; and
- E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

PROCEDURE:

An exception for coverage of Zontivity may be made for members who meet **ALL** of the following criteria:

History of Myocardial Infarction (MI)

- Medical record documentation of a myocardial infarction (MI) occurring less than 12 months prior to starting therapy **AND**
- Medical record documentation of NO prior history of stroke, transient ischemic attack, or intracranial hemorrhage **AND**
- Medical record documentation of concomitant therapy with aspirin alone, a thienopyridine (clopidogrel) alone, or a combination of aspirin and clopidogrel

Peripheral Arterial Disease (PAD)

- Medical record documentation of peripheral arterial disease (PAD) as indicated by a history of intermittent claudication **AND**
- Medical record documentation of a resting ankle/brachial index (ABI) of less than 0.85 **OR** amputation, peripheral bypass, or peripheral angioplasty of the extremities secondary to ischemia **AND**
- Medical record documentation of NO prior history of stroke, transient ischemic attack, or intracranial hemorrhage **AND**
- Medical record documentation of concomitant therapy with aspirin alone, a thienopyridine (clopidogrel) alone, or a combination of aspirin and clopidogrel

MEDISPAN AUTHORIZATION LEVEL: GPI-12



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 339.0

**SECTION: Commercial Drug
SUBJECT: Zontivity**

If an exception is made, Zontivity will be paid for under the member's prescription drug benefit.

Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.

FORMULARY ALTERNATIVES:

cilostazol, clopidogrel, dipyridamole, pentoxifylline, ticlopidine, aspirin/dipyridamole ER, Brilinta, prasugrel*

*prior authorization required

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE
STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND
FEDERAL REGULATORY ENTITIES.**

**THIS POLICY WILL BE REVISED AS NECESSARY AND
REVIEWED NO LESS THAN ANNUALLY.**

Signed: _____

Title: Director, Pharmacy Services

Date: March 1, 2022

- Devised: 9/22/14
- Reviewed: 3/1/15 – annual review
- Revised: 3/1/16 – annual review, changed Aggrenox to aspirin/dipyridamole ER
- Revised: 5/1/16 – updated format, logo, & procedure
- Revised: 3/1/17 – annual review, removed Unicode characters
- Revised: 3/1/18 – annual review, updated signature, updated Effient to generic, corrected typo
- Revised: 3/1/19 – annual review, updated FA
- Revised: 3/1/20 – annual review, added GHP Kids
- Revised: 3/1/21 – annual review, updated logo, added MediSpan approval level
- Revised: 3/1/22 – annual review, updated referenced policies & covered LOBs



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 340.0

**SECTION: Commercial Drug
SUBJECT: Grastek**

Applicable line of business:

Commercial	X	Medicaid	
Medicare		ACA	X
GHP Kids	X	Self-Insured	X

POLICY:

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for Grastek for GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 487.0 Quantity Limit Exceptions

REQUIRED DEFINITIONS:

1. **Attachment** – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. **Exhibit** – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. **Devised** – the date the policy was implemented.
4. **Revised** – the date of every revision to the policy, including typographical and grammatical changes.
5. **Reviewed** – the date documenting the annual review if the policy has no revisions necessary.

ADDITIONAL DEFINITIONS:

1. **Formulary** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. **Non-formulary products** – those medications that are not included in the Formulary.
3. **Healthcare provider** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
4. **NCQA** – National Committee for Quality Assurance.
5. **Medically Necessary or Medical Necessity** – covered services rendered by a provider that the Health Plan determines are:



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 340.0

**SECTION: Commercial Drug
SUBJECT: Grastek**

- A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
- B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
- C. In accordance with current standards of medical practice;
- D. Not primarily for the convenience of the Member, or the Member's Provider; and
- E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

PROCEDURE:

An exception for coverage of Grastek may be made for members who meet **ALL** of the following criteria:

- Medical record documentation that Grastek is prescribed by an allergist, immunologist or a physician qualified to prescribe allergy immunotherapy **AND**
- Medical record documentation of age greater than or equal to 5 years and less than or equal to 65 years **AND**
- Medical record documentation of Timothy grass pollen or cross-reactive grass pollen induced allergic rhinitis confirmed by positive skin test or *in vitro* testing for pollen-specific IgE antibodies **AND**
- Medical record documentation that the member has (or will receive) a prescription for an epinephrine auto-injector **AND**
- Medical record documentation that the member does not have severe, unstable, or uncontrolled asthma **AND**
- Medical record documentation that member will no longer be receiving injectable allergy shots **AND**
- Medical record documentation that Grastek will not be used in combination with sublingual immunotherapy (e.g., Odactra, Oralair, and Ragwitek) **AND**
- Medical record documentation of therapeutic failure on, intolerance to, or contraindication to three (3) formulary alternatives, one of which must be an intranasal glucocorticoid

MEDISPAN AUTHORIZATION LEVEL: GPI-12

QUANTITY LIMIT: 1 tablet per day, 30 day supply per fill should apply, 180 tablets per 365 days



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 340.0

**SECTION: Commercial Drug
SUBJECT: Grastek**

NOTE: If the pollen season is longer than 3 months, a quantity limit exception equivalent to the time necessary for treatment through the remainder of the pollen season will be approved.

If an exception is made, Grastek will be paid for under the member's prescription drug benefit.

Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.

FORMULARY ALTERNATIVES:

fluticasone propionate, triamcinolone acetonide, budesonide, mometasone furoate, levocetirizine tablets, desloratadine tablets, montelukast

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE
STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND
FEDERAL REGULATORY ENTITIES.**

**THIS POLICY WILL BE REVISED AS NECESSARY AND
REVIEWED NO LESS THAN ANNUALLY.**

Signed: _____

Title: Director, Pharmacy Services

Date: March 1, 2022

- Devised: 9/22/14
- Reviewed: 3/1/15 – annual review
- Revised: 3/1/16 – annual review, removed PA indicator from levocetirizine, added desloratadine to FA
- Revised: 5/1/16 – updated format, logo, & procedure
- Reviewed: 3/1/17 – annual review
- Revised: 3/1/18 – annual review, updated signature & prescribed criteria, updated QL to match package size
- Revised: 5/29/18 – added (immunologist, EAI, uncontrolled asthma); updated (therapeutic failure to 3 alternatives, added additional SLIT not to be used in combo, form. alt.)
- Revised: 3/1/19 – annual review, updated note
- Revised: 3/1/20 – annual review, added GHP Kids
- Revised: 3/1/21 – annual review, updated logo, added MediSpan approval level



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 340.0

**SECTION: Commercial Drug
SUBJECT: Grastek**

Revised: 3/1/22 – annual review, updated referenced policies & covered LOBs, corrected typo



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 341.0

**SECTION: Commercial Drug
SUBJECT: Oralair**

Applicable line of business:

Commercial	X	Medicaid	
Medicare		ACA	X
GHP Kids	X	Self-Insured	X

POLICY:

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for Oralair for GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 487.0 Quantity Limit Exceptions

REQUIRED DEFINITIONS:

1. **Attachment** – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. **Exhibit** – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. **Devised** – the date the policy was implemented.
4. **Revised** – the date of every revision to the policy, including typographical and grammatical changes.
5. **Reviewed** – the date documenting the annual review if the policy has no revisions necessary.

ADDITIONAL DEFINITIONS:

1. **Formulary** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. **Non-formulary products** – those medications that are not included in the Formulary.
3. **Healthcare provider** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
4. **NCQA** – National Committee for Quality Assurance.
5. **Medically Necessary or Medical Necessity** – covered services rendered by a provider that the Health Plan determines are:



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 341.0

**SECTION: Commercial Drug
SUBJECT: Oralair**

- A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
- B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
- C. In accordance with current standards of medical practice;
- D. Not primarily for the convenience of the Member, or the Member's Provider; and
- E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

PROCEDURE:

An exception for coverage of Oralair may be made for members who meet **ALL** of the following criteria:

- Medical record documentation that Oralair is prescribed by an allergist, immunologist, or a physician qualified to prescribe allergy immunotherapy **AND**
- Medical record documentation of age greater than or equal to 10 years and less than or equal to 65 years **AND**
- Medical record documentation of grass pollen induced (Timothy, Orchard, Sweet Vernal, Kentucky Blue Grass, Perennial Rye) allergic rhinitis confirmed by positive skin test or *in vitro* testing for pollen-specific IgE antibodies **AND**
- Medical record documentation that the member has (or will receive) a prescription for an epinephrine auto-injector **AND**
- Medical record documentation that the member does not have severe, unstable, or uncontrolled asthma **AND**
- Medical record documentation that member will no longer be receiving injectable allergy shots **AND**
- Medical record documentation that Oralair will not be used in combination with sublingual immunotherapy (e.g., Grastek, Odactra, and Ragwitek) **AND**
- Medical record documentation of therapeutic failure on, intolerance to, or contraindication to three (3) formulary alternatives, one of which must be an intranasal glucocorticoid

MEDISPAN AUTHORIZATION LEVEL: GPI-12

QUANTITY LIMIT: 1 tablet per day, 30 day supply per fill should apply, 210 tablets per 365 days



POLICY NUMBER: 341.0

**POLICY AND PROCEDURE
PHARMACY
MANUAL**

**SECTION: Commercial Drug
SUBJECT: Oralair**

NOTE: If the pollen season is longer than 3 months, a quantity limit exception equivalent to the time necessary for treatment through the remainder of the pollen season will be approved.

If an exception is made, Oralair will be paid for under the member's prescription drug benefit.

Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.

FORMULARY ALTERNATIVES:

fluticasone propionate, triamcinolone acetonide, budesonide, mometasone furoate, levocetirizine tablets, desloratadine tablets, montelukast

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE
STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND
FEDERAL REGULATORY ENTITIES.**

**THIS POLICY WILL BE REVISED AS NECESSARY AND
REVIEWED NO LESS THAN ANNUALLY.**

Signed: _____

Title: Director, Pharmacy Services

Date: March 1, 2022

- Devised: 9/22/14
- Reviewed: 3/1/15 – annual review
- Revised: 3/1/16 – annual review, removed PA indicator from levocetirizine, added desloratadine to FA
- Revised: 5/1/16 – updated format, logo, & procedure
- Reviewed: 3/1/17 – annual review
- Revised: 3/1/18 – annual review, updated signature, updated prescribed criteria, updated QL to match package size, removed duplicate approval language
- Revised: 5/29/18 – added (immunologist, EAI, uncontrolled asthma); updated (therapeutic failure to 3 alternatives, added additional SLIT not to be used in combo, form. alt.)
- Revised: 3/1/19 – annual review, updated note
- Revised: 3/1/20 – annual review, added GHP Kids
- Revised: 3/1/21 – annual review, updated logo, added MediSpan approval level



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 341.0

**SECTION: Commercial Drug
SUBJECT: Oralair**

Revised: 3/1/22 – annual review, updated referenced policies & covered LOBs



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 342.0

**SECTION: Commercial Drug
SUBJECT: Ragwitek**

Applicable line of business:

Commercial	X	Medicaid	
Medicare		ACA	X
GHP Kids	X	Self-Insured	X

POLICY:

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for Ragwitek for GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 487.0 Quantity Limit Exceptions

REQUIRED DEFINITIONS:

1. **Attachment** – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. **Exhibit** – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. **Devised** – the date the policy was implemented.
4. **Revised** – the date of every revision to the policy, including typographical and grammatical changes.
5. **Reviewed** – the date documenting the annual review if the policy has no revisions necessary.

ADDITIONAL DEFINITIONS:

1. **Formulary** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. **Non-formulary products** – those medications that are not included in the Formulary.
3. **Healthcare provider** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
4. **NCQA** – National Committee for Quality Assurance.
5. **Medically Necessary or Medical Necessity** – covered services rendered by a provider that the Health Plan determines are:



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 342.0

**SECTION: Commercial Drug
SUBJECT: Ragwitek**

- A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
- B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
- C. In accordance with current standards of medical practice;
- D. Not primarily for the convenience of the Member, or the Member's Provider; and
- E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

PROCEDURE:

An exception for coverage of Ragwitek may be made for members who meet **ALL** of the following criteria:

- Medical record documentation that Ragwitek is prescribed by an allergist, immunologist, or a physician qualified to prescribe allergy immunotherapy **AND**
- Medical record documentation of age greater than or equal to 18 years and less than or equal to 65 years **AND**
- Medical record documentation of short ragweed pollen induced allergic rhinitis confirmed by positive skin test or *in vitro* testing for pollen-specific IgE antibodies **AND**
- Medical record documentation that the member has (or will receive) a prescription for an epinephrine auto-injector **AND**
- Medical record documentation that the member does not have severe, unstable, or uncontrolled asthma **AND**
- Medical record documentation that member will no longer be receiving injectable allergy shots **AND**
- Medical record documentation that Ragwitek will not be used in combination with sublingual immunotherapy (e.g., Grastek, Odactra, and Oralair) **AND**
- Medical record documentation of therapeutic failure on, intolerance to, or contraindication to three (3) formulary alternatives, one of which must be an intranasal glucocorticoid

MEDISPAN AUTHORIZATION LEVEL: GPI-12

QUANTITY LIMIT: 1 tablet per day, 30 day supply per fill should apply, 180 tablets per 365 days

NOTE: If the pollen season is longer than 3 months, a quantity limit exception equivalent to the time necessary for treatment through the remainder of the pollen season will be approved.

If an exception is made, Ragwitek will be paid for under the member's prescription drug benefit.

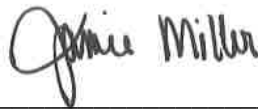
Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.

FORMULARY ALTERNATIVES:

fluticasone propionate, triamcinolone acetonide, budesonide, mometasone furoate, levocetirizine tablets, desloratadine tablets, montelukast

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE
STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND
FEDERAL REGULATORY ENTITIES.**

**THIS POLICY WILL BE REVISED AS NECESSARY AND
REVIEWED NO LESS THAN ANNUALLY.**



Signed: _____

Title: Director, Pharmacy Services

Date: March 1, 2022

Devised: 9/22/14
Revised: 10/1/14 – corrected typo
Reviewed: 3/1/15 – annual review
Revised: 3/1/16 – annual review, removed PA indicator from levocetirizine, added desloratadine to FA
Revised: 5/1/16 – updated format, logo, & procedure
Reviewed: 3/1/17 – annual review
Revised: 3/1/18 – annual review, updated signature, updated prescribed criteria, updated QL to match package size
Revised: 5/29/18 – added (immunologist, EAI, uncontrolled asthma); updated (therapeutic failure to 3 alternatives, added additional SLIT not to be used in combo, form. alt.)
Revised: 3/1/19 – annual review, updated note



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 342.0

**SECTION: Commercial Drug
SUBJECT: Ragwitek**

Revised: 3/1/20 – annual review, added GHP Kids
Revised: 3/1/21 – annual review, updated logo, added MediSpan approval level
Revised: 3/1/22 – annual review, updated referenced policies & covered LOBs



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 343.0

**SECTION: Commercial Drug
SUBJECT: Zydelig**

Applicable line of business:

Commercial	X	Medicaid	
Medicare		ACA	X
GHP Kids	X	Self-Insured	X

POLICY:

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for Zydelig for GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 487.0 Quantity Limit Exceptions

REQUIRED DEFINITIONS:

1. **Attachment** – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. **Exhibit** – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. **Devised** – the date the policy was implemented.
4. **Revised** – the date of every revision to the policy, including typographical and grammatical changes.
5. **Reviewed** – the date documenting the annual review if the policy has no revisions necessary.

ADDITIONAL DEFINITIONS:

1. **Formulary** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. **Non-formulary products** – those medications that are not included in the Formulary.
3. **Healthcare provider** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
4. **NCQA** – National Committee for Quality Assurance.
5. **Medically Necessary or Medical Necessity** – covered services rendered by a provider that the Health Plan determines are:

- A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
- B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
- C. In accordance with current standards of medical practice;
- D. Not primarily for the convenience of the Member, or the Member's Provider; and
- E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

PROCEDURE:

New members to the plan already established on therapy may be eligible for continuity of care coverage as long as there is medical record documentation that the safety and effectiveness of use for the prescribed indication is supported by Food and Drug Administration (FDA) approval or adequate medical and scientific evidence in the medical literature.

An exception for coverage of Zydelig may be made for members who meet the following criteria:

CLL

- Medical record documentation that Zydelig is prescribed by a hematologist or oncologist **AND**
- Medical record documentation of age greater than or equal to 18 years **AND**
- Medical record documentation of a diagnosis of relapsed chronic lymphocytic leukemia (CLL) **AND**
- Medical record documentation of concurrent use with rituximab

FL

- Medical record documentation that Zydelig is prescribed by a hematologist or oncologist **AND**
- Medical record documentation of age greater than or equal to 18 years **AND**
- Medical record documentation of a diagnosis of relapsed follicular B-cell non-Hodgkin lymphoma (FL) **AND**
- Medical record documentation of a therapeutic failure on, intolerance to, or contraindication to at least two prior systemic therapies

SLL

- Medical record documentation that Zydelig is prescribed by a hematologist or oncologist **AND**
- Medical record documentation of age greater than or equal to 18 years **AND**
- Medical record documentation of a diagnosis of relapsed small lymphocytic lymphoma (SLL) **AND**
- Medical record documentation of a therapeutic failure on, intolerance to, or contraindication to at least two prior systemic therapies

MEDISPAN AUTHORIZATION LEVEL: GPI-12, number of claims authorized = 1, enter for the remainder of the calendar year

QUANTITY LIMIT: *No QLs need to be entered within the authorization unless the requested quantity exceeds the QL.*

- QL FOR LETTER ONLY: 2 tablets per day, 30 day supply per fill

RE-AUTHORIZATION CRITERIA: Zydelig is configured as a prior authorization for new starts only. Zydelig will no longer be covered if it is identified that the member is not receiving appropriate follow-up care from the prescribing specialist or if the member has greater than or equal to a 90 day break in therapy.

- Medical record documentation that the member is receiving appropriate follow-up care from the prescribing specialist

If an exception is made, Zydelig will be paid for under the member's prescription drug benefit.

Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.

FORMULARY ALTERNATIVES:

none

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE
STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND
FEDERAL REGULATORY ENTITIES.**

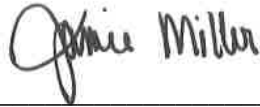
**THIS POLICY WILL BE REVISED AS NECESSARY AND
REVIEWED NO LESS THAN ANNUALLY.**

Geisinger

**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 343.0

**SECTION: Commercial Drug
SUBJECT: Zydelig**



Signed: _____

Title: Director, Pharmacy Services

Date: March 1, 2022

Devised: 9/22/14
Reviewed: 3/1/15 – annual review
Reviewed: 3/1/16 – annual review
Revised: 5/1/16 – updated format, logo, & procedure
Revised: 3/1/17 – annual review, removed Unicode characters
Revised: 10/10/17 – increased authorization duration to 12 months
Revised: 3/1/18 – annual review, updated signature, added grandfather language, updated age & prescriber criteria, updated format of headers, updated QL to match package size
Revised: 3/1/19 – annual review, added QL approval note
Revised: 3/1/20 – annual review, added GHP Kids
Revised: 3/1/21 – annual review, updated logo, added MediSpan approval level, updated QL statement
Revised: 12/2/21 – added one-time PA to approval crit., removed auth duration & added re-auth crit.
Revised: 3/1/22 – annual review, updated referenced policies & covered LOBs



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 344.0

**SECTION: Commercial Drug
SUBJECT: Controlled Substance DUR
Denial**

Applicable line of business:

Commercial	X	Medicaid	
Medicare		ACA	X
GHP Kids	X	Self-Insured	X

POLICY:

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for controlled substance DUR denials for GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 487.0 Quantity Limit Exceptions

REQUIRED DEFINITIONS:

1. **Attachment** – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. **Exhibit** – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. **Devised** – the date the policy was implemented.
4. **Revised** – the date of every revision to the policy, including typographical and grammatical changes.
5. **Reviewed** – the date documenting the annual review if the policy has no revisions necessary.

ADDITIONAL DEFINITIONS:

1. **Formulary** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. **Non-formulary products** – those medications that are not included in the Formulary.
3. **Healthcare provider** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
4. **NCQA** – National Committee for Quality Assurance.
5. **Medically Necessary or Medical Necessity** – covered services rendered by a provider that the Health Plan determines are:



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 344.0

**SECTION: Commercial Drug
SUBJECT: Controlled Substance DUR
Denial**

- A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
- B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
- C. In accordance with current standards of medical practice;
- D. Not primarily for the convenience of the Member, or the Member's Provider; and
- E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

PROCEDURE:

An exception for coverage of the requested controlled substance may be made for members who meet the following criteria:

- A concurrently prescribed medication precludes the use of a controlled substance

MEDISPAN AUTHORIZATION LEVEL: GPI-12

If an exception is made, the requested controlled substance will be paid for under the member's prescription drug benefit.

Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.

FORMULARY ALTERNATIVES:

none

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE
STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND
FEDERAL REGULATORY ENTITIES.**

**THIS POLICY WILL BE REVISED AS NECESSARY AND
REVIEWED NO LESS THAN ANNUALLY.**



POLICY NUMBER: 344.0

**POLICY AND PROCEDURE
PHARMACY
MANUAL**

**SECTION: Commercial Drug
SUBJECT: Controlled Substance DUR
Denial**

Signed: _____

Title: Director, Pharmacy Services

Date: March 1, 2022

Devised: 10/6/14
Reviewed: 3/1/15 – annual review
Revised: 6/8/15 – updated criteria, renamed policy
Reviewed: 3/1/16 – annual review
Revised: 5/1/16 – updated format, logo, & procedure
Reviewed: 3/1/17 – annual review
Revised: 3/1/18 – annual review, updated signature
Reviewed: 3/1/19 – annual review
Revised: 3/1/20 – annual review, added GHP Kids
Revised: 3/1/21 – annual review, updated logo, added MediSpan approval level
Revised: 3/1/22 – annual review, updated referenced policies & covered LOBs



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 348.0

**SECTION: Commercial Drug
SUBJECT: Sivextro Tablets**

Applicable line of business:

Commercial	X	Medicaid	
Medicare		ACA	X
GHP Kids	X	Self-Insured	X

POLICY:

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for Sivextro tablets for GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 487.0 Quantity Limit Exceptions

REQUIRED DEFINITIONS:

1. **Attachment** – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. **Exhibit** – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. **Devised** – the date the policy was implemented.
4. **Revised** – the date of every revision to the policy, including typographical and grammatical changes.
5. **Reviewed** – the date documenting the annual review if the policy has no revisions necessary.

ADDITIONAL DEFINITIONS:

1. **Formulary** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. **Non-formulary products** – those medications that are not included in the Formulary.
3. **Healthcare provider** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
4. **NCQA** – National Committee for Quality Assurance.
5. **Medically Necessary or Medical Necessity** – covered services rendered by a provider that the Health Plan determines are:



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 348.0

**SECTION: Commercial Drug
SUBJECT: Sivextro Tablets**

- A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
- B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
- C. In accordance with current standards of medical practice;
- D. Not primarily for the convenience of the Member, or the Member's Provider; and
- E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

PROCEDURE:

An exception for coverage of Sivextro tablets may be made for members who meet the following criteria:

- Medical record documentation that patient is greater than or equal to 12 years of age **AND**
- Medical record documentation of a diagnosis of a grade 2 or greater acute bacterial skin and skin structure infection (including cellulitis/erysipelas, wound infection, and major cutaneous abscess) caused by: *Staphylococcus aureus*, *Streptococcus pyogenes*, *Streptococcus agalactiae*, *Streptococcus anginosus*, *Streptococcus intermedius*, *Streptococcus constellatus*, or *Enterococcus faecalis* which have been diagnosed and documented with Infectious Disease consultation **AND**
- Medical record documentation of culture and sensitivity showing the patient's infection is not susceptible to alternative antibiotic treatments **OR** a documented history of previous intolerance to or contraindication to other antibiotics shown to be susceptible on the culture and sensitivity **OR**
- Medical record documentation that Sivextro therapy was started during an inpatient setting

MEDISPAN AUTHORIZATION LEVEL: GPI-12

QUANTITY LIMIT: *No QLs need to be entered within the authorization unless the requested quantity exceeds the QL.*

- QL FOR LETTER ONLY: 6 tablets

AUTHORIZATION DURATION: one-time, 6 day approval, RX count 1



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 348.0

**SECTION: Commercial Drug
SUBJECT: Sivextro Tablets**

If an exception is made, Sivextro tablets will be paid for under the member's prescription drug benefit.

Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.

FORMULARY ALTERNATIVES:

clindamycin, cefaclor, cefadroxil, cefdinir, cefditoren, cefpodoxime, cefprozil, cefuroxime, cephalexin, azithromycin, clarithromycin, Ery-tab, erythromycin base, erythromycin ethylsuccinate, erythromycin stearate, amoxicillin, amoxicillin/clav, dicloxacillin, penicillin C, ciprofloxacin, levofloxacin, moxifloxacin, ofloxacin, demeclocycline, doxycycline, minocycline, tetracycline

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE
STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND
FEDERAL REGULATORY ENTITIES.**

**THIS POLICY WILL BE REVISED AS NECESSARY AND
REVIEWED NO LESS THAN ANNUALLY.**

Signed: _____

Title: Director, Pharmacy Services

Date: March 1, 2022

Devised: 12/1/14
Revised: 2/9/15 – added grade 2 infection or greater & revised inpatient criteria
Reviewed: 3/1/15 – annual review
Reviewed: 3/1/16 – annual review
Revised: 5/1/16 – updated format, logo, & procedure
Revised: 3/1/17 – annual review, removed Unicode characters
Revised: 3/1/18 – annual review, updated signature, corrected typo
Revised: 3/1/19 – annual review, added QL approval note, added RX count
Revised: 3/1/20 – annual review, added GHP Kids
Revised: 10/12/20 – updated age from 18 to 12 years
Revised: 3/1/21 – annual review, updated logo, added MediSpan approval level, updated QL statement
Revised: 3/1/22 – annual review, updated referenced policies & covered LOBs, updated FA



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 349.0

**SECTION: Commercial Drug
SUBJECT: Karbinal ER**

Applicable line of business:

Commercial	X	Medicaid	
Medicare		ACA	X
GHP Kids	X	Self-Insured	X

POLICY:

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for Karbinal ER for GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 487.0 Quantity Limit Exceptions

REQUIRED DEFINITIONS:

1. **Attachment** – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. **Exhibit** – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. **Devised** – the date the policy was implemented.
4. **Revised** – the date of every revision to the policy, including typographical and grammatical changes.
5. **Reviewed** – the date documenting the annual review if the policy has no revisions necessary.

ADDITIONAL DEFINITIONS:

1. **Formulary** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. **Non-formulary products** – those medications that are not included in the Formulary.
3. **Healthcare provider** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
4. **NCQA** – National Committee for Quality Assurance.
5. **Medically Necessary or Medical Necessity** – covered services rendered by a provider that the Health Plan determines are:



POLICY NUMBER: 349.0

**POLICY AND PROCEDURE
PHARMACY
MANUAL**

**SECTION: Commercial Drug
SUBJECT: Karbinal ER**

- A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
- B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
- C. In accordance with current standards of medical practice;
- D. Not primarily for the convenience of the Member, or the Member's Provider; and
- E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

PROCEDURE:

An exception for coverage of Karbinal ER may be made for members who meet the following criteria:

- Medical record documentation that patient is greater than or equal to 2 years of age **AND**
- Medical record documentation that Karbinal ER is being used for a Food and Drug Administration (FDA) approved indication **AND**
- Medical record documentation of therapeutic failure on, intolerance to, or contraindication to over the counter loratadine, over the counter cetirizine, over the counter fexofenadine, levocetirizine, immediate-release carbinoxamine, diphenhydramine, **AND** chlorpheniramine

MEDISPAN AUTHORIZATION LEVEL: GPI-12

If an exception is made, Karbinal ER will be paid for under the member's prescription drug benefit.

Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.

FORMULARY ALTERNATIVES:

carbinoxamine, chlorpheniramine, clemastine, cyproheptadine, desloratadine, dexchlorpheniramine, diphenhydramine, levocetirizine, promethazine



POLICY NUMBER: 349.0

**POLICY AND PROCEDURE
PHARMACY
MANUAL**

**SECTION: Commercial Drug
SUBJECT: Karbinal ER**

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE
STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND
FEDERAL REGULATORY ENTITIES.**

**THIS POLICY WILL BE REVISED AS NECESSARY AND
REVIEWED NO LESS THAN ANNUALLY.**

Signed: _____

Title: Director, Pharmacy Services

Date: March 1, 2022

Devised: 12/1/14
Reviewed: 3/1/15 – annual review
Reviewed: 3/1/16 – annual review
Revised: 5/1/16 – updated format, logo, & procedure
Revised: 3/1/17 – annual review, defined abbreviations
Revised: 3/1/18 – annual review, updated signature, defined FDA
Reviewed: 3/1/19 – annual review
Revised: 3/1/20 – annual review, added GHP Kids
Revised: 3/1/21 – annual review, updated logo, added MediSpan approval level
Revised: 3/1/22 – annual review, updated referenced policies & covered LOBs



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 350.0

**SECTION: Commercial Drug
SUBJECT: Bydureon**

Applicable line of business:

Commercial	X	Medicaid	
Medicare		ACA	X
GHP Kids	X	Self-Insured	X

POLICY:

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for Bydureon for GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 487.0 Quantity Limit Exceptions

REQUIRED DEFINITIONS:

1. **Attachment** – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. **Exhibit** – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. **Devised** – the date the policy was implemented.
4. **Revised** – the date of every revision to the policy, including typographical and grammatical changes.
5. **Reviewed** – the date documenting the annual review if the policy has no revisions necessary.

ADDITIONAL DEFINITIONS:

1. **Formulary** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. **Non-formulary products** – those medications that are not included in the Formulary.
3. **Healthcare provider** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
4. **NCQA** – National Committee for Quality Assurance.
5. **Medically Necessary or Medical Necessity** – covered services rendered by a provider that the Health Plan determines are:



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 350.0

**SECTION: Commercial Drug
SUBJECT: Bydureon**

- A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
- B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
- C. In accordance with current standards of medical practice;
- D. Not primarily for the convenience of the Member, or the Member's Provider; and
- E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

PROCEDURE:

An exception for coverage of Bydureon may be made for members who meet the following criteria:

- Electronic step therapy of on-line prescription drug claims history showing 15 days use of Victoza **AND** Ozempic or Rybelsus, within the previous 180 days. If this electronic step is met, the claim will automatically adjudicate **OR**
- If electronic step therapy criteria are not met, prescribing provider should request an exception for coverage indicating one of the following:
 - For members 18 years of age and older: medical record documentation of therapeutic failure on, intolerance to, or contraindication to Victoza **AND** either Ozempic or Rybelsus **OR**
 - For members between 10 and 18 years of age: medical record documentation of therapeutic failure on, intolerance to or contraindication to Victoza

MEDISPAN AUTHORIZATION LEVEL: GPI-12

QUANTITY LIMIT: *No QLs need to be entered within the authorization unless the requested quantity exceeds the QL.*

- **QL FOR LETTER ONLY: 4 syringes per 28 days**

If an exception is made, Bydureon will be paid for under the member's prescription drug benefit.

Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 350.0

**SECTION: Commercial Drug
SUBJECT: Bydureon**

FORMULARY ALTERNATIVES:

Ozempic, Victoza, Rybelsus, Trulicity

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE
STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND
FEDERAL REGULATORY ENTITIES.**

**THIS POLICY WILL BE REVISED AS NECESSARY AND
REVIEWED NO LESS THAN ANNUALLY.**

Signed: _____

Title: Director, Pharmacy Services

Date: March 1, 2022

Devised: 1/13/15
Reviewed: 3/1/15 – annual review
Revised: 3/1/16 – annual review, added Toujeo, Jardiance, Invokana, Synjardy, & Invokamet to FA, updated PA/ST indicator
Revised: 5/1/16 – updated format, logo, & procedure
Revised: 3/1/17 – annual review, corrected typo in FA
Revised: 1/17/18 – added step language, removed failure of Tanzeum and added Ozempic, updated FA, updated signature
Revised: 3/1/18 – annual review, updated FA
Revised: 3/1/19 – annual review, added QL approval note, updated QL, updated FA
Revised: 1/28/20 – added failure of Rybelsus, updated FA
Revised: 3/1/20 – annual review, added GHP Kids
Revised: 3/1/21 – annual review, updated logo, added MediSpan approval level, updated QL statement, corrected Rybelsus typo
Revised: 1/21/22 – added criteria for members 10-18 years of age
Revised: 3/1/22 – annual review, updated referenced policies & covered LOBs, updated FA



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 351.0

**SECTION: Commercial Drug
SUBJECT: Tudorza Pressair**

Applicable line of business:

Commercial	X	Medicaid	
Medicare		ACA	X
GHP Kids	X	Self-Insured	X

POLICY:

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for Tudorza Pressair for GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 487.0 Quantity Limit Exceptions

REQUIRED DEFINITIONS:

1. **Attachment** – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. **Exhibit** – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. **Devised** – the date the policy was implemented.
4. **Revised** – the date of every revision to the policy, including typographical and grammatical changes.
5. **Reviewed** – the date documenting the annual review if the policy has no revisions necessary.

ADDITIONAL DEFINITIONS:

1. **Formulary** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. **Non-formulary products** – those medications that are not included in the Formulary.
3. **Healthcare provider** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
4. **NCQA** – National Committee for Quality Assurance.
5. **Medically Necessary or Medical Necessity** – covered services rendered by a provider that the Health Plan determines are:



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 351.0

**SECTION: Commercial Drug
SUBJECT: Tudorza Pressair**

- A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
- B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
- C. In accordance with current standards of medical practice;
- D. Not primarily for the convenience of the Member, or the Member's Provider; and
- E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

PROCEDURE:

An exception for coverage of Tudorza Pressair may be made for members who meet the following criteria:

- Electronic step therapy of on-line prescription drug claims history showing 15 days use of Spiriva **AND** Incruse Ellipta, within the previous 180 days. If this electronic step is met, the claim will automatically adjudicate **OR**
- Medical record documentation of a therapeutic failure on, intolerance to, or contraindication to Spiriva **AND** Incruse Ellipta

MEDISPAN AUTHORIZATION LEVEL: GPI-12

If an exception is made, Tudorza Pressair will be paid for under the member's prescription drug benefit.

Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.

FORMULARY ALTERNATIVES:

Spiriva Handihaler, Spiriva Respimat, Incruse Ellipta

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE
STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND
FEDERAL REGULATORY ENTITIES.**

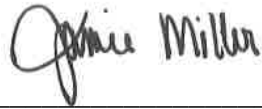
**THIS POLICY WILL BE REVISED AS NECESSARY AND
REVIEWED NO LESS THAN ANNUALLY.**

Geisinger

**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 351.0

**SECTION: Commercial Drug
SUBJECT: Tudorza Pressair**



Signed: _____

Title: Director, Pharmacy Services

Date: March 1, 2022

Devised: 1/13/15
Reviewed: 3/1/15 – annual review
Reviewed: 3/1/16 – annual review
Revised: 5/1/16 – updated format, logo, & procedure
Reviewed: 3/1/17 – annual review
Revised: 3/1/18 – annual review, updated signature, added step therapy language
Revised: 3/1/19 – annual review, updated FA
Revised: 5/24/19 – added failure of Incruse Ellipta
Revised: 3/1/20 – annual review, added GHP Kids
Revised: 3/1/21 – annual review, updated logo, added MediSpan approval level
Revised: 3/1/22 – annual review, updated referenced policies & covered LOBs



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 352.0

**SECTION: Commercial Drug
SUBJECT: Droxidopa**

Applicable line of business:

Commercial	X	Medicaid	
Medicare		ACA	X
GHP Kids	X	Self-Insured	X

POLICY:

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for droxidopa for GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 487.0 Quantity Limit Exceptions

REQUIRED DEFINITIONS:

1. **Attachment** – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. **Exhibit** – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. **Devised** – the date the policy was implemented.
4. **Revised** – the date of every revision to the policy, including typographical and grammatical changes.
5. **Reviewed** – the date documenting the annual review if the policy has no revisions necessary.

ADDITIONAL DEFINITIONS:

1. **Formulary** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. **Non-formulary products** – those medications that are not included in the Formulary.
3. **Healthcare provider** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
4. **NCQA** – National Committee for Quality Assurance.
5. **Medically Necessary or Medical Necessity** – covered services rendered by a provider that the Health Plan determines are:



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 352.0

**SECTION: Commercial Drug
SUBJECT: Droxidopa**

- A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
- B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
- C. In accordance with current standards of medical practice;
- D. Not primarily for the convenience of the Member, or the Member's Provider; and
- E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

PROCEDURE:

An exception for coverage of droxidopa may be made for members who meet the following criteria:

- Medical record documentation that droxidopa is prescribed by a cardiologist or neurologist **AND**
- Medical record documentation of age greater than or equal to 18 years **AND**
- Medical record documentation of a therapeutic failure on, intolerance to, or contraindication to midodrine **AND** fludrocortisone **AND**
- Medical record documentation of a diagnosis of symptomatic neurogenic orthostatic hypotension (NOH) caused by:
 - Primary autonomic failure (Parkinson's Disease, multiple system atrophy, and pure autonomic failure) **OR**
 - Dopamine beta-hydroxylase deficiency **OR**
 - Non-diabetic autonomic neuropathy

MEDISPAN AUTHORIZATION LEVEL: GPI-12, generic only

AUTHORIZATION DURATION: Approval will be given for an initial duration of four (4) weeks. Subsequent approvals will be for an additional three (3) months, requiring medical record documentation of continued or sustained improvement in the symptoms of neurogenic orthostatic hypotension (NOH).

If an exception is made, droxidopa will be paid for under the member's prescription drug benefit.

Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 352.0

**SECTION: Commercial Drug
SUBJECT: Droxidopa**

FORMULARY ALTERNATIVES:
midodrine, fludrocortisone

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE
STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND
FEDERAL REGULATORY ENTITIES.**

**THIS POLICY WILL BE REVISED AS NECESSARY AND
REVIEWED NO LESS THAN ANNUALLY.**

Signed: _____

Title: Director, Pharmacy Services

Date: March 1, 2022

Devised: 2/9/15
Reviewed: 3/1/15 – annual review
Reviewed: 3/1/16 – annual review
Revised: 5/1/16 – updated format, logo, & procedure
Revised: 3/1/17 – annual review, removed Unicode characters, defined abbreviations
Revised: 3/1/18 – annual review, updated signature, updated prescribed criteria, corrected typo
Reviewed: 3/1/19 – annual review
Revised: 3/1/20 – annual review, added GHP Kids
Revised: 3/1/21 – annual review, updated logo, added MediSpan approval level, updated Northera to generic
Revised: 3/1/22 – annual review, updated referenced policies & covered LOBs



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 353.0

**SECTION: Commercial Drug
SUBJECT: Evzio**

Applicable line of business:

Commercial	X	Medicaid	
Medicare		ACA	X
GHP Kids	X	Self-Insured	X

POLICY:

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for Evzio for GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 487.0 Quantity Limit Exceptions

REQUIRED DEFINITIONS:

1. **Attachment** – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. **Exhibit** – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. **Devised** – the date the policy was implemented.
4. **Revised** – the date of every revision to the policy, including typographical and grammatical changes.
5. **Reviewed** – the date documenting the annual review if the policy has no revisions necessary.

ADDITIONAL DEFINITIONS:

1. **Formulary** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. **Non-formulary products** – those medications that are not included in the Formulary.
3. **Healthcare provider** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
4. **NCQA** – National Committee for Quality Assurance.
5. **Medically Necessary or Medical Necessity** – covered services rendered by a provider that the Health Plan determines are:



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 353.0

**SECTION: Commercial Drug
SUBJECT: Evzio**

- A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
- B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
- C. In accordance with current standards of medical practice;
- D. Not primarily for the convenience of the Member, or the Member's Provider; and
- E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

PROCEDURE:

An exception for coverage of Evzio may be made for members who meet the following criteria:

- Patient or caregiver is administering medication outside of a healthcare facility, such as a personal residence or school **AND**
- Medical record documentation of a diagnosis or reason why the patients is at an increased risk of opioid-induced respiratory depression* **AND**
- Medical record documentation of a reason why the patient cannot use generic naloxone syringes **AND** Narcan Nasal Spray

MEDISPAN AUTHORIZATION LEVEL: GPI-12

QUANTITY LIMIT: (One) 1 syringe per fill

NOTE: According to the Evzio website, diagnoses or reasons why patients would be at an increased risk of opioid-induced respiratory depression include:

- History of, or potential for, substance abuse, dependence, and/or addiction
- Accidental exposure and/or unintentional opioid misuse
 - Includes members of the patients' household who may discover and use the prescribed opioid inappropriately
- Prescribed a morphine-equivalent dose of opioids greater than or equal to 20 mg/day
- Currently switching to a different opioid
- Chronic pulmonary disease
- Sleep apnea
- Asthma
- Chronic kidney and/or liver impairment
- Uses CNS depressants (includes benzodiazepines and alcohol)



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 353.0

**SECTION: Commercial Drug
SUBJECT: Evzio**

- Uses certain medications for depression (for example, monoamine oxidase inhibitors)

If an exception is made, Evzio will be paid for under the member's prescription drug benefit.

Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.

FORMULARY ALTERNATIVES:

naloxone 1 mg/mL prefilled syringe, naloxone 0.4 mg/mL prefilled syringe, Narcan Nasal Spray, naloxone nasal spray (generic Narcan), Kloxxado

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE
STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND
FEDERAL REGULATORY ENTITIES.**

**THIS POLICY WILL BE REVISED AS NECESSARY AND
REVIEWED NO LESS THAN ANNUALLY.**

Signed: _____

Title: Director, Pharmacy Services

Date: March 1, 2022

- Devised: 2/9/15
- Reviewed: 3/1/15 – annual review
- Revised: 3/1/16 – annual review, removed PA indicator from FA
- Revised: 5/1/16 – updated format, logo, & procedure
- Revised: 3/1/17 – annual review, removed Unicode character, defined abbreviations, updated FA
- Revised: 3/27/17 – rationale for not using Narcan
- Revised: 3/1/18 – annual review, updated signature
- Revised: 3/1/19 – annual review, updated FA
- Revised: 6/17/19 – removed counseling requirement (approved at 5/2015 P&T meeting)
- Revised: 3/1/20 – annual review, added GHP Kids
- Revised: 3/1/21 – annual review, updated logo, added MediSpan approval level
- Revised: 3/1/22 – annual review, updated referenced policies & covered LOBs, updated FA



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 354.0

**SECTION: Commercial Drug
SUBJECT: Cerdelga**

Applicable line of business:

Commercial	X	Medicaid	
Medicare		ACA	X
GHP Kids	X	Self-Insured	X

POLICY:

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for Cerdelga for GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 487.0 Quantity Limit Exceptions

REQUIRED DEFINITIONS:

1. **Attachment** – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. **Exhibit** – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
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4. **Revised** – the date of every revision to the policy, including typographical and grammatical changes.
5. **Reviewed** – the date documenting the annual review if the policy has no revisions necessary.

ADDITIONAL DEFINITIONS:

1. **Formulary** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. **Non-formulary products** – those medications that are not included in the Formulary.
3. **Healthcare provider** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
4. **NCQA** – National Committee for Quality Assurance.
5. **Medically Necessary or Medical Necessity** – covered services rendered by a provider that the Health Plan determines are:



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 354.0

**SECTION: Commercial Drug
SUBJECT: Cerdelga**

- A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
- B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
- C. In accordance with current standards of medical practice;
- D. Not primarily for the convenience of the Member, or the Member's Provider; and
- E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

PROCEDURE:

An exception for coverage of Cerdelga may be made for members who meet the following criteria:

- Medical record documentation of age greater than or equal to 18 years **AND**
- Medical record documentation of a confirmed diagnosis of Type 1 Gaucher disease along with at least one of the following conditions:
 - anemia; or
 - thrombocytopenia; or
 - bone disease; or
 - hepatomegaly or splenomegaly **AND**
- Medical record documentation that member is a CYP2D6 extensive metabolizer (EMs), intermediate metabolizer (IMs), or poor metabolizer (PMs) as detected by a Food and Drug Administration (FDA) cleared test **AND**
- Medical record documentation that Cerdelga is recommended by a metabolic specialist with experience in treating Gaucher disease

MEDISPAN AUTHORIZATION LEVEL: GPI-12

If an exception is made, Cerdelga will be paid for under the member's prescription drug benefit.

Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.

FORMULARY ALTERNATIVES:

none



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 354.0

**SECTION: Commercial Drug
SUBJECT: Cerdelga**

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE
STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND
FEDERAL REGULATORY ENTITIES.**

**THIS POLICY WILL BE REVISED AS NECESSARY AND
REVIEWED NO LESS THAN ANNUALLY.**

Signed: _____

Title: Director, Pharmacy Services

Date: March 1, 2022

- Devised: 2/9/15
- Reviewed: 3/1/15 – annual review
- Revised: 3/1/16 – annual review
- Revised: 5/1/16 – updated format, logo, & procedure
- Revised: 3/1/17 – annual review, defined abbreviations
- Revised: 3/1/18 – annual review, updated signature, updated age and prescriber criteria
- Revised: 3/1/19 – annual review, corrected typo
- Revised: 3/1/20 – annual review, added GHP Kids
- Revised: 3/1/21 – annual review, updated logo, added MediSpan approval level
- Revised: 3/1/22 – annual review, updated referenced policies & covered LOBs



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 355.0

**SECTION: Commercial Drug
SUBJECT: Zorvolex**

Applicable line of business:

Commercial	X	Medicaid	
Medicare		ACA	X
GHP Kids	X	Self-Insured	X

POLICY:

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for Zorvolex for GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 487.0 Quantity Limit Exceptions

REQUIRED DEFINITIONS:

1. **Attachment** – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. **Exhibit** – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. **Devised** – the date the policy was implemented.
4. **Revised** – the date of every revision to the policy, including typographical and grammatical changes.
5. **Reviewed** – the date documenting the annual review if the policy has no revisions necessary.

ADDITIONAL DEFINITIONS:

1. **Formulary** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. **Non-formulary products** – those medications that are not included in the Formulary.
3. **Healthcare provider** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
4. **NCQA** – National Committee for Quality Assurance.
5. **Medically Necessary or Medical Necessity** – covered services rendered by a provider that the Health Plan determines are:



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 355.0

**SECTION: Commercial Drug
SUBJECT: Zorvolex**

- A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
- B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
- C. In accordance with current standards of medical practice;
- D. Not primarily for the convenience of the Member, or the Member's Provider; and
- E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

PROCEDURE:

An exception for coverage of Zorvolex may be made for members who meet the following criteria:

- Medical record documentation of a diagnosis of mild to moderate acute pain of osteoarthritis **AND**
- Medical record documentation of age greater than or equal to 18 years **AND**
- Medical record documentation of a therapeutic failure on, intolerance to, or contraindication to three formulary nonsteroidal anti-inflammatory drugs (NSAIDs), including:
 - At least one of the following: diclofenac sodium, diclofenac potassium, or diclofenac sodium/misoprostol **AND**
 - At least one of the following: nabumetone, meloxicam, or etodolac

MEDISPAN AUTHORIZATION LEVEL: GPI-12

If an exception is made, Zorvolex will be paid for under the member's prescription drug benefit.

Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.

FORMULARY ALTERNATIVES:

celecoxib, choline magnesium salicylate, diclofenac, diclofenac extended release, diclofenac sodium/misoprostol, diflunisal, etodolac, etodolac extended release, fenoprofen, flurbiprofen, ibuprofen, indomethacin, indomethacin sustained release, ketoprofen, ketorolac, meclofenamate, meloxicam, nabumetone, naproxen, naproxen sodium, naproxen EC, oxaprozin, piroxicam, salsalate, sulindac, tolmetin



POLICY NUMBER: 355.0

**POLICY AND PROCEDURE
PHARMACY
MANUAL**

**SECTION: Commercial Drug
SUBJECT: Zorvolex**

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE
STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND
FEDERAL REGULATORY ENTITIES.**

**THIS POLICY WILL BE REVISED AS NECESSARY AND
REVIEWED NO LESS THAN ANNUALLY.**

Signed: _____

Title: Director, Pharmacy Services

Date: March 1, 2022

Devised: 2/9/15
Reviewed: 3/1/15 – annual review
Revised: 3/1/16 – annual review
Revised: 5/1/16 – updated format, logo, & procedure
Revised: 3/1/17 – annual review, updated bullet formatting of FA criteria
Revised: 3/1/18 – annual review, updated signature, corrected typo
Revised: 3/1/19 – annual review, defined NSAIDs
Revised: 3/1/20 – annual review, added GHP Kids
Revised: 3/1/21 – annual review, updated logo, added MediSpan approval level
Revised: 3/1/22 – annual review, updated referenced policies & covered LOBs



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 356.0

**SECTION: Commercial Drug
SUBJECT: Bunavail**

Applicable line of business:

Commercial	X	Medicaid	
Medicare		ACA	X
GHP Kids	X	Self-Insured	X

POLICY:

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for Bunavail for GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 487.0 Quantity Limit Exceptions

REQUIRED DEFINITIONS:

1. **Attachment** – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. **Exhibit** – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. **Devised** – the date the policy was implemented.
4. **Revised** – the date of every revision to the policy, including typographical and grammatical changes.
5. **Reviewed** – the date documenting the annual review if the policy has no revisions necessary.

ADDITIONAL DEFINITIONS:

1. **Formulary** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. **Non-formulary products** – those medications that are not included in the Formulary.
3. **Healthcare provider** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
4. **NCQA** – National Committee for Quality Assurance.
5. **Medically Necessary or Medical Necessity** – covered services rendered by a provider that the Health Plan determines are:



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 356.0

**SECTION: Commercial Drug
SUBJECT: Bunavail**

- A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
- B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
- C. In accordance with current standards of medical practice;
- D. Not primarily for the convenience of the Member, or the Member's Provider; and
- E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

PROCEDURE:

An exception for coverage of Bunavail may be made for members who meet the following criteria:

- Must be prescribed for the treatment of opioid dependence and the prescriber must have a unique identification number issued by the Drug Enforcement Agency (DEA) certifying prescribing authority for buprenorphine agents **AND**
- Member must be initially referred to and actively involved in formal counseling with a licensed behavioral health provider. Must provide the name of counselor and/or facility or rationale for non-participation **AND**
- For re-authorization, the member must be adherent to Bunavail therapy and must not be using opiates. Must be verified by lab screen (dated within 28 days of request date) for opiates and buprenorphine. The presence of controlled substances other than buprenorphine must be addressed **AND**
- Behavioral health vendor and/or plan case managers may contact prescriber, member, or counselor/facility to ensure compliance with these requirements. Continued approval for the drug is dependent on cooperation with this effort **AND**
- Medical record documentation of rationale for why the member cannot use buprenorphine/naloxone SL tablets **AND** buprenorphine/naloxone SL films

MEDISPAN AUTHORIZATION LEVEL: GPI-12

QUANTITY LIMIT: *No QLs need to be entered within the authorization unless the requested quantity exceeds the QL.*

- **QL FOR LETTER ONLY:**
 - 4.2/0.7 mg and 6.3/1 mg dosage forms: two (2) per day
 - 2.1/0.3 mg dosage form: one (1) per day



POLICY NUMBER: 356.0

**POLICY AND PROCEDURE
PHARMACY
MANUAL**

**SECTION: Commercial Drug
SUBJECT: Bunavail**

AUTHORIZATION DURATION: If approved, initial authorization duration will be 3 months. If approved, subsequent authorization duration will be 12 months.

If an exception is made, Bunavail will be paid for under the member's prescription drug benefit.

Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.

FORMULARY ALTERNATIVES:

buprenorphine/naloxone sublingual film, buprenorphine/naloxone sublingual tablet

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE
STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND
FEDERAL REGULATORY ENTITIES.**

**THIS POLICY WILL BE REVISED AS NECESSARY AND
REVIEWED NO LESS THAN ANNUALLY.**

Signed: _____

Title: Director, Pharmacy Services

Date: March 1, 2022

Devised: 2/9/15
Reviewed: 3/1/15 – annual review
Revised: 3/1/16 – annual review
Revised: 5/1/16 – updated format, logo, & procedure
Revised: 5/27/16 – removed dose reduction requirement
Revised: 3/1/17 – annual review, defined abbreviations
Revised: 10/10/17 – removed induction therapy, added auth duration
Revised: 3/1/18 – annual review, updated signature
Revised: 3/1/19 – annual review, added QL approval note, removed PA indicator from FA
Revised: 3/1/20 – annual review, added GHP Kids
Revised: 3/1/21 – annual review, updated logo, added MediSpan approval level, updated QL statement
Revised: 6/8/21 – removed in network requirement, removed counseling attestation, updated UDS requirement, removed form/attestation criteria, updated alternative criteria, updated FA



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 356.0

**SECTION: Commercial Drug
SUBJECT: Bunavail**

Revised: 3/1/22 – annual review, updated referenced policies & covered LOBs



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 358.0

**SECTION: Commercial Drug
SUBJECT: Harvoni and Ledipasvir
/Sofosbuvir 90/400 mg tablet**

Applicable line of business:

Commercial	X	Medicaid	
Medicare		ACA	X
GHP Kids	X	Self-Insured	X

POLICY:

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for Harvoni and ledipasvir/sofosbuvir 90/400 mg tablet for GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 487.0 Quantity Limit Exceptions

REQUIRED DEFINITIONS:

1. **Attachment** – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. **Exhibit** – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. **Devised** – the date the policy was implemented.
4. **Revised** – the date of every revision to the policy, including typographical and grammatical changes.
5. **Reviewed** – the date documenting the annual review if the policy has no revisions necessary.

ADDITIONAL DEFINITIONS:

1. **Formulary** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. **Non-formulary products** – those medications that are not included in the Formulary.
3. **Healthcare provider** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
4. **NCQA** – National Committee for Quality Assurance.
5. **Medically Necessary or Medical Necessity** – covered services rendered by a provider that the Health Plan determines are:

- A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
- B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
- C. In accordance with current standards of medical practice;
- D. Not primarily for the convenience of the Member, or the Member's Provider; and
- E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

PROCEDURE:

An exception for coverage of Harvoni and ledipasvir/sofosbuvir 90/400 mg tablet may be made for members who meet the following criteria:

- Medical record documentation of age greater than or equal to 3 years using weight-based dosing **AND**
- Medical record documentation of a diagnosis of hepatitis C infection **AND**
- Medical record documentation of the member's hepatitis C genotype **AND**
- Medical record documentation of a diagnosis of hepatitis C virus (HCV) genotype 1, 4, 5 or 6 infection **AND**
- Medical record documentation of METAVIR liver scoring **AND**
- Medical record documentation of a hepatocellular carcinoma screening in those with cirrhosis (METAVIR score F4) **AND**
- Medical record documentation of:
 - Genotype 1
 - As monotherapy **OR**
 - Concurrent therapy with ribavirin if treatment experienced with cirrhosis **OR**
 - Concurrent therapy with ribavirin if treatment naïve or experienced with decompensated cirrhosis **OR**
 - Concurrent therapy with ribavirin if treatment naïve or experienced with or without compensated cirrhosis in liver transplant recipients **OR**
 - Genotype 4
 - As monotherapy **OR**
 - Concurrent therapy with ribavirin if treatment naïve or experienced with decompensated cirrhosis **OR**
 - Concurrent therapy with ribavirin if treatment naïve or experienced with or without compensated cirrhosis in liver transplant recipients **OR**

- Concurrent therapy with ribavirin if treatment experienced with compensated cirrhosis **OR**
 - Genotype 5
 - As monotherapy **OR**
 - Genotype 6
 - As monotherapy **AND**
- Medical record documentation of the member receiving a Food and Drug Administration (FDA) approved medication regimen that is inside the parameters of use approved by the FDA or supported in the widely used compendia available **AND**
- Medical record documentation of appropriate duration of treatment **AND**
- Medical record documentation of previous treatment and treatment response **AND**
- Medical record documentation of concurrent therapy with appropriate dose and duration of ribavirin (weight-based dosing of ribavirin 1200 mg per day if greater than or equal to 75 kg, or 1000 mg per day if less than 75 kg, or 15 mg/kg in pediatric patients less than 47 kg), if indicated **AND**
- Medical record documentation of any potential drug interactions addressed by the prescriber (such as discontinuation of the interacting drug, dose reduction of the interacting drug, or counseling of the recipient of the risks associated with the use of both medications when they interact) **AND**
- Medical record documentation of receiving the following with the past 3 months:
 - Hepatic function panel
 - Complete blood count including differential
 - Basic metabolic panel
 - Baseline hepatitis C virus (HCV) RNA viral load **AND**
- Medical record documentation of a negative pregnancy test if member is female of childbearing potential and receiving ribavirin **AND**
- When concurrent ribavirin therapy is indicated and prescribed, medical record documentation for male members that female partner is not pregnant **AND**
- If the member or their partner are of childbearing potential, medical record documentation that the member was instructed to practice effective contraception during therapy with ribavirin and for 6 months following discontinuation of ribavirin therapy **AND**
- If actively abusing alcohol or intravenous (IV) drugs, or has a history of abuse, has documentation of prescriber counseling regarding the risks of alcohol or IV drug abuse, and an offer of a referral for substance use disorder treatment **AND**
- Medical record documentation that member received pre-treatment readiness education about hepatitis C treatment expectations by a health care provider **AND**
- Medical record documentation that the member commits to the documented planned course of treatment including anticipated blood tests and visits, during and after treatment **AND**

- Medical record documentation that member does not have a limited life expectancy of less than 12 months due to non-liver related co-morbid conditions **AND**
- Medical record documentation of completed:
 - Hepatitis B immunization series **OR**
 - Hepatitis B screening (sAb/sAg and cAb/cAg) **AND** Quantitative hepatitis B virus (HBV) DNA if positive for hepatitis B sAg or cAb or cAg **AND**
 - If there is detectable hepatitis B virus (HBV) DNA, will be treated for Hepatitis B **OR**
 - If negative for hepatitis B sAb, is being vaccinated against Hepatitis B **AND**
- Medical record documentation of human immunodeficiency virus (HIV) screening (HIV Ag/Ab) and if confirmed positive by HIV-1/HIV-2 differentiation immunoassay:
 - Is being treated for human immunodeficiency virus (HIV) **OR**
 - If not being treated for human immunodeficiency virus (HIV), the medical record documents the rationale for the beneficiary not being treated **AND**
- Medical record documentation of therapeutic failure on, intolerance to, or contraindication to Mavyret, if clinically appropriate **AND**
- Medical record documentation that member has been evaluated and treated by a contracted Center of Excellence in hepatitis C management

OR

- Medical record documentation of a hepatitis C negative recipient receiving a transplant from a hepatitis C positive donor **AND**
- Medical record documentation of therapeutic failure on, intolerance to, or contraindication to Mavyret, if clinically appropriate

NOTE: Center of Excellence (COE) requirements do not apply to strategic partner TPA plans (i.e., Northern Light Health).

TREATMENT DURATION:

Consistent with AASLD/ IDSA Guidelines (8 weeks, 12 weeks, 24 weeks)

****8 weeks duration is only for treatment-naïve, Genotype 1 patients who are HIV-uninfected and whose HCV RNA level is < 6million IU/ml**

MEDISPAN AUTHORIZATION LEVEL: GPI-10, if request is for ledipasvir/sofosbuvir 90/400 mg tablet include generic only.

QUANTITY LIMIT: *No QLs need to be entered within the authorization unless the requested quantity exceeds the QL.*

- **QL FOR LETTER ONLY:**
 - 90-400 mg and 45-200 mg tablets: 1 tablet per day, 28 day supply per fill
 - 45-200 mg pellets: 2 packets per day, 28 day supply per fill
 - 37.5-150 mg pellets: 1 packet per day, 28 day supply per fill

If an exception is made, Harvoni or ledipasvir/sofosbuvir 90/400 mg tablet will be paid for under the member's prescription drug benefit.

Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.

FORMULARY ALTERNATIVES:

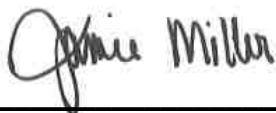
Mavyret*

*prior authorization required

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE
STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND
FEDERAL REGULATORY ENTITIES.**

**THIS POLICY WILL BE REVISED AS NECESSARY AND
REVIEWED NO LESS THAN ANNUALLY.**

Signed: _____



Title: Director, Pharmacy Services

Date: March 1, 2022

Devised: 2/9/15
Reviewed: 3/1/15 – annual review
Revised: 4/13/15 – added Genotype 3
Revised: 10/1/15 – added use of Viekira, updated FA
Revised: 1/29/16 – added HBV/HIV to definitions, added hepatocellular screening criterion,

HPRX02

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Dev. 2/9/15
Rev. 3/1/22



POLICY NUMBER: 358.0

**POLICY AND PROCEDURE
PHARMACY
MANUAL**

**SECTION: Commercial Drug
SUBJECT: Harvoni and Ledipasvir
/Sofosbuvir 90/400 mg tablet**

added severe extrahepatic manifestations of hep C criterion, removed in writing from member commitment, removed use of Viekira Pak

- Reviewed: 3/1/16 – annual review
- Revised: 3/24/16 – added G5 & G6; added/updated regimen for G1, G4 G5, & G6, added auth duration for G5 & G6, corrected typo in auth duration, removed no S/S of decompensated liver disease requirement
- Revised: 5/1/16 – updated format, logo, & procedure
- Revised: 5/27/16 – removed G3, corrected typo in treatment duration, added reauth criteria
- Revised: 7/27/16 – added F2 fibrosis, updated D/A requirement, updated FA
- Revised: 12/7/16 – update drug and alcohol criteria. Removed substance abuse treatment compliance, UDS corresponding with fill history, counseling by GHP. Added Sovaldi to FA.
- Revised: 3/1/17 – annual review, removed Unicode characters, defined abbreviations
- Revised: 6/2/17 – added regimen supported by compendia, added ribavirin for treatment experienced/compensated cirrhosis, removed incomplete course with same DAA, added non-liver co-morbid conditions to life expectancy, removed fibrosis requirement/liver manifestations, added METAVIR score
- Revised: 8/8/17 – revised age criteria to age 12 OR weight greater than 35 kg
- Revised: 11/27/17 – added failure of Mavyret, updated FA, updated signature
- Revised: 1/19/18 – removed prescriber, added Hep B & HIV criteria, updated FA
- Revised: 3/1/18 – annual review, updated Hep B/HIV criteria to match DHS, corrected typo
- Revised: 12/28/18 – added HCV positive transplant indication/FA criteria, added COE
- Revised: 3/1/19 – annual review, defined abbr.
- Revised: 7/23/19 – added TPA COE exclusion, renamed to generic
- Revised: 01/28/20 – updated age criteria to age 3 and weight based dosing, edited treatment duration to consistent with AASLD/IDSA Guidelines and removed continuation criteria
- Revised: 3/1/20 – annual review, added GHP Kids
- Revised: 7/29/20 – added QL for pellets
- Revised: 3/1/21 – annual review, updated logo, added MediSpan approval level, updated QL statement, removed AtlantiCare & St. Lukes, added Harvoni to policy title
- Revised: 3/1/22 – annual review, updated referenced policies & covered LOBs



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 359.0

**SECTION: Commercial Drug
SUBJECT: Xigduo XR**

Applicable line of business:

Commercial	X	Medicaid	
Medicare		ACA	X
GHP Kids	X	Self-Insured	X

POLICY:

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for Xigduo XR for GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 487.0 Quantity Limit Exceptions

REQUIRED DEFINITIONS:

1. **Attachment** – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. **Exhibit** – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. **Devised** – the date the policy was implemented.
4. **Revised** – the date of every revision to the policy, including typographical and grammatical changes.
5. **Reviewed** – the date documenting the annual review if the policy has no revisions necessary.

ADDITIONAL DEFINITIONS:

1. **Formulary** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. **Non-formulary products** – those medications that are not included in the Formulary.
3. **Healthcare provider** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
4. **NCQA** – National Committee for Quality Assurance.
5. **Medically Necessary or Medical Necessity** – covered services rendered by a provider that the Health Plan determines are:



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 359.0

**SECTION: Commercial Drug
SUBJECT: Xigduo XR**

- A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
- B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
- C. In accordance with current standards of medical practice;
- D. Not primarily for the convenience of the Member, or the Member's Provider; and
- E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

PROCEDURE:

An exception for coverage of Xigduo XR may be made for members who meet the following criteria:

- Medical record documentation of a diagnosis of type II diabetes mellitus **AND**
- Medical record documentation of age greater than or equal to 18 years **AND**
- Medical record documentation of therapeutic failure on, intolerance to, or contraindication to Jardiance in combination with metformin, Synjardy, or Synjardy XR **AND**
- Medical record documentation of therapeutic failure on, intolerance to, or contraindication to Invokana in combination with metformin, Invokamet, or Invokamet XR

MEDISPAN AUTHORIZATION LEVEL: GPI-12

QUANTITY LIMIT: *No QLs need to be entered within the authorization unless the requested quantity exceeds the QL.*

- **QL FOR LETTER ONLY:**
 - Xigduo XR 5-1000: 2 tablets per day
 - All Other Strengths: 1 tablet per day

If an exception is made, Xigduo XR will be paid for under the member's prescription drug benefit.

Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 359.0

**SECTION: Commercial Drug
SUBJECT: Xigduo XR**

FORMULARY ALTERNATIVES:

metformin, Jardiance, Synjardy, Synjardy XR, Invokana, Invokamet, Invokamet XR

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE
STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND
FEDERAL REGULATORY ENTITIES.**

**THIS POLICY WILL BE REVISED AS NECESSARY AND
REVIEWED NO LESS THAN ANNUALLY.**

Signed: _____

Title: Director, Pharmacy Services

Date: March 1, 2022

Devised: 4/13/15
Revised: 3/1/16 – annual review, updated Invokamet PA to ST, added Invokana, Synjardy, & Toujeo to FA
Revised: 5/1/16 – updated format, logo, & procedure
Revised: 3/1/17 – annual review, removed Unicode characters, added ST indicator to Jardiance
Revised: 11/28/17 – updated QL, updated signature
Revised: 12/29/17 – removed GFR criteria, updated failure to include Synjardy, updated FA
Revised: 3/1/18 – annual review, updated FA
Revised: 3/1/19 – annual review, added QL approval note, updated FA
Revised: 3/1/20 – annual review, added GHP Kids
Revised: 3/1/21 – annual review, updated logo, added MediSpan approval level, updated QL statement
Revised: 3/1/22 – annual review, updated referenced policies & covered LOBs



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 362.0

**SECTION: Commercial Drug
SUBJECT: Lynparza**

Applicable line of business:

Commercial	X	Medicaid	
Medicare		ACA	X
GHP Kids	X	Self-Insured	X

POLICY:

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for Lynparza for GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 487.0 Quantity Limit Exceptions

REQUIRED DEFINITIONS:

1. **Attachment** – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. **Exhibit** – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
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4. **Revised** – the date of every revision to the policy, including typographical and grammatical changes.
5. **Reviewed** – the date documenting the annual review if the policy has no revisions necessary.

ADDITIONAL DEFINITIONS:

1. **Formulary** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. **Non-formulary products** – those medications that are not included in the Formulary.
3. **Healthcare provider** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
4. **NCQA** – National Committee for Quality Assurance.
5. **Medically Necessary or Medical Necessity** – covered services rendered by a provider that the Health Plan determines are:

- A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
- B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
- C. In accordance with current standards of medical practice;
- D. Not primarily for the convenience of the Member, or the Member's Provider; and
- E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

PROCEDURE:

New members to the plan already established on therapy may be eligible for continuity of care coverage as long as there is medical record documentation that the safety and effectiveness of use for the prescribed indication is supported by Food and Drug Administration (FDA) approval or adequate medical and scientific evidence in the medical literature.

An exception for coverage of Lynparza may be made for members who meet the following criteria:

For Ovarian Cancer

- Medical record documentation that Lynparza is prescribed by an oncologist or hematologist **AND**
- Medical record documentation of age greater than or equal to 18 years **AND**

If the member is in complete/partial response to first-line platinum based chemotherapy:

- Medical record documentation of advanced epithelial ovarian, fallopian tube or primary peritoneal cancer **AND**
- Medical record documentation member has had a complete or partial response to first-line platinum based chemotherapy **AND**
- Medical record documentation that Lynparza will be used as maintenance treatment **AND**
- Medical record documentation of one of the following:
 - Medical record documentation of deleterious or suspected deleterious germline or somatic BRCA-mutation (*gBRCAm* or *sBRCAm*) **OR**
 - Medical record documentation of both of the following:
 - Documentation of homologous recombination deficiency (HRD)-positive status with a deleterious or suspected deleterious *BRCA* mutation **AND**

- Documentation that Lynparza will be prescribed in combination with bevacizumab

OR

If the member has failed three or more prior lines of chemotherapy:

- Medical record documentation of advanced ovarian cancer **AND**
- Medical record documentation of deleterious or suspected deleterious germline *BRCA*-mutated advanced ovarian cancer as verified by a Food and Drug Administration (FDA) approved test **AND**
- Medical record documentation of therapeutic failure on, intolerance to, or contraindication to three or more prior lines of chemotherapy

OR

If the member has platinum-sensitive recurrent disease and has completed two or more lines of platinum-based chemotherapy:

- Medical record documentation of recurrent epithelial ovarian, primary peritoneal, or fallopian tube cancer **AND**
- Medical record documentation of Lynparza being used as maintenance therapy after a complete or partial response to platinum-based chemotherapy **AND**
- Medical record documentation that Lynparza will be used as maintenance therapy

For Metastatic Breast Cancer

- Medical record documentation that Lynparza is prescribed by an oncologist or hematologist **AND**
- Medical record documentation of age greater than or equal to 18 years **AND**
- Medical record documentation of a diagnosis of deleterious or suspected deleterious *gBRCAm*, HER2-negative metastatic breast cancer **AND**
- Medical record documentation that member has been previously treated with chemotherapy in the neoadjuvant, adjuvant, or metastatic setting **AND**
- If hormone receptor (HR)-positive, medical record documentation that prior treatment included endocrine therapy or documentation that endocrine therapy would be considered inappropriate

For Adjuvant Treatment of High Risk Early Breast Cancer

- Medical record documentation that Lynparza is prescribed by an oncologist or hematologist **AND**
- Medical record documentation of age greater than or equal to 18 years **AND**
- Medical record documentation of a diagnosis of deleterious or suspected deleterious *gBRCAm*, HER2-negative high risk early breast cancer* **AND**
- Medical record documentation that member has been previously treated with chemotherapy in the neoadjuvant or adjuvant setting

***NOTE:** In the OlympiA trial, high risk was defined as follows:

- Prior Neoadjuvant Chemotherapy:
 - Triple Negative Breast Cancer (TNBC) or Hormone Receptor Positive Breast cancer must have had residual invasive cancer in the breast and/or the resected lymph nodes (non-pathologic complete response) at the time of surgery.
 - Hormone Receptor Positive Breast Cancer must also have had a score of ≥ 3 based on pre-treatment clinical and post-treatment pathologic stage (CPS), estrogen receptor (ER) status, and histologic grade as shown in the Table 1 below.

Table 1. Early Breast Cancer Stage, Receptor Status, and Grade Scoring Requirements for Study Enrollment

Stage/feature	Points	
Clinical Stage (pre-treatment)	I/IIA	0
	IIB/IIIA	1
	IIIB/IIIC	2
Pathologic Stage (post-treatment)	0/I	0
	IIA/IIB/IIIA/IIIB	1
	IIIC	2
Receptor status	ER positive	0
	ER negative	1
Nuclear grade	Nuclear grade 1-2	0
	Nuclear grade 3	1

- Prior Adjuvant Chemotherapy:
 - TNBC must have had node positive disease or node negative disease with a ≥ 2 cm primary tumor
 - Hormone Receptor Positive, HER2-negative breast cancer must have had ≥ 4 pathologically confirmed positive lymph nodes

For Metastatic Pancreatic Adenocarcinoma

- Medical record documentation that Lynparza is prescribed by an oncologist or hematologist **AND**
- Medical record documentation of age greater than or equal to 18 years **AND**
- Medical record documentation of a diagnosis of deleterious or suspected deleterious *gBRCAm* metastatic pancreatic adenocarcinoma **AND**
- Medical record documentation of Lynparza being used as maintenance therapy after a complete or partial response to platinum-based chemotherapy



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 362.0

**SECTION: Commercial Drug
SUBJECT: Lynparza**

For Metastatic Castration-Resistant Prostate Cancer

- Medical record documentation that Lynparza is prescribed by an oncologist or hematologist **AND**
- Medical record documentation of age greater than or equal to 18 years **AND**
- Medical record documentation of deleterious or suspected deleterious germline or somatic homologous recombination repair (HRR) gene-mutated metastatic castration-resistant prostate cancer (mCRPC) **AND**
- Medical record documentation of progression following prior treatment with Xtandi or Zytiga **AND**
- Medical record documentation that a gonadotropin-releasing hormone (GnRH) analog will be used concurrently **OR** member has had bilateral orchiectomy

NOTE: The FDA approved test is the BRACAnalysis CDx™. The FoundationOne CDx™ is also FDA approved for Lynparza for ovarian and prostate cancer.

MEDISPAN AUTHORIZATION LEVEL: GPI-12

QUANTITY LIMIT: *No QLs need to be entered within the authorization unless the requested quantity exceeds the QL.*

- **QL FOR LETTER ONLY:** 4 tablets per day, 30 day supply per fill

AUTHORIZATION DURATION:

For first-line maintenance of BRCA-mutated advanced ovarian cancer (failure on first-line platinum-based chemotherapy) and for first-line maintenance of HRD-positive advanced ovarian cancer in combination with bevacizumab:

Initial approval will be for 12 months or less if the reviewing provider feels it is medically appropriate. One subsequent approval for Lynparza will be granted for up to an additional 12 months (total of two years of therapy) and will require medical record documentation of continued disease improvement or lack of disease progression. The medication will no longer be covered if the member experiences unacceptable toxicity or worsening of disease

For members requesting approval of treatment beyond two (2) years, medical record documentation will be required showing patient has continued evidence of disease and treating healthcare provider believes member can derive further benefit from continuous treatment. Each additional approval will be for a period of 12 months. Members with complete response at two years, will not be granted additional treatment, per the package labeling.



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 362.0

**SECTION: Commercial Drug
SUBJECT: Lynparza**

For adjuvant treatment of high-risk early breast cancer:

One time authorization for 12 months or less if the reviewing provider feels it is medically appropriate.

Authorization of Lynparza for the adjuvant treatment of high-risk early breast cancer should not exceed the FDA-approved treatment duration of 1 year (12 months). For requests exceeding the above limit, medical record documentation of the following is required:

- Peer-reviewed literature citing well-designed clinical trials to indicate that the member's healthcare outcome will be improved by dosing beyond the FDA-approved treatment duration

For all other indications:

Initial approval will be for 12 months or less if the reviewing provider feels it is medical appropriate. Subsequent approvals will be for an additional 12 months or less if the reviewing provider feels it is medically appropriate and will require medical record documentation of continued disease improvement or lack of disease progression. The medication will no longer be covered if the member experiences unacceptable toxicity or worsening of disease.

If an exception is made, Lynparza will be paid for under the member's prescription drug benefit.

Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.

FORMULARY ALTERNATIVES:

none

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE
STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND
FEDERAL REGULATORY ENTITIES.**

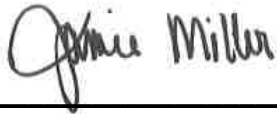
**THIS POLICY WILL BE REVISED AS NECESSARY AND
REVIEWED NO LESS THAN ANNUALLY.**

Geisinger

**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 362.0

**SECTION: Commercial Drug
SUBJECT: Lynparza**



Signed: _____

Title: Director, Pharmacy Services

Date: June 7, 2022

Devised: 4/13/15
Reviewed: 3/1/16 – annual review
Revised: 5/1/16 – updated format, logo, & procedure
Revised: 3/1/17 – annual review, defined abbreviations
Revised: 3/24/17 – increased authorization duration to 12 months
Revised: 11/27/17 – added tablets, updated format of age/prescriber for capsules, updated sig.
Revised: 3/1/18 – annual review, added grandfather language, updated prescriber criteria
Revised: 4/6/18 – added breast cancer indication to tablets
Revised: 3/1/19 – annual review, added QL approval note
Revised: 3/28/19 – removed capsules criteria, added first-line main. indication, updated auth duration
Revised: 3/1/20 – annual review, added GHP Kids
Revised: 4/21/20 – separated indications with headers, added pancreatic cancer indication
Revised: 7/29/20 – Restructured ovarian cancer criteria, added HRD ovarian cancer & prostate cancer
Revised: 3/1/21 – annual review, updated logo, added MediSpan approval level, updated QL statement
Revised: 1/21/22 – removed epithelial, fallopian tube, & peritoneal CA under failure of 3 or more therapies
Revised: 3/1/22 – annual review, updated referenced policies & covered LOBs
Revised: 4/6/22 – updated QL to match package size for one month
Revised: 6/7/22 – added adjuvant treatment of high-risk early breast cancer indication



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 365.0

**SECTION: Commercial Drug
SUBJECT: Ofev**

Applicable line of business:

Commercial	X	Medicaid	
Medicare		ACA	X
GHP Kids	X	Self-Insured	X

POLICY:

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for Ofev for GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 487.0 Quantity Limit Exceptions

REQUIRED DEFINITIONS:

1. **Attachment** – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. **Exhibit** – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. **Devised** – the date the policy was implemented.
4. **Revised** – the date of every revision to the policy, including typographical and grammatical changes.
5. **Reviewed** – the date documenting the annual review if the policy has no revisions necessary.

ADDITIONAL DEFINITIONS:

1. **Formulary** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. **Non-formulary products** – those medications that are not included in the Formulary.
3. **Healthcare provider** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
4. **NCQA** – National Committee for Quality Assurance.
5. **Medically Necessary or Medical Necessity** – covered services rendered by a provider that the Health Plan determines are:

- A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
- B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
- C. In accordance with current standards of medical practice;
- D. Not primarily for the convenience of the Member, or the Member's Provider; and
- E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

PROCEDURE:

An exception for coverage of Ofev may be made for members who meet the following criteria:

Interstitial Pulmonary Fibrosis (IPF)

- Medical record documentation that the diagnosis of interstitial pulmonary fibrosis (IPF) is made by an interdisciplinary team including, but not limited to, specialists from Pulmonary Medicine, Radiology, Thoracic Surgery, Pathology, and/or Rheumatology **AND**
- Medical record documentation of age greater than or equal to 18 years **AND**
- Medical record documentation of a diagnosis of idiopathic pulmonary fibrosis (IPF), confirmed by one of the following:
 - A usual interstitial pneumonia (UIP) pattern on high resolution CT (HRCT) scan alone **OR**
 - Both high resolution CT (HRCT) and surgical lung biopsy pattern suggestive of idiopathic pulmonary fibrosis (IPF) or probable IPF
- Medical record documentation of the exclusion of other known causes of interstitial lung disease (e.g., domestic and occupational environmental exposures, connective tissue disease, and drug toxicity) **AND**
- Medical record documentation that the patient was taught pulmonary rehabilitation techniques **AND**
- Medical record documentation that Ofev and Esbriet are not being used in combination

MEDISPAN AUTHORIZATION LEVEL: GPI-12

QUANTITY LIMIT: *No QLs need to be entered within the authorization unless the requested quantity exceeds the QL.*

- **QL FOR LETTER ONLY:** 2 capsules per day, 30 day supply per fill

Systemic Sclerosis-Associated Interstitial Lung Disease (SSc-ILD)

- Prescription written by or in consultation with a pulmonologist and/or rheumatologist **AND**
- Medical record documentation of patient age greater than or equal to 18 years **AND**
- Medical record documentation of a diagnosis of systemic sclerosis according to American College of Rheumatology (ACR) and European League Against Rheumatism (EULAR) **AND**
- Medical record documentation of systemic sclerosis related to interstitial lung disease confirmed by all of the following:
 - Greater than or equal to 10% fibrosis on a chest high resolution computer tomography **AND**
 - FVC greater than or equal to 40% of predicted normal **AND**
 - DLCO (diffusion capacity of the lung for carbon monoxide) 30-89% of predicted normal

MEDISPAN AUTHORIZATION LEVEL: GPI-12

QUANTITY LIMIT: *No QLs need to be entered within the authorization unless the requested quantity exceeds the QL.*

- **QL FOR LETTER ONLY:** 2 capsules per day, 30 day supply per fill

Note: ACR/ELAR Diagnostic Criteria for Systemic Sclerosis

Item	Sub-item(s)	Weight/score†
Skin thickening of the fingers of both hands extending proximal to the metacarpophalangeal joints (<i>sufficient criterion</i>)	–	9
Skin thickening of the fingers (<i>only count the higher score</i>)	Puffy fingers	2
	Sclerodactyly of the fingers (distal to the metacarpophalangeal joints but proximal to the proximal interphalangeal joints)	4
Fingertip lesions (<i>only count the higher score</i>)	Digital tip ulcers	2
	Fingertip pitting scars	3
Telangiectasia	–	2
Abnormal nailfold capillaries	–	2
Pulmonary arterial hypertension and/or interstitial lung disease (<i>maximum score is 2</i>)	Pulmonary arterial hypertension	2
	Interstitial lung disease	2
Raynaud's phenomenon	–	3
SSc-related autoantibodies (anticentromere, anti-topoisomerase I [anti-Scl-70], anti-RNA polymerase III) (<i>maximum score is 3</i>)	Anticentromere	3
	Anti-topoisomerase I	
	Anti-RNA polymerase III	

* These criteria are applicable to any patient considered for inclusion in an SSc study. The criteria are not applicable to patients with skin thickening sparing the fingers or to patients who have a scleroderma-like disorder that better explains their manifestations (e.g., nephrogenic sclerosing fibrosis, generalized morphea, eosinophilic fasciitis, sclerodema diabeticorum, scleromyxedema, erythromyalgia, porphyria, lichen sclerosis, graft-versus-host disease, diabetic cheiroarthropathy).

† The total score is determined by adding the maximum weight (score) in each category. Patients with a total score of ≥ 9 are classified as having definite SSc.

Chronic Fibrosing Interstitial Lung Disease (ILDs) with a Progressive Phenotype

- Prescription written by or in consultation with a pulmonologist and/or rheumatologist **AND**
- Medical record documentation of patient age greater than or equal to 18 years **AND**
- Medical record documentation of a diagnosis of chronic fibrosing interstitial lung diseases (ILDs) with a progressive phenotype* **AND**
- Medical record documentation of chronic interstitial lung disease confirmed by all of the following:
 - Greater than or equal to 10% fibrosis on a chest high resolution computer tomography **AND**
 - FVC greater than or equal to 45% of predicted normal **AND**
 - DLCO (diffusion capacity of the lung for carbon monoxide) 30-80% of predicted normal **AND**
- Medical record documentation of interstitial lung disease progression despite appropriate management with documentation of one of the following:
 - FVC decline greater than or equal to 10% **OR**
 - FVC decline 5% to less than 10% with documentation of either worsening symptoms **OR** increasing fibrotic changes on imaging **OR**
 - Documentation of both worsening symptoms **AND** increasing fibrotic changes on imaging

***NOTE:** Chronic fibrosing interstitial lung diseases (ILDs) with a progressive phenotype includes, but is not limited to:

- Rheumatoid arthritis associated ILD (RA-ILD)
- Mixed connective tissue disease
- Chronic hypersensitivity pneumonitis (HP)
- Idiopathic nonspecific interstitial pneumonia (iNSIP)
- Unclassifiable idiopathic interstitial pneumonia (uIIP)
- Exposure-related ILD
- Sarcoidosis

MEDISPAN AUTHORIZATION LEVEL: GPI-12

QUANTITY LIMIT: *No QLs need to be entered within the authorization unless the requested quantity exceeds the QL.*

- **QL FOR LETTER ONLY:** 2 capsules per day, 30 day supply per fill



POLICY NUMBER: 365.0

**POLICY AND PROCEDURE
PHARMACY
MANUAL**

**SECTION: Commercial Drug
SUBJECT: Ofev**

If an exception is made, Ofev will be paid for under the member's prescription drug benefit.

Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.

FORMULARY ALTERNATIVES:

Interstitial Pulmonary Fibrosis: Esbriet*

Systemic Sclerosis-Associated Interstitial Lung Disease: none

Chronic Fibrosing Interstitial Lung Diseases: none

*prior authorization required

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE
STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND
FEDERAL REGULATORY ENTITIES.**

**THIS POLICY WILL BE REVISED AS NECESSARY AND
REVIEWED NO LESS THAN ANNUALLY.**

Signed: _____

Title: Director, Pharmacy Services

Date: March 1, 2022

- Devised: 4/13/15
- Reviewed: 3/1/16 – annual review
- Revised: 5/1/16 – updated format, logo, & procedure
- Revised: 3/1/17 – annual review, removed Unicode characters, defined abbreviations
- Revised: 3/1/18 – annual review, updated signature, updated QL to match package size
- Revised: 3/1/19 – annual review, added QL approval note
- Revised: 01/28/20 – added SSc-ILD indication
- Revised: 3/1/20 – annual review, added GHP Kids
- Revised: 11/17/20 – added ILDs indication
- Revised: 3/1/21 – annual review, updated logo, added MediSpan approval level, updated QL statement
- Revised: 3/1/22 – annual review, updated referenced policies & covered LOBs, removed symbols



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 366.0

**SECTION: Commercial Drug
SUBJECT: Esbriet**

Applicable line of business:

Commercial	X	Medicaid	
Medicare		ACA	X
GHP Kids	X	Self-Insured	X

POLICY:

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for Esbriet for GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 487.0 Quantity Limit Exceptions

REQUIRED DEFINITIONS:

1. **Attachment** – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. **Exhibit** – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. **Devised** – the date the policy was implemented.
4. **Revised** – the date of every revision to the policy, including typographical and grammatical changes.
5. **Reviewed** – the date documenting the annual review if the policy has no revisions necessary.

ADDITIONAL DEFINITIONS:

1. **Formulary** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. **Non-formulary products** – those medications that are not included in the Formulary.
3. **Healthcare provider** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
4. **NCQA** – National Committee for Quality Assurance.
5. **Medically Necessary or Medical Necessity** – covered services rendered by a provider that the Health Plan determines are:



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 366.0

**SECTION: Commercial Drug
SUBJECT: Esbriet**

- A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
- B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
- C. In accordance with current standards of medical practice;
- D. Not primarily for the convenience of the Member, or the Member's Provider; and
- E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

PROCEDURE:

An exception for coverage of Esbriet may be made for members who meet the following criteria:

- Medical record documentation that the diagnosis of interstitial pulmonary fibrosis (IPF) is made by an interdisciplinary team including, but not limited to, specialists from Pulmonary Medicine, Radiology, Thoracic Surgery, Pathology, and/or Rheumatology **AND**
- Medical record documentation of age greater than or equal to 18 years **AND**
- Medical record documentation of a diagnosis of idiopathic pulmonary fibrosis (IPF), confirmed by one of the following:
 - A usual interstitial pneumonia (UIP) pattern on high resolution CT (HRCT) scan alone **OR**
 - Both high resolution CT (HRCT) and surgical lung biopsy pattern suggestive of IPF or probable IPF
- Medical record documentation of the exclusion of other known causes of interstitial lung disease (e.g., domestic and occupational environmental exposures, connective tissue disease, and drug toxicity) **AND**
- Medical record documentation that the patient was taught pulmonary rehabilitation techniques **AND**
- Medical record documentation that Esbriet and Ofev are not being used in combination

MEDISPAN AUTHORIZATION LEVEL: GPI-10

QUANTITY LIMIT: *No QLs need to be entered within the authorization unless the requested quantity exceeds the QL.*

- **QL FOR LETTER ONLY:** 9 capsules per day, 30 day supply per fill



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 366.0

**SECTION: Commercial Drug
SUBJECT: Esbriet**

If an exception is made, Esbriet will be paid for under the member's prescription drug benefit.

Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.

FORMULARY ALTERNATIVES:

Ofev*

*prior authorization required

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE
STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND
FEDERAL REGULATORY ENTITIES.**

**THIS POLICY WILL BE REVISED AS NECESSARY AND
REVIEWED NO LESS THAN ANNUALLY.**

Signed: _____

Title: Director, Pharmacy Services

Date: March 1, 2022

Devised: 4/13/15
Reviewed: 3/1/16 – annual review
Revised: 5/1/16 – updated format, logo, & procedure
Revised: 3/1/17 – annual review, removed Unicode characters, defined abbreviations
Revised: 3/1/18 – annual review, updated signature, updated QL to match package size
Revised: 3/1/19 – annual review, added QL approval note
Revised: 3/1/20 – annual review, added GHP Kids
Revised: 3/1/21 – annual review, updated logo, added MediSpan approval level, updated QL statement
Revised: 3/1/22 – annual review, updated referenced policies & covered LOBs



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 367.0

**SECTION: Commercial Drug
SUBJECT: Ibrance**

Applicable line of business:

Commercial	X	Medicaid	
Medicare		ACA	X
GHP Kids	X	Self-Insured	X

POLICY:

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for Ibrance for GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 487.0 Quantity Limit Exceptions

REQUIRED DEFINITIONS:

1. **Attachment** – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. **Exhibit** – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. **Devised** – the date the policy was implemented.
4. **Revised** – the date of every revision to the policy, including typographical and grammatical changes.
5. **Reviewed** – the date documenting the annual review if the policy has no revisions necessary.

ADDITIONAL DEFINITIONS:

1. **Formulary** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. **Non-formulary products** – those medications that are not included in the Formulary.
3. **Healthcare provider** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
4. **NCQA** – National Committee for Quality Assurance.
5. **Medically Necessary or Medical Necessity** – covered services rendered by a provider that the Health Plan determines are:



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 367.0

**SECTION: Commercial Drug
SUBJECT: Ibrance**

- A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
- B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
- C. In accordance with current standards of medical practice;
- D. Not primarily for the convenience of the Member, or the Member's Provider; and
- E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

PROCEDURE:

New members to the plan already established on therapy may be eligible for continuity of care coverage as long as there is medical record documentation that the safety and effectiveness of use for the prescribed indication is supported by Food and Drug Administration (FDA) approval or adequate medical and scientific evidence in the medical literature.

An exception for coverage of Ibrance may be made for members who meet the following criteria:

Ibrance as Initial Endocrine Therapy

- Medical record documentation that Ibrance is prescribed by an oncologist **AND**
- Medical record documentation of a diagnosis of hormone receptor positive (HR-positive), HER2 negative advanced or metastatic breast cancer **AND**
- Ibrance is being prescribed as initial endocrine based therapy in postmenopausal women **OR** men receiving testicular steroidogenesis suppression treated with a luteinizing hormone-releasing hormone (LHRH) agonist (i.e., goserelin, etc.) **AND**
- Medical record documentation that Ibrance will be prescribed in combination with an aromatase inhibitor (i.e., letrozole, etc.)

Ibrance Following Disease Progression on Endocrine Therapy

- Medical record documentation that Ibrance is prescribed by an oncologist **AND**
- Medical record documentation of a diagnosis of hormone receptor positive (HR-positive), HER2 negative advanced or metastatic breast cancer **AND**
- Ibrance is being prescribed after disease progression following endocrine therapy **AND**
- Medical record documentation that Ibrance is being used in combination with fulvestrant **AND**



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 367.0

**SECTION: Commercial Drug
SUBJECT: Ibrance**

- **If the request is for a pre/peri-menopausal woman:** Medical record documentation that the member is receiving ovarian suppression with a luteinizing hormone-releasing hormone (LHRH) agonist (i.e., goserelin, etc.)

MEDISPAN AUTHORIZATION LEVEL: GPI-10, number of claims authorized = 1, enter for the remainder of the calendar year

QUANTITY LIMIT: *No QLs need to be entered within the authorization unless the requested quantity exceeds the QL.*

- **QL FOR LETTER ONLY:** 21 capsules per 28 days, 28 day supply per fill

RE-AUTHORIZATION CRITERIA: Ibrance is configured as a prior authorization for new starts only. Ibrance will no longer be covered if it is identified that the member is not receiving appropriate follow-up care from the prescribing specialist or if the member has greater than or equal to a 90 day break in therapy.

- Medical record documentation that the member is receiving appropriate follow-up care from the prescribing specialist

If an exception is made, Ibrance will be paid for under the member's prescription drug benefit.

Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.

FORMULARY ALTERNATIVES:

none

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE
STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND
FEDERAL REGULATORY ENTITIES.**

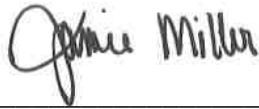
**THIS POLICY WILL BE REVISED AS NECESSARY AND
REVIEWED NO LESS THAN ANNUALLY.**

Geisinger

**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 367.0

**SECTION: Commercial Drug
SUBJECT: Ibrance**



Signed: _____

Title: Director, Pharmacy Services

Date: March 1, 2022

Devised: 4/13/15
Revised: 12/16/15 – Corrected quantity limit
Reviewed: 3/1/16 – annual review
Revised: 5/1/16 – updated format, logo, & procedure
Revised: 5/27/16 – added use in combination with fulvestrant
Reviewed: 3/1/17 – annual review
Revised: 6/2/17 – removed age, added advanced BC, clarified indications, updated auth dur.
Revised: 3/1/18 – annual review, updated signature & prescriber criteria, added grandfather language
Revised: 3/1/19 – annual review, added QL approval note
Revised: 5/24/19 – separated indications, added men to initial endocrine, re-formatted LHRH criteria
Revised: 3/1/20 – annual review, added GHP Kids
Revised: 3/1/21 – annual review, updated logo, added MediSpan approval level, updated QL statement
Revised: 11/24/21 – added one-time PA to approval crit., removed auth duration & added re-auth crit.
Revised: 3/1/22 – annual review, updated referenced policies & covered LOBs



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 368.0

**SECTION: Commercial Drug
SUBJECT: Velphoro**

Applicable line of business:

Commercial	X	Medicaid	
Medicare		ACA	X
GHP Kids	X	Self-Insured	X

POLICY:

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for Velphoro for GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 487.0 Quantity Limit Exceptions

REQUIRED DEFINITIONS:

1. **Attachment** – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. **Exhibit** – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
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4. **Revised** – the date of every revision to the policy, including typographical and grammatical changes.
5. **Reviewed** – the date documenting the annual review if the policy has no revisions necessary.

ADDITIONAL DEFINITIONS:

1. **Formulary** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. **Non-formulary products** – those medications that are not included in the Formulary.
3. **Healthcare provider** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
4. **NCQA** – National Committee for Quality Assurance.
5. **Medically Necessary or Medical Necessity** – covered services rendered by a provider that the Health Plan determines are:



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 368.0

**SECTION: Commercial Drug
SUBJECT: Velphoro**

- A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
- B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
- C. In accordance with current standards of medical practice;
- D. Not primarily for the convenience of the Member, or the Member's Provider; and
- E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

PROCEDURE:

An exception for coverage of Velphoro may be made for members who meet the following criteria:

- Medical record documentation of a diagnosis of chronic kidney disease requiring dialysis **AND**
- Medical record documentation of therapeutic failure on, intolerance to, or contraindication to calcium acetate **AND** sevelamer carbonate **AND** lanthanum carbonate

MEDISPAN AUTHORIZATION LEVEL: GPI-12

If an exception is made, Velphoro will be paid for under the member's prescription drug benefit.

Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.

FORMULARY ALTERNATIVES:

calcium acetate, Eliphos, sevelamer carbonate, lanthanum carbonate, Fosrenol powder packet

Geisinger

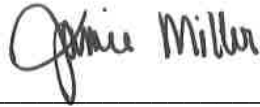
**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 368.0

**SECTION: Commercial Drug
SUBJECT: Velphoro**

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE
STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND
FEDERAL REGULATORY ENTITIES.**

**THIS POLICY WILL BE REVISED AS NECESSARY AND
REVIEWED NO LESS THAN ANNUALLY.**



Signed: _____

Title: Director, Pharmacy Services

Date: March 1, 2022

Devised: 4/13/15
Reviewed: 3/1/16 – annual review
Revised: 5/1/16 – updated format, logo, & procedure
Revised: 3/1/17 – annual review, updated FA
Revised: 3/1/18 – annual review, updated signature, updated FA
Revised: 4/5/18 – updated FA criteria to generics and removed Ca level info, updated FA
Reviewed: 3/1/19 – annual review
Revised: 3/1/20 – annual review, added GHP Kids
Revised: 3/1/21 – annual review, updated logo, added MediSpan approval level
Revised: 3/1/22 – annual review, updated referenced policies & covered LOBs



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 371.0

**SECTION: Commercial Drug
SUBJECT: Belsomra**

Applicable line of business:

Commercial	X	Medicaid	
Medicare		ACA	X
GHP Kids	X	Self-Insured	X

POLICY:

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for Belsomra for GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 487.0 Quantity Limit Exceptions

REQUIRED DEFINITIONS:

1. **Attachment** – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. **Exhibit** – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. **Devised** – the date the policy was implemented.
4. **Revised** – the date of every revision to the policy, including typographical and grammatical changes.
5. **Reviewed** – the date documenting the annual review if the policy has no revisions necessary.

ADDITIONAL DEFINITIONS:

1. **Formulary** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. **Non-formulary products** – those medications that are not included in the Formulary.
3. **Healthcare provider** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
4. **NCQA** – National Committee for Quality Assurance.
5. **Medically Necessary or Medical Necessity** – covered services rendered by a provider that the Health Plan determines are:



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 371.0

**SECTION: Commercial Drug
SUBJECT: Belsomra**

- A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
- B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
- C. In accordance with current standards of medical practice;
- D. Not primarily for the convenience of the Member, or the Member's Provider; and
- E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

PROCEDURE:

An exception for coverage of Belsomra may be made for members who meet the following criteria:

- Medical record documentation of age greater than or equal to 18 years **AND**
- Medical record documentation of a diagnosis of insomnia **AND**
- Medical record documentation of therapeutic failure on, intolerance to, or contraindication to three (3) formulary alternatives

MEDISPAN AUTHORIZATION LEVEL: GPI-12

QUANTITY LIMIT: *No QLs need to be entered within the authorization unless the requested quantity exceeds the QL.*

- QL FOR LETTER ONLY: 1 tablet per day

If an exception is made, Belsomra will be paid for under the member's prescription drug benefit.

Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.

FORMULARY ALTERNATIVES:

eszopiclone, zaleplon, zolpidem, zolpidem ER, amitriptyline, mirtazapine, trazodone, estazolam, flurazepam, quazepam, temazepam, triazolam



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 371.0

**SECTION: Commercial Drug
SUBJECT: Belsomra**

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE
STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND
FEDERAL REGULATORY ENTITIES.**

**THIS POLICY WILL BE REVISED AS NECESSARY AND
REVIEWED NO LESS THAN ANNUALLY.**

Signed: _____

Title: Director, Pharmacy Services

Date: March 1, 2022

Devised: 6/5/15
Reviewed: 3/1/16 – annual review
Revised: 5/1/16 – updated format, logo, & procedure, removed QL from FA
Revised: 3/1/17 – annual review removed Unicode characters
Revised: 3/1/18 – annual review, updated signature, updated age criteria
Revised: 3/1/19 – annual review, added QL approval note
Revised: 3/1/20 – annual review, added GHP Kids
Revised: 3/1/21 – annual review, updated logo, added MediSpan approval level, updated QL statement
Revised: 3/1/22 – annual review, updated referenced policies & covered LOBs



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 372.0

**SECTION: Commercial Drug
SUBJECT: Farydak**

Applicable line of business:

Commercial	X	Medicaid	
Medicare		ACA	X
GHP Kids	X	Self-Insured	X

POLICY:

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for Farydak for GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 487.0 Quantity Limit Exceptions

REQUIRED DEFINITIONS:

1. **Attachment** – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. **Exhibit** – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. **Devised** – the date the policy was implemented.
4. **Revised** – the date of every revision to the policy, including typographical and grammatical changes.
5. **Reviewed** – the date documenting the annual review if the policy has no revisions necessary.

ADDITIONAL DEFINITIONS:

1. **Formulary** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. **Non-formulary products** – those medications that are not included in the Formulary.
3. **Healthcare provider** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
4. **NCQA** – National Committee for Quality Assurance.
5. **Medically Necessary or Medical Necessity** – covered services rendered by a provider that the Health Plan determines are:

- A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
- B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
- C. In accordance with current standards of medical practice;
- D. Not primarily for the convenience of the Member, or the Member's Provider; and
- E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

PROCEDURE:

New members to the plan already established on therapy may be eligible for continuity of care coverage as long as there is medical record documentation that the safety and effectiveness of use for the prescribed indication is supported by Food and Drug Administration (FDA) approval or adequate medical and scientific evidence in the medical literature.

An exception for coverage of Farydak may be made for members who meet the following criteria:

- Medical record documentation that Farydak is prescribed by a hematologist or oncologist **AND**
- Medical record documentation of a diagnosis of multiple myeloma **AND**
- Medical record documentation that Farydak will be prescribed in combination with Velcade* and dexamethasone **AND**
- Medical record documentation of therapeutic failure on, intolerance to, or contraindication to two prior therapies: bortezomib (Velcade*) and an immunomodulatory agent (including but not limited to Pomalyst*, Revlimid*, Thalomid*)

MEDISPAN AUTHORIZATION LEVEL: GPI-12

QUANTITY LIMIT: *No QLs need to be entered within the authorization unless the requested quantity exceeds the QL.*

- **QL FOR LETTER ONLY:** 6 capsules per 21 day cycle

AUTHORIZATION DURATION: Initial approval will be for 6 months or less if the reviewing provider feels it is medically appropriate. Subsequent approvals will be for an additional 6 months or less if the reviewing provider feels it is medically appropriate and

Geisinger

**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 372.0

**SECTION: Commercial Drug
SUBJECT: Farydak**

will require medical record documentation of continued disease improvement or lack of disease progression. The medication will no longer be covered if the member experiences unacceptable toxicity or worsening of disease. Farydak is limited to 12 months per lifetime.

If an exception is made, Farydak will be paid for under the member's prescription drug benefit.

Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.

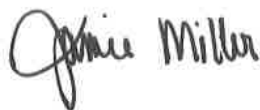
FORMULARY ALTERNATIVES:

Thalomid, Pomalyst*, Revlimid*

*prior authorization required

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE
STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND
FEDERAL REGULATORY ENTITIES.**

**THIS POLICY WILL BE REVISED AS NECESSARY AND
REVIEWED NO LESS THAN ANNUALLY.**



Signed: _____

Title: Director, Pharmacy Services

Date: March 1, 2022

Devised: 6/5/15
Revised: 3/1/16 – annual review, updated criteria to reflect Farydak policy approved at May 2015 P&T meeting
Revised: 5/1/16 – updated format, logo, & procedure
Reviewed: 3/1/17 – annual review
Revised: 3/1/18 – annual review, updated signature, updated prescriber criteria, added grandfather language
Revised: 3/1/19 – annual review, added QL approval note
Revised: 3/1/20 – annual review, added GHP Kids
Revised: 3/1/21 – annual review, updated logo, added MediSpan approval level, updated QL statement
Revised: 3/1/22 – annual review, updated referenced policies & covered LOBs

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Dev. 6/5/15

Rev. 3/1/22



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 373.0

**SECTION: Commercial Drug
SUBJECT: Lenvima**

Applicable line of business:

Commercial	X	Medicaid	
Medicare		ACA	X
GHP Kids	X	Self-Insured	X

POLICY:

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for Lenvima for GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 487.0 Quantity Limit Exceptions

REQUIRED DEFINITIONS:

1. **Attachment** – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. **Exhibit** – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. **Devised** – the date the policy was implemented.
4. **Revised** – the date of every revision to the policy, including typographical and grammatical changes.
5. **Reviewed** – the date documenting the annual review if the policy has no revisions necessary.

ADDITIONAL DEFINITIONS:

1. **Formulary** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. **Non-formulary products** – those medications that are not included in the Formulary.
3. **Healthcare provider** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
4. **NCQA** – National Committee for Quality Assurance.
5. **Medically Necessary or Medical Necessity** – covered services rendered by a provider that the Health Plan determines are:

- A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
- B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
- C. In accordance with current standards of medical practice;
- D. Not primarily for the convenience of the Member, or the Member's Provider; and
- E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

PROCEDURE:

New members to the plan already established on therapy may be eligible for continuity of care coverage as long as there is medical record documentation that the safety and effectiveness of use for the prescribed indication is supported by Food and Drug Administration (FDA) approval or adequate medical and scientific evidence in the medical literature.

An exception for coverage of Lenvima may be made for members who meet the following criteria:

Thyroid Cancer

- Medical record documentation that Lenvima is prescribed by a hematologist or oncologist **AND**
- Medical record documentation of locally recurrent or metastatic, progressive, radioactive iodine-refractory differentiated thyroid cancer

Renal Cell Carcinoma

- Medical record documentation that Lenvima is prescribed by an oncologist **AND**
- Medical record documentation of one of the following:
 - Medical record documentation of use in combination with everolimus (generic Afinitor) for surgically unresectable advanced or metastatic renal cell carcinoma with predominant clear-cell histology **AND**
 - Medical record documentation of a therapeutic failure on or intolerance to one prior anti-angiogenic therapy, including, but not limited to, sunitinib (generic Sutent), Votrient (pazopanib), Inlyta (axitinib), Nexavar (sorafenib), Avastin (bevacizumab), everolimus (generic Afinitor), or Torisel (temsirolimus)

OR

- Medical record documentation in combination with pembrolizumab for the treatment of advanced renal cell carcinoma (RCC) **AND**

- Medical record documentation the Lenvima in combination with pembrolizumab (Ketyruda) are being used as first-line treatment for advanced disease

Hepatocellular Carcinoma

- Medical record documentation that Lenvima is prescribed by a hematologist or oncologist **AND**
- Medical record documentation that Lenvima is being used for the treatment of unresectable hepatocellular carcinoma (HCC) **AND**
- Medical record documentation that patient has Child-Pugh Class A liver disease **AND**
- Medical record documentation that patient has not received prior therapy for unresectable hepatocellular carcinoma **AND**
- Medical record documentation that the appropriate dose of Lenvima is prescribed based on patient's body weight (greater than 60kg: Lenvima 12mg once daily, less than 60kg: Lenvima 8mg once daily)

Endometrial Cancer

- Medical record documentation that Lenvima is prescribed by a hematologist/oncologist **AND**
- Medical record documentation of a diagnosis of advanced endometrial carcinoma **AND**
- Medical record documentation of disease progression following at least one prior systemic therapy **AND**
- Medical record documentation that the member is not a candidate for curative surgery or radiation **AND**
- Medical record documentation that tumors are **not** microsatellite instability-high (MSI-H) or mismatch repair deficient (dMMR) **AND**
- Medical record documentation that Lenvima will be given in combination with pembrolizumab (Keytruda)

MEDISPAN AUTHORIZATION LEVEL: GPI-12, number of claims authorized = 1, enter for the remainder of the calendar year

QUANTITY LIMIT: *No QLs need to be entered within the authorization unless the requested quantity exceeds the QL.*

- **QL FOR LETTER ONLY:**
 - 4 mg daily dose pack: 1 capsule per day, 30 days supply per fill
 - 8 mg daily dose pack: 2 capsules per day, 30 days supply per fill
 - 10 mg daily dose pack: 1 capsule per day, 30 days supply per fill
 - 12 mg daily dose pack: 3 capsules per day, 30 days supply per fill
 - 14 mg daily dose pack: 2 capsules per day, 30 days supply per fill

- 18 mg daily dose pack: 3 capsules per day, 30 days supply per fill
- 20 mg daily dose pack: 2 capsules per day, 30 days supply per fill
- 24 mg daily dose pack: 3 capsules per day, 30 days supply per fill

RE-AUTHORIZATION CRITERIA: Lenvima is configured as a prior authorization for new starts only. Lenvima will no longer be covered if it is identified that the member is not receiving appropriate follow-up care from the prescribing specialist or if the member has greater than or equal to a 90 day break in therapy.

- Medical record documentation that the member is receiving appropriate follow-up care from the prescribing specialist

If an exception is made, Lenvima will be paid for under the member's prescription drug benefit.

Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.

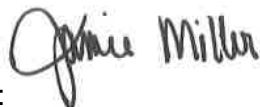
FORMULARY ALTERNATIVES:

Renal Cell Carcinoma: Caprelsa*, Cometriq*, Nexavar*

*prior authorization required

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE
STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND
FEDERAL REGULATORY ENTITIES.**

**THIS POLICY WILL BE REVISED AS NECESSARY AND
REVIEWED NO LESS THAN ANNUALLY.**



Signed: _____

Title: Director, Pharmacy Services

Date: March 1, 2022

Devised: 6/5/15

Reviewed: 3/1/16 – annual review



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 373.0

**SECTION: Commercial Drug
SUBJECT: Lenvima**

- Revised: 5/1/16 – updated format, logo, & procedure
- Revised: 7/22/16 – added RCC indication
- Reviewed: 3/1/17 – annual review
- Revised: 10/10/17 – increased authorization duration to 12 months
- Revised: 3/1/18 – annual review, updated signature, added grandfather language, updated prescriber criteria, updated format of headers
- Revised: 12/28/18 – added HCC indication, updated FA
- Revised: 3/1/19 – annual review, added QL approval note, updated QL from 1/19 P&T
- Revised: 10/28/19 – corrected hepatocellular carcinoma typo
- Revised: 11/20/19 – added endometrial carcinoma indication
- Revised: 3/1/20 – annual review, added GHP Kids
- Revised: 3/1/21 – annual review, updated logo, added MediSpan approval level, updated QL statement
- Revised: 11/1/21 – added use with pembrolizumab for RCC, added one-time PA to approval crit., removed auth duration & added re-auth crit.
- Revised: 3/1/22 – annual review, updated referenced policies & covered LOBs, removed symbols



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 375.0

**SECTION: Commercial Drug
SUBJECT: Savaysa**

Applicable line of business:

Commercial	X	Medicaid	
Medicare		ACA	X
GHP Kids	X	Self-Insured	X

POLICY:

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for Savaysa for GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 487.0 Quantity Limit Exceptions

REQUIRED DEFINITIONS:

1. **Attachment** – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. **Exhibit** – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. **Devised** – the date the policy was implemented.
4. **Revised** – the date of every revision to the policy, including typographical and grammatical changes.
5. **Reviewed** – the date documenting the annual review if the policy has no revisions necessary.

ADDITIONAL DEFINITIONS:

1. **Formulary** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. **Non-formulary products** – those medications that are not included in the Formulary.
3. **Healthcare provider** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
4. **NCQA** – National Committee for Quality Assurance.
5. **Medically Necessary or Medical Necessity** – covered services rendered by a provider that the Health Plan determines are:



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 375.0

**SECTION: Commercial Drug
SUBJECT: Savaysa**

- A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
- B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
- C. In accordance with current standards of medical practice;
- D. Not primarily for the convenience of the Member, or the Member's Provider; and
- E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

PROCEDURE:

An exception for coverage of Savaysa may be made for members who meet the following criteria:

- Medical record documentation of a diagnosis of stroke and systemic embolism risk reduction in patients with non-valvular atrial fibrillation **OR**
- Medical record documentation that Savaysa is being used for treatment of deep vein thrombosis and/or pulmonary embolism **AND** one of the following:
 - Patient weight greater than 60 kg **OR**
 - Patient weight less than or equal to 60 kg **AND** Savaysa being dosed as 30 mg per day
- Medical record documentation of therapeutic failure on, intolerance to, or contraindication to Eliquis **AND** Xarelto

MEDISPAN AUTHORIZATION LEVEL: GPI-14

QUANTITY LIMIT: *No QLs need to be entered within the authorization unless the requested quantity exceeds the QL.*

- **QL FOR LETTER ONLY:** 1 tablet per day

If an exception is made, Savaysa will be paid for under the member's prescription drug benefit.

Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.

FORMULARY ALTERNATIVES:

warfarin, Eliquis, Xarelto



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 375.0

**SECTION: Commercial Drug
SUBJECT: Savaysa**

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE
STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND
FEDERAL REGULATORY ENTITIES.**

**THIS POLICY WILL BE REVISED AS NECESSARY AND
REVIEWED NO LESS THAN ANNUALLY.**

Signed: _____

Title: Director, Pharmacy Services

Date: March 1, 2022

- Devised: 6/5/15
- Revised: 9/21/15 – corrected typos
- Reviewed: 3/1/16 – annual review
- Revised: 5/1/16 – updated format, logo, & procedure
- Revised: 3/1/17 – annual review, removed Unicode characters
- Revised: 3/1/18 – annual review, updated signature
- Reviewed: 3/1/19 – annual review
- Revised: 3/1/20 – annual review, added GHP Kids
- Revised: 3/1/21 – annual review, updated logo, added MediSpan approval level, updated QL statement
- Revised: 3/1/22 – annual review, updated referenced policies & covered LOBs



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 376.0

**SECTION: Commercial Drug
SUBJECT: Mircera**

Applicable line of business:

Commercial	X	Medicaid	
Medicare		ACA	X
GHP Kids	X	Self-Insured	X

POLICY:

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for Mircera for GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 487.0 Quantity Limit Exceptions

REQUIRED DEFINITIONS:

1. **Attachment** – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. **Exhibit** – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. **Devised** – the date the policy was implemented.
4. **Revised** – the date of every revision to the policy, including typographical and grammatical changes.
5. **Reviewed** – the date documenting the annual review if the policy has no revisions necessary.

ADDITIONAL DEFINITIONS:

1. **Formulary** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. **Non-formulary products** – those medications that are not included in the Formulary.
3. **Healthcare provider** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
4. **NCQA** – National Committee for Quality Assurance.
5. **Medically Necessary or Medical Necessity** – covered services rendered by a provider that the Health Plan determines are:



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 376.0

**SECTION: Commercial Drug
SUBJECT: Mircera**

- A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
- B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
- C. In accordance with current standards of medical practice;
- D. Not primarily for the convenience of the Member, or the Member's Provider; and
- E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

PROCEDURE:

An exception for coverage of Mircera may be made for members who meet the following criteria:

For new starts:

- Medical record documentation of use for the treatment of anemia associated with chronic kidney disease (CKD) in adult patients on dialysis and patients not on dialysis **AND**
- Medical record documentation of hemoglobin (hgb) less than 10 g/dL for new starts **AND**
- Medical record documentation of ferritin greater than or equal to 100 ng/mL or transferrin level saturation greater than or equal to 20%

For continuation of therapy, a repeat hemoglobin (hgb) should be submitted after 3 months of therapy. The following criteria will apply to requests for continuation of therapy:

- Medical record documentation of use for the treatment of anemia associated with chronic kidney disease (CKD) in adult patients on dialysis and patients not on dialysis **AND**
- Medical record documentation of hemoglobin (hgb) less than 12 g/dL for continuation of therapy **AND**
- Medical record documentation of ferritin greater than or equal to 100 ng/mL or transferrin level saturation greater than or equal to 20%

NOTE: In individuals whose hemoglobin (hgb) is greater than or equal to 12 g/dL or rises by 1 g/dL in any two-week period, additional doses should be withheld

MEDISPAN AUTHORIZATION LEVEL: GPI-12

AUTHORIZATION DURATION: 3 months



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 376.0

**SECTION: Commercial Drug
SUBJECT: Mircera**

If an exception is made, Mircera will be paid for under the member's prescription drug benefit.

Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.

FORMULARY ALTERNATIVES:

Epopgen*, Procrit*, Aranesp*, Retacrit*

*prior authorization required

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE
STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND
FEDERAL REGULATORY ENTITIES.**

**THIS POLICY WILL BE REVISED AS NECESSARY AND
REVIEWED NO LESS THAN ANNUALLY.**

Signed: _____

Title: Director, Pharmacy Services

Date: March 1, 2022

Devised: 6/5/15
Revised: 9/21/15 – corrected typos
Reviewed: 3/1/16 – annual review
Revised: 5/1/16 – updated format, logo, & procedure
Revised: 3/1/17 – annual review, defined abbreviations
Revised: 3/1/18 – annual review, updated signature
Reviewed: 3/1/19 – annual review
Revised: 3/1/20 – annual review, added GHP Kids
Revised: 3/1/21 – annual review, updated logo, added MediSpan approval level, updated FA
Revised: 3/1/22 – annual review, updated referenced policies & covered LOBs



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 379.0

**SECTION: Commercial Drug
SUBJECT: Cosentyx**

Applicable line of business:

Commercial	X	Medicaid	
Medicare		ACA	X
GHP Kids	X	Self-Insured	X

POLICY:

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for Cosentyx for GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 487.0 Quantity Limit Exceptions

REQUIRED DEFINITIONS:

1. **Attachment** – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. **Exhibit** – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. **Devised** – the date the policy was implemented.
4. **Revised** – the date of every revision to the policy, including typographical and grammatical changes.
5. **Reviewed** – the date documenting the annual review if the policy has no revisions necessary.

ADDITIONAL DEFINITIONS:

1. **Formulary** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. **Non-formulary products** – those medications that are not included in the Formulary.
3. **Healthcare provider** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
4. **NCQA** – National Committee for Quality Assurance.
5. **Medically Necessary or Medical Necessity** – covered services rendered by a provider that the Health Plan determines are:

- A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
- B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
- C. In accordance with current standards of medical practice;
- D. Not primarily for the convenience of the Member, or the Member's Provider; and
- E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

PROCEDURE:

New members to the plan already established on therapy may be eligible for continuity of care coverage as long as there is medical record documentation that the safety and effectiveness of use for the prescribed indication is supported by Food and Drug Administration (FDA) approval or adequate medical and scientific evidence in the medical literature.

For Plaque Psoriasis

An exception for coverage of Cosentyx may be made for members who meet the following criteria:

- Medical record documentation that Cosentyx is prescribed by a dermatologist **AND**
- Medical record documentation of age greater than or equal to 6 years **AND**
- Medical record documentation of a diagnosis of moderate to severe plaque psoriasis characterized by greater than or equal to 5 % of body surface area involved or disease involving crucial body areas such as the hands, feet, face, or genitals **AND**
- Medical record documentation that Cosentyx is not being used concurrently with a tumor necrosis factor (TNF) blocker or other biologic agent **AND**
- Medical record documentation of therapeutic failure on, intolerance to, or contraindication to topical corticosteroids **AND** at least two to three months of systemic therapy (including but not limited to methotrexate and/or cyclosporine or phototherapy **OR** medical record documentation of therapeutic failure on or intolerance to prior biologic therapy

MEDISPAN AUTHORIZATION LEVEL: GPI-10

QUANTITY LIMIT

- 75 mg every 4 weeks
 1. In PA Hub: Add PA, OQL, number of claims authorized 1, max quantity dispensed 2 with a duration of one-month.

- QL FOR LETTER: Loading dose: 2 mL per 28 days;
Maintenance dose: 0.5 mL per 28 days
- 150 mg every 4 weeks
 1. In Darwin: Add PA, OQL, number of claims authorized 1, max quantity dispensed 4 with a duration of 3 weeks.
 2. In PA Hub: Add OUP, DS, Max Days Supply 56. Start date of this authorization is one-day after loading dose ends.
 - QL FOR LETTER: Loading dose: 4 mL per 28 days;
Maintenance dose: 2 mL per 56 days
- 300 mg every 4 weeks
 1. In PA Hub: Add PA, OQL, number of claims authorized 1, max quantity dispensed 8 with a duration of one-month.
 - QL FOR LETTER: Loading dose: 8 mL per 28 days;
Maintenance dose: 2 mL per 28 days

RE-AUTHORIZATION CRITERIA: Cosentyx is configured as a prior authorization for new starts only. Cosentyx will no longer be covered if it is identified that the member is not receiving appropriate follow-up care from the prescribing specialist or if the member has greater than or equal to a 90 day break in therapy.

- Medical record documentation that the member is receiving appropriate follow-up care from the prescribing specialist

FORMULARY ALTERNATIVES:

cyclosporine, methotrexate

Low-potency topical corticosteroids: alclometasone dipropionate 0.5% cream and ointment (Aclovate); fluocinolone acetonide 0.01% soln. (Synalar); hydrocortisone 2.5% cream, ointment, and lotion (Hytone)

Medium-potency topical corticosteroids: betamethasone valerate 0.1% cream (Valisone); fluocinolone acetonide 0.025% cream and ointment (Synalar); fluticasone propionate 0.05% cream, ointment, and lotion (Cutivate); triamcinolone 0.1% cream, ointment and lotion (Kenalog); triamcinolone acetonide 0.025% cream, ointment and lotion (Kenalog); triamcinolone acetonide 0.147 mg/g aerosol (Kenalog Spray)

High-potency topical corticosteroids: augmented betamethasone dipropionate 0.05% cream (Diprolene AF); betamethasone valerate 0.1% ointment (Valisone); triamcinolone 0.5% cream (Kenalog); fluocinonide 0.05% cream, ointment and gel (Lidex)

Very high-potency topical corticosteroids: augmented betamethasone dipropionate 0.05% ointment, gel and lotion (Diprolene); clobetasol 0.05% cream, ointment, and scalp lotion (Temovate) diflorasone diacetate 0.05% cream and ointment (ApexiCon/Psorcon)

For Psoriatic Arthritis

An exception for coverage of Cosentyx may be made for members who meet the following criteria:

- Medical record documentation of a diagnosis of moderately to severely active psoriatic arthritis which must include the following:
 - Documentation of either active psoriatic lesions or a documentation history of psoriasis **AND**
- Medical record documentation that Cosentyx is prescribed by a rheumatologist or dermatologist **AND**
- Medical record documentation of age greater than or equal to 2 years **AND**
- Medical record documentation that Cosentyx is not being used concurrently with a tumor necrosis factor (TNF) blocker or other biologic agent **AND**
- **For peripheral disease:** Medical record documentation of therapeutic failure on, intolerance to, or contraindication to methotrexate **AND** an adequate trial of at least two (2) formulary nonsteroidal anti-inflammatory drugs (NSAIDs) **OR** medical record documentation of therapeutic failure on or intolerance to prior biologic therapy **OR**
- **For axial disease:** Medical record documentation of therapeutic failure on, intolerance to, or contraindication to an adequate trial of at least two (2) formulary nonsteroidal anti-inflammatory drugs (NSAIDs) **OR** medical record documentation of therapeutic failure on or intolerance to prior biologic therapy **AND**
- If the request is for a pediatric member, medical record documentation that the prescribed dosing is appropriate for member's weight

NOTE:

For pediatric patients weighing ≥ 15 kg and < 50 kg: Inject 75 mg subcutaneously at weeks 0, 1, 2, 3, and 4 and every 4 weeks thereafter

For pediatric patients weighing ≥ 50 kg: Inject 150mg subcutaneously at weeks 0, 1, 2, 3, and 4 and every 4 weeks thereafter

MEDISPAN AUTHORIZATION LEVEL: GPI-10

QUANTITY LIMIT

- 75 mg every 4 weeks
 1. In Darwin: Add PA, OQL, number of claims authorization 1, max quantity dispensed 2 with a duration of one month.
 - QL FOR LETTER: Loading dose: 2 mL per 28 days;
Maintenance dose: 0.5 mL per 28 days
- 150 mg every 4 weeks
 1. In Darwin: Add PA, OQL, number of claims authorized 1, max quantity dispensed 4 with a duration of 3 weeks.

2. In PA Hub: Add OUP, DS, Max Days Supply 56. Start date of this authorization is one-day after loading dose ends.
 - QL FOR LETTER: Loading dose: 4 mL per 28 days;
Maintenance dose: 2 mL per 56 days
- 300 mg every 4 weeks
 1. In PA Hub: Add PA, OQL, number of claims authorized 1, max quantity dispensed 8 with a duration of one-month.
 - QL FOR LETTER: Loading dose: 8 mL per 28 days;
Maintenance dose: 2 mL per 28 days

RE-AUTHORIZATION CRITERIA: Cosentyx is configured as a prior authorization for new starts only. Cosentyx will no longer be covered if it is identified that the member is not receiving appropriate follow-up care from the prescribing specialist or if the member has greater than or equal to a 90 day break in therapy.

- Medical record documentation that the member is receiving appropriate follow-up care from the prescribing specialist

FORMULARY ALTERNATIVES:

methotrexate, celecoxib, choline magnesium salicylate, diclofenac, diclofenac extended release, diflunisal, etodolac, etodolac extended release, fenoprofen, flurbiprofen, ibuprofen, indomethacin, indomethacin sustained release, ketoprofen, ketorolac, meclofenamate, meloxicam, nabumetone, naproxen, naproxen sodium, naproxen EC, oxaprozin, piroxicam, salsalate, sulindac, tolmetin

For Ankylosing Spondylitis

An exception for coverage of Cosentyx may be made for members who meet the following criteria:

- Medical record documentation of a diagnosis of ankylosing spondylitis **AND**
- Medical record documentation that Cosentyx is prescribed by a rheumatologist **AND**
- Medical record documentation of age greater than or equal to 18 years **AND**
- Medical record documentation of therapeutic failure on, intolerance to, or contraindication to an adequate trial of at least two (2) formulary nonsteroidal anti-inflammatory drugs (NSAIDs) **OR** medical record documentation of therapeutic failure on or intolerance to prior biologic therapy
- Medical record documentation that Cosentyx is not being used concurrently with a tumor necrosis factor (TNF) blocker or other biologic agent **AND**
- Medical record documentation that the medication is being dose as 150 mg every 4 weeks with or without a loading dose of 150 mg at Weeks 0, 1, 2, 3, and 4

MEDISPAN AUTHORIZATION LEVEL: GPI-10

QUANTITY LIMIT

- 150 mg every 4 weeks
 1. In Darwin: Add PA, OQL, number of claims authorized 1, max quantity dispensed 4 with a duration of 3 weeks.
 2. In PA Hub: Add OUP, DS, Max Days Supply 56. Start date of this authorization is one-day after loading dose ends.
 - QL FOR LETTER: Loading dose: 4 mL per 28 days;
Maintenance dose: 2 mL per 56 days
- 300 mg every 4 weeks
 1. In PA Hub: Add PA, OQL, number of claims authorized 1, max quantity dispensed 8 with a duration of one-month.
 - QL FOR LETTER: Loading dose: 8 mL per 28 days;
Maintenance dose: 2 mL per 28 days

RE-AUTHORIZATION CRITERIA: Cosentyx is configured as a prior authorization for new starts only. Cosentyx will no longer be covered if it is identified that the member is not receiving appropriate follow-up care from the prescribing specialist or if the member has greater than or equal to a 90 day break in therapy.

- Medical record documentation that the member is receiving appropriate follow-up care from the prescribing specialist



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 379.0

**SECTION: Commercial Drug
SUBJECT: Cosentyx**

FORMULARY ALTERNATIVES:

choline magnesium salicylate, diclofenac, diclofenac extended release, diflunisal, etodolac, etodolac extended release, fenoprofen, flurbiprofen, ibuprofen, indomethacin, indomethacin sustained release, ketoprofen, ketorolac, meclufenamate, meloxicam, nabumetone, naproxen, naproxen sodium, naproxen EC, oxaprozin, piroxicam, salsalate, sulindac, tolmetin

For Non-radiographic Axial Spondylarthritis (nr-axSpA):

An exception for coverage of Cosentyx may be made for members who meet the following criteria:

- Medical record documentation of a diagnosis of non-radiographic axial spondylarthritis **AND**
- Medical record documentation of age greater than or equal to 18 years **AND**
- Medical record documentation that Cosentyx is prescribed by a rheumatologist **AND**
- Medical record documentation of at least one of the following:
 - C-reactive protein (CRP) level above the upper limit of normal (10 mg/dL) OR
 - Sacroiliitis on magnetic resonance imaging (MRI)

AND

- Medical record documentation of therapeutic failure on, intolerance to, or contraindication to at least two (2) nonsteroidal anti-inflammatory drugs (NSAIDs) **AND**
- Medical record documentation that Cosentyx is not being used concurrently with a tumor necrosis factor (TNF) blocker or other biologic agent **AND**
- Medical record documentation that the medication is being dosed as 150 mg every 4 weeks with or without a loading dose of 150 mg at Weeks 0, 1, 2, 3, and 4

MEDISPAN AUTHORIZATION LEVEL: GPI-10

QUANTITY LIMIT

- 150 mg every 4 weeks
 1. In Darwin: Add PA, OQL, number of claims authorized 1, max quantity dispensed 4 with a duration of 3 weeks.
 2. In PA Hub: Add OUP, DS, Max Days Supply 56. Start date of this authorization is one-day after loading dose ends.
 - QL FOR LETTER: Loading dose: 4 mL per 28 days; Maintenance dose: 2 mL per 56 days

RE-AUTHORIZATION CRITERIA: Cosentyx is configured as a prior authorization for new starts only. Cosentyx will no longer be covered if it is identified that the member is not receiving appropriate follow-up care from the prescribing specialist or if the member has greater than or equal to a 90 day break in therapy.

- Medical record documentation that the member is receiving appropriate follow-up care from the prescribing specialist



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 379.0

**SECTION: Commercial Drug
SUBJECT: Cosentyx**

FORMULARY ALTERNATIVES:

choline magnesium salicylate, diclofenac, diclofenac extended release, diflunisal, etodolac, etodolac extended release, fenoprofen, flurbiprofen, ibuprofen, indomethacin, indomethacin sustained release, ketoprofen, ketorolac, meclufenamate, meloxicam, nabumetone, naproxen, naproxen sodium, naproxen EC, oxaprozin, piroxicam, salsalate, sulindac, tolmetin

For Enthesitis-Related Arthritis

An exception for coverage of Cosentyx may be made for members who meet the following criteria:

- Medical record documentation of a diagnosis of enthesitis-related arthritis **AND**
- Medical record documentation that Cosentyx is prescribed by a rheumatologist **AND**
- Medical record documentation of age greater than or equal to 4 years **AND**
- Medical record documentation of therapeutic failure on, intolerance to, or contraindication to an adequate trial of at least two (2) formulary nonsteroidal anti-inflammatory drugs (NSAIDs) **AND**
- Medical record documentation that Cosentyx is not being used concurrently with a tumor necrosis factor (TNF) blocker or other biologic agent **AND**
- Medical record documentation that the prescribed dosing is appropriate for patient's weight

NOTE:

For pediatric patients weighing ≥ 15 kg and < 50 kg: Inject 75 mg subcutaneously at weeks 0, 1, 2, 3, and 4 and every 4 weeks thereafter

For pediatric patients weighing ≥ 50 kg: Inject 150mg subcutaneously at weeks 0, 1, 2, 3, and 4 and every 4 weeks thereafter

MEDISPAN AUTHORIZATION LEVEL: GPI-10

QUANTITY LIMIT

- 75 mg every 4 weeks
 1. In Darwin: Add PA, OQL, number of claims authorization 1, max quantity dispensed 2 with a duration of one month.
 - QL FOR LETTER: Loading dose: 2 mL per 28 days;
Maintenance dose: 0.5 mL per 28 days
- 150 mg every 4 weeks
 1. In Darwin: Add PA, OQL, number of claims authorized 1, max quantity dispensed 4 with a duration of 3 weeks.
 2. In PA Hub: Add OUP, DS, Max Days Supply 56. Start date of this authorization is one-day after loading dose ends.
 - QL FOR LETTER: Loading dose: 4 mL per 28 days;
Maintenance dose: 2 mL per 56 days

RE-AUTHORIZATION CRITERIA: Cosentyx is configured as a prior authorization for new starts only. Cosentyx will no longer be covered if it is identified that the member is not receiving appropriate follow-up care from the prescribing specialist or if the member has greater than or equal to a 90 day break in therapy.

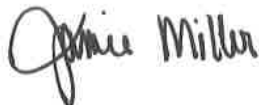
- Medical record documentation that the member is receiving appropriate follow-up care from the prescribing specialist

If an exception is made, Cosentyx will be paid for under the member's prescription drug benefit.

Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE
STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND
FEDERAL REGULATORY ENTITIES.**

**THIS POLICY WILL BE REVISED AS NECESSARY AND
REVIEWED NO LESS THAN ANNUALLY.**



Signed: _____

Title: Director, Pharmacy Services

Date: June 7, 2022

Devised: 7/22/15
Revised: 3/1/16 – annual review
Revised: 5/1/16 – updated format, logo, & procedure
Revised: 7/22/16 – added psoriatic arthritis and ankylosing spondylitis indications
Revised: 3/1/17 – annual review, removed Unicode characters, corrected typo in RA auth durat.
Revised: 3/24/17 – annual review, corrected RA criteria to PsO
Revised: 8/8/17 – updated induction QL's for all indications
Revised: 3/1/18 – annual review, updated signature, added grandfather language, updated age & prescriber criteria
Revised: 5/30/18 – added combination with other biologic agents, updated therapeutic failures, updated FA
Revised: 3/1/19 – annual review, defined abbr.
Revised: 6/4/19 – updated QL and added authorization parameters
Revised: 10/12/20 – added non-radiographic axial spondylarthritis



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 379.0

**SECTION: Commercial Drug
SUBJECT: Cosentyx**

Revised: 3/1/21 – annual review, updated logo, added MediSpan approval level, updated QL statement
Revised: 11/22/21 – updated approval level from NDC to GPI-10, updated/corrected QL language, removed
auth duration, added reauth criteria, updated age to 6 for PsO, added QL for 75 mg for PsO
Revised: 3/1/22 – annual review, updated referenced policies & covered LOBs, updated how QL's are entered
Revised: 6/7/22 – added Enthesitis-related arthritis ind., updated age, note, & QL for PsA



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 380.0

**SECTION: Commercial Drug
SUBJECT: Rytary**

Applicable line of business:

Commercial	X	Medicaid	
Medicare		ACA	X
GHP Kids	X	Self-Insured	X

POLICY:

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for Rytary for GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 487.0 Quantity Limit Exceptions

REQUIRED DEFINITIONS:

1. **Attachment** – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. **Exhibit** – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. **Devised** – the date the policy was implemented.
4. **Revised** – the date of every revision to the policy, including typographical and grammatical changes.
5. **Reviewed** – the date documenting the annual review if the policy has no revisions necessary.

ADDITIONAL DEFINITIONS:

1. **Formulary** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. **Non-formulary products** – those medications that are not included in the Formulary.
3. **Healthcare provider** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
4. **NCQA** – National Committee for Quality Assurance.
5. **Medically Necessary or Medical Necessity** – covered services rendered by a provider that the Health Plan determines are:



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 380.0

**SECTION: Commercial Drug
SUBJECT: Rytary**

- A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
- B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
- C. In accordance with current standards of medical practice;
- D. Not primarily for the convenience of the Member, or the Member's Provider; and
- E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

PROCEDURE:

An exception for coverage of Rytary may be made for members who meet the following criteria:

- Medical record documentation of a diagnosis of Parkinson's disease, post-encephalitis parkinsonism, **OR** parkinsonism which may follow carbon monoxide intoxication or manganese intoxication **AND**
- Medical record documentation of therapeutic failure on, intolerance to, or contraindication to three (3) formulary alternatives, one of which must be immediate release carbidopa/levodopa

MEDISPAN AUTHORIZATION LEVEL: GPI-12

If an exception is made, Rytary will be paid for under the member's prescription drug benefit.

Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.

FORMULARY ALTERNATIVES:

carbidopa/levodopa ODT, carbidopa/levodopa tablet, carbidopa/levodopa ER tablet, carbidopa/levodopa/entacapone, pramipexole, ropinirole, ropinirole ER, bromocriptine, selegiline, amantadine, benztropine, trihexyphenidyl, rasagiline

Geisinger

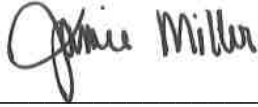
**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 380.0

**SECTION: Commercial Drug
SUBJECT: Rytary**

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE
STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND
FEDERAL REGULATORY ENTITIES.**

**THIS POLICY WILL BE REVISED AS NECESSARY AND
REVIEWED NO LESS THAN ANNUALLY.**



Signed: _____

Title: Director, Pharmacy Services

Date: March 1, 2022

Devised: 7/22/15
Revised: 3/1/16 – annual review
Revised: 5/1/16 – updated format, logo, & procedure
Reviewed: 3/1/17 – annual review
Revised: 3/1/18 – annual review, updated signature
Reviewed: 3/1/19 – annual review
Revised: 3/1/20 – annual review, added GHP Kids
Revised: 3/1/21 – annual review, updated logo, added MediSpan approval level
Revised: 3/1/22 – annual review, updated referenced policies & covered LOBs, updated FA



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 381.0

**SECTION: Commercial Drug
SUBJECT: Namzaric**

Applicable line of business:

Commercial	X	Medicaid	
Medicare		ACA	X
GHP Kids	X	Self-Insured	X

POLICY:

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for Namzaric for GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 487.0 Quantity Limit Exceptions

REQUIRED DEFINITIONS:

1. **Attachment** – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. **Exhibit** – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. **Devised** – the date the policy was implemented.
4. **Revised** – the date of every revision to the policy, including typographical and grammatical changes.
5. **Reviewed** – the date documenting the annual review if the policy has no revisions necessary.

ADDITIONAL DEFINITIONS:

1. **Formulary** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. **Non-formulary products** – those medications that are not included in the Formulary.
3. **Healthcare provider** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
4. **NCQA** – National Committee for Quality Assurance.
5. **Medically Necessary or Medical Necessity** – covered services rendered by a provider that the Health Plan determines are:



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 381.0

**SECTION: Commercial Drug
SUBJECT: Namzaric**

- A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
- B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
- C. In accordance with current standards of medical practice;
- D. Not primarily for the convenience of the Member, or the Member's Provider; and
- E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

PROCEDURE:

An exception for coverage of Namzaric may be made for members who meet the following criteria:

- Medical record documentation of a diagnosis of moderate to severe Alzheimer's dementia **AND**
- Medical record documentation of age greater than or equal to 18 years **AND**
- Medical record documentation of an intolerance to, contraindication to, or therapeutic failure on memantine **AND** donepezil used in combination

MEDISPAN AUTHORIZATION LEVEL: GPI-10

QUANTITY LIMIT: *No QLs need to be entered within the authorization unless the requested quantity exceeds the QL.*

- **QL FOR LETTER ONLY:** 1 tablet per day

If an exception is made, Namzaric will be paid for under the member's prescription drug benefit.

Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.

FORMULARY ALTERNATIVES:

memantine, donepezil, galantamine, rivastigmine

Geisinger

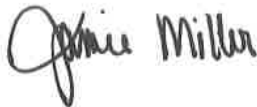
**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 381.0

**SECTION: Commercial Drug
SUBJECT: Namzaric**

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE
STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND
FEDERAL REGULATORY ENTITIES.**

**THIS POLICY WILL BE REVISED AS NECESSARY AND
REVIEWED NO LESS THAN ANNUALLY.**



Signed: _____

Title: Director, Pharmacy Services

Date: March 1, 2022

Devised: 7/22/15
Revised: 3/1/16 – annual review
Revised: 5/1/16 – updated format, logo, & procedure
Reviewed: 3/1/17 – annual review
Revised: 3/1/18 – annual review, updated signature, updated age criteria
Revised: 3/1/19 – annual review, added QL approval note
Revised: 3/1/20 – annual review, added GHP Kids
Revised: 3/1/21 – annual review, updated logo, added MediSpan approval level, updated QL statement
Revised: 3/1/22 – annual review, updated referenced policies & covered LOBs



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 382.0

**SECTION: Commercial Drug
SUBJECT: Corlanor**

Applicable line of business:

Commercial	X	Medicaid	
Medicare		ACA	X
GHP Kids	X	Self-Insured	X

POLICY:

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for Corlanor for GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 487.0 Quantity Limit Exceptions

REQUIRED DEFINITIONS:

1. **Attachment** – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. **Exhibit** – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. **Devised** – the date the policy was implemented.
4. **Revised** – the date of every revision to the policy, including typographical and grammatical changes.
5. **Reviewed** – the date documenting the annual review if the policy has no revisions necessary.

ADDITIONAL DEFINITIONS:

1. **Formulary** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. **Non-formulary products** – those medications that are not included in the Formulary.
3. **Healthcare provider** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
4. **NCQA** – National Committee for Quality Assurance.
5. **Medically Necessary or Medical Necessity** – covered services rendered by a provider that the Health Plan determines are:

- A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
- B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
- C. In accordance with current standards of medical practice;
- D. Not primarily for the convenience of the Member, or the Member's Provider; and
- E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

PROCEDURE:

An exception for coverage of Corlanor may be made for members who meet the following criteria:

- Medical record documentation that Corlanor is prescribed by a cardiologist **AND**
- Medical record documentation of being in sinus rhythm with resting heart rate greater than or equal to the lower limit of the normal range based on age* **AND**
- Medical record documentation of therapeutic failure on, intolerance to, or contraindication to the maximum tolerated dose of 2 formulary beta-blockers, one of which must be carvedilol **AND**
- Medical record documentation of one of the following:
 - Medical record documentation of age greater than or equal to 18 years **AND**
 - Medical record documentation of stable, symptomatic heart failure with a left ventricular ejection fraction less than or equal to 35% **AND**
 - Medical record documentation of hospitalization for worsening heart failure within the previous 12 months

OR

- Medical record documentation of age greater than or equal to 6 months and less than 18 years **AND**
 - Medical record documentation of stable, symptomatic heart failure due to dilated cardiomyopathy **AND**
 - Medical record documentation of class II to IV heart failure according to New York Heart Association [NYHA] functional class or Ross classification **AND**
 - Medical record documentation of a left ventricular ejection fraction less than or equal to 45%

AND

- If the request is for Corlanor Solution: Documentation of one of the following:
 - Medical record documentation of member weight less than 40 kg **OR**

- Medical record documentation of therapeutic failure on, intolerance to, or contraindication to Corlanor tablets **OR**
- Medical record documentation that member has dysphagia or is unable to swallow tablets

MEDISPAN AUTHORIZATION LEVEL: GPI-12

QUANTITY LIMIT: *No QLs need to be entered within the authorization unless the requested quantity exceeds the QL.*

- **QL FOR LETTER ONLY:**
 - Tablets: 2 tablets per day
 - Solution: 20 mL per day

***NOTE: Lower limit of normal heart rate based on age**

- Age 6 - 12 months: HR ≥ 105 bpm
- Age 1 - 3 years: HR ≥ 95 bpm
- Age 3 - 5 years: HR ≥ 75 bpm
- Age 5 and older: HR ≥ 70 bpm

If an exception is made, Corlanor will be paid for under the member's prescription drug benefit.

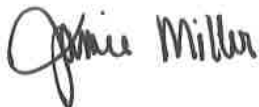
Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.

FORMULARY ALTERNATIVES:

carvedilol, metoprolol succinate, bisoprolol

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE
STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND
FEDERAL REGULATORY ENTITIES.**

**THIS POLICY WILL BE REVISED AS NECESSARY AND
REVIEWED NO LESS THAN ANNUALLY.**



Signed: _____



POLICY NUMBER: 382.0

**POLICY AND PROCEDURE
PHARMACY
MANUAL**

**SECTION: Commercial Drug
SUBJECT: Corlanor**

Title: Director, Pharmacy Services

Date: March 1, 2022

Devised: 7/22/15
Revised: 3/1/16 – annual review
Revised: 5/1/16 – updated format, logo, & procedure
Revised: 3/1/17 – annual review, removed Unicode characters
Revised: 3/1/18 – annual review, updated signature, updated prescriber criteria
Revised: 3/1/19 – annual review, added QL approval note
Revised: 3/1/20 – annual review, added GHP Kids
Revised: 10/12/20 – updated HR criteria to be based on age, added criteria for 6 months-18 years, added criteria for solution, added QL for solution, added HR table
Revised: 3/1/21 – annual review, updated logo, added MediSpan approval level, updated QL statement
Revised: 3/1/22 – annual review, updated referenced policies & covered LOBs



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 383.0

**SECTION: Commercial Drug
SUBJECT: Natpara**

Applicable line of business:

Commercial	X	Medicaid	
Medicare		ACA	X
GHP Kids	X	Self-Insured	X

POLICY:

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for Natpara for GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 487.0 Quantity Limit Exceptions

REQUIRED DEFINITIONS:

1. **Attachment** – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. **Exhibit** – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. **Devised** – the date the policy was implemented.
4. **Revised** – the date of every revision to the policy, including typographical and grammatical changes.
5. **Reviewed** – the date documenting the annual review if the policy has no revisions necessary.

ADDITIONAL DEFINITIONS:

1. **Formulary** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. **Non-formulary products** – those medications that are not included in the Formulary.
3. **Healthcare provider** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
4. **NCQA** – National Committee for Quality Assurance.
5. **Medically Necessary or Medical Necessity** – covered services rendered by a provider that the Health Plan determines are:



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 383.0

**SECTION: Commercial Drug
SUBJECT: Natpara**

- A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
- B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
- C. In accordance with current standards of medical practice;
- D. Not primarily for the convenience of the Member, or the Member's Provider; and
- E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

PROCEDURE:

An exception for coverage of Natpara may be made for members who meet the following criteria:

- Medical record documentation of a diagnosis of hypocalcemia secondary to hypoparathyroidism **AND**
- Medical record documentation that Natpara is prescribed by an endocrinologist **AND**
- Medical record documentation of no increased baseline risk for osteosarcoma **AND**
- Medical record documentation that previous treatment with calcium supplements and active forms of vitamin D were not successful in treated hypocalcemia **AND**
- Medical record documentation that Natpara will be used concurrently with a calcium supplement

MEDISPAN AUTHORIZATION LEVEL: GPI-12

QUANTITY LIMIT: *No QLs need to be entered within the authorization unless the requested quantity exceeds the QL.*

- **QL FOR LETTER ONLY:** 2 cartridges (1 pack) per 28 days

AUTHORIZATION DURATION: Authorization duration will be for a period of 6 months. Reauthorization will require the following criterion be met:

- Medical record documentation that the lowest dose of Natpara is being used to achieve a total serum calcium (albumin-corrected) within the lower half of the normal total serum calcium range (approximately 8.0 to 9.0 mg/dL)

If an exception is made, Natpara will be paid for under the member's prescription drug benefit.



POLICY NUMBER: 383.0

**POLICY AND PROCEDURE
PHARMACY
MANUAL**

**SECTION: Commercial Drug
SUBJECT: Natpara**

Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.

FORMULARY ALTERNATIVES:

none

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE
STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND
FEDERAL REGULATORY ENTITIES.**

**THIS POLICY WILL BE REVISED AS NECESSARY AND
REVIEWED NO LESS THAN ANNUALLY.**

Signed: _____

Title: Director, Pharmacy Services

Date: March 1, 2022

Devised: 7/22/15
Revised: 3/1/16 – annual review
Revised: 5/1/16 – updated format, logo, & procedure
Revised: 3/1/17 – annual review, corrected typo
Revised: 3/1/18 – annual review, updated signature, updated prescriber criteria
Revised: 3/1/19 – annual review, added QL approval note
Revised: 3/1/20 – annual review, added GHP Kids
Revised: 3/1/21 – annual review, updated logo, added MediSpan approval level, updated QL statement
Revised: 3/1/22 – annual review, updated referenced policies & covered LOBs



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 384.0

**SECTION: Commercial Drug
SUBJECT: Vyvanse**

Applicable line of business:

Commercial	X	Medicaid	
Medicare		ACA	X
GHP Kids	X	Self-Insured	X

POLICY:

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for Vyvanse for GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 487.0 Quantity Limit Exceptions

REQUIRED DEFINITIONS:

1. **Attachment** – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. **Exhibit** – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. **Devised** – the date the policy was implemented.
4. **Revised** – the date of every revision to the policy, including typographical and grammatical changes.
5. **Reviewed** – the date documenting the annual review if the policy has no revisions necessary.

ADDITIONAL DEFINITIONS:

1. **Formulary** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. **Non-formulary products** – those medications that are not included in the Formulary.
3. **Healthcare provider** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
4. **NCQA** – National Committee for Quality Assurance.
5. **Medically Necessary or Medical Necessity** – covered services rendered by a provider that the Health Plan determines are:



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 384.0

**SECTION: Commercial Drug
SUBJECT: Vyvanse**

- A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
- B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
- C. In accordance with current standards of medical practice;
- D. Not primarily for the convenience of the Member, or the Member's Provider; and
- E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

PROCEDURE:

New members to the plan already established on therapy may be eligible for continuity of care coverage as long as there is medical record documentation that the safety and effectiveness of use for the prescribed indication is supported by Food and Drug Administration (FDA) approval or adequate medical and scientific evidence in the medical literature.

An exception for coverage of Vyvanse may be made for members who meet the following criteria:

ADHD

- Medical record documentation of a diagnosis of attention deficit disorder (ADD) or attention deficit hyperactivity disorder (ADHD) **AND**
- Medical record documentation of therapeutic failure on, intolerance to, or contraindication to Metadate CD^Ω **AND** amphetamine/dextroamphetamine SR combination

^Ω = **From the Metadate CD package insert, "Metadate CD may be swallowed whole with the aid of liquids, or alternately, the capsule may be opened and the capsule contents sprinkled onto a small amount (tablespoon) of applesauce and given immediately, and not stored for future use. Drinking some fluids e.g., water, should follow the intake of the sprinkles with applesauce. The capsules and the capsule contents must not be crushed or chewed."**

MEDISPAN AUTHORIZATION LEVEL: GPI-10

QUANTITY LIMIT: *No QLs need to be entered within the authorization unless the requested quantity exceeds the QL.*

- **QL FOR LETTER ONLY:** 1 capsule or chewable tablet per day



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 384.0

**SECTION: Commercial Drug
SUBJECT: Vyvanse**

Binge Eating Disorder

- Medical record documentation of binge eating disorder made by a licensed mental health provider with the number of binge eating episodes per week documented **AND**
- Medical record documentation that member is a non-responder to psychotherapy **OR** member is receiving concurrent psychotherapy

AUTHORIZATION DURATION: Authorization will be for a period of six (6) months. Reauthorization will require documentation showing a lower number of binge eating episodes per week compared to baseline.

MEDISPAN AUTHORIZATION LEVEL: GPI-10

QUANTITY LIMIT: *No QLs need to be entered within the authorization unless the requested quantity exceeds the QL.*

- **QL FOR LETTER ONLY:** 1 capsule or chewable tablet per day

If an exception is made, Vyvanse will be paid for under the member's prescription drug benefit.

Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.

FORMULARY ALTERNATIVES:

ADHD

dextroamphetamine, dextroamphetamine/amphetamine combination, dextroamphetamine/amphetamine SR combination, methylphenidate, methylphenidate sustained-release, methylphenidate extended-release, Metadate CD

Binge Eating Disorder

none

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE
STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND
FEDERAL REGULATORY ENTITIES.**

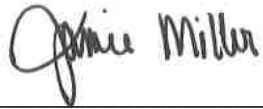
**THIS POLICY WILL BE REVISED AS NECESSARY AND
REVIEWED NO LESS THAN ANNUALLY.**

Geisinger

**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 384.0

**SECTION: Commercial Drug
SUBJECT: Vyvanse**



Signed: _____

Title: Director, Pharmacy Services

Date: March 1, 2022

Devised: 7/22/15 – devised new policy utilizing ADHD criteria from policy 94.0. See policy 94.0 for previous policy updates. Binge eating disorder added.
Reviewed: 3/1/16 – annual review
Revised: 5/1/16 – updated format, logo, & procedure
Reviewed: 3/1/17 – annual review
Revised: 3/1/18 – annual review, updated signature, updated format of headers & ADHD criteria, added grandfather language
Reviewed: 3/1/19 – annual review
Revised: 11/20/19 – added QL
Revised: 3/1/20 – annual review, added GHP Kids
Revised: 3/1/21 – annual review, updated logo, added MediSpan approval level, updated QL statement
Revised: 3/1/22 – annual review, updated referenced policies & covered LOBs



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 385.0

**SECTION: Commercial Drug
SUBJECT: Zubsolv**

Applicable line of business:

Commercial	X	Medicaid	
Medicare		ACA	X
GHP Kids	X	Self-Insured	X

POLICY:

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for Zubsolv for GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 487.0 Quantity Limit Exceptions

REQUIRED DEFINITIONS:

1. **Attachment** – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. **Exhibit** – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
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5. **Reviewed** – the date documenting the annual review if the policy has no revisions necessary.

ADDITIONAL DEFINITIONS:

1. **Formulary** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. **Non-formulary products** – those medications that are not included in the Formulary.
3. **Healthcare provider** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
4. **NCQA** – National Committee for Quality Assurance.
5. **Medically Necessary or Medical Necessity** – covered services rendered by a provider that the Health Plan determines are:



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 385.0

**SECTION: Commercial Drug
SUBJECT: Zubsolv**

- A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
- B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
- C. In accordance with current standards of medical practice;
- D. Not primarily for the convenience of the Member, or the Member's Provider; and
- E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

PROCEDURE:

A formulary exception for coverage of Zubsolv may be made for members who meet the following criteria:

- Must be prescribed for the treatment of opioid dependence and the prescriber must have a unique identification number issued by the Drug Enforcement Agency (DEA) certifying prescribing authority for buprenorphine agents **AND**
- Member must be initially referred to and actively involved in formal counseling with a licensed behavioral health provider. Must provide the name of counselor and/or facility or rationale for non-participation **AND**
- For re-authorization member must be adherent to Zubsolv therapy and must not be using opiates. Must be verified by lab screen (dated within 28 days of request date) for opiates and buprenorphine. The presence of controlled substances other than buprenorphine must be addressed **AND**
- Behavioral health vendor and/or plan case managers may contact prescriber, member, or counselor/facility to ensure compliance with these requirements. Continued approval for the drug is dependent on cooperation with this effort **AND**
- Medical record documentation of rationale for why the member cannot use buprenorphine/naloxone SL tablets **AND** buprenorphine/naloxone SL films

AUTHORIZATION DURATION: If approved, initial authorization duration will be 3 months. If approved, subsequent authorization duration will be 12 months.

MEDISPAN AUTHORIZATION LEVEL: GPI-12

QUANTITY LIMIT: *No QLs need to be entered within the authorization unless the requested quantity exceeds the QL.*

- **QL FOR LETTER ONLY:** 34 day supply per fill



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 385.0

**SECTION: Commercial Drug
SUBJECT: Zubsolv**

If a formulary exception is approved Zubsolv will be paid for under the member's prescription drug benefit.

Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.

FORMULARY ALTERNATIVES:

buprenorphine/naloxone sublingual tablets, buprenorphine/naloxone sublingual films

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE
STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND
FEDERAL REGULATORY ENTITIES.**

**THIS POLICY WILL BE REVISED AS NECESSARY AND
REVIEWED NO LESS THAN ANNUALLY.**

Signed: _____

Title: Director, Pharmacy Services

Date: March 1, 2022

- Devised: 7/22/15
- Reviewed: 3/1/16 – annual review
- Revised: 5/1/16 – updated format, logo, & procedure, updated approval statement to Zubsolv
- Revised: 5/27/16 – removed dose reduction requirement
- Revised: 7/27/16 – extended renewal authorization to 12 months
- Revised: 3/1/17 – annual review, defined abbreviations
- Revised: 3/1/18 – annual review, updated signature, removed QL indicator
- Revised: 3/1/19 – annual review, removed PA indicator from FA
- Revised: 3/1/20 – annual review, added GHP Kids
- Revised: 3/1/21 – annual review, updated logo, added MediSpan approval level, updated QL statement, updated FA
- Revised: 6/8/21 – removed in network, criteria, removed, buprenorphine/naloxone criteria, updated re-auth bullet, updated FA bullet, updated FA
- Revised: 3/1/22 – annual review, updated referenced policies & covered LOBs



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 386.0

**SECTION: Commercial Drug
SUBJECT: Cresemba Capsules**

Applicable line of business:

Commercial	X	Medicaid	
Medicare		ACA	X
GHP Kids	X	Self-Insured	X

POLICY:

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for Cresemba capsules for GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 487.0 Quantity Limit Exceptions

REQUIRED DEFINITIONS:

1. **Attachment** – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. **Exhibit** – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. **Devised** – the date the policy was implemented.
4. **Revised** – the date of every revision to the policy, including typographical and grammatical changes.
5. **Reviewed** – the date documenting the annual review if the policy has no revisions necessary.

ADDITIONAL DEFINITIONS:

1. **Formulary** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. **Non-formulary products** – those medications that are not included in the Formulary.
3. **Healthcare provider** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
4. **NCQA** – National Committee for Quality Assurance.
5. **Medically Necessary or Medical Necessity** – covered services rendered by a provider that the Health Plan determines are:



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 386.0

**SECTION: Commercial Drug
SUBJECT: Cresemba Capsules**

- A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
- B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
- C. In accordance with current standards of medical practice;
- D. Not primarily for the convenience of the Member, or the Member's Provider; and
- E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

PROCEDURE:

A formulary exception for coverage of Cresemba capsules may be made for members who meet the following criteria:

Treatment of Aspergillosis and Mucormycosis

- Medical record documentation of age greater than or equal to 18 years **AND**
- Medical record documentation that Cresemba is being used for the treatment of invasive aspergillosis **OR** for the treatment of invasive mucormycosis

Prophylaxis of Aspergillosis and Candida

- Medical record documentation of age greater than or equal to 18 years **AND**
- Medical record documentation that Cresemba is prescribed by an oncologist, hematologist, infectious disease specialist, or transplant service provider **AND**
- Medical record documentation of use for prophylaxis of invasive Aspergillus or Candida infections in patients at high risk of developing these infections due to being severely immunocompromised **AND**
- Medical record documentation that member requires treatment with an anti-cancer medication that interacts with posaconazole

AUTHORIZATION DURATION: 3 months. Reauthorization will be based on the following criteria:

- Medical record documentation of a culture and sensitivity showing the isolates are susceptible to Cresemba **AND**
- Medical record documentation that the appropriate dose is being prescribed (2 capsules per day)

MEDISPAN AUTHORIZATION LEVEL: GPI-12



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 386.0

**SECTION: Commercial Drug
SUBJECT: Cresemba Capsules**

QUANTITY LIMIT: *No QLs need to be entered within the authorization unless the requested quantity exceeds the QL.*

- **QL FOR LETTER ONLY:** 2 capsules per day

If a formulary exception is approved Cresemba capsules will be paid for under the member's prescription drug benefit.

Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.

FORMULARY ALTERNATIVES:

itraconazole*, voriconazole suspension, voriconazole tablets*#

*prior authorization required, #quantity limits apply

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE
STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND
FEDERAL REGULATORY ENTITIES.**

**THIS POLICY WILL BE REVISED AS NECESSARY AND
REVIEWED NO LESS THAN ANNUALLY.**

Signed: _____

Title: Director, Pharmacy Services

Date: March 1, 2022

Devised: 9/19/15
Revised: 12/7/15 – updated QL to read 2 capsules per day only
Revised: 3/1/16 – annual review, corrected typo in first bullet
Revised: 5/1/16 – updated format, logo, & procedure
Reviewed: 3/1/17 – annual review
Revised: 3/1/18 – annual review, updated signature, updated age criteria, removed QL indicator
Revised: 3/1/19 – annual review, added QL approval note
Revised: 3/1/21 – annual review, updated logo, added MediSpan approval level, updated QL statement
Revised: 8/24/21 – added prophylaxis of aspergillosis and Candida indication



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 386.0

**SECTION: Commercial Drug
SUBJECT: Cresemba Capsules**

Revised: 3/1/22 – annual review, updated referenced policies & covered LOBs



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 387.0

**SECTION: Commercial Drug
SUBJECT: Cholbam**

Applicable line of business:

Commercial	X	Medicaid	
Medicare		ACA	X
GHP Kids	X	Self-Insured	X

POLICY:

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for Cholbam for GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 487.0 Quantity Limit Exceptions

REQUIRED DEFINITIONS:

1. **Attachment** – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. **Exhibit** – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. **Devised** – the date the policy was implemented.
4. **Revised** – the date of every revision to the policy, including typographical and grammatical changes.
5. **Reviewed** – the date documenting the annual review if the policy has no revisions necessary.

ADDITIONAL DEFINITIONS:

1. **Formulary** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. **Non-formulary products** – those medications that are not included in the Formulary.
3. **Healthcare provider** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
4. **NCQA** – National Committee for Quality Assurance.
5. **Medically Necessary or Medical Necessity** – covered services rendered by a provider that the Health Plan determines are:



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 387.0

**SECTION: Commercial Drug
SUBJECT: Cholbam**

- A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
- B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
- C. In accordance with current standards of medical practice;
- D. Not primarily for the convenience of the Member, or the Member's Provider; and
- E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

PROCEDURE:

A formulary exception for coverage of Cholbam may be made for members who meet the following criteria:

- Medical record documentation of one of the following:
 - Bile acid synthesis disorders due to single enzyme defects (SEDs) **OR**
 - Peroxisomal disorders (PDs) including Zellweger spectrum disorders in patients who exhibit manifestations of liver disease, steatorrhea, or complications from decreased fat soluble vitamin absorption **AND**
- Medical record documentation that diagnosis has been confirmed with an abnormal urinary bile acid by Fast Atom Bombardment ionization – Mass Spectrometry (FAB-MS) analysis **AND**
- Medical record documentation that Cholbam is prescribed by a gastroenterologist, hepatologist, or metabolic specialist with experience in the diagnosis and treatment of bile acid synthesis and peroxisomal disorders **AND**
- For the treatment of peroxisomal disorders: medical record documentation that Cholbam will be used as adjunctive therapy **AND**
- Medical record documentation of baseline alanine aminotransferase/aspartate aminotransferase (ALT/AST), total bilirubin, and body weight

AUTHORIZATION DURATION: Initial approval will be for 3 months or less if the reviewing provider feels it is medically appropriate. Subsequent approvals will be for an additional 12 months or less if the reviewing provider feels it is medically appropriate and will require medical record documentation of a response to therapy, defined as the following:

- Member must meet at least two of the following laboratory criteria **OR** one laboratory criterion and the clinical weight criterion
 - Laboratory Criteria:



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 387.0

**SECTION: Commercial Drug
SUBJECT: Cholbam**

- Alanine aminotransferase (ALT) or aspartate aminotransferase (AST) values reduced to less than 50 U/L, or baseline levels reduced by 80%
 - Total bilirubin values reduced to less than or equal to 1 mg/dL; and
 - No evidence of cholestasis on liver biopsy
- Clinical Criteria
- Body weight increased by 10% or stable at greater than the 50th percentile; and

MEDISPAN AUTHORIZATION LEVEL: GPI-12

If a formulary exception is approved Cholbam will be paid for under the member's prescription drug benefit.

Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.

FORMULARY ALTERNATIVES:

none

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE
STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND
FEDERAL REGULATORY ENTITIES.**

**THIS POLICY WILL BE REVISED AS NECESSARY AND
REVIEWED NO LESS THAN ANNUALLY.**

Signed: _____

Title: Director, Pharmacy Services

Date: March 1, 2022

Devised: 9/19/15
Reviewed: 3/1/16 – annual review
Revised: 5/1/16 – updated format, logo, & procedure
Reviewed: 3/1/17 – annual review
Revised: 3/1/18 – annual review, updated signature, updated prescriber criteria



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 387.0

**SECTION: Commercial Drug
SUBJECT: Cholbam**

Revised: 3/1/19 – annual review, defined abbr.
Revised: 3/1/20 – annual review, added GHP Kids
Revised: 3/1/21 – annual review, updated logo, added MediSpan approval level
Revised: 3/1/22 – annual review, updated referenced policies & covered LOBs



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 388.0

**SECTION: Commercial Drug
SUBJECT: Rexulti**

Applicable line of business:

Commercial	X	Medicaid	
Medicare		ACA	X
GHP Kids	X	Self-Insured	X

POLICY:

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for Rexulti for GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 487.0 Quantity Limit Exceptions

REQUIRED DEFINITIONS:

1. **Attachment** – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. **Exhibit** – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. **Devised** – the date the policy was implemented.
4. **Revised** – the date of every revision to the policy, including typographical and grammatical changes.
5. **Reviewed** – the date documenting the annual review if the policy has no revisions necessary.

ADDITIONAL DEFINITIONS:

1. **Formulary** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. **Non-formulary products** – those medications that are not included in the Formulary.
3. **Healthcare provider** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
4. **NCQA** – National Committee for Quality Assurance.
5. **Medically Necessary or Medical Necessity** – covered services rendered by a provider that the Health Plan determines are:

- A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
- B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
- C. In accordance with current standards of medical practice;
- D. Not primarily for the convenience of the Member, or the Member's Provider; and
- E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

PROCEDURE:

New members to the plan already established on therapy may be eligible for continuity of care coverage as long as there is medical record documentation that the safety and effectiveness of use for the prescribed indication is supported by Food and Drug Administration (FDA) approval or adequate medical and scientific evidence in the medical literature.

A formulary exception for coverage of Rexulti may be made for members who meet the following criteria:

Schizophrenia

- Medical record documentation of a diagnosis of schizophrenia **AND**
- Medical record documentation of age greater than or equal to 13 years **AND**
- Medical record documentation of a therapeutic failure on, intolerance to, or contraindication to three generic, formulary atypical antipsychotics

Major Depressive Disorder

- Medical record documentation of a diagnosis of major depressive disorder (MDD) **AND** medical record documentation that the patient is using Rexulti as adjunctive therapy **AND**
- Medical record documentation of age greater than or equal to 18 years **AND**
- Medical record documentation of therapeutic failure on, intolerance to, or contraindication to at least a 4 week trial of combination therapy with aripiprazole and an antidepressant **AND**
- One of the following:
 - Medical record documentation of therapeutic failure on, intolerance to, or contraindication to at least a 4 week trial of combination antidepressant therapy (such as a selective serotonin reuptake inhibitor [SSRI] and bupropion

- or a serotonin and norepinephrine reuptake inhibitor [SNRI] and bupropion)
OR
- Medical record documentation of therapeutic failure on, intolerance to, or contraindication to at least a 4 week trial of an antidepressant with augmentation therapy (including, but not limited to lithium, valproate, carbamazepine and lamotrigine)

MEDISPAN AUTHORIZATION LEVEL: GPI-12

QUANTITY LIMIT: *No QLs need to be entered within the authorization unless the requested quantity exceeds the QL.*

- QL FOR LETTER ONLY: 1 tablet per day

If a formulary exception is approved Rexulti will be paid for under the member's prescription drug benefit.

Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.

FORMULARY ALTERNATIVES:

Schizophrenia: aripiprazole, clozapine, olanzapine, quetiapine, risperidone, ziprasidone, Seroquel XR

MDD:

- Selective serotonin reuptake inhibitor (SSRI): citalopram, fluoxetine, paroxetine, sertraline, escitalopram
- Serotonin and norepinephrine reuptake inhibitor (SNRI): duloxetine, venlafaxine, desvenlafaxine
- Bupropion
- Tricyclic Antidepressants: amitriptyline, desipramine, doxepin, imipramine, nortriptyline
- Mirtazapine
- Augmentation Therapy: lithium, valproate, carbamazepine and lamotrigine



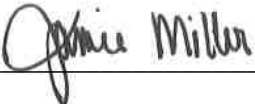
**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 388.0

**SECTION: Commercial Drug
SUBJECT: Rexulti**

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE
STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND
FEDERAL REGULATORY ENTITIES.**

**THIS POLICY WILL BE REVISED AS NECESSARY AND
REVIEWED NO LESS THAN ANNUALLY.**

Signed:  _____

Title: Director, Pharmacy Services

Date: April 6, 2022

Devised: 9/19/15
Revised: 3/1/16 – annual review, added OR to MDD criteria
Revised: 5/1/16 – updated format, logo, & procedure
Revised: 7/14/16 – updated bullet formatting for MDD alternatives
Revised: 3/1/17 – annual review, defined abbrev., removed Unicode characters, updated FA
Revised: 3/1/18 – annual review, updated signature, added grandfather language, updated age criteria, corrected typo
Revised: 3/1/19 – annual review, added QL approval note, removed note
Revised: 3/1/20 – annual review, added GHP Kids
Revised: 3/1/21 – annual review, updated logo, added MediSpan approval level, updated QL statement, updated FA
Revised: 3/1/22 – annual review, updated referenced policies & covered LOBs
Revised: 4/6/22 – split criteria by indication, updated age for schizophrenia to 13 years



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 390.0

**SECTION: Commercial Drug
SUBJECT: Afrezza**

Applicable line of business:

Commercial	X	Medicaid	
Medicare		ACA	X
GHP Kids	X	Self-Insured	X

POLICY:

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for Afrezza for GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 487.0 Quantity Limit Exceptions

REQUIRED DEFINITIONS:

1. **Attachment** – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. **Exhibit** – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. **Devised** – the date the policy was implemented.
4. **Revised** – the date of every revision to the policy, including typographical and grammatical changes.
5. **Reviewed** – the date documenting the annual review if the policy has no revisions necessary.

ADDITIONAL DEFINITIONS:

1. **Formulary** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. **Non-formulary products** – those medications that are not included in the Formulary.
3. **Healthcare provider** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
4. **NCQA** – National Committee for Quality Assurance.
5. **Medically Necessary or Medical Necessity** – covered services rendered by a provider that the Health Plan determines are:

- A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
- B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
- C. In accordance with current standards of medical practice;
- D. Not primarily for the convenience of the Member, or the Member's Provider; and
- E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

PROCEDURE:

A formulary exception for coverage of Afrezza may be made for members who meet the following criteria:

- Medical record documentation of a diagnosis of diabetes mellitus **AND**
- Medical record documentation that the patient does not have asthma or chronic obstructive pulmonary disease (COPD) **AND**
- Medical record documentation that the patient is 18 years of age or older **AND**
- Medical record documentation that the patient is unable to use subcutaneous insulin due to a clinically justifiable reason (i.e., patient is unable to hold/maneuver syringes/pens*) **AND**
- Medical record documentation of a therapeutic failure on, intolerance to, or contraindication to Novolog

***NOTE:** Fear of needles is not considered a clinically justifiable reason for not using subcutaneous insulin.

MEDISPAN AUTHORIZATION LEVEL: GPI-12

If a formulary exception is approved Afrezza will be paid for under the member's prescription drug benefit.

Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.

FORMULARY ALTERNATIVES:

Novolog, insulin aspart

Geisinger

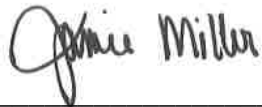
**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 390.0

**SECTION: Commercial Drug
SUBJECT: Afrezza**

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE
STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND
FEDERAL REGULATORY ENTITIES.**

**THIS POLICY WILL BE REVISED AS NECESSARY AND
REVIEWED NO LESS THAN ANNUALLY.**



Signed: _____

Title: Director, Pharmacy Services

Date: March 1, 2022

Devised: 9/19/15
Revised: 3/1/16 – annual review
Revised: 5/1/16 – updated format, logo, & procedure
Revised: 3/1/17 – annual review, defined abbreviations
Revised: 3/1/18 – annual review, updated signature
Reviewed: 3/1/19 – annual review
Revised: 3/1/20 – annual review, added GHP Kids
Revised: 3/1/21 – annual review, updated logo, added MediSpan approval level, updated FA
Revised: 3/1/22 – annual review, updated referenced policies & covered LOBs



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 391.0

**SECTION: Commercial Drug
SUBJECT: Toujeo**

Applicable line of business:

Commercial	X	Medicaid	
Medicare		ACA	X
GHP Kids	X	Self-Insured	X

POLICY:

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for Toujeo for GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 487.0 Quantity Limit Exceptions

REQUIRED DEFINITIONS:

1. **Attachment** – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. **Exhibit** – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. **Devised** – the date the policy was implemented.
4. **Revised** – the date of every revision to the policy, including typographical and grammatical changes.
5. **Reviewed** – the date documenting the annual review if the policy has no revisions necessary.

ADDITIONAL DEFINITIONS:

1. **Formulary** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. **Non-formulary products** – those medications that are not included in the Formulary.
3. **Healthcare provider** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
4. **NCQA** – National Committee for Quality Assurance.
5. **Medically Necessary or Medical Necessity** – covered services rendered by a provider that the Health Plan determines are:



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 391.0

**SECTION: Commercial Drug
SUBJECT: Toujeo**

- A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
- B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
- C. In accordance with current standards of medical practice;
- D. Not primarily for the convenience of the Member, or the Member's Provider; and
- E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

PROCEDURE:

A formulary exception for coverage of Toujeo may be made for members who meet the following criteria:

- Medical record documentation of peer-reviewed literature citing well-designed clinical trials to indicate that use of Toujeo has been shown to be safe and effective in patients under the age of 18 years

MEDISPAN AUTHORIZATION LEVEL: GPI-14 (must enter 2710400300D233 & 2710400300D236)

If a formulary exception is approved Toujeo will be paid for under the member's prescription drug benefit.

Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.

FORMULARY ALTERNATIVES:

Lantus, Tresiba, Levemir

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE
STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND
FEDERAL REGULATORY ENTITIES.**

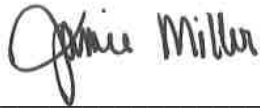
**THIS POLICY WILL BE REVISED AS NECESSARY AND
REVIEWED NO LESS THAN ANNUALLY.**

Geisinger

**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 391.0

**SECTION: Commercial Drug
SUBJECT: Toujeo**



Signed: _____

Title: Director, Pharmacy Services

Date: March 1, 2022

Devised: 9/22/15
Revised: 3/1/16 – annual review
Revised: 5/1/16 – updated format, logo, & procedure
Reviewed: 3/1/17 – annual review
Revised: 3/1/18 – annual review, updated signature, updated FA
Reviewed: 3/1/19 – annual review
Revised: 3/1/20 – annual review, added GHP Kids
Revised: 3/1/21 – annual review, updated logo, added MediSpan approval level
Revised: 3/1/22 – annual review, updated referenced policies & covered LOBs



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 392.0

**SECTION: Commercial Drug
SUBJECT: Praluent**

Applicable line of business:

Commercial	X	Medicaid	
Medicare		ACA	X
GHP Kids	X	Self-Insured	X

POLICY:

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for Praluent for GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 487.0 Quantity Limit Exceptions

REQUIRED DEFINITIONS:

1. **Attachment** – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. **Exhibit** – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. **Devised** – the date the policy was implemented.
4. **Revised** – the date of every revision to the policy, including typographical and grammatical changes.
5. **Reviewed** – the date documenting the annual review if the policy has no revisions necessary.

ADDITIONAL DEFINITIONS:

1. **Formulary** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. **Non-formulary products** – those medications that are not included in the Formulary.
3. **Healthcare provider** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
4. **NCQA** – National Committee for Quality Assurance.
5. **Medically Necessary or Medical Necessity** – covered services rendered by a provider that the Health Plan determines are:

- A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
 - B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
 - C. In accordance with current standards of medical practice;
 - D. Not primarily for the convenience of the Member, or the Member's Provider; and
 - E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.
6. **Therapeutic failure to statins, Zetia, fibrates, and/or bile acid sequestrants** – inability to reach target LDL goals (<100 mg/dL for primary prevention in HeFH or HoFH or <70 mg/dL for ASCVD or secondary prevention in HeFH or HoFH) despite a ≥ 3 month trial with the patient taking ≥ 90% of the prescribed doses.
 7. **Intolerance to statins** – increased LFT's, intolerable myalgia (muscle symptoms without creatinine kinase [CK] elevations) or myopathy (muscle symptoms with CK elevations), or myositis (elevations in CK without muscle symptoms), which persists after two retrials with a different dose or different dosing strategy (i.e., every other day administration) of alternatives moderate- or high-intensity statin
 8. **Contraindication to statins** – active liver disease, previous history of rhabdomyolysis, or hypersensitivity

PROCEDURE:

A formulary exception for coverage of Praluent may be made for members who meet the following criteria:

- Medical record documentation of a diagnosis of:
 - Clinical atherosclerotic cardiovascular disease (ASCVD), including acute coronary syndromes (a history of myocardial infarction or unstable angina), coronary or other arterial revascularization, stroke, transient ischemic attack, or peripheral arterial disease presumed to be of atherosclerotic origin **OR**
 - Primary hyperlipidemia **OR**
 - Heterozygous familial hypercholesterolemia **AND** either:
 - Genetic testing to confirm a mutation in the low-density lipoprotein (LDL) receptor, PCSK9, or ApoB gene **OR**
 - Medical record documentation of definite heterozygous familial hypercholesterolemia (HeFH) (score greater than 8) on the diagnostic criteria scoring system (Table 1) as defined by the Dutch Lipid Clinic Network diagnostic criteria **OR**
 - Homozygous familial hypercholesterolemia (HoFH) **AND** either:

- Genetic testing to confirm diagnosis showing a mutation in the low-density lipoprotein (LDL) receptor (LDLr) gene, apolipoprotein B (ApoB) gene, proprotein convertase subtilisin/kexin type 9 (PCSK9) gene, or LDL protein receptor adaptor 1 (LDLRAP1) gene **OR**
- Diagnosis made based on a history of an untreated low-density lipoprotein cholesterol (LDL-C) greater than 500 mg/dL **AND** either xanthoma before 10 years of age **OR** evidence of heterozygous familial hypercholesterolemia (HeFH) in both parents **AND**
- Medical record documentation of a baseline low-density lipoprotein (LDL) drawn within 3 months of the start of PCSK9 therapy showing:
 - Low-density lipoprotein (LDL) greater than 100 if the member is using Praluent for primary prevention **OR**
 - Low-density lipoprotein (LDL) greater than 70 if the member is using Praluent for secondary prevention **AND**
- Medical record documentation of age greater than or equal to 18 years **AND**
- Medical record documentation that patient is currently on and is adherent to (taking at least 90% of prescribed doses over the past three months) maximally tolerated dose of atorvastatin or rosuvastatin or has documented therapeutic failure on, intolerance to, or contraindication to atorvastatin and rosuvastatin **AND**
- Medical record documentation that non-pharmacologic therapies are in place including cholesterol lowering diet, exercise, and weight management strategies **AND**
- Medical record documentation of a therapeutic failure on, intolerance to, or contraindication to ezetimibe **AND**
- Medical record documentation that Praluent is not being used in combination with another PCSK9 inhibitor

Adherence calculations must be supported by claims data or physician attestation if no claims history is available (i.e., if the patient is new to the plan or did not use insurance for their statin prescriptions).

MEDISPAN AUTHORIZATION LEVEL: GPI-12

QUANTITY LIMIT: *No QLs need to be entered within the authorization unless the requested quantity exceeds the QL.*

- **QL FOR LETTER ONLY:** 2 mL per 28 days

AUTHORIZATION DURATION: Initial authorizations for Praluent will be approved for a period of 12 months. Reauthorizations will be for a period of 12 months each provided the following criteria are met:

- Medical record documentation of an up to date low density lipoprotein (LDL) cholesterol level since the date of the previous review showing the patient has had a clinically significant response to treatment with a PCSK9 inhibitor **AND**
- Medical record documentation that the patient is not experiencing any significant adverse events related to therapy **AND**
- Claims history and attestation from the provider showing the patient is adherent to PCSK9 therapy **AND**
- Claims history or attestation from the provider that the patient is staying adherent to (filling at least 90% of doses) statin therapy (if statin tolerant) **AND**
- Medical record documentation that Praluent continues to not be used in combination with another PCSK9 inhibitor

Table 1. Diagnostic criteria for the clinical diagnosis of HeFH (WHO)

	Criteria	Score
Family history	First-degree relative known with premature CAD* and/or first-degree relative with LDL-C >95th percentile	1
	First-degree relative with Tx and/or children <18 with LDL-C >95th centile	2
Clinical history	Patient has premature CAD*	2
	Patient has premature cerebral/peripheral vascular disease	1
Physical examination	Tx	6
	Arcus cornealis below the age of 45 years	4
LDL-C	>8.5 mmol/L (more than ~330 mg/dL)	8
	6.5-8.4 mmol/L (~250-329 mg/dL)	5
	5.0-6.4 mmol/L (~190-249 mg/dL)	3
	4.0-4.9 mmol/L (~155-189 mg/dL)	1
Definite FH		Score >8
Probable FH		Score 6-8
Possible FH		Score 3-5
No diagnosis		Score <3

If a formulary exception is approved Praluent will be paid for under the member's prescription drug benefit.

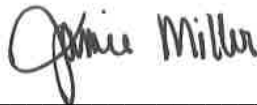
Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.

FORMULARY ALTERNATIVES:

atorvastatin, rosuvastatin, ezetimibe, colesevelam, cholestyramine, colestipol, fenofibrate, fenofibric acid, gemfibrozil

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE
STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND
FEDERAL REGULATORY ENTITIES.**

**THIS POLICY WILL BE REVISED AS NECESSARY AND
REVIEWED NO LESS THAN ANNUALLY.**



Signed: _____

Title: Director, Pharmacy Services

Date: April 6, 2022

Devised: 9/22/15

Revised: 11/18/15 – added bile acid sequestrants (BAS) to therapeutic failure definition, removed rhabdomyolysis from intolerance definition, added lipidologist to prescriber criteria, added within 3 months to baseline LDL criteria, updated failure on statin wording, added max LDL criteria to BAS criteria, clarified concomitant therapy criteria and PCSK9 adherence reauth criteria, added statin adherence to reauth criteria, added “*Prior auth required” wording in formulary alternatives

Reviewed: 3/1/16 – annual review

Revised: 5/1/16 – updated format, logo, & procedure

Revised: 5/27/16 – Updated failure of statin definition, updated intolerance to statins definition, added ASCVD to diagnosis, added PCSK9 and Apo B to HeFH diagnosis, added LDL values to baseline LDL requirement, updated Crestor to rosuvastatin, removed LDL > 70 from statin requirement, updated combination therapy bullet, added fibrate to bile acid sequestrant requirements, added no combination use with PCSK9, Juxtapid, or Kynamro to initial and renewal criteria, updated FA

Revised: 3/1/17 – annual review, removed Unicode, defined abbrev., updated Zetia to ezetimibe

Revised: 6/2/17 – revised statin bullet, removed combo therapy bullet, added if statin toleration to reauth

Revised: 3/1/18 – annual review, updated signature, updated prescriber & age criteria, corrected typo

Revised: 12/28/18 – removed failure of BAS

Revised: 3/1/19 – annual review, added QL approval note, removed GPID approval

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Dev. 9/22/15

Rev. 4/6/22



POLICY NUMBER: 392.0

**POLICY AND PROCEDURE
PHARMACY
MANUAL**

**SECTION: Commercial Drug
SUBJECT: Praluent**

Revised: 10/1/19 – extended initial auth duration to 12 months
Revised: 3/1/20 – annual review, added GHP Kids
Revised: 3/1/21 – annual review, updated logo, added MediSpan approval level, updated QL statement, reinserted LOB table
Revised: 6/4/21 – added diag. of primary hyperlipidemia & HoFH, updated baseline LDL requirement, removed references to Kynamro
Revised: 11/24/21 – removed specialist requirement
Revised: 3/1/22 – annual review, updated referenced policies & covered LOBs, updated FA
Revised: 4/6/22 – updated ESC/EAS to Dutch Lipid and HoFH mutations, removed combo with Juxtapid



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 393.0

**SECTION: Commercial Drug
SUBJECT: Repatha**

Applicable line of business:

Commercial	X	Medicaid	
Medicare		ACA	X
GHP Kids	X	Self-Insured	X

POLICY:

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for Repatha for GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 487.0 Quantity Limit Exceptions

REQUIRED DEFINITIONS:

1. **Attachment** – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. **Exhibit** – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
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5. **Reviewed** – the date documenting the annual review if the policy has no revisions necessary.

ADDITIONAL DEFINITIONS:

1. **Formulary** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. **Non-formulary products** – those medications that are not included in the Formulary.
3. **Healthcare provider** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
4. **NCQA** – National Committee for Quality Assurance.
5. **Medically Necessary or Medical Necessity** – covered services rendered by a provider that the Health Plan determines are:

- A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
 - B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
 - C. In accordance with current standards of medical practice;
 - D. Not primarily for the convenience of the Member, or the Member's Provider; and
 - E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.
6. **Therapeutic failure to statins, ezetimibe, fibrates, and/or bile acid sequestrants** – inability to reach target LDL goals (<100 mg/dL for primary prevention in HeFH or HoFH or <70 mg/dL for ASCVD or secondary prevention in HeFH or HoFH) despite a ≥ 3 month trial with the patient taking ≥ 90% of the prescribed doses.
 7. **Intolerance to statins** – increased LFT's, intolerable myalgia (muscle symptoms without creatinine kinase [CK] elevations) or myopathy (muscle symptoms with CK elevations), or myositis (elevations in CK without muscle symptoms), which persists after two retrials with a different dose or different dosing strategy (i.e., every other day administration) of alternatives moderate- or high-intensity statin
 8. **Contraindication to statins** – active liver disease, previous history of rhabdomyolysis, or hypersensitivity

PROCEDURE:

A formulary exception for coverage of Repatha may be made for members who meet the following criteria:

- Medical record documentation of a diagnosis of:
 - Clinical atherosclerotic cardiovascular disease (ASCVD), including acute coronary syndromes (a history of myocardial infarction or unstable angina), coronary or other arterial revascularization, stroke, transient ischemic attack, or peripheral arterial disease presumed to be of atherosclerotic origin **OR**
 - Primary hyperlipidemia **OR**
 - Heterozygous familial hypercholesterolemia (HeFH) **AND** either:
 - Genetic testing to confirm a mutation in the low-density lipoprotein (LDL) receptor, PCSK9, or ApoB gene **OR**
 - Medical record documentation of definite heterozygous familial hypercholesterolemia (HeFH) (score greater than 8) on the diagnostic criteria scoring system (Table 1) as defined by the Dutch Lipid Clinic Network diagnostic criteria **OR**
 - Homozygous familial hypercholesterolemia (HoFH) **AND** either:

- Genetic testing to confirm diagnosis showing a mutation in the low-density lipoprotein (LDL) receptor (LDLr) gene, apolipoprotein B (APOB) gene, proprotein convertase subtilisin/kexin type 9 (PCSK9) gene, or LDL protein receptor adaptor 1 (LDLRAP1) gene **OR**
- Diagnosis made based on a history of an untreated low-density lipoprotein cholesterol (LDL-C) greater than 500 mg/dL **AND** either xanthoma before 10 years of age **OR** evidence of heterozygous familial hypercholesterolemia (HeFH) in both parents **AND**
- Medical record documentation of a baseline low-density lipoprotein (LDL) drawn within 3 months of the start of PCSK9 therapy
 - Low-density lipoprotein (LDL) greater than 130 mg/dL if the member is greater than or equal to 10 years of age and less than 18 years of age **OR**
 - Low-density lipoprotein (LDL) greater than 100 mg/dL if the member is greater than or equal to 18 years of age and using Repatha for primary prevention **OR**
 - Low-density lipoprotein (LDL) greater than 70 mg/dL if the member is using Repatha for secondary prevention **AND**
- Medical record documentation of age greater than or equal to 18 years if the diagnosis is clinical atherosclerotic cardiovascular disease (ASCVD) or heterozygous familial hypercholesterolemia (HeFH) or primary hyperlipidemia **OR** medical record documentation of age greater than or equal to 10 years if the diagnosis is homozygous familial hypercholesterolemia (HoFH) **AND**
- Medical record documentation that patient is currently on and is adherent to (taking at least 90% of prescribed doses over the past three months) maximally tolerated dose of atorvastatin or rosuvastatin or has documented therapeutic failure on, intolerance to, or contraindication to atorvastatin and rosuvastatin **AND**
- Medical record documentation that non-pharmacologic therapies are in place including cholesterol lowering diet, exercise, and weight management strategies **AND**
- Medical record documentation of a therapeutic failure on, intolerance to, or contraindication to ezetimibe **AND**
- Medical record documentation that Repatha is not being used in combination with another PCSK9 inhibitor **AND**
- If requesting Repatha Syringe or Repatha Sureclick 420 mg dose (3 mL), medical record documentation of therapeutic failure on, intolerance to, or contraindication to Repatha Pushtronex **OR**
- If requesting 420 mg every 2 weeks:
 - Medical record documentation of a diagnosis of Homozygous Familial Hypercholesterolemia (HoFH) **AND**
 - One of the following:
 - Medical record documentation that the member has been on 420 mg once monthly for 12 weeks and a clinically meaningful response has not been achieved **OR**

- Medical record documentation that the member is on lipid apheresis every 2 weeks

Adherence calculations must be supported by claims data or physician attestation if no claims history is available (i.e., if the patient is new to the plan or did not use insurance for their statin prescriptions).

MEDISPAN AUTHORIZATION LEVEL: GPI-10

QUANTITY LIMIT: *No QLs need to be entered within the authorization unless the requested quantity exceeds the QL.*

- **QL FOR LETTER ONLY:**
 - Pen/Syringe: 2 mL per 28 days
 - Pushtronex: 3.5 mL per 28 days

AUTHORIZATION DURATION: Initial authorizations for Repatha will be approved for a period of 12 months. Reauthorizations will be for a period of 12 months each provided the following criteria are met:

- Medical record documentation of an up to date low density lipoprotein (LDL) cholesterol level since the date of the previous review showing the patient has had a clinically significant response to treatment with a PCSK9 inhibitor **AND**
- Medical record documentation that the patient is not experiencing any significant adverse events related to therapy **AND**
- Claims history and attestation from the provider showing the patient is adherent to PCSK9 therapy **AND**
- Claims history or attestation from the provider that the patient is staying adherent to (filling at least 90% of doses) statin therapy (if statin tolerant) **AND**
- Medical record documentation that Repatha continues to not be used in combination with another PCSK9 inhibitor **AND**
- If requesting Repatha Syringe or Repatha Sureclick 420 mg dose (3 mL), medical record documentation of therapeutic failure on, intolerance to, or contraindication to Repatha Pushtronex **OR**
- If requesting 420 mg every 2 weeks:
 - Medical record documentation of a diagnosis of Homozygous Familial Hypercholesterolemia (HoFH) **AND**
 - One of the following:
 - Medical record documentation that the member has been on 420 mg once monthly for 12 weeks and a clinically meaningful response has not been achieved **OR**
 - Medical record documentation that the member is on lipid apheresis every 2 weeks

Table 1. Diagnostic criteria for the clinical diagnosis of HeFH (WHO)

	Criteria	Score
Family history	First-degree relative known with premature CAD* and/or first-degree relative with LDL-C >95th percentile	1
	First-degree relative with Tx and/or children <18 with LDL-C >95th centile	2
Clinical history	Patient has premature CAD*	2
	Patient has premature cerebral/peripheral vascular disease	1
Physical examination	Tx	6
	Arcus cornealis below the age of 45 years	4
LDL-C	>8.5 mmol/L (more than ~330 mg/dL)	8
	6.5-8.4 mmol/L (~250-329 mg/dL)	5
	5.0-6.4 mmol/L (~190-249 mg/dL)	3
	4.0-4.9 mmol/L (~155-189 mg/dL)	1
Definite FH		Score >8
Probable FH		Score 6-8
Possible FH		Score 3-5
No diagnosis		Score <3

If a formulary exception is approved Repatha will be paid for under the member's prescription drug benefit.

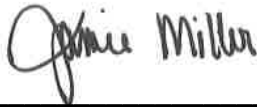
Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.

FORMULARY ALTERNATIVES:

atorvastatin, rosuvastatin, ezetimibe, colesvelam, cholestyramine, colestipol, fenofibrate, fenofibric acid, gemfibrozil

THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND FEDERAL REGULATORY ENTITIES.

THIS POLICY WILL BE REVISED AS NECESSARY AND REVIEWED NO LESS THAN ANNUALLY.



Signed: _____

Title: Director, Pharmacy Services

Date: April 6, 2022

- Devised: 11/18/15
- Revised: 3/1/16 – annual review, updated Praluent reference in first line of procedure to Repatha
- Revised: 5/1/16 – updated format, logo, & procedure
- Revised: 5/27/16 – Updated failure of statin definition, updated intolerance to statins definition, added PCSK9 and Apo B to HeFH diagnosis, added LDL values to baseline LDL requirement, updated Crestor to rosuvastatin, removed LDL > 70 from statin requirement, updated combination therapy bullet, added fibrate to bile acid sequestrant requirement, added no combination use with PCSK9, Juxtapid, or Kynamro to initial and renewal criteria, updated FA
- Revised: 7/8/16 – corrected typo in quantity limit
- Revised: 3/1/17 – annual review, updated Zetia to ezetimibe, removed Unicode, defined abbrev.
- Revised: 6/2/17 – updated statin bullet, removed combo therapy bullet, added if statin tolerant to reauth, added Pushtronex QL
- Revised: 8/8/17 – updated QL, added requirement to use Pushtronex for 420 mg dose
- Revised: 3/1/18 – annual review, updated signature, updated age & prescriber criteria, corrected typo
- Revised: 5/30/18 – removed failure of bile acid sequestrants
- Revised: 3/1/19 – annual review, added QL approval note
- Revised: 10/1/19 – increased initial auth duration to 12 months for all indications
- Revised: 3/1/20 – annual review, added GHP Kids
- Revised: 3/1/21 – annual review, updated logo, added MediSpan approval level, updated QL statement, updated Zetia to generic in definitions
- Revised: 6/4/21 – added primary hyperlipidemia diag., updated baseline LDL requirements, removed references to Kynamro, added criteria to initial & renewal for 420 mg q2 week dosing
- Revised: 7/1/21 – added primary hyperlipidemia to age greater than 18 criteria
- Revised: 11/24/21 – removed specialist requirement
- Revised: 3/1/22 – annual review, updated referenced policies & covered LOBs, updated FA
- Revised: 4/6/22 – updated ESC/EAS to Dutch Lipid and HoFH mutations, updated ages for baseline LDL, decreased age for HoFH, removed combo with Juxtapid



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 394.0

**SECTION: Commercial Drug
SUBJECT: Glatopa**

Applicable line of business:

Commercial	X	Medicaid	
Medicare		ACA	X
GHP Kids	X	Self-Insured	X

POLICY:

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for Glatopa for GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 487.0 Quantity Limit Exceptions

REQUIRED DEFINITIONS:

1. **Attachment** – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. **Exhibit** – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
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4. **Revised** – the date of every revision to the policy, including typographical and grammatical changes.
5. **Reviewed** – the date documenting the annual review if the policy has no revisions necessary.

ADDITIONAL DEFINITIONS:

1. **Formulary** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. **Non-formulary products** – those medications that are not included in the Formulary.
3. **Healthcare provider** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
4. **NCQA** – National Committee for Quality Assurance.
5. **Medically Necessary or Medical Necessity** – covered services rendered by a provider that the Health Plan determines are:



POLICY NUMBER: 394.0

**POLICY AND PROCEDURE
PHARMACY
MANUAL**

**SECTION: Commercial Drug
SUBJECT: Glatopa**

- A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
- B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
- C. In accordance with current standards of medical practice;
- D. Not primarily for the convenience of the Member, or the Member's Provider; and
- E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

PROCEDURE:

New members to the plan already established on therapy may be eligible for continuity of care coverage as long as there is medical record documentation that the safety and effectiveness of use for the prescribed indication is supported by Food and Drug Administration (FDA) approval or adequate medical and scientific evidence in the medical literature.

A formulary exception for coverage of Glatopa may be made for members who meet the following criteria:

- Medical record documentation of a diagnosis of relapsing forms of multiple sclerosis **AND**
- Medical record documentation of a therapeutic failure on, intolerance to, or contraindication to glatiramer acetate 20 mg/mL

MEDISPAN AUTHORIZATION LEVEL: GPI-14 (must enter 6240003010E520 & 6240003010E540)

If a formulary exception is approved Glatopa will be paid for under the member's prescription drug benefit

Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.

FORMULARY ALTERNATIVES:

glatiramer acetate, Gilenya, dimethyl fumarate, Betaseron, Plegridy, Extavia, Aubagio 14 mg, Avonex, Rebif, Mayzent



POLICY NUMBER: 394.0

**POLICY AND PROCEDURE
PHARMACY
MANUAL**

**SECTION: Commercial Drug
SUBJECT: Glatopa**

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE
STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND
FEDERAL REGULATORY ENTITIES.**

**THIS POLICY WILL BE REVISED AS NECESSARY AND
REVIEWED NO LESS THAN ANNUALLY.**

Signed: _____

Title: Director, Pharmacy Services

Date: March 1, 2022

Devised: 11/20/15
Revised: 3/1/16 – annual review, added Gilenya, Tecfidera, and Betaseron to FA
Revised: 5/1/16 – updated format, logo, & procedure
Revised: 3/1/17 – annual review, updated FA
Revised: 3/1/18 – annual review, updated signature, added grandfather language
Revised: 3/1/19 – annual review, updated Copaxone to glatiramer
Revised: 3/1/20 – annual review, added GHP Kids
Revised: 3/1/21 – annual review, updated logo, added MediSpan approval level, updated FA
Revised: 3/1/22 – annual review, updated referenced policies & covered LOBs



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 395.0

**SECTION: Commercial Drug
SUBJECT: Orkambi**

Applicable line of business:

Commercial	X	Medicaid	
Medicare		ACA	X
GHP Kids	X	Self-Insured	X

POLICY:

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for Orkambi for GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 487.0 Quantity Limit Exceptions

REQUIRED DEFINITIONS:

1. **Attachment** – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. **Exhibit** – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. **Devised** – the date the policy was implemented.
4. **Revised** – the date of every revision to the policy, including typographical and grammatical changes.
5. **Reviewed** – the date documenting the annual review if the policy has no revisions necessary.

ADDITIONAL DEFINITIONS:

1. **Formulary** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. **Non-formulary products** – those medications that are not included in the Formulary.
3. **Healthcare provider** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
4. **NCQA** – National Committee for Quality Assurance.
5. **Medically Necessary or Medical Necessity** – covered services rendered by a provider that the Health Plan determines are:



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 395.0

**SECTION: Commercial Drug
SUBJECT: Orkambi**

- A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
- B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
- C. In accordance with current standards of medical practice;
- D. Not primarily for the convenience of the Member, or the Member's Provider; and
- E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

PROCEDURE:

A formulary exception for coverage of Orkambi may be made for members who meet the following criteria:

- Medical record documentation that Orkambi is prescribed by a pulmonologist or cystic fibrosis specialist **AND**
- Medical record documentation of patient age greater than or equal to 2 years **AND**
- Medical record documentation of a diagnosis of cystic fibrosis (CF) **AND**
- Medical record documentation that the member is homozygous for the *F508del* CFTR (cystic fibrosis transmembrane conductance regulator) mutation as documentation by an Food and Drug Administration (FDA)-cleared cystic fibrosis (CF) mutation test

MEDISPAN AUTHORIZATION LEVEL: GPI-10

QUANTITY LIMIT: *No QLs need to be entered within the authorization unless the requested quantity exceeds the QL.*

- **QL FOR LETTER ONLY:**
 - 4 tablets per day, 30 day supply per fill
 - 2 packets per day, 28 day supply per fill

AUTHORIZATION DURATION: Initial approval will be for four (4) months and subsequent approvals will be for twelve (12) months. Additional authorizations will require medical record documentation of improvement or stabilization in the signs and symptoms of cystic fibrosis. The medication will no longer be covered if the member experiences worsening of disease.

If a formulary exception is approved Orkambi will be paid for under the member's prescription drug benefit.



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 395.0

**SECTION: Commercial Drug
SUBJECT: Orkambi**

Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.

FORMULARY ALTERNATIVES:

none

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE
STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND
FEDERAL REGULATORY ENTITIES.**

**THIS POLICY WILL BE REVISED AS NECESSARY AND
REVIEWED NO LESS THAN ANNUALLY.**

Signed: _____

Title: Director, Pharmacy Services

Date: March 1, 2022

- Devised: 11/20/15
- Revised: 3/1/16 – annual review
- Revised: 5/1/16 – updated format, logo, & procedure
- Revised: 1/25/17 – updated age to 6 years
- Revised: 3/1/17 – annual review, defined abbreviations
- Revised: 1/17/18 – updated prescriber criteria, auth duration to 4 months, updated signature
- Reviewed: 3/1/18 – annual review
- Revised: 7/27/18 – removed baseline FEV₁ requirement, updated re-auth to improvement or stabilization of CF
- Revised: 3/1/19 – annual review, added QL approval note
- Revised: 01/28/20 – updated age to 2 years, added QL for packets
- Revised: 3/1/20 – annual review, added GHP Kids
- Revised: 3/1/21 – annual review, updated logo, added MediSpan approval level, updated QL statement
- Revised: 3/1/22 – annual review, updated referenced policies & covered LOBs



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 396.0

**SECTION: Commercial Drug
SUBJECT: Lonsurf**

Applicable line of business:

Commercial	X	Medicaid	
Medicare		ACA	X
GHP Kids	X	Self-Insured	X

POLICY:

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for Lonsurf for GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 487.0 Quantity Limit Exceptions

REQUIRED DEFINITIONS:

1. **Attachment** – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. **Exhibit** – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. **Devised** – the date the policy was implemented.
4. **Revised** – the date of every revision to the policy, including typographical and grammatical changes.
5. **Reviewed** – the date documenting the annual review if the policy has no revisions necessary.

ADDITIONAL DEFINITIONS:

1. **Formulary** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. **Non-formulary products** – those medications that are not included in the Formulary.
3. **Healthcare provider** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
4. **NCQA** – National Committee for Quality Assurance.
5. **Medically Necessary or Medical Necessity** – covered services rendered by a provider that the Health Plan determines are:

- A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
- B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
- C. In accordance with current standards of medical practice;
- D. Not primarily for the convenience of the Member, or the Member's Provider; and
- E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

PROCEDURE:

New members to the plan already established on therapy may be eligible for continuity of care coverage as long as there is medical record documentation that the safety and effectiveness of use for the prescribed indication is supported by Food and Drug Administration (FDA) approval or adequate medical and scientific evidence in the medical literature.

A formulary exception for coverage of Lonsurf may be made for members who meet the following criteria:

Metastatic Colorectal Cancer

- Medical record documentation that Lonsurf is prescribed by a hematologist or oncologist **AND**
- Medical record documentation of age greater than or equal to 18 years **AND**
- Medical record documentation of a diagnosis of metastatic colorectal cancer **AND**
- Medical record documentation of previous treatment with fluoropyrimidine-, oxaliplatin-, and irinotecan-based chemotherapy, an anti-VEGF (vascular endothelial growth factor) biological therapy, and if RAS wild-type, an anti-EGFR (epidermal growth factor receptor) therapy

Metastatic Gastric or Gastroesophageal Junction Adenocarcinoma

- Medical record documentation that Lonsurf is prescribed by a hematologist or oncologist **AND**
- Medical record documentation of age greater than or equal to 18 years **AND**
- Medical record documentation of a diagnosis of metastatic gastric or gastroesophageal junction adenocarcinoma **AND**
- Medical record documentation of previous treatment with at least two prior lines of chemotherapy that included a fluoropyrimidine, a platinum, either a taxane or irinotecan and if appropriate, HER2/neu-targeted therapy



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 396.0

**SECTION: Commercial Drug
SUBJECT: Lonsurf**

MEDISPAN AUTHORIZATION LEVEL: GPI-12, number of claims authorized = 1, enter for the remainder of the calendar year

QUANTITY LIMIT: *No QLs need to be entered within the authorization unless the requested quantity exceeds the QL.*

- **QL FOR LETTER ONLY:**
 - 15 mg/6.14 mg tablet: 100 tablets per 28 days
 - 20 mg/8.19 mg tablet: 80 tablets per 28 days

RE-AUTHORIZATION CRITERIA: Lonsurf is configured as a prior authorization for new starts only. Lonsurf will no longer be covered if it is identified that the member is not receiving appropriate follow-up care from the prescribing specialist or if the member has greater than or equal to a 90 day break in therapy.

- Medical record documentation that the member is receiving appropriate follow-up care from the prescribing specialist

If a formulary exception is approved Lonsurf will be paid for under the member's prescription drug benefit.

Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.

FORMULARY ALTERNATIVES:

capecitabine, Stivarga*

*prior authorization required

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE
STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND
FEDERAL REGULATORY ENTITIES.**

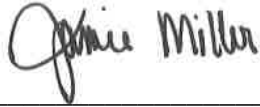
**THIS POLICY WILL BE REVISED AS NECESSARY AND
REVIEWED NO LESS THAN ANNUALLY.**

Geisinger

**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 396.0

**SECTION: Commercial Drug
SUBJECT: Lonsurf**



Signed: _____

Title: Director, Pharmacy Services

Date: March 1, 2022

Devised: 11/20/15
Revised: 3/1/16 – annual review, corrected 2 typos in 4th bullet
Revised: 5/1/16 – updated format, logo, & procedure
Revised: 3/1/17 – annual review, defined abbreviations, removed Unicode characters
Revised: 10/10/17 – increased authorization duration to 12 months
Revised: 3/1/18 – annual review, updated signature, updated age & prescriber criteria, added grandfather language
Revised: 6/1/18 – updated QL
Revised: 3/1/19 – annual review, added QL approval note
Revised: 5/24/19 – added metastatic gastric or gastroesophageal junction adenocarcinoma indication
Revised: 3/1/20 – annual review, added GHP Kids
Revised: 3/1/21 – annual review, updated logo, added MediSpan approval level, updated QL statement
Revised: 11/29/21 – added one-time PA to approval crit., removed auth duration & added re-auth crit.
Revised: 3/1/22 – annual review, updated referenced policies & covered LOBs



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 397.0

**SECTION: Commercial Drug
SUBJECT: Odomzo**

Applicable line of business:

Commercial	X	Medicaid	
Medicare		ACA	X
GHP Kids	X	Self-Insured	X

POLICY:

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for Odomzo for GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 487.0 Quantity Limit Exceptions

REQUIRED DEFINITIONS:

1. **Attachment** – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. **Exhibit** – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. **Devised** – the date the policy was implemented.
4. **Revised** – the date of every revision to the policy, including typographical and grammatical changes.
5. **Reviewed** – the date documenting the annual review if the policy has no revisions necessary.

ADDITIONAL DEFINITIONS:

1. **Formulary** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. **Non-formulary products** – those medications that are not included in the Formulary.
3. **Healthcare provider** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
4. **NCQA** – National Committee for Quality Assurance.
5. **Medically Necessary or Medical Necessity** – covered services rendered by a provider that the Health Plan determines are:



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 397.0

**SECTION: Commercial Drug
SUBJECT: Odomzo**

- A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
- B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
- C. In accordance with current standards of medical practice;
- D. Not primarily for the convenience of the Member, or the Member's Provider; and
- E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

PROCEDURE:

New members to the plan already established on therapy may be eligible for continuity of care coverage as long as there is medical record documentation that the safety and effectiveness of use for the prescribed indication is supported by Food and Drug Administration (FDA) approval or adequate medical and scientific evidence in the medical literature.

A formulary exception for coverage of Odomzo may be made for members who meet the following criteria:

- Medical record documentation that Odomzo is prescribed by an oncologist or dermatologist **AND**
- Medical record documentation of age greater than or equal to 18 years **AND**
- Medical record documentation of a diagnosis of locally advanced basal cell carcinoma (BCC) that has recurred following surgery or radiation therapy, or those who are not candidates for surgery or radiation therapy **AND**
- Medical record documentation of Odomzo treatment supported by multidisciplinary board consultation per National Comprehensive Cancer Network (NCCN) guidelines

MEDISPAN AUTHORIZATION LEVEL: GPI-12, number of claims authorized = 1, enter for the remainder of the calendar year

QUANTITY LIMIT: *No QLs need to be entered within the authorization unless the requested quantity exceeds the QL.*

- **QL FOR LETTER ONLY:** 1 capsule per day, 30 day supply per fill



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 397.0

**SECTION: Commercial Drug
SUBJECT: Odomzo**

RE-AUTHORIZATION CRITERIA: Odomzo is configured as a prior authorization for new starts only. Odomzo will no longer be covered if it is identified that the member is not receiving appropriate follow-up care from the prescribing specialist or if the member has greater than or equal to a 90 day break in therapy.

- Medical record documentation that the member is receiving appropriate follow-up care from the prescribing specialist

If a formulary exception is approved Odomzo will be paid for under the member's prescription drug benefit.

Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.

FORMULARY ALTERNATIVES:

Erivedge*

*prior authorization required

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE
STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND
FEDERAL REGULATORY ENTITIES.**

**THIS POLICY WILL BE REVISED AS NECESSARY AND
REVIEWED NO LESS THAN ANNUALLY.**

Signed: _____

Title: Director, Pharmacy Services

Date: March 1, 2022

- Devised: 11/20/15
Revised: 3/1/16 – annual review, corrected typo in 4th bullet
Revised: 5/1/16 – updated format, logo, & procedure
Revised: 7/8/16 – updated QL to capsule
Revised: 3/1/17 – annual review, removed Unicode characters, defined abbreviations
Revised: 10/10/17 – increased authorization duration to 12 months



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 397.0

**SECTION: Commercial Drug
SUBJECT: Odomzo**

- Revised: 3/1/18 – annual review, updated signature, updated age & prescriber criteria, added grandfather language, added DS limit
- Reviewed: 3/1/19 – annual review, added QL approval note
- Revised: 3/1/20 – annual review, added GHP Kids
- Revised: 3/1/21 – annual review, updated logo, added MediSpan approval level, updated QL statement
- Revised: 11/30/21 – added one-time PA to approval crit., removed auth duration & added re-auth crit.
- Revised: 3/1/22 – annual review, updated referenced policies & covered LOBs



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 401.0

**SECTION: Commercial Drug
SUBJECT: Cotellic**

Applicable line of business:

Commercial	X	Medicaid	
Medicare		ACA	X
GHP Kids	X	Self-Insured	X

POLICY:

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for Cotellic for GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 487.0 Quantity Limit Exceptions

REQUIRED DEFINITIONS:

1. **Attachment** – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. **Exhibit** – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. **Devised** – the date the policy was implemented.
4. **Revised** – the date of every revision to the policy, including typographical and grammatical changes.
5. **Reviewed** – the date documenting the annual review if the policy has no revisions necessary.

ADDITIONAL DEFINITIONS:

1. **Formulary** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. **Non-formulary products** – those medications that are not included in the Formulary.
3. **Healthcare provider** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
4. **NCQA** – National Committee for Quality Assurance.
5. **Medically Necessary or Medical Necessity** – covered services rendered by a provider that the Health Plan determines are:



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 401.0

**SECTION: Commercial Drug
SUBJECT: Cotellic**

- A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
- B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
- C. In accordance with current standards of medical practice;
- D. Not primarily for the convenience of the Member, or the Member's Provider; and
- E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

PROCEDURE:

New members to the plan already established on therapy may be eligible for continuity of care coverage as long as there is medical record documentation that the safety and effectiveness of use for the prescribed indication is supported by Food and Drug Administration (FDA) approval or adequate medical and scientific evidence in the medical literature.

A formulary exception for coverage of Cotellic may be made for members who meet the following criteria:

- Medical record documentation that Cotellic is prescribed by a hematologist, oncologist, or dermatologist **AND**
- Medical record documentation of a diagnosis of unresectable or metastatic melanoma **AND**
- Medical record documentation of BRAF V600E or V600K mutation as detected by aa Food and Drug Administration (FDA)-approved test **AND**
- Medical record documentation of concomitant use with Zelboraf (vemurafenib)

MEDISPAN AUTHORIZATION LEVEL: GPI-12, number of claims authorized = 1, enter for the remainder of the calendar year

QUANTITY LIMIT: *No QLs need to be entered within the authorization unless the requested quantity exceeds the QL.*

- **QL FOR LETTER ONLY:** 3 tablets per day, 30 day supply per fill



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 401.0

**SECTION: Commercial Drug
SUBJECT: Cotellic**

RE-AUTHORIZATION CRITERIA: Cotellic is configured as a prior authorization for new starts only. Cotellic will no longer be covered if it is identified that the member is not receiving appropriate follow-up care from the prescribing specialist or if the member has greater than or equal to a 90 day break in therapy.

- Medical record documentation that the member is receiving appropriate follow-up care from the prescribing specialist

If a formulary exception is approved Cotellic will be paid for under the member's prescription drug benefit.

Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.

FORMULARY ALTERNATIVES:

Mekinist*, Tafinlar*, Zelboraf*

*prior authorization required

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE
STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND
FEDERAL REGULATORY ENTITIES.**

**THIS POLICY WILL BE REVISED AS NECESSARY AND
REVIEWED NO LESS THAN ANNUALLY.**

Signed: _____

Title: Director, Pharmacy Services

Date: March 1, 2022

Devised: 1/29/16

Revised: 3/1/16 – annual review, corrected 2 typos in 5th bullet

Revised: 5/1/16 – updated format, logo, & procedure

Revised: 3/1/17 – annual review, defined abbreviations

Revised: 10/10/17 – increased authorization duration to 12 months

Revised: 3/1/18 – annual review, updated signature, added grandfather language, updated

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Dev. 1/29/16

Rev. 3/1/22



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 401.0

**SECTION: Commercial Drug
SUBJECT: Cotellic**

prescriber criteria, corrected typo

- Revised: 10/1/18 – added dermatologist, added “diagnosis,” removed first line or no prior therapy
- Revised: 3/1/19 – annual review, added QL approval note
- Revised: 3/1/20 – annual review, added GHP Kids
- Revised: 3/1/21 – annual review, updated logo, added MediSpan approval level, updated QL statement
- Revised: 11/24/21 – added one-time PA to approval crit., removed auth duration & added re-auth crit.
- Revised: 3/1/22 – annual review, updated referenced policies & covered LOBs



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 402.0

**SECTION: Commercial Drug
SUBJECT: Keveyis**

Applicable line of business:

Commercial	X	Medicaid	
Medicare		ACA	X
GHP Kids	X	Self-Insured	X

POLICY:

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for Keveyis for GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 487.0 Quantity Limit Exceptions

REQUIRED DEFINITIONS:

1. **Attachment** – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. **Exhibit** – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. **Devised** – the date the policy was implemented.
4. **Revised** – the date of every revision to the policy, including typographical and grammatical changes.
5. **Reviewed** – the date documenting the annual review if the policy has no revisions necessary.

ADDITIONAL DEFINITIONS:

1. **Formulary** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. **Non-formulary products** – those medications that are not included in the Formulary.
3. **Healthcare provider** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
4. **NCQA** – National Committee for Quality Assurance.
5. **Medically Necessary or Medical Necessity** – covered services rendered by a provider that the Health Plan determines are:



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 402.0

**SECTION: Commercial Drug
SUBJECT: Keveyis**

- A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
- B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
- C. In accordance with current standards of medical practice;
- D. Not primarily for the convenience of the Member, or the Member's Provider; and
- E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

PROCEDURE:

A formulary exception for coverage of Keveyis may be made for members who meet the following criteria:

- Medical record documentation of a diagnosis of primary hyperkalemic periodic paralysis, primary hypokalemic periodic paralysis, or related variants **AND**
- Medical record documentation of age greater than or equal to 18 years **AND**
- Medical record documentation that patient's condition was diagnosed by a neurologist with neuromuscular expertise **AND**
- Medical record documentation of therapeutic failure on, intolerance to, or contraindication to acetazolamide **AND**
- **For hypokalemic periodic paralysis only:** Medical record documentation of therapeutic failure on, intolerance to, or contraindication to spironolactone

MEDISPAN AUTHORIZATION LEVEL: GPI-12

QUANTITY LIMIT: *No QLs need to be entered within the authorization unless the requested quantity exceeds the QL.*

- **QL FOR LETTER ONLY:** 4 tablets per day, 34 day supply per fill

If a formulary exception is approved Keveyis will be paid for under the member's prescription drug benefit.

Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.

Geisinger

**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 402.0

**SECTION: Commercial Drug
SUBJECT: Keveyis**

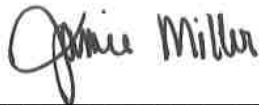
FORMULARY ALTERNATIVES:

For hyperkalemic periodic paralysis: acetazolamide

For hypokalemic periodic paralysis: acetazolamide, spironolactone

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE
STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND
FEDERAL REGULATORY ENTITIES.**

**THIS POLICY WILL BE REVISED AS NECESSARY AND
REVIEWED NO LESS THAN ANNUALLY.**



Signed: _____

Title: Director, Pharmacy Services

Date: March 1, 2022

Devised: 1/29/16
Revised: 3/1/16 – annual review
Revised: 5/1/16 – updated format, logo, & procedure
Reviewed: 3/1/17 – annual review
Revised: 3/1/18 – annual review, updated signature, updated age criteria
Revised: 3/1/19 – annual review, added QL approval note
Revised: 3/1/20 – annual review, added GHP Kids
Revised: 3/1/21 – annual review, updated logo, added MediSpan approval level, updated QL statement
Revised: 3/1/22 – annual review, updated referenced policies & covered LOBs



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 403.0

**SECTION: Commercial Drug
SUBJECT: Ninlaro**

Applicable line of business:

Commercial	X	Medicaid	
Medicare		ACA	X
GHP Kids	X	Self-Insured	X

POLICY:

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for Ninlaro for GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 487.0 Quantity Limit Exceptions

REQUIRED DEFINITIONS:

1. **Attachment** – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. **Exhibit** – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. **Devised** – the date the policy was implemented.
4. **Revised** – the date of every revision to the policy, including typographical and grammatical changes.
5. **Reviewed** – the date documenting the annual review if the policy has no revisions necessary.

ADDITIONAL DEFINITIONS:

1. **Formulary** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. **Non-formulary products** – those medications that are not included in the Formulary.
3. **Healthcare provider** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
4. **NCQA** – National Committee for Quality Assurance.
5. **Medically Necessary or Medical Necessity** – covered services rendered by a provider that the Health Plan determines are:



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 403.0

**SECTION: Commercial Drug
SUBJECT: Ninlaro**

- A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
- B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
- C. In accordance with current standards of medical practice;
- D. Not primarily for the convenience of the Member, or the Member's Provider; and
- E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

PROCEDURE:

New members to the plan already established on therapy may be eligible for continuity of care coverage as long as there is medical record documentation that the safety and effectiveness of use for the prescribed indication is supported by Food and Drug Administration (FDA) approval or adequate medical and scientific evidence in the medical literature.

A formulary exception for coverage of Ninlaro may be made for members who meet the following criteria:

- Medical record documentation that Ninlaro is prescribed by a hematologist or oncologist **AND**
- Medical record documentation of a diagnosis of multiple myeloma **AND**
- Medical record documentation that Ninlaro will be used in combination with Revlimid* and dexamethasone **AND**
- Medical record documentation of therapeutic failure on, intolerance to, or contraindication to at least one prior therapy

MEDISPAN AUTHORIZATION LEVEL: GPI-12, number of claims authorized = 1, enter for the remainder of the calendar year

QUANTITY LIMIT: *No QLs need to be entered within the authorization unless the requested quantity exceeds the QL.*

- **QL FOR LETTER ONLY:** 3 capsules per 28 days



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 403.0

**SECTION: Commercial Drug
SUBJECT: Ninlaro**

RE-AUTHORIZATION CRITERIA: Ninlaro is configured as a prior authorization for new starts only. Ninlaro will no longer be covered if it is identified that the member is not receiving appropriate follow-up care from the prescribing specialist or if the member has greater than or equal to a 90 day break in therapy.

- Medical record documentation that the member is receiving appropriate follow-up care from the prescribing specialist

If a formulary exception is approved Ninlaro will be paid for under the member's prescription drug benefit.

Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.

FORMULARY ALTERNATIVES:

Thalomid, Farydak*, Pomalyst*, Revlimid*

*prior authorization required

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE
STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND
FEDERAL REGULATORY ENTITIES.**

**THIS POLICY WILL BE REVISED AS NECESSARY AND
REVIEWED NO LESS THAN ANNUALLY.**

Signed: _____

Title: Director, Pharmacy Services

Date: March 1, 2022

Devised: 1/29/16
Revised: 3/1/16 – annual review
Revised: 5/1/16 – updated format, logo, & procedure
Reviewed: 3/1/17 – annual review
Revised: 10/10/17 – increased authorization duration to 12 months
Revised: 3/1/18 – annual review, updated signature, added grandfather language, updated prescriber criteria



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 403.0

**SECTION: Commercial Drug
SUBJECT: Ninlaro**

- Revised: 3/1/19 – annual review, added QL approval note, removed GPID note
- Revised: 3/1/20 – annual review, added GHP Kids
- Revised: 3/1/21 – annual review, updated logo, added MediSpan approval level, updated QL statement
- Revised: 11/30/21 – added one-time PA to approval crit., removed auth duration & added re-auth crit.
- Revised: 3/1/22 – annual review, updated referenced policies & covered LOBs



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 405.0

**SECTION: Commercial Drug
SUBJECT: Tagrisso**

Applicable line of business:

Commercial	X	Medicaid	
Medicare		ACA	X
GHP Kids	X	Self-Insured	X

POLICY:

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for Tagrisso for GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 487.0 Quantity Limit Exceptions

REQUIRED DEFINITIONS:

1. **Attachment** – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. **Exhibit** – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. **Devised** – the date the policy was implemented.
4. **Revised** – the date of every revision to the policy, including typographical and grammatical changes.
5. **Reviewed** – the date documenting the annual review if the policy has no revisions necessary.

ADDITIONAL DEFINITIONS:

1. **Formulary** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. **Non-formulary products** – those medications that are not included in the Formulary.
3. **Healthcare provider** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
4. **NCQA** – National Committee for Quality Assurance.
5. **Medically Necessary or Medical Necessity** – covered services rendered by a provider that the Health Plan determines are:



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 405.0

**SECTION: Commercial Drug
SUBJECT: Tagrisso**

- A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
- B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
- C. In accordance with current standards of medical practice;
- D. Not primarily for the convenience of the Member, or the Member's Provider; and
- E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

PROCEDURE:

New members to the plan already established on therapy may be eligible for continuity of care coverage as long as there is medical record documentation that the safety and effectiveness of use for the prescribed indication is supported by Food and Drug Administration (FDA) approval or adequate medical and scientific evidence in the medical literature.

A formulary exception for coverage of Tagrisso may be made for members who meet the following criteria:

Metastatic Non-Small Cell Lung Cancer (NSCLC)

- Medical record documentation that Tagrisso is prescribed by a hematologist or oncologist **AND**
- Medical record documentation of metastatic non-small cell lung cancer (NSCLC) **AND**
- Medical record documentation of an epidermal growth factor receptor (EGFR) exon 19 deletion, EGFR exon 21L858R mutation, or EGFR T790 mutation **AND**
- Medical record documentation of one of the following:
 - If member has epidermal growth factor receptor (EGFR) exon 19 deletion or exon 21 L858R mutation: Medical record documentation that Tagrisso is being used as first-line treatment **OR**
 - If member has epidermal growth factor receptor (EGFR) T790 mutation positive disease: Medical record documentation of failure on or intolerance to prior tyrosine kinase inhibitor therapy with Iressa (gefitinib), Gilotrif (afatinib), or Tarceva (erlotinib)

METASTATIC NSCLC AUTHORIZATION DURATION: Initial approval will be for 12 months or less if the reviewing provider feels it is medically appropriate. Subsequent approvals will be for an additional 12 months or less if the reviewing provider feels it is medically appropriate and will require medical record documentation of continued disease



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 405.0

**SECTION: Commercial Drug
SUBJECT: Tagrisso**

improvement or lack of disease progression. The medication will no longer be covered if the member experiences unacceptable toxicity or worsening of disease.

Adjuvant Treatment of Non-Small Cell Lung Cancer (NSCLC)

- Medical record documentation that Tagrisso is prescribed by a hematologist or oncologist **AND**
- Medical record documentation of non-small cell lung cancer (NSCLC) **AND**
- Medical record documentation that Tagrisso is being used as adjuvant treatment following complete tumor resection **AND**
- Medical record documentation that tumors have an epidermal growth factor receptor (EGFR) exon 19 deletion or exon 21 L858R mutation

ADJUVANT TREATMENT OF NSCLC AUTHORIZATION DURATION: Initial approval will be for **12 months**. **Up to two (2)** subsequent approvals will each be for an additional 12 months or less if the reviewing provider feels it is medically appropriate to equal **a total treatment duration of 3 years** and will require medical record documentation of continued disease improvement or lack of disease progression. The medication will no longer be covered if the member experiences unacceptable toxicity or worsening of disease.

Authorization of Tagrisso for adjuvant treatment of Non-Small Cell Lung Cancer (NSCLC) will not exceed the FDA-approved treatment duration of 3 years (36 months). For requests exceeding the above limit, documentation will be required of peer-reviewed literature citing well-designed clinical trials to indicate that the member's healthcare outcome will be improved by dosing beyond the FDA-approved treatment duration.

MEDISPAN AUTHORIZATION LEVEL: GPI-12

QUANTITY LIMIT: *No QLs need to be entered within the authorization unless the requested quantity exceeds the QL.*

- **QL FOR LETTER ONLY:** 1 tablet per day, 30 day supply per fill

If a formulary exception is approved Tagrisso will be paid for under the member's prescription drug benefit.

Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 405.0

**SECTION: Commercial Drug
SUBJECT: Tagrisso**

FORMULARY ALTERNATIVES:

EGFR T790 mutation: Gilotrif*, Iressa*, erlotinib*

*prior authorization required

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE
STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND
FEDERAL REGULATORY ENTITIES.**

**THIS POLICY WILL BE REVISED AS NECESSARY AND
REVIEWED NO LESS THAN ANNUALLY.**

Signed: _____

Title: Director, Pharmacy Services

Date: March 1, 2022

Devised: 1/29/16
Revised: 3/1/16 – annual review
Revised: 5/1/16 – updated format, logo, & procedure
Revised: 3/1/17 – annual review, defined abbreviations
Revised: 10/10/17 – increased authorization duration to 12 months
Revised: 3/1/18 – annual review, updated signature, added grandfather language, updated prescriber criteria, corrected typo
Revised: 8/7/18 – added exon 19 deletion and exon 21 L858R mutations, updated FA
Revised: 3/1/19 – annual review, added QL approval note, defined abbr.
Revised: 3/1/20 – annual review, added GHP Kids
Revised: 3/1/21 – annual review, updated logo, added MediSpan approval level, updated QL statement
Revised: 3/26/21 – added adjuvant treatment of NSCLC indication
Revised: 3/1/22 – annual review, updated referenced policies & covered LOBs, updated FA



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 408.0

**SECTION: Commercial Drug
SUBJECT: Alecensa**

Applicable line of business:

Commercial	X	Medicaid	
Medicare		ACA	X
GHP Kids	X	Self-Insured	X

POLICY:

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for Alecensa for GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 487.0 Quantity Limit Exceptions

REQUIRED DEFINITIONS:

1. **Attachment** – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. **Exhibit** – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. **Devised** – the date the policy was implemented.
4. **Revised** – the date of every revision to the policy, including typographical and grammatical changes.
5. **Reviewed** – the date documenting the annual review if the policy has no revisions necessary.

ADDITIONAL DEFINITIONS:

1. **Formulary** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. **Non-formulary products** – those medications that are not included in the Formulary.
3. **Healthcare provider** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
4. **NCQA** – National Committee for Quality Assurance.
5. **Medically Necessary or Medical Necessity** – covered services rendered by a provider that the Health Plan determines are:

- A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
- B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
- C. In accordance with current standards of medical practice;
- D. Not primarily for the convenience of the Member, or the Member's Provider; and
- E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

PROCEDURE:

New members to the plan already established on therapy may be eligible for continuity of care coverage as long as there is medical record documentation that the safety and effectiveness of use for the prescribed indication is supported by Food and Drug Administration (FDA) approval or adequate medical and scientific evidence in the medical literature.

A formulary exception for coverage of Alecensa may be made for members who meet the following criteria:

- Medical record documentation that Alecensa is prescribed by a hematologist or oncologist **AND**
- Medical record documentation of a diagnosis of anaplastic lymphoma kinase (ALK)-positive, metastatic non-small cell lung cancer

MEDISPAN AUTHORIZATION LEVEL: GPI-12, number of claims authorized = 1, enter for the remainder of the calendar year

QUANTITY LIMIT: *No QLs need to be entered within the authorization unless the requested quantity exceeds the QL.*

- **QL FOR LETTER ONLY:** 8 capsules per day, 30 day supply per fill

RE-AUTHORIZATION CRITERIA: Alecensa is configured as a prior authorization for new starts only. Alecensa will no longer be covered if it is identified that the member is not receiving appropriate follow-up care from the prescribing specialist or if the member has greater than or equal to a 90 day break in therapy.

- Medical record documentation that the member is receiving appropriate follow-up care from the prescribing specialist



POLICY NUMBER: 408.0

**POLICY AND PROCEDURE
PHARMACY
MANUAL**

**SECTION: Commercial Drug
SUBJECT: Alecensa**

If a formulary exception is approved Alecensa will be paid for under the member's prescription drug benefit.

Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.

FORMULARY ALTERNATIVES:

Xalkori*, Zykadia*

*prior authorization required

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE
STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND
FEDERAL REGULATORY ENTITIES.**

**THIS POLICY WILL BE REVISED AS NECESSARY AND
REVIEWED NO LESS THAN ANNUALLY.**

Signed: _____

Title: Director, Pharmacy Services

Date: March 1, 2022

Devised: 3/23/16
Revised: 5/1/16 – updated format, logo, & procedure
Reviewed: 3/1/17 – annual review
Revised: 10/10/17 – increased authorization duration to 12 months
Revised: 1/17/18 – removed prior failure, updated signature, updated prescriber criteria
Revised: 3/1/18 – annual review, added grandfather language
Revised: 3/1/19 – annual review, added QL approval note
Revised: 3/1/20 – annual review, added GHP Kids
Revised: 3/1/21 – annual review, updated logo, added MediSpan approval level, updated QL statement
Revised: 11/24/21 – added one-time PA to approval crit., removed auth duration & added re-auth crit.
Revised: 3/1/22 – annual review, updated referenced policies & covered LOBs



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 409.0

**SECTION: Commercial Drug
SUBJECT: Seebri Neohaler**

Applicable line of business:

Commercial	X	Medicaid	
Medicare		ACA	X
GHP Kids	X	Self-Insured	X

POLICY:

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for Seebri Neohaler for GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 487.0 Quantity Limit Exceptions

REQUIRED DEFINITIONS:

1. **Attachment** – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. **Exhibit** – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. **Devised** – the date the policy was implemented.
4. **Revised** – the date of every revision to the policy, including typographical and grammatical changes.
5. **Reviewed** – the date documenting the annual review if the policy has no revisions necessary.

ADDITIONAL DEFINITIONS:

1. **Formulary** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. **Non-formulary products** – those medications that are not included in the Formulary.
3. **Healthcare provider** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
4. **NCQA** – National Committee for Quality Assurance.
5. **Medically Necessary or Medical Necessity** – covered services rendered by a provider that the Health Plan determines are:



POLICY NUMBER: 409.0

**POLICY AND PROCEDURE
PHARMACY
MANUAL**

**SECTION: Commercial Drug
SUBJECT: Seebri Neohaler**

- A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
- B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
- C. In accordance with current standards of medical practice;
- D. Not primarily for the convenience of the Member, or the Member's Provider; and
- E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

PROCEDURE:

A formulary exception for coverage of Seebri Neohaler may be made for members who meet the following criteria:

- Medical record documentation of a diagnosis of chronic obstructive pulmonary disease (COPD) **AND**
- Medical record documentation of therapeutic failure on, intolerance to, or contraindication to Spiriva **AND** Incruse Ellipta

MEDISPAN AUTHORIZATION LEVEL: GPI-12

If a formulary exception is approved Seebri Neohaler will be paid for under the member's prescription drug benefit.

Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.

FORMULARY ALTERNATIVES:

Spiriva HandiHaler, Spiriva Respimat, Incruse Ellipta

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE
STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND
FEDERAL REGULATORY ENTITIES.**

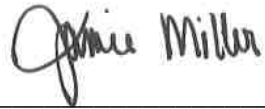
**THIS POLICY WILL BE REVISED AS NECESSARY AND
REVIEWED NO LESS THAN ANNUALLY.**

Geisinger

**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 409.0

**SECTION: Commercial Drug
SUBJECT: Seebri Neohaler**



Signed: _____

Title: Director, Pharmacy Services

Date: March 1, 2022

Devised: 3/23/16
Revised: 5/1/16 – updated format, logo, & procedure
Reviewed: 3/1/17 – annual review
Revised: 3/1/18 – annual review, updated signature, updated FA
Revised: 7/20/18 – added failure of Incruse Ellipta
Reviewed: 3/1/19 – annual review
Revised: 3/1/20 – annual review, added GHP Kids
Revised: 3/1/21 – annual review, updated logo, added MediSpan approval level
Revised: 3/1/22 – annual review, updated referenced policies & covered LOBs



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 410.0

**SECTION: Commercial Drug
SUBJECT: Utibron Neohaler**

Applicable line of business:

Commercial	X	Medicaid	
Medicare		ACA	X
GHP Kids	X	Self-Insured	X

POLICY:

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for Utibron Neohaler for GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 487.0 Quantity Limit Exceptions

REQUIRED DEFINITIONS:

1. **Attachment** – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. **Exhibit** – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. **Devised** – the date the policy was implemented.
4. **Revised** – the date of every revision to the policy, including typographical and grammatical changes.
5. **Reviewed** – the date documenting the annual review if the policy has no revisions necessary.

ADDITIONAL DEFINITIONS:

1. **Formulary** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. **Non-formulary products** – those medications that are not included in the Formulary.
3. **Healthcare provider** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
4. **NCQA** – National Committee for Quality Assurance.
5. **Medically Necessary or Medical Necessity** – covered services rendered by a provider that the Health Plan determines are:



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 410.0

**SECTION: Commercial Drug
SUBJECT: Utibron Neohaler**

- A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
- B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
- C. In accordance with current standards of medical practice;
- D. Not primarily for the convenience of the Member, or the Member's Provider; and
- E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

PROCEDURE:

A formulary exception for coverage of Utibron Neohaler may be made for members who meet the following criteria:

- Medical record documentation of a diagnosis of chronic obstructive pulmonary disease (COPD) **AND**
- Medical record documentation of therapeutic failure on, intolerance to, or contraindication to Anoro Ellipta

MEDISPAN AUTHORIZATION LEVEL: GPI-12

If a formulary exception is approved Utibron Neohaler will be paid for under the member's prescription drug benefit.

Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.

FORMULARY ALTERNATIVES:

Anoro Ellipta

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE
STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND
FEDERAL REGULATORY ENTITIES.**

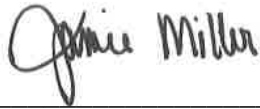
**THIS POLICY WILL BE REVISED AS NECESSARY AND
REVIEWED NO LESS THAN ANNUALLY.**

Geisinger

**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 410.0

**SECTION: Commercial Drug
SUBJECT: Utibron Neohaler**



Signed: _____

Title: Director, Pharmacy Services

Date: March 1, 2022

Devised: 3/23/16
Revised: 5/1/16 – updated format, logo, & procedure
Reviewed: 3/1/17 – annual review
Revised: 3/1/18 – annual review, updated signature
Reviewed: 3/1/19 – annual review
Revised: 3/1/20 – annual review, added GHP Kids
Revised: 3/1/21 – annual review, updated logo, added MediSpan approval level
Revised: 3/1/22 – annual review, updated referenced policies & covered LOBs



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 411.0

**SECTION: Commercial Drug
SUBJECT: Viberzi**

Applicable line of business:

Commercial	X	Medicaid	
Medicare		ACA	X
GHP Kids	X	Self-Insured	X

POLICY:

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for Viberzi for GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 487.0 Quantity Limit Exceptions

REQUIRED DEFINITIONS:

1. **Attachment** – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. **Exhibit** – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. **Devised** – the date the policy was implemented.
4. **Revised** – the date of every revision to the policy, including typographical and grammatical changes.
5. **Reviewed** – the date documenting the annual review if the policy has no revisions necessary.

ADDITIONAL DEFINITIONS:

1. **Formulary** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. **Non-formulary products** – those medications that are not included in the Formulary.
3. **Healthcare provider** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
4. **NCQA** – National Committee for Quality Assurance.
5. **Medically Necessary or Medical Necessity** – covered services rendered by a provider that the Health Plan determines are:



POLICY NUMBER: 411.0

**POLICY AND PROCEDURE
PHARMACY
MANUAL**

**SECTION: Commercial Drug
SUBJECT: Viberzi**

- A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
- B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
- C. In accordance with current standards of medical practice;
- D. Not primarily for the convenience of the Member, or the Member's Provider; and
- E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

PROCEDURE:

A formulary exception for coverage of Viberzi may be made for members who meet the following criteria:

- Medical record documentation of age greater than or equal to 18 years **AND**
- Medical record documentation that Viberzi is prescribed by a gastroenterologist **AND**
- Medical record documentation of irritable bowel syndrome with diarrhea (IBS-D) **AND**
- Medical record documentation of inadequate response or intolerance to two of the following:
 - loperamide
 - antispasmodics (dicyclomine, hyoscyamine)
 - alosetron (if female) **AND**
- Medical record documentation member does not have:
 - History of severe constipation or sequelae from constipation **OR**
 - Biliary duct obstruction or sphincter of Oddi dysfunction **OR**
 - History of pancreatitis or structural disease of the pancreas **OR**
 - Excessive alcohol intake (more than 3 alcoholic beverages per day) **OR**
 - Severe hepatic impairment

MEDISPAN AUTHORIZATION LEVEL: GPI-12

QUANTITY LIMIT: *No QLs need to be entered within the authorization unless the requested quantity exceeds the QL.*

- **QL FOR LETTER ONLY: 2 tablets per day**

If a formulary exception is approved Viberzi will be paid for under the member's prescription drug benefit.



POLICY NUMBER: 411.0

**POLICY AND PROCEDURE
PHARMACY
MANUAL**

**SECTION: Commercial Drug
SUBJECT: Viberzi**

Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.

FORMULARY ALTERNATIVES:

alosetron (if female), dicyclomine, diphenoxylate-atropine, loperamide

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE
STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND
FEDERAL REGULATORY ENTITIES.**

**THIS POLICY WILL BE REVISED AS NECESSARY AND
REVIEWED NO LESS THAN ANNUALLY.**

Signed: _____

Title: Director, Pharmacy Services

Date: March 1, 2022

Devised: 3/23/16
Revised: 5/1/16 – updated format, logo, & procedure
Reviewed: 3/1/17 – annual review
Revised: 3/1/18 – annual review, updated signature, updated age & prescriber criteria, corrected typo
Revised: 3/1/19 – annual review, added QL approval note
Revised: 3/1/20 – annual review, added GHP Kids
Revised: 3/1/21 – annual review, updated logo, added MediSpan approval level, updated QL statement
Revised: 3/1/22 – annual review, updated referenced policies & covered LOBs



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 412.0

**SECTION: Commercial Drug
SUBJECT: Strensiq**

Applicable line of business:

Commercial	X	Medicaid	
Medicare		ACA	X
GHP Kids	X	Self-Insured	X

POLICY:

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for Strensiq for GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 487.0 Quantity Limit Exceptions

REQUIRED DEFINITIONS:

1. **Attachment** – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. **Exhibit** – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. **Devised** – the date the policy was implemented.
4. **Revised** – the date of every revision to the policy, including typographical and grammatical changes.
5. **Reviewed** – the date documenting the annual review if the policy has no revisions necessary.

ADDITIONAL DEFINITIONS:

1. **Formulary** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. **Non-formulary products** – those medications that are not included in the Formulary.
3. **Healthcare provider** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
4. **NCQA** – National Committee for Quality Assurance.
5. **Medically Necessary or Medical Necessity** – covered services rendered by a provider that the Health Plan determines are:

- A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
- B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
- C. In accordance with current standards of medical practice;
- D. Not primarily for the convenience of the Member, or the Member's Provider; and
- E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

PROCEDURE:

A formulary exception for coverage of Strensiq may be made for members who meet the following criteria:

- Medical record documentation that Strensiq is prescribed by an endocrinologist or metabolic specialist **AND**
- Medical record documentation of a diagnosis of perinatal/infantile- or juvenile-onset hypophosphatasia (HPP) **AND**
- Medical record documentation of low total serum alkaline phosphatase activity (see chart below for typical lowest normal reference values) **AND**
- Medical record documentation that member will receive a weight and diagnosis appropriate dosing regimen

Table 2. Typical Lowest Normal Reference Values for Serum Alkaline Phosphatase Activity in North America

Age	Lowest Normal Total Serum or Plasma Alkaline Phosphatase Activity (U/L)	
	Male	Female
0-30 days	60	60
1-11 months	70	70
1-3 years	125	125
4-11 years	150	150
12-13 years	160	110
14-15 years	130	55
16-19 years	60	40
>20 years	40	40

MEDISPAN AUTHORIZATION LEVEL: GPI-12

QUANTITY LIMIT: *No QLs need to be entered within the authorization unless the requested quantity exceeds the QL.*

- QL FOR LETTER ONLY: 30 day supply per fill

AUTHORIZATION DURATION: Initial approval will be for a period of 3 months or less if the reviewing provider feels it is medically appropriate. Subsequent approvals will be for an additional 12 months or less if the reviewing provider feels it is medically appropriate and will require medical record documentation of continued disease improvement or lack of disease progression.

NOTE:

- Perinatal/Infantile-Onset HPP
 - Recommended dosage regimen is 2 mg/kg administered subcutaneously three times per week, or 1 mg/kg administered six times per week. Injection site reactions may limit the tolerability of the six times per week regimen.
 - The dose may be increased to 3 mg/kg three times per week for insufficient efficacy.
- Juvenile-Onset HPP
 - Recommended dosage regimen is 2 mg/kg administered subcutaneously three times per week, or 1 mg/kg administered six times per week. Injection site reactions may limit the tolerability of the six times per week regimen.

If a formulary exception is approved Strensiq will be paid for under the member's prescription drug benefit.

Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.

FORMULARY ALTERNATIVES:

none

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE
STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND
FEDERAL REGULATORY ENTITIES.**

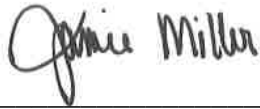
**THIS POLICY WILL BE REVISED AS NECESSARY AND
REVIEWED NO LESS THAN ANNUALLY.**

Geisinger

**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 412.0

**SECTION: Commercial Drug
SUBJECT: Strensiq**



Signed: _____

Title: Director, Pharmacy Services

Date: March 1, 2022

Devised: 3/23/16
Revised: 5/1/16 – updated format, logo, & procedure
Reviewed: 3/1/17 – annual review
Revised: 3/1/18 – annual review, updated signature, updated prescriber criteria
Reviewed: 3/1/19 – annual review
Revised: 3/1/20 – annual review, added GHP Kids
Revised: 3/1/21 – annual review, updated logo, added MediSpan approval level, updated QL statement
Revised: 3/1/22 – annual review, updated referenced policies & covered LOBs

Applicable line of business:

Commercial	X	Medicaid	
Medicare		ACA	X
GHP Kids	X	Self-Insured	X

POLICY:

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for buprenorphine buccal films for GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 487.0 Quantity Limit Exceptions

REQUIRED DEFINITIONS:

1. **Attachment** – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. **Exhibit** – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. **Devised** – the date the policy was implemented.
4. **Revised** – the date of every revision to the policy, including typographical and grammatical changes.
5. **Reviewed** – the date documenting the annual review if the policy has no revisions necessary.

ADDITIONAL DEFINITIONS:

1. **Formulary** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. **Non-formulary products** – those medications that are not included in the Formulary.
3. **Healthcare provider** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).

4. **NCQA** – National Committee for Quality Assurance.
5. **Medically Necessary or Medical Necessity** – covered services rendered by a provider that the Health Plan determines are:
 - A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
 - B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
 - C. In accordance with current standards of medical practice;
 - D. Not primarily for the convenience of the Member, or the Member's Provider; and
 - E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

PROCEDURE:

A formulary exception for coverage of buprenorphine buccal film may be made for members who meet the following criteria:

- Medical record documentation that buprenorphine buccal films are prescribed by a pain management specialist **AND**
- Medical record documentation of pain severe enough to require daily, around-the-clock, long-term opioid treatment and for which alternative treatment options are inadequate **AND**
- Medical record documentation of therapeutic failure on, intolerance to, or contraindication to 3 formulary alternatives, one of which must be morphine sulfate ER

QUANTITY LIMIT: 2 films per day

MEDISPAN AUTHORIZATION LEVEL: GPI-12, generic only

If a formulary exception is approved buprenorphine buccal film will be paid for under the member's prescription drug benefit.

Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.

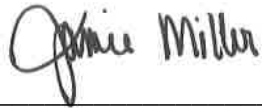
FORMULARY ALTERNATIVES:

fentanyl patch*, morphine sulfate extended release*, tramadol extended release*,
Oxycontin*

*prior authorization required

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE
STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND
FEDERAL REGULATORY ENTITIES.**

**THIS POLICY WILL BE REVISED AS NECESSARY AND
REVIEWED NO LESS THAN ANNUALLY.**



Signed: _____

Title: Director, Pharmacy Services

Date: March 1, 2022

Devised: 5/27/16

Reviewed: 3/1/17 – annual review

Revised: 3/1/18 – annual review, updated signature, updated prescriber criteria

Retired: 8/21/18

Revised: 9/1/21 – policy reinstated, updated to generic, added GPI, clarified abbreviations

Revised: 3/1/22 – annual review, updated referenced policies & covered LOBs, updated FA to include PA *



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 414.0

**SECTION: Commercial Drug
SUBJECT: Veltassa**

Applicable line of business:

Commercial	X	Medicaid	
Medicare		ACA	X
GHP Kids	X	Self-Insured	X

POLICY:

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for Veltassa for GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 487.0 Quantity Limit Exceptions

REQUIRED DEFINITIONS:

1. **Attachment** – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
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5. **Reviewed** – the date documenting the annual review if the policy has no revisions necessary.

ADDITIONAL DEFINITIONS:

1. **Formulary** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. **Non-formulary products** – those medications that are not included in the Formulary.
3. **Healthcare provider** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
4. **NCQA** – National Committee for Quality Assurance.
5. **Medically Necessary or Medical Necessity** – covered services rendered by a provider that the Health Plan determines are:



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 414.0

**SECTION: Commercial Drug
SUBJECT: Veltassa**

- A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
- B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
- C. In accordance with current standards of medical practice;
- D. Not primarily for the convenience of the Member, or the Member's Provider; and
- E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

PROCEDURE:

A formulary exception for coverage of Veltassa may be made for members who meet the following criteria:

- Medical record documentation of a diagnosis of mild to moderate hyperkalemia (serum potassium greater than or equal to 5.1 mEq/L and less than 6.5 mEq/L) **AND**
- Medical record documentation of age greater than or equal to 18 years **AND**
- Medical record documentation that attempt has been made to identify and correct the underlying cause of the patient's hyperkalemia **OR** rationale as to why the underlying cause cannot be corrected **AND**
- For mild hyperkalemia (serum potassium greater than or equal to 5.1 mEq/L and less than 5.5 mEq/L): Medical record documentation that a low potassium diet has been tried and was unsuccessful at controlling the patient's serum potassium level **AND**
- Medical record documentation of a therapeutic failure on, intolerance to, or contraindication to loop diuretic or thiazide diuretic therapy

MEDISPAN AUTHORIZATION LEVEL: GPI-12

QUANTITY LIMIT: *No QLS need to be entered within the authorization unless the requested quantity exceeds the QL.*

- **QL FOR LETTER ONLY:** 1 packet per day

If a formulary exception is approved Veltassa will be paid for under the member's prescription drug benefit.

Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 414.0

**SECTION: Commercial Drug
SUBJECT: Veltassa**

FORMULARY ALTERNATIVES:
sodium polystyrene sulfonate

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE
STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND
FEDERAL REGULATORY ENTITIES.**

**THIS POLICY WILL BE REVISED AS NECESSARY AND
REVIEWED NO LESS THAN ANNUALLY.**

Signed: _____

Title: Director, Pharmacy Services

Date: March 1, 2022

Devised: 5/27/16
Revised: 3/1/17 – annual review, removed Unicode characters
Revised: 3/1/18 – annual review, updated signature
Revised: 3/1/19 – annual review, added QL approval note
Revised: 3/1/20 – annual review, added GHP Kids
Revised: 3/1/21 – annual review, updated logo, added MediSpan approval level, updated QL statement
Revised: 3/1/22 – annual review, updated referenced policies & covered LOBs



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 415.0

**SECTION: Commercial Drug
SUBJECT: Meloxicam Capsules
(generic Vivlodex)**

Applicable line of business:

Commercial	X	Medicaid	
Medicare		ACA	X
GHP Kids	X	Self-Insured	X

POLICY:

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for meloxicam capsules (generic Vivlodex) for GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 487.0 Quantity Limit Exceptions

REQUIRED DEFINITIONS:

1. **Attachment** – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
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4. **Revised** – the date of every revision to the policy, including typographical and grammatical changes.
5. **Reviewed** – the date documenting the annual review if the policy has no revisions necessary.

ADDITIONAL DEFINITIONS:

1. **Formulary** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. **Non-formulary products** – those medications that are not included in the Formulary.
3. **Healthcare provider** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
4. **NCQA** – National Committee for Quality Assurance.
5. **Medically Necessary or Medical Necessity** – covered services rendered by a provider that the Health Plan determines are:



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 415.0

**SECTION: Commercial Drug
SUBJECT: Meloxicam Capsules
(generic Vivlodex)**

- A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
- B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
- C. In accordance with current standards of medical practice;
- D. Not primarily for the convenience of the Member, or the Member's Provider; and
- E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

PROCEDURE:

A formulary exception for coverage of meloxicam capsules (generic Vivlodex) may be made for members who meet the following criteria:

- Medical record documentation of a diagnosis of osteoarthritis **AND**
- Medical record documentation of age greater than or equal to 18 years **AND**
- Medical record documentation of a therapeutic failure on, intolerance to, or contraindication to three (3) generic formulary nonsteroidal anti-inflammatory drugs (NSAIDs), one of which must be meloxicam

MEDISPAN AUTHORIZATION LEVEL: GPI-12, generic only

QUANTITY LIMIT: *No QLs need to be entered within the authorization unless the requested quantity exceeds the QL.*

- **QL FOR LETTER ONLY:** 1 capsule per day

If a formulary exception is approved meloxicam capsules (generic Vivlodex) will be paid for under the member's prescription drug benefit.

Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.

FORMULARY ALTERNATIVES:

celecoxib, choline magnesium salicylate, diclofenac, diclofenac extended release, diflunisal, etodolac, etodolac extended release, fenoprofen, flurbiprofen, ibuprofen, indomethacin, indomethacin sustained release, ketoprofen, ketorolac, meclufenamate,

Geisinger

**POLICY AND PROCEDURE
PHARMACY
MANUAL**

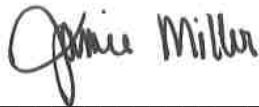
POLICY NUMBER: 415.0

**SECTION: Commercial Drug
SUBJECT: Meloxicam Capsules
(generic Vivlodex)**

meloxicam, nabumetone, naproxen, naproxen sodium, naproxen EC, oxaprozin, piroxicam, salsalate, sulindac, tolmetin

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE
STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND
FEDERAL REGULATORY ENTITIES.**

**THIS POLICY WILL BE REVISED AS NECESSARY AND
REVIEWED NO LESS THAN ANNUALLY.**



Signed: _____

Title: Director, Pharmacy Services

Date: March 1, 2022

Devised: 5/27/16
Revised: 3/1/17 – annual review, removed Unicode characters, defined abbreviations
Revised: 3/1/18 – annual review, updated signature
Revised: 3/1/19 – annual review, added QL approval note, removed GPID note
Revised: 3/1/20 – annual review, added GHP Kids
Revised: 3/1/21 – annual review, updated logo, added MediSpan approval level, updated QL statement, updated Vivlodex to generic
Revised: 3/1/22 – annual review, updated referenced policies & covered LOBs



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 416.0

**SECTION: Commercial Drug
SUBJECT: Vraylar**

Applicable line of business:

Commercial	X	Medicaid	
Medicare		ACA	X
GHP Kids	X	Self-Insured	X

POLICY:

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for Vraylar for GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 487.0 Quantity Limit Exceptions

REQUIRED DEFINITIONS:

1. **Attachment** – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. **Exhibit** – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. **Devised** – the date the policy was implemented.
4. **Revised** – the date of every revision to the policy, including typographical and grammatical changes.
5. **Reviewed** – the date documenting the annual review if the policy has no revisions necessary.

ADDITIONAL DEFINITIONS:

1. **Formulary** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. **Non-formulary products** – those medications that are not included in the Formulary.
3. **Healthcare provider** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
4. **NCQA** – National Committee for Quality Assurance.
5. **Medically Necessary or Medical Necessity** – covered services rendered by a provider that the Health Plan determines are:



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 416.0

**SECTION: Commercial Drug
SUBJECT: Vraylar**

- A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
- B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
- C. In accordance with current standards of medical practice;
- D. Not primarily for the convenience of the Member, or the Member's Provider; and
- E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

PROCEDURE:

New members to the plan already established on therapy may be eligible for continuity of care coverage as long as there is medical record documentation that the safety and effectiveness of use for the prescribed indication is supported by Food and Drug Administration (FDA) approval or adequate medical and scientific evidence in the medical literature.

A formulary exception for coverage of Vraylar may be made for members who meet the following criteria:

Schizophrenia or Manic/Mixed Episode associated with Bipolar I Disorder

- Medical record documentation of age greater than or equal to 18 years **AND**
- Medical record documentation that Vraylar is being used for:
 - Schizophrenia **OR**
 - Acute treatment of manic or mixed episodes associated with bipolar I disorder **AND**
- Medical record documentation of a therapeutic failure on, intolerance to, or contraindication to three (3) generic, formulary atypical antipsychotics

Bipolar Depression

- Medical record documentation of age greater than or equal to 18 years **AND**
- Medical record documentation that Vraylar is being used for the treatment of depressive episodes associated with bipolar I disorder (bipolar depression) **AND**
- Medical record documentation of therapeutic failure on, intolerance to, or contraindication to quetiapine

MEDISPAN AUTHORIZATION LEVEL: GPI-10



POLICY NUMBER: 416.0

**POLICY AND PROCEDURE
PHARMACY
MANUAL**

**SECTION: Commercial Drug
SUBJECT: Vraylar**

QUANTITY LIMIT: *No QLs need to be entered within the authorization unless the requested quantity exceeds the QL.*

- **QL FOR LETTER ONLY:** 1 capsule per day

If a formulary exception is approved Vraylar will be paid for under the member's prescription drug benefit.

Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.

FORMULARY ALTERNATIVES:

Schizophrenia or Manic/Mixed Episode associated with Bipolar I Disorder: aripiprazole, clozapine, olanzapine, paliperidone*, quetiapine, risperidone, ziprasidone

Bipolar Depression: quetiapine, olanzapine/fluoxetine

*prior authorization required

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE
STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND
FEDERAL REGULATORY ENTITIES.**

**THIS POLICY WILL BE REVISED AS NECESSARY AND
REVIEWED NO LESS THAN ANNUALLY.**

Signed: _____

Title: Director, Pharmacy Services

Date: March 1, 2022

- Devised: 5/27/16
- Revised: 3/1/17 – annual review, removed Unicode characters
- Revised: 3/1/18 – annual review, updated signature, added grandfather language
- Revised: 3/1/19 – annual review, added QL approval note, removed GPID note
- Revised: 7/23/19 – added bipolar depression indication
- Revised: 3/1/20 – annual review, added GHP Kids



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 416.0

**SECTION: Commercial Drug
SUBJECT: Vraylar**

Revised: 3/1/21 – annual review, updated logo, added MediSpan approval level, updated QL statement
Revised: 3/1/22 – annual review, updated referenced policies & covered LOBs



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 417.0

**SECTION: Commercial Drug
SUBJECT: Venclexta**

Applicable line of business:

Commercial	X	Medicaid	
Medicare		ACA	X
GHP Kids	X	Self-Insured	X

POLICY:

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for Venclexta for GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 487.0 Quantity Limit Exceptions

REQUIRED DEFINITIONS:

1. **Attachment** – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. **Exhibit** – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. **Devised** – the date the policy was implemented.
4. **Revised** – the date of every revision to the policy, including typographical and grammatical changes.
5. **Reviewed** – the date documenting the annual review if the policy has no revisions necessary.

ADDITIONAL DEFINITIONS:

1. **Formulary** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. **Non-formulary products** – those medications that are not included in the Formulary.
3. **Healthcare provider** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
4. **NCQA** – National Committee for Quality Assurance.
5. **Medically Necessary or Medical Necessity** – covered services rendered by a provider that the Health Plan determines are:



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 417.0

**SECTION: Commercial Drug
SUBJECT: Venclexta**

- A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
- B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
- C. In accordance with current standards of medical practice;
- D. Not primarily for the convenience of the Member, or the Member's Provider; and
- E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

PROCEDURE:

New members to the plan already established on therapy may be eligible for continuity of care coverage as long as there is medical record documentation that the safety and effectiveness of use for the prescribed indication is supported by Food and Drug Administration (FDA) approval or adequate medical and scientific evidence in the medical literature.

A formulary exception for coverage of Venclexta may be made for members who meet the following criteria:

CLL or SLL

- Medical record documentation that Venclexta is prescribed by a hematologist or oncologist **AND**
- Medical record documentation of age greater than or equal to 18 years **AND**
- Medical record documentation of chronic lymphocytic leukemia (CLL) or small lymphocytic lymphoma (SLL)

AML

- Medical record documentation that Venclexta is prescribed by a hematologist or oncologist **AND**
- Medical record documentation of age 75 years or older **OR** medical record documentation of a comorbidity that precludes member from receiving intensive induction chemotherapy **AND**
- Medical record documentation of newly-diagnosed acute myeloid leukemia (AML) **AND**
- Medical record documentation that Venclexta will be used in combination with azacytidine, decitabine, or low-dose cytarabine



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 417.0

**SECTION: Commercial Drug
SUBJECT: Venclexta**

MEDISPAN AUTHORIZATION LEVEL: GPI-10, number of claims authorized = 1, enter for the remainder of the calendar year

QUANTITY LIMIT: *No QLs need to be entered within the authorization unless the requested quantity exceeds the QL.*

- **QL FOR LETTER ONLY:**
 - 10 mg tablet: 2 tablets per day, 30 day supply per fill
 - 50 mg tablet: 1 tablet per day, 30 day supply per fill
 - 100 mg tablet, 6 tablets per day, 30 day supply per fill
 - Starter Pack: 42 tablets per 28 days

RE-AUTHORIZATION CRITERIA: Venclexta is configured as a prior authorization for new starts only. Venclexta will no longer be covered if it is identified that the member is not receiving appropriate follow-up care from the prescribing specialist or if the member has greater than or equal to a 90 day break in therapy.

- Medical record documentation that the member is receiving appropriate follow-up care from the prescribing specialist

If a formulary exception is approved Venclexta will be paid for under the member's prescription drug benefit.

Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.

FORMULARY ALTERNATIVES:

CLL/SLL: Imbruvica*, Calquence*, Zydelig*

AML: Daurismo*, Tibsovo*, Idhifa*

*prior authorization required

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE
STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND
FEDERAL REGULATORY ENTITIES.**

**THIS POLICY WILL BE REVISED AS NECESSARY AND
REVIEWED NO LESS THAN ANNUALLY.**



POLICY NUMBER: 417.0

**POLICY AND PROCEDURE
PHARMACY
MANUAL**

**SECTION: Commercial Drug
SUBJECT: Venclexta**

Signed: _____

Title: Director, Pharmacy Services

Date: March 1, 2022

- Devised: 5/27/16
- Revised: 3/1/17 – annual review, removed Unicode characters
- Revised: 10/10/17 – increased authorization duration to 12 months
- Revised: 3/1/18 – annual review, updated signature, added grandfather language, updated prescriber criteria
- Revised: 8/21/18 – added SLL, added without 17p deletion, updated FA
- Revised: 2/6/19 – added AML indication, add SLL abbreviation, updated 100mg QL, added QL CSR note
- Reviewed: 3/1/19 – annual review
- Revised: 3/21/19 – updated age/comorbidity criteria, updated FA
- Revised: 7/23/19 – removed 17p deletion requirement/note, removed prior therapy failure from CLL/SLL
- Revised: 2/04/20 – updated FA
- Revised: 3/1/20 – annual review, added GHP Kids
- Revised: 3/1/21 – annual review, updated logo, added MediSpan approval level, updated QL statement
- Revised: 12/1/21 – added one-time PA to approval crit., removed auth duration & added re-auth crit.
- Revised: 3/1/22 – annual review, updated referenced policies & covered LOBs



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 418.0

**SECTION: Commercial Drug
SUBJECT: Uptravi**

Applicable line of business:

Commercial	X	Medicaid	
Medicare		ACA	X
GHP Kids	X	Self-Insured	X

POLICY:

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for Uptravi for GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 487.0 Quantity Limit Exceptions

REQUIRED DEFINITIONS:

1. **Attachment** – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. **Exhibit** – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. **Devised** – the date the policy was implemented.
4. **Revised** – the date of every revision to the policy, including typographical and grammatical changes.
5. **Reviewed** – the date documenting the annual review if the policy has no revisions necessary.

ADDITIONAL DEFINITIONS:

1. **Formulary** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. **Non-formulary products** – those medications that are not included in the Formulary.
3. **Healthcare provider** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
4. **NCQA** – National Committee for Quality Assurance.
5. **Medically Necessary or Medical Necessity** – covered services rendered by a provider that the Health Plan determines are:

- A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
- B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
- C. In accordance with current standards of medical practice;
- D. Not primarily for the convenience of the Member, or the Member's Provider; and
- E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

PROCEDURE:

A formulary exception for coverage of Uptravi may be made for members who meet the following criteria:

- Medical record documentation that Uptravi is prescribed by a cardiologist or pulmonologist **AND**
- Medical record documentation of a diagnosis of World Health Organization (WHO) Group I, functional class II or III pulmonary hypertension **AND**
- Medical record documentation of use in combination with, or failure on, intolerance to, or contraindication to sildenafil and/or an endothelin receptor antagonist (Tracleer [bosentan], Letairis [ambrisentan], or Opsumit [macitentan])

MEDISPAN AUTHORIZATION LEVEL: GPI-10

QUANTITY LIMIT: *No QLs need to be entered within the authorization unless the requested quantity exceeds the QL.*

- **QL FOR LETTER ONLY:**
 - Uptravi 200 mcg tablets: 140 tablets per 28 days
 - Uptravi 200-800 mcg tablet starter pack: 200 tablets per 28 days, one (1) fill per 180 days
 - All other strengths: 2 tablets per day, 30 day supply per fill

If a formulary exception is approved Uptravi will be paid for under the member's prescription drug benefit.

Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.

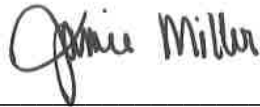
FORMULARY ALTERNATIVES:

bosentan*, Orenitram*, treprostinil* (generic Remodulin), Tyvaso*, Ventavis*, Adempas*,
Opsumit*, ambrisentan*, tadalafil* (generic Adcirca), sildenafil* (generic Revatio)

*prior authorization required

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE
STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND
FEDERAL REGULATORY ENTITIES.**

**THIS POLICY WILL BE REVISED AS NECESSARY AND
REVIEWED NO LESS THAN ANNUALLY.**



Signed: _____

Title: Director, Pharmacy Services

Date: March 1, 2022

Devised: 5/27/16
Revised: 7/27/16 – added QL, updated FA
Reviewed: 3/1/17 – annual review
Revised: 3/1/18 – annual review, updated signature, updated prescriber criteria
Revised: 3/1/19 – annual review, added QL approval note
Revised: 5/24/19 – updated 200 & starter pack QL, updated FA where generics available
Revised: 3/1/20 – annual review, added GHP Kids
Revised: 3/1/21 – annual review, updated logo, added MediSpan approval level, updated QL statement,
updated FA
Revised: 3/1/22 – annual review, updated referenced policies & covered LOBs



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 419.0

**SECTION: Commercial Drug
SUBJECT: Zepatier**

Applicable line of business:

Commercial	X	Medicaid	
Medicare		ACA	X
GHP Kids	X	Self-Insured	X

POLICY:

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for Zepatier for GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 487.0 Quantity Limit Exceptions

REQUIRED DEFINITIONS:

1. **Attachment** – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. **Exhibit** – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. **Devised** – the date the policy was implemented.
4. **Revised** – the date of every revision to the policy, including typographical and grammatical changes.
5. **Reviewed** – the date documenting the annual review if the policy has no revisions necessary.

ADDITIONAL DEFINITIONS:

1. **Formulary** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. **Non-formulary products** – those medications that are not included in the Formulary.
3. **Healthcare provider** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
4. **NCQA** – National Committee for Quality Assurance.
5. **Medically Necessary or Medical Necessity** – covered services rendered by a provider that the Health Plan determines are:

- A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
 - B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
 - C. In accordance with current standards of medical practice;
 - D. Not primarily for the convenience of the Member, or the Member's Provider; and
 - E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.
6. **HBV** – Hepatitis B Virus
 7. **HCV** – Hepatitis C Virus
 8. **HIV** – Human Immunodeficiency Virus

PROCEDURE:

A formulary exception for coverage of Zepatier may be made for members who meet the following criteria:

- Medical record documentation of age greater than or equal to 12 years of age **OR** weighing at least 30 kg **AND**
- Medical record documentation of a diagnosis of hepatitis C infection **AND**
- Medical record documentation of the member's hepatitis C genotype **AND**
- Medical record documentation of a diagnosis of hepatitis C virus (HCV) genotype 1 or 4 infection **AND**
- Medical record documentation of METAVIR liver scoring **AND**
- Medical record documentation of a hepatocellular carcinoma screening in those with cirrhosis (METAVIR score F4) **AND**
- Medical record documentation that the member does not have moderate or severe hepatic impairment (Child-Pugh B or C) **AND**
- Medical record documentation of:
 - Genotype 1a
 - As monotherapy if treatment-naïve or peginterferon alfa + ribavirin experienced without baseline NS5A polymorphisms **OR**
 - Concurrent therapy with ribavirin if treatment-naïve or peginterferon alfa + ribavirin experienced with baseline NS5A polymorphisms **OR**
 - Concurrent therapy with ribavirin if peginterferon alfa + ribavirin + hepatitis C virus (HCV) NS3/4A protease inhibitor experienced **OR**
 - Genotype 1b
 - As monotherapy if treatment-naïve or peginterferon alfa + ribavirin experienced **OR**

- Concurrent therapy with ribavirin if peginterferon alfa + ribavirin + hepatitis C virus (HCV) NS3/4A protease inhibitor experienced **OR**
- Genotype 4
 - As monotherapy if treatment naïve or if treatment experienced with peginterferon alfa + ribavirin who experienced virologic relapse following treatments **OR**
 - Concurrent therapy with ribavirin if treatment experienced with peginterferon alfa + ribavirin who experienced virologic failure during treatment **AND**
- Medical record documentation of the member receiving a Food and Drug Administration (FDA) approved medication regimen that is inside the parameters of use approved by the FDA or supported in the widely used compendia available **AND**
- Medical record documentation of appropriate duration of treatment **AND**
- Medical record documentation of previous treatment and treatment response **AND**
- Medical record documentation of concurrent therapy with appropriate dose and duration of ribavirin (less than 66 kg – 800 mg per day, 66 to 80 kg = 1000 mg per day, 81 to 105 kg = 1200 mg per day, greater than 105 kg = 1400 mg per day), if indicated **AND**
- Medical record documentation of any potential drug interactions addressed by the prescriber (such as discontinuation of the interacting drug, dose reduction of the interacting drug, or counseling of the recipient of the risks associated with the use of both medications when they interact) **AND**
- Medical record documentation of receiving the following within the past 3 months:
 - Hepatic function panel
 - Complete blood count including differential
 - Basic metabolic panel
 - Baseline hepatitis C virus (HCV) RNA viral load **AND**
- Medical record documentation of a negative pregnancy test if member is female of childbearing potential and receiving ribavirin **AND**
- When concurrent ribavirin therapy is indicated and prescribed, medical record documentation for male members that female partner is not pregnant **AND**
- If the member or their partner are of childbearing potential, medical record documentation that the member was instructed to practice effective contraception during therapy with ribavirin and for 6 months following discontinuation of ribavirin therapy **AND**
- If actively abusing alcohol or intravenous (IV) drugs, or has a history of abuse, has documentation of prescriber counseling regarding the risks of alcohol or IV drug abuse, and an offer of a referral for substance use disorder treatment **AND**
- Medical record documentation that member received pre-treatment readiness education about hepatitis C treatment expectations by a health care provider **AND**

- Medical record documentation that the member commits to the documented planned course of treatment including anticipated blood tests and visits, during and after treatment **AND**
- Medical record documentation that member does not have a limited life expectancy of less than 12 months due to non-liver related co-morbid conditions **AND**
- Medical record documentation of completed:
 - Hepatitis B immunization series **OR**
 - Hepatitis B screening (sAb/sAg and cAb/cAg) **AND** Quantitative hepatitis B virus (HBV) DNA if positive for hepatitis B sAg or cAb or cAg **AND**
 - If there is detectable hepatitis B virus (HBV) DNA, will be treated for Hepatitis B **OR**
 - If negative for hepatitis B sAb, is being vaccinated against Hepatitis B **AND**
- Medical record documentation of human immunodeficiency virus (HIV) screening (HIV Ag/Ab) and if confirmed positive by HIV-1/HIV-2 differentiation immunoassay:
 - Is being treated for human immunodeficiency virus (HIV) **OR**
 - If not being treated for human immunodeficiency virus (HIV), the medical record documents the rationale for the beneficiary not being treated **AND**
- Medical record documentation of therapeutic failure on, intolerance to, or contraindication to Mavyret, if clinical appropriate **AND**
- Medical record documentation that member has been evaluated and treated by a contracted Center of Excellence in hepatitis C management

OR

- Medical record documentation of a hepatitis C negative recipient receiving a transplant from a hepatitis C positive donor **AND**
- Medical record documentation of therapeutic failure on, intolerance to, or contraindication to Mavyret, if clinically appropriate

NOTE: Center of Excellence (COE) requirements do not apply to strategic partner TPA plans (i.e., Northern Light Health).

MEDISPAN AUTHORIZATION LEVEL: GPI-12

QUANTITY LIMIT: *No QLs need to be entered within the authorization unless the requested quantity exceeds the QL.*

- **QL FOR LETTER ONLY:** 1 tablet per day, 28 day supply per fill



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 419.0

**SECTION: Commercial Drug
SUBJECT: Zepatier**

AUTHORIZATION DURATION: Per AASLD/IDSA guidelines

If a formulary exception is approved Zepatier will be paid for under the member's prescription drug benefit.

Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.

FORMULARY ALTERNATIVES (if applicable):

Mavyret*

*prior authorization required

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE
STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND
FEDERAL REGULATORY ENTITIES.**

**THIS POLICY WILL BE REVISED AS NECESSARY AND
REVIEWED NO LESS THAN ANNUALLY.**

Signed: _____

Title: Director, Pharmacy Services

Date: April 6, 2022

- Devised: 5/27/16
- Revised: 11/22/16 – added F2 fibrosis, referral to substance use treatment. Removed 6 months abstinence, substance use treatment compliance, UDS/fill history, GHP representative. Updated FA
- Revised: 3/1/17 – annual review, defined abbreviations
- Revised: 6/2/17 – added regimen supported by compendia, added virologic relapse/failure to G4, removed failure with same DAA, added non-liver related co-morbid conditions to life expectancy, removed fibrosis/liver manifestations requirement, added METAVIR score
- Revised: 11/27/17 – added failure of Mavyret, updated FA, updated signature
- Revised: 1/19/18 – updated age format & FA, removed prescriber, added Hep B & HIV criteria
- Revised: 3/1/18 – annual review, updated Hep B/HIV criteria to match DHS
- Revised: 12/28/18 – added HCV positive transplant indication/FA criteria, added COE
- Revised: 3/1/19 – annual review, defined abbr.



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 419.0

**SECTION: Commercial Drug
SUBJECT: Zepatier**

- Revised: 7/23/19 – added TPA COE exclusion
- Revised: 3/1/20 – annual review, added GHP Kids
- Revised: 3/1/21 – annual review, updated logo, added MediSpan approval level, updated QL statement, removed AtlantiCare and St Lukes
- Revised: 3/1/22 – annual review, updated referenced policies & covered LOBs
- Revised: 4/6/12 – updated age to 12 or weight \geq 30 kg, updated auth duration to reference guidelines



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 420.0

**SECTION: Commercial Drug
SUBJECT: Cabometyx**

Applicable line of business:

Commercial	X	Medicaid	
Medicare		ACA	X
GHP Kids	X	Self-Insured	X

POLICY:

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for Cabometyx for GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 487.0 Quantity Limit Exceptions

REQUIRED DEFINITIONS:

1. **Attachment** – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. **Exhibit** – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. **Devised** – the date the policy was implemented.
4. **Revised** – the date of every revision to the policy, including typographical and grammatical changes.
5. **Reviewed** – the date documenting the annual review if the policy has no revisions necessary.

ADDITIONAL DEFINITIONS:

1. **Formulary** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. **Non-formulary products** – those medications that are not included in the Formulary.
3. **Healthcare provider** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
4. **NCQA** – National Committee for Quality Assurance.
5. **Medically Necessary or Medical Necessity** – covered services rendered by a provider that the Health Plan determines are:

- A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
- B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
- C. In accordance with current standards of medical practice;
- D. Not primarily for the convenience of the Member, or the Member's Provider; and
- E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

PROCEDURE:

New members to the plan already established on therapy may be eligible for continuity of care coverage as long as there is medical record documentation that the safety and effectiveness of use for the prescribed indication is supported by Food and Drug Administration (FDA) approval or adequate medical and scientific evidence in the medical literature.

A formulary exception for coverage of Cabometyx may be made for members who meet the following criteria:

Renal Cell Carcinoma

- Medical record documentation that Cabometyx is prescribed by an oncologist **AND**
- Medical record documentation of use in combination with nivolumab (Opdivo) for previously untreated advanced renal cell carcinoma **OR**
- Medical record documentation of use as a single agent for relapse or for surgically unresectable advanced or metastatic renal cell carcinoma **AND**
- If the requested dose is 80 mg daily: Medical record documentation that the patient is using Cabometyx in combination with a strong CYP3A4 inducer, including but not limited to, rifampin, phenytoin, carbamazepine, phenobarbital, rifabutin, rifapentine, and St. John's Wort

Hepatocellular Carcinoma

- Medical record documentation that Cabometyx is prescribed by an oncologist **AND**
- Medical record documentation of a diagnosis of hepatocellular carcinoma (HCC) **AND**
- Medical record documentation of therapeutic failure on, intolerance to, or contraindication to sorafenib (Nexavar) **AND**
- If the requested dose is 80 mg daily: Medical record documentation that the patient is using Cabometyx in combination with a strong CYP3A4 inducer, including but not

limited to, rifampin, phenytoin, carbamazepine, phenobarbital, rifabutin, rifapentine, and St. John's Wort

Differentiated Thyroid Cancer (DTC)

- Medical record documentation that Cabometyx is prescribed by a hematologist or oncologist **AND**
- Medical record documentation of age greater than or equal to 12 years **AND**
- Medical record documentation of locally advanced or metastatic differentiated thyroid cancer (DTC) **AND**
- Medical record documentation of progression following prior VEGFR-targeted therapy **AND**
- Medical record documentation that radioactive iodine-refractory or ineligible

MEDISPAN AUTHORIZATION LEVEL: GPI-12, number of claims authorized = 1, enter for the remainder of the calendar year

QUANTITY LIMIT: *No QLs need to be entered within the authorization unless the requested quantity exceeds the QL.*

- **QL FOR LETTER ONLY:**
 - If approved for 20 mg, 40 mg, or 60 mg daily dose: QL 1 per day, 30 day supply per fill
 - If approved for 80 mg daily, dosed as one 20 mg + one 60 mg tablet: QL 1 per day, 30 day supply per fill
 - If approved for 80 mg daily, dosed as two 40 mg tablets daily: QL 2 per day, 30 day supply per fill

RE-AUTHORIZATION CRITERIA: Cabometyx is configured as a prior authorization for new starts only. Cabometyx will no longer be covered if it is identified that the member is not receiving appropriate follow-up care from the prescribing specialist or if the member has greater than or equal to a 90 day break in therapy.

- Medical record documentation that the member is receiving appropriate follow-up care from the prescribing specialist

If a formulary exception is approved Cabometyx will be paid for under the member's prescription drug benefit.

Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 420.0

**SECTION: Commercial Drug
SUBJECT: Cabometyx**

FORMULARY ALTERNATIVES:

Renal Cell Carcinoma: everolimus (generic Afinitor)*, Inlyta*, Lenvima*, Nexavar*, sunitinib*, Votrient*

Hepatocellular Carcinoma: Nexavar*

*prior authorization required

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE
STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND
FEDERAL REGULATORY ENTITIES.**

**THIS POLICY WILL BE REVISED AS NECESSARY AND
REVIEWED NO LESS THAN ANNUALLY.**

Signed: _____

Title: Director, Pharmacy Services

Date: March 1, 2022

Devised: 7/21/16
Reviewed: 3/1/17 – annual review
Revised: 10/10/17 – increased authorization duration to 12 months
Revised: 1/17/18 – removed 'predominant clear-cell histology' from indication, removed prior failure, updated signature
Revised: 3/1/18 – annual review, added grandfather language, updated prescriber criteria
Revised: 3/1/19 – annual review, added QL approved note, removed GPID note
Revised: 3/28/19 – added HCC indication, updated FA
Revised: 3/1/20 – annual review, added GHP Kids
Revised: 3/1/21 – annual review, updated logo, added MediSpan approval level, updated QL statement
Revised: 3/26/21 – added in combination with Opdivo for advanced RCC
Revised: 11/24/21 – added one-time PA to approval crit., removed auth duration & added re-auth crit.
Revised: 1/5/22 – added DTC indication
Revised: 3/1/22 – annual review, updated referenced policies & covered LOBs, updated FA



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 421.0

**SECTION: Commercial Drug
SUBJECT: Nuplazid**

Applicable line of business:

Commercial	X	Medicaid	
Medicare		ACA	X
GHP Kids	X	Self-Insured	X

POLICY:

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for Nuplazid for GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 487.0 Quantity Limit Exceptions

REQUIRED DEFINITIONS:

1. **Attachment** – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. **Exhibit** – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. **Devised** – the date the policy was implemented.
4. **Revised** – the date of every revision to the policy, including typographical and grammatical changes.
5. **Reviewed** – the date documenting the annual review if the policy has no revisions necessary.

ADDITIONAL DEFINITIONS:

1. **Formulary** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. **Non-formulary products** – those medications that are not included in the Formulary.
3. **Healthcare provider** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
4. **NCQA** – National Committee for Quality Assurance.
5. **Medically Necessary or Medical Necessity** – covered services rendered by a provider that the Health Plan determines are:



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 421.0

**SECTION: Commercial Drug
SUBJECT: Nuplazid**

- A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
- B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
- C. In accordance with current standards of medical practice;
- D. Not primarily for the convenience of the Member, or the Member's Provider; and
- E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

PROCEDURE:

New members to the plan already established on therapy may be eligible for continuity of care coverage as long as there is medical record documentation that the safety and effectiveness of use for the prescribed indication is supported by Food and Drug Administration (FDA) approval or adequate medical and scientific evidence in the medical literature.

A formulary exception for coverage of Nuplazid may be made for members who meet the following criteria:

- Medical record documentation of age greater than or equal to 18 years **AND**
- Medical record documentation of diagnosis of Parkinson's disease psychosis (defined by illusions, a false sense of presence, hallucinations, or delusions) **AND**
- Medical record documentation that the diagnosis is established by or in consultation with a neurologist **AND**
- Medical record documentation that the psychosis is not due to other conditions (which may include, but are not limited to, another mental disorder or physiological effects of a substance)

MEDISPAN AUTHORIZATION LEVEL: GPI-10

QUANTITY LIMIT: *No QLs need to be entered within the authorization unless the requested quantity exceeds the QL.*

- **QL FOR LETTER ONLY:** 1 per day, 30 day supply per fill

AUTHORIZATION DURATION: Approval will be given for an initial duration of three (3) months. For continuation of coverage, medical record documentation of clinical improvement or lack of progression in signs and symptoms of Parkinson's disease psychosis on three (3) months of Nuplazid therapy is required.

After the initial three (3) month approval, subsequent approvals for coverage will be for a duration of one (1) year. Reevaluation of coverage will be every one (1) year requiring medical record documentation of continued or sustained improvement in the signs and symptoms of Parkinson's disease psychosis while on Nuplazid therapy.

If a formulary exception is approved Nuplazid will be paid for under the member's prescription drug benefit.

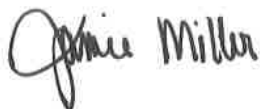
Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.

FORMULARY ALTERNATIVES:

none

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE
STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND
FEDERAL REGULATORY ENTITIES.**

**THIS POLICY WILL BE REVISED AS NECESSARY AND
REVIEWED NO LESS THAN ANNUALLY.**



Signed: _____

Title: Director, Pharmacy Services

Date: March 1, 2022

Devised: 7/21/16
Reviewed: 3/1/17 – annual review
Revised: 3/1/18 – annual review, updated signature, updated age criteria, added grandfather language
Revised: 10/8/18 – updated QL
Revised: 3/1/19 – annual review, added QL approval note



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 421.0

**SECTION: Commercial Drug
SUBJECT: Nuplazid**

Revised: 3/1/20 – annual review, added GHP Kids

Revised: 3/1/21 – annual review, updated logo, added MediSpan approval level, removed 17 mg QL due to D/C, updated QL statement

Revised: 3/1/22 – annual review, updated referenced policies & covered LOBs



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 422.0

**SECTION: Commercial Drug
SUBJECT: Briviact**

Applicable line of business:

Commercial	X	Medicaid	
Medicare		ACA	X
GHP Kids	X	Self-Insured	X

POLICY:

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for Briviact for GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 487.0 Quantity Limit Exceptions

REQUIRED DEFINITIONS:

1. **Attachment** – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. **Exhibit** – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. **Devised** – the date the policy was implemented.
4. **Revised** – the date of every revision to the policy, including typographical and grammatical changes.
5. **Reviewed** – the date documenting the annual review if the policy has no revisions necessary.

ADDITIONAL DEFINITIONS:

1. **Formulary** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. **Non-formulary products** – those medications that are not included in the Formulary.
3. **Healthcare provider** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
4. **NCQA** – National Committee for Quality Assurance.
5. **Medically Necessary or Medical Necessity** – covered services rendered by a provider that the Health Plan determines are:



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 422.0

**SECTION: Commercial Drug
SUBJECT: Briviact**

- A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
- B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
- C. In accordance with current standards of medical practice;
- D. Not primarily for the convenience of the Member, or the Member's Provider; and
- E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

PROCEDURE:

New members to the plan already established on therapy may be eligible for continuity of care coverage as long as there is medical record documentation that the safety and effectiveness of use for the prescribed indication is supported by Food and Drug Administration (FDA) approval or adequate medical and scientific evidence in the medical literature.

A formulary exception for coverage of Briviact may be made for members who meet the following criteria:

- Medical record documentation of a diagnosis of partial-onset seizures **AND**
- Medical record documentation of age greater than or equal to 1 month **AND**
- Medical record documentation of therapeutic failure on, intolerance to, or contraindication to at least three formulary alternatives, one of which must be levetiracetam **AND**
- Medical record documentation that Briviact is not being used in combination with levetiracetam

MEDISPAN AUTHORIZATION LEVEL: GPI-10

QUANTITY LIMIT: *No QLs need to be entered within the authorization unless the requested quantity exceeds the QL.*

- **QL FOR LETTER ONLY:** 2 tablets per day or 20 mL per day of oral solution

If a formulary exception is approved Briviact will be paid for under the member's prescription drug benefit.



POLICY NUMBER: 422.0

**POLICY AND PROCEDURE
PHARMACY
MANUAL**

**SECTION: Commercial Drug
SUBJECT: Briviact**

Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.

FORMULARY ALTERNATIVES:

Patients > 1 month of age: carbamazepine, levetiracetam solution, phenobarbital, phenytoin, pregabalin

Patients > 6 months of age: levetiracetam IR

Patients > 2 years of age: lamotrigine IR, oxcarbazepine, topiramate IR, topiramate ER*

Patients > 3 years of age: gabapentin

Patients > 4 years of age: Aptiom*, Vimpat*

Additional formulary alternatives for patients over certain ages: Divalproex (10+), levetiracetam ER (12+), tiagabine (12+), Fycompa* (12+), lamotrigine ER (13+), felbamate (14+), and zonisamide (16+)

*prior authorization required

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE
STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND
FEDERAL REGULATORY ENTITIES.**

**THIS POLICY WILL BE REVISED AS NECESSARY AND
REVIEWED NO LESS THAN ANNUALLY.**

Signed: _____

Title: Director, Pharmacy Services

Date: March 1, 2022

Devised: 7/22/16
Reviewed: 3/1/17 – annual review
Revised: 11/27/17 – removed adjunctive therapy requirement, updated signature
Revised: 3/1/18 – annual review, added grandfather language

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Dev. 7/22/16

Rev. 3/1/22



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 422.0

**SECTION: Commercial Drug
SUBJECT: Briviact**

- Revised: 8/7/18 – updated age to 4 years, updated FA
- Revised: 3/1/19 – annual review, added QL approval note
- Revised: 11/15/19 – updated FA
- Revised: 3/1/20 – annual review, added GHP Kids
- Revised: 3/1/21 – annual review, updated logo, added MediSpan approval level, updated QL statement
- Revised: 11/22/21 – updated age to 1 month, updated FA
- Revised: 3/1/22 – annual review, updated referenced policies & covered LOBs



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 423.0

**SECTION: Commercial Drug
SUBJECT: Adzenys XR-ODT**

Applicable line of business:

Commercial	X	Medicaid	
Medicare		ACA	X
GHP Kids	X	Self-Insured	X

POLICY:

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for Adzenys XR-ODT for GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 487.0 Quantity Limit Exceptions

REQUIRED DEFINITIONS:

1. **Attachment** – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. **Exhibit** – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. **Devised** – the date the policy was implemented.
4. **Revised** – the date of every revision to the policy, including typographical and grammatical changes.
5. **Reviewed** – the date documenting the annual review if the policy has no revisions necessary.

ADDITIONAL DEFINITIONS:

1. **Formulary** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. **Non-formulary products** – those medications that are not included in the Formulary.
3. **Healthcare provider** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
4. **NCQA** – National Committee for Quality Assurance.
5. **Medically Necessary or Medical Necessity** – covered services rendered by a provider that the Health Plan determines are:



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 423.0

**SECTION: Commercial Drug
SUBJECT: Adzenys XR-ODT**

- A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
- B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
- C. In accordance with current standards of medical practice;
- D. Not primarily for the convenience of the Member, or the Member's Provider; and
- E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

PROCEDURE:

New members to the plan already established on therapy may be eligible for continuity of care coverage as long as there is medical record documentation that the safety and effectiveness of use for the prescribed indication is supported by Food and Drug Administration (FDA) approval or adequate medical and scientific evidence in the medical literature.

A formulary exception for coverage of Adzenys XR-ODT may be made for members who meet the following criteria:

- Medical record documentation of a diagnosis of attention deficit hyperactivity disorder (ADHD) **AND**
- Medical record documentation of age greater than or equal to 6 years **AND**
- Medical record documentation of a therapeutic failure on, intolerance to, or contraindication to methylphenidate CD (generic Metadate CD) **AND** amphetamine/dextroamphetamine SR combination

MEDISPAN AUTHORIZATION LEVEL: GPI-12

If a formulary exception is approved Adzenys XR-ODT will be paid for under the member's prescription drug benefit.

Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.



POLICY NUMBER: 423.0

**POLICY AND PROCEDURE
PHARMACY
MANUAL**

**SECTION: Commercial Drug
SUBJECT: Adzenys XR-ODT**

FORMULARY ALTERNATIVES:

dextroamphetamine, dextroamphetamine/amphetamine combination, dextroamphetamine/amphetamine SR combination, methylphenidate, methylphenidate sustained-release, methylphenidate extended-release, Metadate CD, guanfacine ER, atomoxetine

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE
STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND
FEDERAL REGULATORY ENTITIES.**

**THIS POLICY WILL BE REVISED AS NECESSARY AND
REVIEWED NO LESS THAN ANNUALLY.**

Signed: _____

Title: Director, Pharmacy Services

Date: March 1, 2022

Devised: 7/22/16
Reviewed: 3/1/17 – annual review
Revised: 3/1/18 – annual review, updated signature, added grandfather language, updated age criteria & FA
Reviewed: 3/1/19 – annual review
Revised: 3/1/20 – annual review, added GHP Kids
Revised: 3/1/21 – annual review, updated logo, added MediSpan approval level
Revised: 3/1/22 – annual review, updated referenced policies & covered LOBs



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 424.0

**SECTION: Commercial Drug
SUBJECT: Dyanavel**

Applicable line of business:

Commercial	X	Medicaid	
Medicare		ACA	X
GHP Kids	X	Self-Insured	X

POLICY:

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for Dyanavel for GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 487.0 Quantity Limit Exceptions

REQUIRED DEFINITIONS:

1. **Attachment** – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. **Exhibit** – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. **Devised** – the date the policy was implemented.
4. **Revised** – the date of every revision to the policy, including typographical and grammatical changes.
5. **Reviewed** – the date documenting the annual review if the policy has no revisions necessary.

ADDITIONAL DEFINITIONS:

1. **Formulary** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. **Non-formulary products** – those medications that are not included in the Formulary.
3. **Healthcare provider** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
4. **NCQA** – National Committee for Quality Assurance.



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 424.0

**SECTION: Commercial Drug
SUBJECT: Dyanavel**

5. **Medically Necessary or Medical Necessity** – covered services rendered by a provider that the Health Plan determines are:
- A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
 - B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
 - C. In accordance with current standards of medical practice;
 - D. Not primarily for the convenience of the Member, or the Member's Provider; and
 - E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

PROCEDURE:

New members to the plan already established on therapy may be eligible for continuity of care coverage as long as there is medical record documentation that the safety and effectiveness of use for the prescribed indication is supported by Food and Drug Administration (FDA) approval or adequate medical and scientific evidence in the medical literature.

A formulary exception for coverage of Dyanavel may be made for members who meet the following criteria:

- Medical record documentation of a diagnosis of attention deficit hyperactivity disorder (ADHD) **AND**
- Medical record documentation of age greater than or equal to 6 years **AND**
- Medical record documentation of a therapeutic failure on, intolerance to, or contraindication to methylphenidate CD (generic Metadate CD) **AND** amphetamine/dextroamphetamine SR combination

MEDISPAN AUTHORIZATION LEVEL: GPI-10

If a formulary exception is approved Dyanavel will be paid for under the member's prescription drug benefit.

Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.

Geisinger

**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 424.0

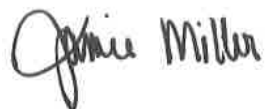
**SECTION: Commercial Drug
SUBJECT: Dyanavel**

FORMULARY ALTERNATIVES:

dextroamphetamine, dextroamphetamine/amphetamine combination, dextroamphetamine/amphetamine SR combination, methylphenidate, methylphenidate sustained-release, methylphenidate extended-release, Metadate CD, guanfacine ER, atomoxetine

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE
STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND
FEDERAL REGULATORY ENTITIES.**

**THIS POLICY WILL BE REVISED AS NECESSARY AND
REVIEWED NO LESS THAN ANNUALLY.**



Signed: _____

Title: Director, Pharmacy Services

Date: March 1, 2022

Devised: 7/22/16

Revised: 3/1/17 – annual review, corrected spelling of Dyanavel

Revised: 3/1/18 – annual review, updated signature, added grandfather language, updated age criteria & FA, corrected typo in policy name

Reviewed: 3/1/19 – annual review

Revised: 3/1/20 – annual review, added GHP Kids

Revised: 3/1/21 – annual review, updated logo, added MediSpan approval level

Revised: 3/1/22 – annual review, updated referenced policies & covered LOBs



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 425.0

**SECTION: Commercial Drug
SUBJECT: Evekeo**

Applicable line of business:

Commercial	X	Medicaid	
Medicare		ACA	X
GHP Kids	X	Self-Insured	X

POLICY:

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for Evekeo for GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 487.0 Quantity Limit Exceptions

REQUIRED DEFINITIONS:

1. **Attachment** – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. **Exhibit** – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. **Devised** – the date the policy was implemented.
4. **Revised** – the date of every revision to the policy, including typographical and grammatical changes.
5. **Reviewed** – the date documenting the annual review if the policy has no revisions necessary.

ADDITIONAL DEFINITIONS:

1. **Formulary** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. **Non-formulary products** – those medications that are not included in the Formulary.
3. **Healthcare provider** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
4. **NCQA** – National Committee for Quality Assurance.
5. **Medically Necessary or Medical Necessity** – covered services rendered by a provider that the Health Plan determines are:



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 425.0

**SECTION: Commercial Drug
SUBJECT: Evekeo**

- A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
- B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
- C. In accordance with current standards of medical practice;
- D. Not primarily for the convenience of the Member, or the Member's Provider; and
- E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

PROCEDURE:

New members to the plan already established on therapy may be eligible for continuity of care coverage as long as there is medical record documentation that the safety and effectiveness of use for the prescribed indication is supported by Food and Drug Administration (FDA) approval or adequate medical and scientific evidence in the medical literature.

A formulary exception for coverage of Evekeo may be made for members who meet the following criteria:

Attention Deficit Hyperactivity Disorder (ADHD) (Evekeo & Evekeo ODT)

- Medical record documentation of a diagnosis of attention deficit hyperactivity disorder (ADHD) **AND**
- Medical record documentation of age greater than or equal to 3 years **AND**
- **For members greater than or equal to 6 years of age:** Medical record documentation of a therapeutic failure on, intolerance to, or contraindication to three of the following formulary alternatives: dexamethylphenidate immediate release, dextroamphetamine immediate release, dextroamphetamine/amphetamine immediate release, or methylphenidate immediate release
- **For members greater than or equal to 3 years of age:** Medical record documentation of a therapeutic failure on, intolerance to, or contraindication to dextroamphetamine immediate release **AND** dextroamphetamine/amphetamine immediate release

Narcolepsy (Evekeo Only)

- Prescription written for Evekeo **AND**
- Medical record documentation of a diagnosis of narcolepsy **AND**
- Medical record documentation of age greater than or equal to 12 years **AND**



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 425.0

**SECTION: Commercial Drug
SUBJECT: Evekeo**

- Medical record documentation of a therapeutic failure on, intolerance to, or contraindication to dextroamphetamine immediate release, dextroamphetamine/amphetamine immediate release **AND** methylphenidate immediate release

MEDISPAN AUTHORIZATION LEVEL: GPI-12

QUANTITY LIMIT: *No QLs need to be entered within the authorization unless the requested quantity exceeds the QL.*

- **QL FOR LETTER ONLY:**
 - Evekeo ODT 2.5 mg tablet: 2 tablets per day
 - Evekeo ODT 5 mg tablet: 2 tablets per day
 - Evekeo ODT 10 mg tablet: 2 tablets per day
 - Evekeo ODT 15 mg tablet: 2 tablets per day
 - Evekeo ODT 20 mg tablet: 2 tablets per day
 - Evekeo 5 mg tablet: 3 tablets per day
 - Evekeo 10 mg tablet: 6 tablets per day

If a formulary exception is approved Evekeo will be paid for under the member's prescription drug benefit.

Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.

FORMULARY ALTERNATIVES:

ADHD:

- **For members greater than or equal to 6 years of age:** dexmethylphenidate immediate release, dextroamphetamine immediate release, dextroamphetamine/amphetamine immediate release, methylphenidate immediate release, atomoxetine, guanfacine extended release
- **For members greater than or equal to 3 years of age:** dextroamphetamine immediate release, dextroamphetamine/amphetamine immediate release

Narcolepsy:

dextroamphetamine immediate release, dextroamphetamine/amphetamine immediate release, methylphenidate immediate release

Geisinger

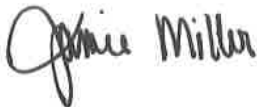
**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 425.0

**SECTION: Commercial Drug
SUBJECT: Evekeo**

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE
STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND
FEDERAL REGULATORY ENTITIES.**

**THIS POLICY WILL BE REVISED AS NECESSARY AND
REVIEWED NO LESS THAN ANNUALLY.**



Signed: _____

Title: Director, Pharmacy Services

Date: March 1, 2022

Devised: 7/22/16
Revised: 3/1/17 – annual review, removed Unicode characters
Revised: 3/1/18 – annual review, updated signature
Revised: 3/1/18 – annual review, updated signature, added grandfather language, updated age criteria & FA
Reviewed: 3/1/19 – annual review
Revised: 3/1/20 – annual review, added GHP Kids
Revised: 3/1/21 – annual review, updated logo, added MediSpan approval level
Revised: 11/1/21 – added Evekeo vs. Evekeo ODT distinction to each indication, added Evekeo required criterion to narcolepsy, added QL's, updated GPI level
Revised: 3/1/22 – annual review, updated referenced policies & covered LOBs



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 426.0

**SECTION: Commercial Drug
SUBJECT: Xuriden**

Applicable line of business:

Commercial	X	Medicaid	
Medicare		ACA	X
GHP Kids	X	Self-Insured	X

POLICY:

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for Xuriden for GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 487.0 Quantity Limit Exceptions

REQUIRED DEFINITIONS:

1. **Attachment** – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. **Exhibit** – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. **Devised** – the date the policy was implemented.
4. **Revised** – the date of every revision to the policy, including typographical and grammatical changes.
5. **Reviewed** – the date documenting the annual review if the policy has no revisions necessary.

ADDITIONAL DEFINITIONS:

1. **Formulary** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. **Non-formulary products** – those medications that are not included in the Formulary.
3. **Healthcare provider** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
4. **NCQA** – National Committee for Quality Assurance.
5. **Medically Necessary or Medical Necessity** – covered services rendered by a provider that the Health Plan determines are:

- A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
- B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
- C. In accordance with current standards of medical practice;
- D. Not primarily for the convenience of the Member, or the Member's Provider; and
- E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

PROCEDURE:

A formulary exception for coverage of Xuriden may be made for members who meet the following criteria:

- Medical record documentation of a diagnosis of hereditary orotic aciduria as evidenced by at least one of the following:
 - Assay of the orotate phosphoribosyltransferase and orotidylic acid decarboxylase enzymes in the patient's erythrocytes showing deficiency in both enzymes or deficiency in orotidylic acid decarboxylase alone **OR**
 - Orotic acid crystals visualized in the urine via microscopy

AND

- Medical record documentation of an appropriate dose for the patient's weight* **AND**
- Medical record documentation that Xuriden is prescribed by a metabolic specialist, medical geneticist, or other physician with experience in the diagnosis and treatment of inborn errors of metabolism

NOTE: *Appropriate dosing for Xuriden is 60 mg/kg or 120 mg/kg once daily. Xuriden is available only in 2 gram, single-use packets. The maximum daily dose should not exceed 8 grams.

MEDISPAN AUTHORIZATION LEVEL: GPI-12

QUANTITY LIMIT: *No QLs need to be entered within the authorization unless the requested quantity exceeds the QL.*

- **QL FOR LETTER ONLY:** 4 packets per day

If a formulary exception is approved Xuriden will be paid for under the member's prescription drug benefit.



POLICY NUMBER: 426.0

**POLICY AND PROCEDURE
PHARMACY
MANUAL**

**SECTION: Commercial Drug
SUBJECT: Xuriden**

Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.

FORMULARY ALTERNATIVES:

none

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE
STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND
FEDERAL REGULATORY ENTITIES.**

**THIS POLICY WILL BE REVISED AS NECESSARY AND
REVIEWED NO LESS THAN ANNUALLY.**

Signed: _____

Title: Director, Pharmacy Services

Date: March 1, 2022

Devised: 7/22/16
Reviewed: 3/1/17 – annual review
Revised: 3/1/18 – annual review, updated signature, updated prescriber criteria
Revised: 3/1/19 – annual review, added QL approval note
Revised: 3/1/20 – annual review, added GHP Kids
Revised: 3/1/21 – annual review, updated logo, added MediSpan approval level, updated QL statement
Revised: 3/1/22 – annual review, updated referenced policies & covered LOBs



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 428.0

**SECTION: Commercial Drug
SUBJECT: Bosentan Tablets and
Tracleer Tablets for
Oral Suspension**

Applicable line of business:

Commercial	X	Medicaid	
Medicare		ACA	X
GHP Kids	X	Self-Insured	X

POLICY:

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for bosentan tablets and Tracleer tablets for oral suspension for GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 487.0 Quantity Limit Exceptions

REQUIRED DEFINITIONS:

1. **Attachment** – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. **Exhibit** – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. **Devised** – the date the policy was implemented.
4. **Revised** – the date of every revision to the policy, including typographical and grammatical changes.
5. **Reviewed** – the date documenting the annual review if the policy has no revisions necessary.

ADDITIONAL DEFINITIONS:

1. **Formulary** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. **Non-formulary products** – those medications that are not included in the Formulary.
3. **Healthcare provider** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
4. **NCQA** – National Committee for Quality Assurance.
5. **Medically Necessary or Medical Necessity** – covered services rendered by a provider that the Health Plan determines are:



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 428.0

**SECTION: Commercial Drug
SUBJECT: Bosentan Tablets and
Tracleer Tablets for
Oral Suspension**

- A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
- B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
- C. In accordance with current standards of medical practice;
- D. Not primarily for the convenience of the Member, or the Member's Provider; and
- E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

PROCEDURE:

A formulary exception for coverage of bosentan tablets and Tracleer tablets for oral suspension may be made for members who meet the following criteria:

- Medical record documentation that bosentan is prescribed by a cardiologist or pulmonologist **AND**
- Medical record documentation of a diagnosis of functional class II, III, or IV pulmonary arterial hypertension

MEDISPAN AUTHORIZATION LEVEL: GPI-12, if request is for bosentan tablets include generic only.

QUANTITY LIMIT: *No QLs need to be entered within the authorization unless the requested quantity exceeds the QL.*

- **QL FOR LETTER ONLY:** 2 tablets per day, 30 day supply per fill

If a formulary exception is approved bosentan tablets or Tracleer tablets for oral suspension will be paid for under the member's prescription drug benefit.

Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.

Geisinger

**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 428.0

**SECTION: Commercial Drug
SUBJECT: Bosentan Tablets and
Tracleer Tablets for
Oral Suspension**

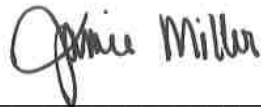
FORMULARY ALTERNATIVES:

Uptravi*, Orenitram*, treprostinil* (generic Remodulin), Tyvaso*, Ventavis*, Adempas*,
Opsumit*, ambrisentan*, tadalafil* (generic Adcirca), sildenafil* (generic Revatio)

*prior authorization required

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE
STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND
FEDERAL REGULATORY ENTITIES.**

**THIS POLICY WILL BE REVISED AS NECESSARY AND
REVIEWED NO LESS THAN ANNUALLY.**



Signed: _____

Title: Director, Pharmacy Services

Date: March 1, 2022

Devised: 7/22/16
Reviewed: 3/1/17 – annual review
Revised: 3/1/18 – annual review, updated signature, updated prescriber criteria
Revised: 3/1/19 – annual review, added QL approval note
Revised: 11/21/19 – updated Tracleer to generic bosentan, updated all others w/ available generics
Revised: 3/1/20 – annual review, added GHP Kids
Revised: 3/1/21 – annual review, updated logo, added MediSpan approval level, updated policy to include
Tracleer tablets for oral suspension, updated QL statement
Revised: 3/1/22 – annual review, updated referenced policies & covered LOBs



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 429.0

**SECTION: Commercial Drug
SUBJECT: Impavido**

Applicable line of business:

Commercial	X	Medicaid	
Medicare		ACA	X
GHP Kids	X	Self-Insured	X

POLICY:

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for Impavido for GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 487.0 Quantity Limit Exceptions

REQUIRED DEFINITIONS:

1. **Attachment** – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. **Exhibit** – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. **Devised** – the date the policy was implemented.
4. **Revised** – the date of every revision to the policy, including typographical and grammatical changes.
5. **Reviewed** – the date documenting the annual review if the policy has no revisions necessary.

ADDITIONAL DEFINITIONS:

1. **Formulary** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. **Non-formulary products** – those medications that are not included in the Formulary.
3. **Healthcare provider** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
4. **NCQA** – National Committee for Quality Assurance.
5. **Medically Necessary or Medical Necessity** – covered services rendered by a provider that the Health Plan determines are:



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 429.0

**SECTION: Commercial Drug
SUBJECT: Impavido**

- A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
- B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
- C. In accordance with current standards of medical practice;
- D. Not primarily for the convenience of the Member, or the Member's Provider; and
- E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

PROCEDURE:

A formulary exception for coverage of Impavido may be made for members who meet the following criteria:

- Medical record documentation of age greater than or equal to 12 years **AND**
- Medical record documentation that the patient weighs at least 30 kg **AND**
- Medical record documentation that Impavido is prescribed by a board-certified infectious disease specialist **AND**
- Medical record documentation of one of the following, confirmed by testing:
 - Visceral leishmaniasis caused by *L. donovani*
 - Cutaneous leishmaniasis caused by *L. braziliensis* **OR** *L. guyanensis* **OR** *L. panamensis*
 - Mucosal leishmaniasis caused by *L. braziliensis* **AND**
- Medical record documentation of a negative pregnancy test for women of childbearing age **AND**
- Medical record documentation member has been counseled on use of contraception during therapy and for 5 months after **AND**
- Medical record documentation of no history of Sjögren-Larsson-Syndrome **AND**
- If diagnosis is visceral leishmaniasis, medical record documentation of therapeutic failure on, intolerance to or contraindication to Liposomal Amphotericin B

MEDISPAN AUTHORIZATION LEVEL: GPI-12

QUANTITY LIMIT: QL must be entered within authorization.

- One-time fill for the following based on weight:
 - **30-44 kg:** 56 capsules per 28 days
 - **45 kg or greater:** 84 capsules per 28 days

AUTHORIZATION DURATION: one (1) month



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 429.0

**SECTION: Commercial Drug
SUBJECT: Impavido**

If a formulary exception is approved Impavido will be paid for under the member's prescription drug benefit.

Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.

FORMULARY ALTERNATIVES:

ketoconazole, fluconazole, itraconazole*, Nebupent

*prior authorization required

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE
STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND
FEDERAL REGULATORY ENTITIES.**

**THIS POLICY WILL BE REVISED AS NECESSARY AND
REVIEWED NO LESS THAN ANNUALLY.**

Signed: _____

Title: Director, Pharmacy Services

Date: March 1, 2022

- Devised: 9/21/16
- Revised: 11/22/16 – corrected typo, updated formulary alternatives, updated formatting
- Reviewed: 3/1/17 – annual review
- Revised: 3/1/18 – annual review, updated signature, updated age & prescriber criteria
- Reviewed: 3/1/19 – annual review
- Revised: 3/1/20 – annual review, added GHP Kids
- Revised: 3/1/21 – annual review, updated logo, added MediSpan approval level, updated QL statement
- Revised: 3/1/22 – annual review, updated referenced policies & covered LOBs



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 431.0

**SECTION: Commercial Drug
SUBJECT: Taltz**

Applicable line of business:

Commercial	X	Medicaid	
Medicare		ACA	X
GHP Kids	X	Self-Insured	X

POLICY:

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for Taltz for GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 487.0 Quantity Limit Exceptions

REQUIRED DEFINITIONS:

1. **Attachment** – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. **Exhibit** – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. **Devised** – the date the policy was implemented.
4. **Revised** – the date of every revision to the policy, including typographical and grammatical changes.
5. **Reviewed** – the date documenting the annual review if the policy has no revisions necessary.

ADDITIONAL DEFINITIONS:

1. **Formulary** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. **Non-formulary products** – those medications that are not included in the Formulary.
3. **Healthcare provider** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
4. **NCQA** – National Committee for Quality Assurance.
5. **Medically Necessary or Medical Necessity** – covered services rendered by a provider that the Health Plan determines are:



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 431.0

**SECTION: Commercial Drug
SUBJECT: Taltz**

- A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
- B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
- C. In accordance with current standards of medical practice;
- D. Not primarily for the convenience of the Member, or the Member's Provider; and
- E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

PROCEDURE:

New members to the plan already established on therapy may be eligible for continuity of care coverage as long as there is medical record documentation that the safety and effectiveness of use for the prescribed indication is supported by Food and Drug Administration (FDA) approval or adequate medical and scientific evidence in the medical literature.

For treatment of plaque psoriasis

A formulary exception for coverage of Taltz may be made for members who meet the following criteria:

- Medical record documentation that Taltz is prescribed by a dermatologist **AND**
- Medical record documentation of age greater than or equal to 18 years **AND**
- Medical record documentation of a diagnosis of moderate to severe plaque psoriasis characterized by greater than 5% of body surface area involved or disease involving crucial body areas such as the hands, feet, face, or genitals **AND**
- Medical record documentation of an intolerance to, contraindication to, or therapeutic failure on a minimum 3 month trial of Humira* **AND** Cosentyx* **AND**
- Medical record documentation that Taltz is not being used concurrently with a tumor necrosis factor TNF blocker or other biologic agent

RE-AUTHORIZATION CRITERIA: Taltz is configured as a prior authorization for new starts only. Taltz will no longer be covered if it is identified that the member is not receiving appropriate follow-up care from the prescribing specialist or if the member has greater than or equal to a 90 day break in therapy.

- Medical record documentation that the member is receiving appropriate follow-up care from the prescribing specialist

MEDISPAN AUTHORIZATION LEVEL: GPI-10



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 431.0

**SECTION: Commercial Drug
SUBJECT: Taltz**

QUANTITY LIMIT: *QLs must be entered within the authorization.*

- 160 mg once, followed by 80 mg at weeks 2, 4, 6, 8, 10, and 12; then 80 mg every 4 weeks
 1. In PA Hub: Add PA, OQL, enter 3 in max number of claims authorized with a duration of 3 months
 - **QL FOR LETTER:** Loading dose: 8 mL per 3 months; Maintenance dose: 1 mL per 28 days

FORMULARY ALTERNATIVES:

methotrexate, cyclosporine, azathioprine, acitretin*, Humira*^, Cosentyx*^

*prior authorization required, ^quantity limits apply

For treatment of pediatric plaque psoriasis

A formulary exception for coverage of Taltz may be made for members who meet the following criteria:

- Medical record documentation that Taltz is prescribed by a dermatologist **AND**
- Medical record documentation of age greater than or equal to 6 years **AND**
- Medical record documentation that the prescribed dosage is appropriate for the member's weight **AND**
- Medical record documentation of a diagnosis of moderate to severe plaque psoriasis characterized by greater than 5% of body surface area involved or disease involving crucial body areas such as the hands, feet, face, or genitals **AND**
- Medical record documentation of an intolerance to, contraindication to, or therapeutic failure on at least two (2) topical corticosteroids **AND**
- Medical record documentation that Taltz is not being used concurrently with a tumor necrosis factor TNF blocker or other biologic agent

RE-AUTHORIZATION CRITERIA: Taltz is configured as a prior authorization for new starts only. Taltz will no longer be covered if it is identified that the member is not receiving appropriate follow-up care from the prescribing specialist or if the member has greater than or equal to a 90 day break in therapy.

- Medical record documentation that the member is receiving appropriate follow-up care from the prescribing specialist

MEDISPAN AUTHORIZATION LEVEL: GPI-10

QUANTITY LIMIT: *QLs must be entered within the authorization.*

- 160 mg once, followed by 80 mg every 4 weeks
 1. In PA Hub: Add PA, OQL, max quantity dispensed 2, max number of claims authorized 1, with a duration of 1 month
 - QL FOR LETTER: Loading dose: 2 mL per 28 days; Maintenance dose: 1 mL per 28 days



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 431.0

**SECTION: Commercial Drug
SUBJECT: Taltz**

FORMULARY ALTERNATIVES:

Low-potency topical corticosteroids: aclometasone dipropionate 0.5% cream and ointment (Aclovate); fluocinolone acetonide 0.01% soln. (Synalar); hydrocortisone 2.5% cream, ointment, and lotion (Hytone)

Medium-potency topical corticosteroids: betamethasone valerate 0.1% cream (Valisone); fluocinolone acetonide 0.025% cream and ointment (Synalar); fluticasone propionate 0.05% cream, ointment, and lotion (Cutivate); triamcinolone 0.1% cream, ointment and lotion (Kenalog); triamcinolone acetonide 0.025% cream, ointment and lotion (Kenalog); triamcinolone acetonide 0.147 mg/g aerosol (Kenalog Spray)

High-potency topical corticosteroids: augmented betamethasone dipropionate 0.05% cream (Diprolene AF); betamethasone valerate 0.1% ointment (Valisone); triamcinolone 0.5% cream (Kenalog); fluocinonide 0.05% cream, ointment and gel (Lidex)

Very high-potency topical corticosteroids: augmented betamethasone dipropionate 0.05% ointment, gel and lotion (Diprolene); clobetasol 0.05% cream, ointment, and scalp lotion (Temovate) diflorasone diacetate 0.05% cream and ointment (ApexiCon/Psorcon)



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 431.0

**SECTION: Commercial Drug
SUBJECT: Taltz**

For treatment of psoriatic arthritis

A formulary exception for coverage of Taltz may be made for members who meet the following criteria:

- Medical record documentation that Taltz is prescribed by a dermatologist or rheumatologist **AND**
- Medical record documentation of age greater than or equal to 18 years **AND**
- Medical record documentation of a diagnosis of moderately to severely active psoriatic arthritis which must include the following:
 - Documentation of either active psoriatic lesions or a documented history of psoriasis **AND**
- Medical record documentation of an intolerance to, contraindication to, or therapeutic failure on a minimum 3 month trial of Humira* **AND** Cosentyx* **AND**
- Medical record documentation that Taltz is not being used concurrently with a tumor necrosis factor (TNF) blocker or other biologic agent

RE-AUTHORIZATION CRITERIA: Taltz is configured as a prior authorization for new starts only. Taltz will no longer be covered if it is identified that the member is not receiving appropriate follow-up care from the prescribing specialist or if the member has greater than or equal to a 90 day break in therapy.

- Medical record documentation that the member is receiving appropriate follow-up care from the prescribing specialist

MEDISPAN AUTHORIZATION LEVEL: GPI-10

NOTE: If member has coexistent plaque psoriasis, the loading dose quantity limit should be entered as outlined under the plaque psoriasis subsection of the Taltz criteria.

QUANTITY LIMIT: *QLs must be entered within the authorization.*

- 160 mg once, followed by 80 mg every 4 weeks
 1. In PA Hub: Add PA, OQL, max quantity dispensed 2, max number of claims authorized 1, with a duration of 1 month
 - QL FOR LETTER: Loading dose: 2 mL per 28 days; Maintenance dose: 1 mL per 28 days

FORMULARY ALTERNATIVES:

methotrexate, cyclosporine, azathioprine, acitretin*, Humira*^, Cosentyx*^

*prior authorization required, ^quantity limits apply



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 431.0

**SECTION: Commercial Drug
SUBJECT: Taltz**

For treatment of ankylosing spondylitis

A formulary exception for coverage of Taltz may be made for members who meet the following criteria:

- Medical record documentation that Taltz is prescribed by a rheumatologist **AND**
- Medical record documentation of age greater than or equal to 18 years **AND**
- Medical record documentation of a diagnosis of ankylosing spondylitis **AND**
- Medical record documentation of an intolerance to, contraindication to, or therapeutic failure on a minimum 3 month trial of Humira* **AND** Cosentyx* **AND**
- Medical record documentation that Taltz is not being used concurrently with a tumor necrosis factor (TNF) blocker or other biologic agent

RE-AUTHORIZATION CRITERIA: Taltz is configured as a prior authorization for new starts only. Taltz will no longer be covered if it is identified that the member is not receiving appropriate follow-up care from the prescribing specialist or if the member has greater than or equal to a 90 day break in therapy.

- Medical record documentation that the member is receiving appropriate follow-up care from the prescribing specialist

MEDISPAN AUTHORIZATION LEVEL: GPI-10

QUANTITY LIMIT: *QLs must be entered within the authorization.*

- 160 mg once, followed by 80 mg every 4 weeks
 1. In PA Hub: Add PA, OQL, max quantity dispensed 2, max number of claims authorized 1, with a duration of 1 month
 - QL FOR LETTER: Loading dose: 2 mL per 28 days; Maintenance dose: 1 mL per 28 days

FORMULARY ALTERNATIVES:

Humira*^, Cosentyx*^

*prior authorization required, ^quantity limits apply



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 431.0

**SECTION: Commercial Drug
SUBJECT: Taltz**

For treatment of non-radiographic axial spondyloarthritis

A formulary exception for coverage of Taltz may be made for members who meet the following criteria:

- Medical record documentation that Taltz is prescribed by a rheumatologist **AND**
- Medical record documentation of age greater than or equal to 18 years **AND**
- Medical record documentation of a diagnosis of non-radiographic axial spondylarthritis **AND**
- Medical record documentation of at least one of the following:
 - C-reactive protein (CRP) level above the upper limit of normal (10 mg/dL) **OR**
 - Sacroiliitis on magnetic resonance imaging (MRI)

AND

- Medical record documentation of an intolerance to, contraindication to, or therapeutic failure on a minimum 3 month trial of Cosentyx* **AND**
- Medical record documentation that Taltz is not being used concurrently with a tumor necrosis factor (TNF) blocker or other biologic agent

RE-AUTHORIZATION CRITERIA: Taltz is configured as a prior authorization for new starts only. Taltz will no longer be covered if it is identified that the member is not receiving appropriate follow-up care from the prescribing specialist or if the member has greater than or equal to a 90 day break in therapy.

- Medical record documentation that the member is receiving appropriate follow-up care from the prescribing specialist

MEDISPAN AUTHORIZATION LEVEL: GPI-10, number of claims authorized = 1, enter for the remainder of the calendar year

QUANTITY LIMIT: *No QLs need to be entered within the authorization unless the requested quantity exceeds the QL.*

- QL FOR LETTER ONLY: 1 mL per 28 days

FORMULARY ALTERNATIVES:

Cosentyx*^

*prior authorization required, ^quantity limits apply



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 431.0

**SECTION: Commercial Drug
SUBJECT: Taltz**

If a formulary exception is approved Taltz will be paid for under the member's prescription drug benefit.

Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE
STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND
FEDERAL REGULATORY ENTITIES.**

**THIS POLICY WILL BE REVISED AS NECESSARY AND
REVIEWED NO LESS THAN ANNUALLY.**

Signed: _____

Title: Director, Pharmacy Services

Date: April 6, 2022

- Devised: 9/21/16
- Revised: 11/22/16 – updated formatting, changed > to greater than
- Reviewed: 3/1/17 – annual review
- Revised: 3/1/18 – annual review, updated signature, added grandfather language, updated age & prescriber criteria
- Revised: 4/10/18 – added indication headers, PP (removed failure of Enbrel, added failure of Cosentyx, added no other agent), added PsA indication, updated FA
- Revised: 3/1/19 – annual review, defined abbr.
- Revised: 11/22/19 – updated FA
- Revised: 1/28/20 – added ankylosing spondylitis indication, updated FA
- Revised: 3/1/20 – annual review, added GHP Kids
- Revised: 4/20/20 – added note under PsA indication, defined QL
- Revised: 10/12/20 – added pediatric plaque psoriasis & non-radiographic axial spondylarthritis, corrected typo in auth duration to address appropriate indication
- Revised: 3/1/21 – annual review, updated logo, added MediSpan approval level, updated QL statement
- Revised: 12/2/21 – added one-time PA to approval crit., removed auth duration & added re-auth crit., updated QL auth entry to account for PA NSO
- Revised: 3/1/22 – annual review, updated referenced policies & covered LOBs, updated how QL's are entered
- Revised: 4/6/22 – updated loading dose for PsA, AS, and ped. PsO from 3 mL to 2 mL



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 432.0

**SECTION: Commercial Drug
SUBJECT: Zembrace Symtouch**

Applicable line of business:

Commercial	X	Medicaid	
Medicare		ACA	X
GHP Kids	X	Self-Insured	X

POLICY:

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for Zembrace Symtouch for GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 487.0 Quantity Limit Exceptions
- Policy 296.0 Triptan Quantity Limit Exceptions

REQUIRED DEFINITIONS:

1. **Attachment** – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. **Exhibit** – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. **Devised** – the date the policy was implemented.
4. **Revised** – the date of every revision to the policy, including typographical and grammatical changes.
5. **Reviewed** – the date documenting the annual review if the policy has no revisions necessary.

ADDITIONAL DEFINITIONS:

1. **Formulary** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. **Non-formulary products** – those medications that are not included in the Formulary.
3. **Healthcare provider** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
4. **NCQA** – National Committee for Quality Assurance.

5. **Medically Necessary or Medical Necessity** – covered services rendered by a provider that the Health Plan determines are:
- A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
 - B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
 - C. In accordance with current standards of medical practice;
 - D. Not primarily for the convenience of the Member, or the Member's Provider; and
 - E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

PROCEDURE:

A formulary exception for coverage of Zembrace Symtouch may be made for members who meet the following criteria:

- Medical record documentation of a diagnosis of migraines with or without aura **AND**
- Medical record documentation of age greater than or equal to 18 years **AND**
- Medical record documentation the member is not using concurrent opioid or barbiturate therapy for migraine treatment **AND**
- Medical record documentation of therapeutic failure on, intolerance to, or contraindication to 3 different preferred alternative triptan products (one of which must be a generic sumatriptan injection)

MEDISPAN AUTHORIZATION LEVEL: GPI-14

QUANTITY LIMIT: *No QLs need to be entered within the authorization unless the requested quantity exceeds the QL.*

- QL FOR LETTER ONLY: 8 mL per 28 days

If a formulary exception is approved Zembrace Symtouch will be paid for under the member's prescription drug benefit.

Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.



POLICY NUMBER: 432.0

**POLICY AND PROCEDURE
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**SECTION: Commercial Drug
SUBJECT: Zembrace Symtouch**

FORMULARY ALTERNATIVES:

naratriptan^, rizatriptan^, sumatriptan^, zolmitriptan^

^quantity limits apply

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE
STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND
FEDERAL REGULATORY ENTITIES.**

**THIS POLICY WILL BE REVISED AS NECESSARY AND
REVIEWED NO LESS THAN ANNUALLY.**

Signed: _____

Title: Director, Pharmacy Services

Date: March 1, 2022

Devised: 9/21/16
Revised: 11/22/16 – updated formatting and formulary alternatives
Reviewed: 3/1/17 – annual review
Revised: 3/1/18 – annual review, updated signature & age criteria, added AND after 3rd criteria, defined QL
Revised: 3/1/19 – annual review, updated QL
Revised: 3/1/20 – annual review, added GHP Kids
Revised: 3/1/21 – annual review, updated logo, added MediSpan approval level, updated QL statement
Revised: 3/1/22 – annual review, updated referenced policies & covered LOBs



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 433.0

**SECTION: Commercial Drug
SUBJECT: Zinbryta**

Applicable line of business:

Commercial	X	Medicaid	
Medicare		ACA	X
GHP Kids	X	Self-Insured	X

POLICY:

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for Zinbryta for GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 487.0 Quantity Limit Exceptions

REQUIRED DEFINITIONS:

1. **Attachment** – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. **Exhibit** – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. **Devised** – the date the policy was implemented.
4. **Revised** – the date of every revision to the policy, including typographical and grammatical changes.
5. **Reviewed** – the date documenting the annual review if the policy has no revisions necessary.

ADDITIONAL DEFINITIONS:

1. **Formulary** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. **Non-formulary products** – those medications that are not included in the Formulary.
3. **Healthcare provider** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
4. **NCQA** – National Committee for Quality Assurance.
5. **Medically Necessary or Medical Necessity** – covered services rendered by a provider that the Health Plan determines are:



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 433.0

**SECTION: Commercial Drug
SUBJECT: Zinbryta**

- A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
- B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
- C. In accordance with current standards of medical practice;
- D. Not primarily for the convenience of the Member, or the Member's Provider; and
- E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

PROCEDURE:

New members to the plan already established on therapy may be eligible for continuity of care coverage as long as there is medical record documentation that the safety and effectiveness of use for the prescribed indication is supported by Food and Drug Administration (FDA) approval or adequate medical and scientific evidence in the medical literature.

A formulary exception for coverage of Zinbryta may be made for members who meet the following criteria:

- Medical record documentation that Zinbryta is prescribed by a neurologist **AND**
- Medical record documentation off a diagnosis of a relapsing form of multiple sclerosis **AND**
- Medical record documentation of age greater than or equal to 18 years **AND**
- Medical record documentation of therapeutic failure on, contraindication to, or intolerance to three formulary alternatives

MEDISPAN AUTHORIZATION LEVEL: GPI-12

QUANTITY LIMIT: *No QLs need to be entered within the authorization unless the requested quantity exceeds the QL.*

- **QL FOR LETTER ONLY:** 1 ml (1 syringe) per 28 days

If a formulary exception is approved, Zinbryta will be paid for under the member's prescription drug benefit.

Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.



POLICY NUMBER: 433.0

**POLICY AND PROCEDURE
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**SECTION: Commercial Drug
SUBJECT: Zinbryta**

FORMULARY ALTERNATIVES:

Aubagio 14mg, Avonex, Betaseron, glatiramer acetate, Extavia, Gilenya, Plegridy, Rebif, dimethyl fumarate, Mayzent

^Quantity limits apply to all formulary alternatives

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE
STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND
FEDERAL REGULATORY ENTITIES.**

**THIS POLICY WILL BE REVISED AS NECESSARY AND
REVIEWED NO LESS THAN ANNUALLY.**

Signed: _____

Title: Director, Pharmacy Services

Date: March 1, 2022

Devised: 9/21/16

Revised: 11/21/16 – updated criteria to match P&T approval of 3 formulary alternatives, adjusted formatting, corrected typo, updated formulary alternatives

Revised: 3/1/17 – annual review, added QL indicator to FA

Revised: 3/1/18 – annual review, updated signature, added grandfather language, updated age & prescriber criteria

Revised: 3/1/19 – annual review, added QL approval note, updated FA

Revised: 3/1/20 – annual review, added GHP Kids

Revised: 3/1/21 – annual review, updated logo, added MediSpan approval level, updated QL statement & FA

Revised: 3/1/22 – annual review, updated referenced policies & covered LOBs



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 434.0

**SECTION: Commercial Drug
SUBJECT: Epclusa and
Sofosbuvir/Velpatasvir**

Applicable line of business:

Commercial	X	Medicaid	
Medicare		ACA	X
GHP Kids	X	Self-Insured	X

POLICY:

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for Epclusa and sofosbuvir/velpatasvir for GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 487.0 Quantity Limit Exceptions

REQUIRED DEFINITIONS:

1. **Attachment** – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. **Exhibit** – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. **Devised** – the date the policy was implemented.
4. **Revised** – the date of every revision to the policy, including typographical and grammatical changes.
5. **Reviewed** – the date documenting the annual review if the policy has no revisions necessary.

ADDITIONAL DEFINITIONS:

1. **Formulary** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. **Non-formulary products** – those medications that are not included in the Formulary.
3. **Healthcare provider** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
4. **NCQA** – National Committee for Quality Assurance.
5. **Medically Necessary or Medical Necessity** – covered services rendered by a provider that the Health Plan determines are:



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 434.0

**SECTION: Commercial Drug
SUBJECT: Epclusa and
Sofosbuvir/Velpatasvir**

- A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
 - B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
 - C. In accordance with current standards of medical practice;
 - D. Not primarily for the convenience of the Member, or the Member's Provider; and
 - E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.
6. **HBV** – Hepatitis B Virus
 7. **HCV** – Hepatitis C Virus
 8. **HIV** – Human Immunodeficiency Virus

PROCEDURE:

A formulary exception for coverage of Epclusa and sofosbuvir/velpatasvir may be made for members who meet the following criteria:

- Medical record documentation of age greater than or equal to 3 years **AND**
- Medical record documentation that proper weight-based dosing is being prescribed **AND**
- Medical record documentation of a diagnosis of hepatitis C infection **AND**
- Medical record documentation of the member's hepatitis C genotype **AND**
- Medical record documentation of a diagnosis of hepatitis C virus (HCV) genotype 1, 2, 3, 4, 5, or 6 infection **AND**
- Medical record documentation of METAVIR liver scoring **AND**
- Medical record documentation of a hepatocellular carcinoma screening in those with cirrhosis (METAVIR score F4) **AND**
- Medical record documentation of the member receiving a Food and Drug Administration (FDA) approved medication regimen that is inside the parameters of use approved by the FDA or supported in the widely used compendia available **OR**
- Medical record documentation of:
 - Genotype 1, 2, 3, 4, 5, 6
 - As monotherapy if treatment-naïve or peginterferon alfa + ribavirin based regimen experienced **OR**
 - Concurrent therapy with ribavirin if decompensated cirrhosis **AND**
- Medical record documentation of appropriate duration of treatment **AND**
- Medical record documentation of previous treatment and treatment response **AND**

- Medical record documentation of concurrent therapy with appropriate dose and duration of weight-based ribavirin, if indicated **AND**
- Medical record documentation of any potential drug interactions addressed by the prescriber (such as discontinuation of the interacting drug, dose reduction of the interacting drug, or counseling of the recipient of the risks associated with the use of both medications when they interact) **AND**
- Medical record documentation of receiving the following within the past 3 months:
 - Hepatic function panel
 - Complete blood count including differential
 - Basic metabolic panel
 - Baseline hepatitis C virus (HCV) RNA viral load **AND**
- Medical record documentation of a negative pregnancy test if member is female of childbearing potential and receiving ribavirin **AND**
- When concurrent ribavirin therapy is indicated and prescribed, medical record documentation for male members that their female partner is not pregnant **AND**
- If the member or their partner are of childbearing potential, medical record documentation that the member was instructed to practice effective contraception during therapy with ribavirin and for 6 months following discontinuation of ribavirin therapy **AND**
- If actively abusing alcohol or intravenous (IV) drugs, or has a history of abuse, has documentation of prescriber counseling regarding the risks of alcohol or IV drug abuse, and an offer of a referral for substance use disorder treatment **AND**
- Medical record documentation that member received pre-treatment readiness education about hepatitis C treatment expectations by a health care provider **AND**
- Medical record documentation that the member commits to the documented planned course of treatment including anticipated blood tests and visits, during and after treatment **AND**
- Medical record documentation that member does not have a limited life expectancy of less than 12 months due to non-liver related co-morbid conditions **AND**
- Medical record documentation of completed:
 - Hepatitis B immunization series **OR**
 - Hepatitis B screening (sAb/sAg and cAb/cAg) **AND** Quantitative hepatitis B virus (HBV) DNA if positive for hepatitis B sAg or cAb or cAg **AND**
 - If there is detectable hepatitis B virus (HBV) DNA, will be treated for Hepatitis B **OR**
 - If negative for hepatitis B sAb, is being vaccinated against Hepatitis B **AND**
- Medical record documentation of human immunodeficiency virus (HIV) screening (HIV Ag/Ab) and if confirmed positive by HIV-1/HIV-2 differentiation immunoassay:
 - Is being treated for human immunodeficiency virus (HIV) **OR**

- If not being treated for human immunodeficiency virus (HIV), the medical record documents the rationale for the beneficiary not being treated **AND**
- Medical record documentation of a therapeutic failure on, intolerance to Mavyret, if clinically appropriate **AND**
- Medical record documentation that member has been evaluated and treated by a contracted Center of Excellence in hepatitis C management

OR

- Medical record documentation of a hepatitis C negative recipient receiving a transplant from a hepatitis C positive donor **AND**
- Medical record documentation of therapeutic failure on, intolerance to, or contraindication to Mavyret, if clinically appropriate **AND**
- If member is greater than or equal to 18 years or weighs greater than or equal to 30 kilograms and the request is for 200/50 mg or 150 mg/37.5 mg strength, medical record documentation of why 400/100 mg tablets cannot be used

NOTE 1: Center of Excellence (COE) requirements do not apply to strategic partner TPA plans (i.e., Northern Light Health).

NOTE 2: Treatment naïve, genotype 3 patients with compensated cirrhosis require NS5A RAS Y93H testing for velpatasvir.

MEDISPAN AUTHORIZATION LEVEL: GPI-14, if request is for sofosbuvir/velpatasvir 400/100 include generic only.

QUANTITY LIMIT: *No QLS need to be entered within the authorization unless the requested quantity exceeds the QL.*

- **QL FOR LETTER ONLY:**
 - Tablets: one (1) tablet per day, 28 day supply per fill
 - 150/37.5 mg packets: one (1) packet per day, 28 day supply per fill
 - 200/50 mg packets: two (2) packets per day, 28 day supply per fill

AUTHORIZATION DURATION: According to IDSA/AASLD Guidelines (longer treatment duration is recommended when ribavirin ineligible)

If a formulary exception is approved Epclusa or sofosbuvir/velpatasvir will be paid for under the member's prescription drug benefit.



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 434.0

**SECTION: Commercial Drug
SUBJECT: Epclusa and
Sofosbuvir/Velpatasvir**

Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.

FORMULARY ALTERNATIVES:

Mavyret*, ledipasvir-sofosbuvir 400/90 mg*

*prior authorization required

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE
STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND
FEDERAL REGULATORY ENTITIES.**

**THIS POLICY WILL BE REVISED AS NECESSARY AND
REVIEWED NO LESS THAN ANNUALLY.**

Signed: _____

Title: Director, Pharmacy Services

Date: March 1, 2022

Devised: 11/21/16
Revised: 3/1/17 – annual review, removed Unicode characters, defined abbreviations
Revised: 6/2/17 – removed fibrosis/liver manifestations requirement, added METAVIR scoring.
Revised: 10/10/17 – changed AND to OR after regimen approved by FDA or compendia
Revised: 11/27/17 – updated failure to specifically Mavyret, updated FA, updated signature
Revised: 1/18/18 – updated age format & FA, removed prescriber, added Hep B & HIV criteria
Revised: 1/22/18 – added Hep B vaccination series
Revised: 3/1/18 – annual review, updated Hep B/HIV criteria to match DHS
Revised: 12/28/18 – added HCV positive transplant indication/FA criteria, added COE
Revised: 3/1/19 – annual review, defined abbr.
Revised: 7/23/19 – added TPA COE exclusion, renamed to generic
Revised: 3/1/20 – annual review, added GHP Kids
Revised: 7/29/20 – updated age to 6 years and added weight, updated ribavirin to weight based, removed eGFR requirement, updated auth duration to guideline based
Revised: 3/1/21 – annual review, updated logo, added MediSpan approval level, removed St Lukes & AtlantiCare, updated QL statement, clarified policy to Epclusa 200/50 and generic 400/100
Revised: 11/23/21 – removed strengths from policy title etc., updated age to 3 years, added proper weight based dosing, added criteria requiring 400/100 tablets, added NS5A RAS Y93H note, updated to GPI-14, added QL for 100/50 tabs and packets, updated FA

HPRX02

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Dev. 11/21/16
Rev. 3/1/22

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**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 434.0

**SECTION: Commercial Drug
SUBJECT: Epclusa and
Sofosbuvir/Velpatasvir**

Revised: 3/1/22 – annual review, updated referenced policies & covered LOBs



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 435.0

**SECTION: Commercial Drug
SUBJECT: Bevespi Aerosphere**

Applicable line of business:

Commercial	X	Medicaid	
Medicare		ACA	X
GHP Kids	X	Self-Insured	X

POLICY:

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for Bevespi Aerosphere for GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 487.0 Quantity Limit Exceptions

REQUIRED DEFINITIONS:

1. **Attachment** – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. **Exhibit** – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. **Devised** – the date the policy was implemented.
4. **Revised** – the date of every revision to the policy, including typographical and grammatical changes.
5. **Reviewed** – the date documenting the annual review if the policy has no revisions necessary.

ADDITIONAL DEFINITIONS:

1. **Formulary** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. **Non-formulary products** – those medications that are not included in the Formulary.
3. **Healthcare provider** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
4. **NCQA** – National Committee for Quality Assurance.
5. **Medically Necessary or Medical Necessity** – covered services rendered by a provider that the Health Plan determines are:



POLICY NUMBER: 435.0

**POLICY AND PROCEDURE
PHARMACY
MANUAL**

**SECTION: Commercial Drug
SUBJECT: Bevespi Aerosphere**

- A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
- B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
- C. In accordance with current standards of medical practice;
- D. Not primarily for the convenience of the Member, or the Member's Provider; and
- E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

PROCEDURE:

A formulary exception for coverage of Bevespi Aerosphere may be made for members who meet the following criteria:

- Medical record documentation of a diagnosis of chronic obstructive pulmonary disease (COPD) **AND**
- Medical record documentation of therapeutic failure on, intolerance to, or contraindication to Anoro Ellipta

MEDISPAN AUTHORIZATION LEVEL: GPI-12

If a formulary exception is approved Bevespi Aerosphere will be paid for under the member's prescription drug benefit.

Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.

FORMULARY ALTERNATIVES:

Anoro Ellipta, fluticasone/salmeterol, Wixela Inhub, Atrovent, Breo Ellipta, Incruse Ellipta, Serevent Diskus, Spiriva, Trelegy Ellipta

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE
STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND
FEDERAL REGULATORY ENTITIES.**

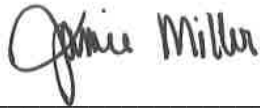
**THIS POLICY WILL BE REVISED AS NECESSARY AND
REVIEWED NO LESS THAN ANNUALLY.**

Geisinger

**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 435.0

**SECTION: Commercial Drug
SUBJECT: Bevespi Aerosphere**



Signed: _____

Title: Director, Pharmacy Services

Date: March 1, 2022

Devised: 11/22/16
Reviewed: 3/1/17 – annual review
Revised: 3/1/18 – annual review, updated signature, updated FA
Revised: 3/1/19 – annual review, updated FA
Revised: 3/1/20 – annual review, added GHP Kids
Revised: 3/1/21 – annual review, updated logo, added MediSpan approval level, updated FA
Revised: 3/1/22 – annual review, updated referenced policies & covered LOBs



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 436.0

**SECTION: Commercial Drug
SUBJECT: Relistor Tablets**

Applicable line of business:

Commercial	X	Medicaid	
Medicare		ACA	X
GHP Kids	X	Self-Insured	X

POLICY:

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for Relistor tablets for GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 487.0 Quantity Limit Exceptions

REQUIRED DEFINITIONS:

1. **Attachment** – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. **Exhibit** – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. **Devised** – the date the policy was implemented.
4. **Revised** – the date of every revision to the policy, including typographical and grammatical changes.
5. **Reviewed** – the date documenting the annual review if the policy has no revisions necessary.

ADDITIONAL DEFINITIONS:

1. **Formulary** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. **Non-formulary products** – those medications that are not included in the Formulary.
3. **Healthcare provider** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
4. **NCQA** – National Committee for Quality Assurance.
5. **Medically Necessary or Medical Necessity** – covered services rendered by a provider that the Health Plan determines are:



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 436.0

**SECTION: Commercial Drug
SUBJECT: Relistor Tablets**

- A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
- B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
- C. In accordance with current standards of medical practice;
- D. Not primarily for the convenience of the Member, or the Member's Provider; and
- E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

PROCEDURE:

A formulary exception for coverage of Relistor Tablets may be made for members who meet the following criteria:

- Medical record documentation of a diagnosis of chronic non-cancer pain, including patients with chronic pain related to prior cancer or its treatment **AND**
- Medical record documentation of opioid-induced constipation **AND**
- Medical record documentation that member is currently on opioid therapy **AND**
- Medical record documentation of therapeutic failure on, intolerance to, or contraindication to lubiprostone **AND** Movantik

MEDISPAN AUTHORIZATION LEVEL: GPI-12

QUANTITY LIMIT: *No QLs need to be entered within the authorization unless the requested quantity exceeds the QL.*

- **QL FOR LETTER ONLY:** 3 tablets per day

If a formulary exception is approved Relistor Tablets will be paid for under the member's prescription drug benefit.

Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.

FORMULARY ALTERNATIVES:

lubiprostone, Movantik



POLICY NUMBER: 436.0

**POLICY AND PROCEDURE
PHARMACY
MANUAL**

**SECTION: Commercial Drug
SUBJECT: Relistor Tablets**

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE
STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND
FEDERAL REGULATORY ENTITIES.**

**THIS POLICY WILL BE REVISED AS NECESSARY AND
REVIEWED NO LESS THAN ANNUALLY.**

Signed: _____

Title: Director, Pharmacy Services

Date: March 1, 2022

- Devised: 11/22/16
- Reviewed: 3/1/17 – annual review
- Revised: 3/1/18 – annual review, updated signature
- Revised: 4/6/18 – updated cancer diagnosis criteria to include prior cancer
- Revised: 3/1/19 – annual review, added QL approval note
- Revised: 3/1/20 – annual review, added GHP Kids
- Revised: 3/1/21 – annual review, updated logo, added MediSpan approval level, updated QL statement, updated Amitiza to generic
- Revised: 3/1/22 – annual review, updated referenced policies & covered LOBs



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 437.0

**SECTION: Commercial Drug
SUBJECT: Ocaliva**

Applicable line of business:

Commercial	X	Medicaid	
Medicare		ACA	X
GHP Kids	X	Self-Insured	X

POLICY:

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for Ocaliva for GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 487.0 Quantity Limit Exceptions

REQUIRED DEFINITIONS:

1. **Attachment** – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. **Exhibit** – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. **Devised** – the date the policy was implemented.
4. **Revised** – the date of every revision to the policy, including typographical and grammatical changes.
5. **Reviewed** – the date documenting the annual review if the policy has no revisions necessary.

ADDITIONAL DEFINITIONS:

1. **Formulary** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. **Non-formulary products** – those medications that are not included in the Formulary.
3. **Healthcare provider** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
4. **NCQA** – National Committee for Quality Assurance.
5. **Medically Necessary or Medical Necessity** – covered services rendered by a provider that the Health Plan determines are:

- A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
- B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
- C. In accordance with current standards of medical practice;
- D. Not primarily for the convenience of the Member, or the Member's Provider; and
- E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

PROCEDURE:

A formulary exception for coverage of Ocaliva may be made for members who meet the following criteria:

- Medical record documentation of a diagnosis of primary biliary cholangitis (primary biliary cirrhosis) **AND**
- Medical record documentation that Ocaliva is prescribed by a board-certified gastroenterologist, hepatologist, or liver transplant specialist **AND**
- Medical record documentation that Ocaliva is not being used in members with complete biliary obstruction **AND**
 - Medical record documentation of contraindication to or intolerance to UDCA (ursodiol tablets, Urso Forte, or Urso 250) **OR**
 - Medical record documentation of inadequate biochemical response* to an appropriate dose** of UDCA (ursodiol tablets, Urso Forte, or Urso 250) for at least 1 year **AND** that Ocaliva will be prescribed in combination with UDCA

MEDISPAN AUTHORIZATION LEVEL: GPI-12

QUANTITY LIMIT: *No QLs need to be entered within the authorization unless the requested quantity exceeds the QL.*

- **QL FOR LETTER ONLY:** one (1) tablet per day, 30 day supply per fill

AUTHORIZATION DURATION: Initial approval will be for a period of six (6) months. The following documentation is required for reauthorization:

- Medical record documentation of monitoring liver function tests, including alkaline phosphatase and bilirubin **AND**
- Medical record documentation of high density lipoprotein-cholesterol (HDL-C) **AND**

- Medical record documentation of a positive response to Ocaliva based on reduction in alkaline phosphatase and bilirubin

If approved, reauthorization will be for one (1) year. Reevaluation will be every one (1) year requiring medical record documentation of continued or sustained improvement of primary biliary cholangitis defined by alkaline phosphatase and bilirubin levels.

***Note:** Inadequate response: ALP greater than or equal to 1.67 times the upper limit of normal (ULN) and/or if total bilirubin was between 1 and 2 times the ULN.

ULN for females: ALP is 118 U/L and bilirubin is 1.1 mg/dL.

ULN for males: ALP is 124 U/L and bilirubin is 1.5 mg/dL.

****Note:** Appropriate dose of UDCA: 13 to 15 mg/kg/day in 2 to 4 divided doses.

If a formulary exception is approved Ocaliva will be paid for under the member's prescription drug benefit.

Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.

FORMULARY ALTERNATIVES:

ursodiol

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE
STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND
FEDERAL REGULATORY ENTITIES.**

**THIS POLICY WILL BE REVISED AS NECESSARY AND
REVIEWED NO LESS THAN ANNUALLY.**

Signed:  _____

Title: Director, Pharmacy Services

Date: March 1, 2022

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Dev. 11/22/16

Rev. 3/1/22



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 437.0

**SECTION: Commercial Drug
SUBJECT: Ocaliva**

Devised: 11/22/16
Revised: 1/25/17 – corrected typo in policy section
Revised: 3/1/17 – annual review, defined abbreviations in criteria
Revised: 3/1/18 – annual review, updated signature, updated prescriber criteria, added DS limit
Revised: 3/1/19 – annual review, added QL approval note
Revised: 3/1/20 – annual review, added GHP Kids
Revised: 3/1/21 – annual review, updated logo, added MediSpan approval level, updated QL statement
Revised: 3/1/22 – annual review, updated referenced policies & covered LOBs



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 439.0

**SECTION: Commercial Drug
SUBJECT: Emverm**

Applicable line of business:

Commercial	X	Medicaid	
Medicare		ACA	X
GHP Kids	X	Self-Insured	X

POLICY:

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for Emverm for GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 487.0 Quantity Limit Exceptions

REQUIRED DEFINITIONS:

1. **Attachment** – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. **Exhibit** – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. **Devised** – the date the policy was implemented.
4. **Revised** – the date of every revision to the policy, including typographical and grammatical changes.
5. **Reviewed** – the date documenting the annual review if the policy has no revisions necessary.

ADDITIONAL DEFINITIONS:

1. **Formulary** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. **Non-formulary products** – those medications that are not included in the Formulary.
3. **Healthcare provider** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
4. **NCQA** – National Committee for Quality Assurance.
5. **Medically Necessary or Medical Necessity** – covered services rendered by a provider that the Health Plan determines are:



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 439.0

**SECTION: Commercial Drug
SUBJECT: Emverm**

- A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
- B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
- C. In accordance with current standards of medical practice;
- D. Not primarily for the convenience of the Member, or the Member's Provider; and
- E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

PROCEDURE:

A formulary exception for coverage of Emverm may be made for members who meet the following criteria:

- Medical record documentation of a diagnosis of at least one of the following: *Ancylostoma duodenale* or *Necator americanus* (hookworms), *Ascaris lumbricoides* (roundworms), *Enterobius vermicularis* (pinworms), or *Trichuris trichiura* (whipworms)

QUANTITY LIMIT:

- *Enterobius vermicularis* (pinworms): two fills of 1 tablet each within 30 days
- All other Food and Drug Administration approved indications: two fills of 6 tablets each within 30 days

If a formulary exception is approved Emverm will be paid for under the member's prescription drug benefit.

Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.

FORMULARY ALTERNATIVES:

none



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 439.0

**SECTION: Commercial Drug
SUBJECT: Emverm**

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE
STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND
FEDERAL REGULATORY ENTITIES.**

**THIS POLICY WILL BE REVISED AS NECESSARY AND
REVIEWED NO LESS THAN ANNUALLY.**

Signed: _____

Title: Director, Pharmacy Services

Date: March 1, 2022

Devised: 3/24/17
Revised: 3/1/18 – annual review, updated signature
Reviewed: 3/1/19 – annual review
Revised: 3/1/20 – annual review, added GHP Kids
Revised: 3/1/21 – annual review, updated logo, added MediSpan approval level
Revised: 3/1/22 – annual review, updated referenced policies & covered LOBs



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 440.0

**SECTION: Commercial Drug
SUBJECT: Aspirin/Omeprazole**

Applicable line of business:

Commercial	X	Medicaid	
Medicare		ACA	X
GHP Kids	X	Self-Insured	X

POLICY:

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for aspirin/omeprazole for GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 487.0 Quantity Limit Exceptions

REQUIRED DEFINITIONS:

1. **Attachment** – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. **Exhibit** – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. **Devised** – the date the policy was implemented.
4. **Revised** – the date of every revision to the policy, including typographical and grammatical changes.
5. **Reviewed** – the date documenting the annual review if the policy has no revisions necessary.

ADDITIONAL DEFINITIONS:

1. **Formulary** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. **Non-formulary products** – those medications that are not included in the Formulary.
3. **Healthcare provider** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
4. **NCQA** – National Committee for Quality Assurance.
5. **Medically Necessary or Medical Necessity** – covered services rendered by a provider that the Health Plan determines are:



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 440.0

**SECTION: Commercial Drug
SUBJECT: Aspirin/Omeprazole**

- A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
- B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
- C. In accordance with current standards of medical practice;
- D. Not primarily for the convenience of the Member, or the Member's Provider; and
- E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

PROCEDURE:

A formulary exception for coverage of aspirin/omeprazole may be made for members who meet the following criteria:

- Medical record documentation of aspirin, component of aspirin/omeprazole, being used for secondary prevention of cardiovascular and/or cerebrovascular events as evident by one of the following:
 - History of ischemic stroke or transient ischemia of the brain due to fibrin platelet emboli
 - Previous myocardial infarction or unstable angina pectoris
 - Diagnosis of chronic stable angina pectoris
 - History of prior revascularization procedure (coronary artery bypass graft or percutaneous transluminal coronary angioplasty) when there is a pre-existing condition for which aspirin is already indicated **AND**
- Medical record documentation of risk of developing aspirin associated gastric ulcers as evident by one of the following:
 - Medical record documentation of age greater than or equal to 55 years
 - Medical record documentation indicating a history of gastric ulcers **AND**
- Medical record documentation of therapeutic failure on, intolerance to, or contraindication to omeprazole, pantoprazole, lansoprazole, **AND** rabeprazole with concurrent use of aspirin

MEDISPAN AUTHORIZATION LEVEL: GPI-12, generic only

QUANTITY LIMIT: *No QLs need to be entered within the authorization unless the requested quantity exceeds the QL.*

- **QL FOR LETTER ONLY:** one (1) tablet per day



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 440.0

**SECTION: Commercial Drug
SUBJECT: Aspirin/Omeprazole**

If a formulary exception is approved aspirin/omeprazole will be paid for under the member's prescription drug benefit.

Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.

FORMULARY ALTERNATIVES:

omeprazole, pantoprazole, lansoprazole, rabeprazole, esomeprazole, aspirin 81 mg

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE
STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND
FEDERAL REGULATORY ENTITIES.**

**THIS POLICY WILL BE REVISED AS NECESSARY AND
REVIEWED NO LESS THAN ANNUALLY.**

Signed: _____

Title: Director, Pharmacy Services

Date: March 1, 2022

Devised: 3/27/17

Revised: 3/1/18 – annual review, updated signature, updated age & ulcer history criteria

Revised: 3/1/19 – annual review, added QL approval note, updated FA

Revised: 3/1/20 – annual review, added GHP Kids

Revised: 3/1/21 – annual review, updated logo, added MediSpan approval level, updated QL statement, updated Yosprala to generic

Revised: 3/1/22 – annual review, updated referenced policies & covered LOBs, corrected typo



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 441.0

**SECTION: Commercial Drug
SUBJECT: GoNitro**

Applicable line of business:

Commercial	X	Medicaid	
Medicare		ACA	X
GHP Kids	X	Self-Insured	X

POLICY:

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for GoNitro for GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 487.0 Quantity Limit Exceptions

REQUIRED DEFINITIONS:

1. **Attachment** – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. **Exhibit** – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. **Devised** – the date the policy was implemented.
4. **Revised** – the date of every revision to the policy, including typographical and grammatical changes.
5. **Reviewed** – the date documenting the annual review if the policy has no revisions necessary.

ADDITIONAL DEFINITIONS:

1. **Formulary** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. **Non-formulary products** – those medications that are not included in the Formulary.
3. **Healthcare provider** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
4. **NCQA** – National Committee for Quality Assurance.
5. **Medically Necessary or Medical Necessity** – covered services rendered by a provider that the Health Plan determines are:



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 441.0

**SECTION: Commercial Drug
SUBJECT: GoNitro**

- A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
- B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
- C. In accordance with current standards of medical practice;
- D. Not primarily for the convenience of the Member, or the Member's Provider; and
- E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

PROCEDURE:

A formulary exception for coverage of GoNitro may be made for members who meet the following criteria:

- Medical record documentation of a reason why the patient cannot use nitroglycerin sublingual tablets **AND** nitroglycerin translingual spray

MEDISPAN AUTHORIZATION LEVEL: GPI-12

If a formulary exception is approved GoNitro will be paid for under the member's prescription drug benefit.

Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.

FORMULARY ALTERNATIVES:

nitroglycerin sublingual tablets, nitroglycerin translingual spray

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE
STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND
FEDERAL REGULATORY ENTITIES.**

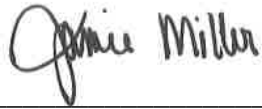
**THIS POLICY WILL BE REVISED AS NECESSARY AND
REVIEWED NO LESS THAN ANNUALLY.**

Geisinger

**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 441.0

**SECTION: Commercial Drug
SUBJECT: GoNitro**



Signed: _____

Title: Director, Pharmacy Services

Date: March 7, 2022

Devised: 3/24/17
Revised: 3/1/18 – annual review, updated signature, corrected spelling of GoNitro
Reviewed: 3/1/19 – annual review
Revised: 3/1/20 – annual review, added GHP Kids
Revised: 3/1/21 – annual review, updated logo, added MediSpan approval level
Revised: 3/1/22 – annual review, updated referenced policies & covered LOBs
Revised: 3/7/22 – corrected policy number typo



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 442.0

**SECTION: Commercial Drug
SUBJECT: Rubraca**

Applicable line of business:

Commercial	X	Medicaid	
Medicare		ACA	X
GHP Kids	X	Self-Insured	X

POLICY:

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for Rubraca for GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 487.0 Quantity Limit Exceptions

REQUIRED DEFINITIONS:

1. **Attachment** – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. **Exhibit** – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. **Devised** – the date the policy was implemented.
4. **Revised** – the date of every revision to the policy, including typographical and grammatical changes.
5. **Reviewed** – the date documenting the annual review if the policy has no revisions necessary.

ADDITIONAL DEFINITIONS:

1. **Formulary** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. **Non-formulary products** – those medications that are not included in the Formulary.
3. **Healthcare provider** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
4. **NCQA** – National Committee for Quality Assurance.
5. **Medically Necessary or Medical Necessity** – covered services rendered by a provider that the Health Plan determines are:

- A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
- B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
- C. In accordance with current standards of medical practice;
- D. Not primarily for the convenience of the Member, or the Member's Provider; and
- E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

PROCEDURE:

New members to the plan already established on therapy may be eligible for continuity of care coverage as long as there is medical record documentation that the safety and effectiveness of use for the prescribed indication is supported by Food and Drug Administration (FDA) approval or adequate medical and scientific evidence in the medical literature.

A formulary exception for coverage of Rubraca may be made for members who meet the following criteria:

Ovarian Cancer

- Medical record documentation that Rubraca is prescribed by an oncologist or hematologist **AND**
- Medical record documentation of age greater than or equal to 18 years **AND**
- Medical record documentation of a diagnosis of recurrent epithelial ovarian, fallopian tube, or primary peritoneal cancer **AND** medical record documentation of Rubraca being used as maintenance treatment after a complete or partial response to platinum-based chemotherapy **OR**
- Medical record documentation of deleterious BRCA mutation (germline and/or somatic)-associated epithelial ovarian, fallopian tube, or primary peritoneal cancer (as verified by a Food and Drug Administration-approved test) who have been treated with two or more chemotherapies

Prostate Cancer

- Medical record documentation that Rubraca is prescribed by an oncologist or hematologist **AND**
- Medical record documentation of age greater than or equal to 18 years **AND**
- Medical record documentation of deleterious BRCA mutation (germline and/or somatic)-associated metastatic castration-resistant prostate cancer (mCRPC) **AND**

- Medical record documentation of prior treatment with androgen-receptor directed therapy and a taxane-based chemotherapy **AND**
- Medical record documentation that a gonadotropin-releasing hormone (GnRH) analog will be used concurrently **OR** member has had bilateral orchiectomy

MEDISPAN AUTHORIZATION LEVEL: GPI-12, number of claims authorized = 1, enter for the remainder of the calendar year

QUANTITY LIMIT: *No QLs need to be entered within the authorization unless the requested quantity exceeds the QL.*

- **QL FOR LETTER ONLY:** four (4) tablets per day, 30 day supply per fill

NOTE: For Ovarian Cancer, the Food and Drug Administration approved test is BRACAnalysis CDx, FoundationOne CDx, FoundationFocus CDxBRCA Assay (see <http://www.fda.gov/CompanionDiagnostics>)

RE-AUTHORIZATION CRITERIA: Rubraca is configured as a prior authorization for new starts only. Rubraca will no longer be covered if it is identified that the member is not receiving appropriate follow-up care from the prescribing specialist or if the member has greater than or equal to a 90 day break in therapy.

- Medical record documentation that the member is receiving appropriate follow-up care from the prescribing specialist

If a formulary exception is approved Rubraca will be paid for under the member's prescription drug benefit.

Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.

FORMULARY ALTERNATIVES:

For Breast Cancer: Lynparza*

*prior authorization required



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 442.0

**SECTION: Commercial Drug
SUBJECT: Rubraca**

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE
STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND
FEDERAL REGULATORY ENTITIES.**

**THIS POLICY WILL BE REVISED AS NECESSARY AND
REVIEWED NO LESS THAN ANNUALLY.**

Signed: _____

Title: Director, Pharmacy Services

Date: March 1, 2022

Devised: 3/24/17

Revised: 3/1/18 – annual review, updated signature, added grandfather language, updated age & prescriber criteria

Revised: 12/28/18 – added recurrent epithelial ovarian, fallopian tube, or primary peritoneal indication, updated deleterious BRCA mutation to include epithelial ovarian, fallopian tube, or primary peritoneal, updated note

Revised: 3/1/19 – annual review, added QL approval note

Revised: 3/1/20 – annual review, added GHP Kids

Revised: 7/29/20 – added prostate cancer indication

Revised: 3/1/21 – annual review, updated logo, added MediSpan approval level, updated QL statement

Revised: 12/1/21 – added one-time PA to approval crit., removed auth duration & added re-auth crit.

Revised: 3/1/22 – annual review, updated referenced policies & covered LOBs



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 443.0

**SECTION: Commercial Drug
SUBJECT: Nuedexta**

Applicable line of business:

Commercial	X	Medicaid	
Medicare		ACA	X
GHP Kids	X	Self-Insured	X

POLICY:

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for Nuedexta for GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 487.0 Quantity Limit Exceptions

REQUIRED DEFINITIONS:

1. **Attachment** – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. **Exhibit** – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. **Devised** – the date the policy was implemented.
4. **Revised** – the date of every revision to the policy, including typographical and grammatical changes.
5. **Reviewed** – the date documenting the annual review if the policy has no revisions necessary.

ADDITIONAL DEFINITIONS:

1. **Formulary** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. **Non-formulary products** – those medications that are not included in the Formulary.
3. **Healthcare provider** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
4. **NCQA** – National Committee for Quality Assurance.
5. **Medically Necessary or Medical Necessity** – covered services rendered by a provider that the Health Plan determines are:



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 443.0

**SECTION: Commercial Drug
SUBJECT: Nuedexta**

- A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
- B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
- C. In accordance with current standards of medical practice;
- D. Not primarily for the convenience of the Member, or the Member's Provider; and
- E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

PROCEDURE:

A formulary exception for coverage of Nuedexta may be made for members who meet the following criteria:

- Medical record documentation of a diagnosis of pseudobulbar affect (PBA)

MEDISPAN AUTHORIZATION LEVEL: GPI-12

QUANTITY LIMIT: *No QLs need to be entered within the authorization unless the requested quantity exceeds the QL.*

- **QL FOR LETTER ONLY:** two (2) capsules per day

If a formulary exception is approved Nuedexta will be paid for under the member's prescription drug benefit.

Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.

FORMULARY ALTERNATIVES:

none

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE
STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND
FEDERAL REGULATORY ENTITIES.**

**THIS POLICY WILL BE REVISED AS NECESSARY AND
REVIEWED NO LESS THAN ANNUALLY.**



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 443.0

**SECTION: Commercial Drug
SUBJECT: Nuedexta**

Signed: _____

Title: Director, Pharmacy Services

Date: March 1, 2022

Devised: 3/27/18
Revised: 3/1/18 – annual review, updated signature
Revised: 3/1/19 – annual review, added QL approval note
Revised: 3/1/20 – annual review, added GHP Kids
Revised: 3/1/21 – annual review, updated logo, added MediSpan approval level
Revised: 3/1/22 – annual review, updated referenced policies & covered LOBs



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 444.0

**SECTION: Commercial Drug
SUBJECT: ProAir Digihaler and
ProAir Respiclick**

Applicable line of business:

Commercial	X	Medicaid	
Medicare		ACA	X
GHP Kids	X	Self-Insured	X

POLICY:

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for ProAir Digihaler and ProAir Respiclick for GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 487.0 Quantity Limit Exceptions

REQUIRED DEFINITIONS:

1. **Attachment** – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. **Exhibit** – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. **Devised** – the date the policy was implemented.
4. **Revised** – the date of every revision to the policy, including typographical and grammatical changes.
5. **Reviewed** – the date documenting the annual review if the policy has no revisions necessary.

ADDITIONAL DEFINITIONS:

1. **Formulary** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. **Non-formulary products** – those medications that are not included in the Formulary.
3. **Healthcare provider** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
4. **NCQA** – National Committee for Quality Assurance.
5. **Medically Necessary or Medical Necessity** – covered services rendered by a provider that the Health Plan determines are:



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 444.0

**SECTION: Commercial Drug
SUBJECT: ProAir Digihaler and
ProAir Respiclick**

- A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
- B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
- C. In accordance with current standards of medical practice;
- D. Not primarily for the convenience of the Member, or the Member's Provider; and
- E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

PROCEDURE:

A formulary exception for coverage of ProAir Digihaler and ProAir Respiclick may be made for members who meet the following criteria:

- Medical record documentation of therapeutic failure on, intolerance to, or contraindication to albuterol HFA

MEDISPAN AUTHORIZATION LEVEL: GPI-12

If a formulary exception is approved ProAir Digihaler or ProAir Respiclick will be paid for under the member's prescription drug benefit.

Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.

FORMULARY ALTERNATIVES:

albuterol HFA

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE
STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND
FEDERAL REGULATORY ENTITIES.**

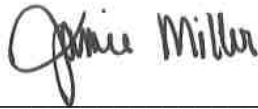
**THIS POLICY WILL BE REVISED AS NECESSARY AND
REVIEWED NO LESS THAN ANNUALLY.**

Geisinger

**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 444.0

**SECTION: Commercial Drug
SUBJECT: ProAir Digihaler and
ProAir Respiclick**



Signed: _____

Title: Director, Pharmacy Services

Date: 3/1/22

Devised: 3/27/18

Revised: 3/1/18 – annual review, updated signature

Reviewed: 3/1/19 – annual review

Revised: 11/15/19 – updated policy name to generic

Revised: 3/1/20 – annual review, added GHP Kids

Revised: 10/12/20 – updated to ProAir Digihaler/Respiclick, updated Ventolin to albuterol (generic now form.)

Revised: 3/1/21 – annual review, updated logo, added MediSpan approval level

Revised: 3/1/22 – annual review, updated referenced policies & covered LOBs



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 445.0

**SECTION: Commercial Drug
SUBJECT: Diabetic Testing Supplies**

Applicable line of business:

Commercial	X	Medicaid	
Medicare		ACA	X
GHP Kids	X	Self-Insured	X

POLICY:

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for diabetic testing supplies for GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 487.0 Quantity Limit Exceptions

REQUIRED DEFINITIONS:

1. **Attachment** – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. **Exhibit** – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. **Devised** – the date the policy was implemented.
4. **Revised** – the date of every revision to the policy, including typographical and grammatical changes.
5. **Reviewed** – the date documenting the annual review if the policy has no revisions necessary.

ADDITIONAL DEFINITIONS:

1. **Formulary** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. **Non-formulary products** – those medications that are not included in the Formulary.
3. **Healthcare provider** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
4. **NCQA** – National Committee for Quality Assurance.
5. **Medically Necessary or Medical Necessity** – covered services rendered by a provider that the Health Plan determines are:



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 445.0

**SECTION: Commercial Drug
SUBJECT: Diabetic Testing Supplies**

- A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
- B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
- C. In accordance with current standards of medical practice;
- D. Not primarily for the convenience of the Member, or the Member's Provider; and
- E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

PROCEDURE:

A formulary exception for coverage of non-preferred diabetic testing supplies may be made for members who meet the following criteria:

- Medical record documentation of Type I, Type II, or gestational diabetes **AND**
- Medical record documentation of a contraindication to, intolerance to, or therapeutic failure on a LifeScan product **OR**
- Medical record documentation of use of an insulin pump requiring a specific monitor brand **OR**
- Medical record documentation of the requirement of a feature not available from a LifeScan Product (i.e., speech capability)

MEDISPAN AUTHORIZATION LEVEL: NDC-9

QUANTITY LIMIT: *No QLs need to be entered within the authorization unless the requested quantity exceeds the QL.*

- **QL FOR LETTER ONLY: 200 strips per 30 days**

If a formulary exception is approved the non-preferred diabetic testing supplies will be paid for under the member's prescription drug benefit.

Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.

FORMULARY ALTERNATIVES:

One Touch Ultra 2, One Touch UltraMini, One Touch Verio, One Touch Verio IQ, One Touch Verio Sync

Geisinger

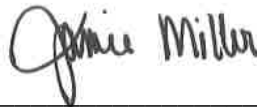
**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 445.0

**SECTION: Commercial Drug
SUBJECT: Diabetic Testing Supplies**

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE
STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND
FEDERAL REGULATORY ENTITIES.**

**THIS POLICY WILL BE REVISED AS NECESSARY AND
REVIEWED NO LESS THAN ANNUALLY.**



Signed: _____

Title: Director, Pharmacy Services

Date: March 1, 2022

Devised: 3/27/17
Revised: 3/1/18 – annual review, updated signature
Reviewed: 3/1/19 – annual review
Revised: 3/1/20 – annual review, added GHP Kids
Revised: 3/1/21 – annual review, updated logo, added MediSpan approval level, added test strip QL
Revised: 3/1/22 – annual review, updated referenced policies & covered LOBs



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 446.0

**SECTION: Commercial Drug
SUBJECT: Emflaza**

Applicable line of business:

Commercial	X	Medicaid	
Medicare		ACA	X
GHP Kids	X	Self-Insured	X

POLICY:

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for Emflaza for GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 487.0 Quantity Limit Exceptions

REQUIRED DEFINITIONS:

1. **Attachment** – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. **Exhibit** – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. **Devised** – the date the policy was implemented.
4. **Revised** – the date of every revision to the policy, including typographical and grammatical changes.
5. **Reviewed** – the date documenting the annual review if the policy has no revisions necessary.

ADDITIONAL DEFINITIONS:

1. **Formulary** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. **Non-formulary products** – those medications that are not included in the Formulary.
3. **Healthcare provider** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
4. **NCQA** – National Committee for Quality Assurance.
5. **Medically Necessary or Medical Necessity** – covered services rendered by a provider that the Health Plan determines are:



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 446.0

**SECTION: Commercial Drug
SUBJECT: Emflaza**

- A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
- B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
- C. In accordance with current standards of medical practice;
- D. Not primarily for the convenience of the Member, or the Member's Provider; and
- E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

PROCEDURE:

A formulary exception for coverage of Emflaza may be made for members who meet the following criteria:

- Medical record documentation that Emflaza is prescribed by a neurologist or pediatric neurologist **AND**
- Medical record documentation of interdisciplinary team involvement including, but not limited to, neurology, pulmonology, and cardiology **AND**
- Medical record documentation of a diagnosis of Duchenne muscular dystrophy (DMD), confirmed by genetic testing **AND**
- Medical record documentation of age greater than or equal to 2 years **AND**
- Medical record documentation of a therapeutic failure on, intolerance to, or contraindication to prednisone

MEDISPAN AUTHORIZATION LEVEL: GPI-10

QUANTITY LIMIT: *No QLs need to be entered within the authorization unless the requested quantity exceeds the QL.*

- **QL FOR LETTER ONLY:**
 - 6 mg tablet: 2 tablets per day
 - 18 mg tablet: 1 tablet per day
 - 30 mg tablet: 2 tablets per day
 - 36 mg tablet: no quantity limit
 - 22.75 mg/mL: no quantity limit

NOTE: Emflaza tablets may be crushed and served immediately after mixing with applesauce.



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 446.0

**SECTION: Commercial Drug
SUBJECT: Emflaza**

If a formulary exception is approved Emflaza will be paid for under the member's prescription drug benefit.

Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.

FORMULARY ALTERNATIVES:

prednisone

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE
STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND
FEDERAL REGULATORY ENTITIES.**

**THIS POLICY WILL BE REVISED AS NECESSARY AND
REVIEWED NO LESS THAN ANNUALLY.**

Signed: _____

Title: Director, Pharmacy Services

Date: March 1, 2022

Devised: 6/2/17
Revised: 3/1/18 – annual review, updated signature, updated prescriber criteria
Revised: 3/1/19 – annual review, added QL approval note, removed QL note
Revised: 11/20/19 – updated age criteria to 2 years and older
Revised: 3/1/20 – annual review, added GHP Kids
Revised: 3/1/21 – annual review, updated logo, added MediSpan approval level, updated QL statement
Revised: 3/1/22 – annual review, updated referenced policies & covered LOBs



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 447.0

**SECTION: Commercial Drug
SUBJECT: Kisqali**

Applicable line of business:

Commercial	X	Medicaid	
Medicare		ACA	X
GHP Kids	X	Self-Insured	X

POLICY:

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for Kisqali for GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 487.0 Quantity Limit Exceptions

REQUIRED DEFINITIONS:

1. **Attachment** – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. **Exhibit** – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. **Devised** – the date the policy was implemented.
4. **Revised** – the date of every revision to the policy, including typographical and grammatical changes.
5. **Reviewed** – the date documenting the annual review if the policy has no revisions necessary.

ADDITIONAL DEFINITIONS:

1. **Formulary** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. **Non-formulary products** – those medications that are not included in the Formulary.
3. **Healthcare provider** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
4. **NCQA** – National Committee for Quality Assurance.
5. **Medically Necessary or Medical Necessity** – covered services rendered by a provider that the Health Plan determines are:

- A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
- B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
- C. In accordance with current standards of medical practice;
- D. Not primarily for the convenience of the Member, or the Member's Provider; and
- E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

PROCEDURE:

New members to the plan already established on therapy may be eligible for continuity of care coverage as long as there is medical record documentation that the safety and effectiveness of use for the prescribed indication is supported by Food and Drug Administration (FDA) approval or adequate medical and scientific evidence in the medical literature.

A formulary exception for coverage of Kisqali may be made for members who meet the following criteria:

Kisqali as Initial Endocrine Therapy

- Medical record documentation that Kisqali is prescribed by an oncologist **AND**
- Medical record documentation of diagnosis of hormone-receptor (HR) positive, HER2-negative, advanced or metastatic breast cancer **AND**
- Medical record documentation that Kisqali is being prescribed as initial endocrine therapy **AND**
- Medical record documentation that Kisqali will be used in combination with an aromatase inhibitor or fulvestrant **AND**
- Medical record documentation of one of the following:
 - Medical record documentation of postmenopausal status **OR**
 - Medical record documentation of pre/perimenopausal status or member is male **AND** that member will be treated with a luteinizing hormone-releasing hormone (LHRH) agonist **AND**

Kisqali Following Disease Progression on Endocrine Therapy

- Medical record documentation that Kisqali is prescribed by an oncologist **AND**
- Medical record documentation of diagnosis of hormone-receptor (HR) positive, HER2-negative, advanced or metastatic breast cancer **AND**



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 447.0

**SECTION: Commercial Drug
SUBJECT: Kisqali**

- Medical record documentation that Kisqali is being prescribed after disease progression following endocrine therapy **AND**
- Medical record documentation that Kisqali will be used in combination with fulvestrant **AND**
- Medical record documentation of one of the following:
 - Medical record documentation of postmenopausal status **OR**
 - Medical record documentation of pre/perimenopausal status **AND** that member will be treated with a luteinizing hormone-releasing hormone (LHRH) agonist

MEDISPAN AUTHORIZATION LEVEL: GPI-12 (must include 2153107050B7 & 2199000260B7), number of claims authorized = 1, enter for the remainder of the calendar year

QUANTITY LIMIT: *No QLs need to be entered within the authorization unless the requested quantity exceeds the QL.*

- **QL FOR LETTER ONLY:**
 - Kisqali 200 mg per day: 21 tablets per 28 days
 - Kisqali 400 mg per day: 42 tablets per 28 days
 - Kisqali 600 mg per day: 63 tablets per 28 days
 - Kisqali/Femara 200 mg per day co-pack: 49 tablets per 28 days
 - Kisqali/Femara 400 mg per day co-pack: 70 tablets per 28 days
 - Kisqali/Femara 600 mg per day co-pack: 91 tablets per 28 days

RE-AUTHORIZATION CRITERIA: Kisqali is configured as a prior authorization for new starts only. Kisqali will no longer be covered if it is identified that the member is not receiving appropriate follow-up care from the prescribing specialist or if the member has greater than or equal to a 90 day break in therapy.

- Medical record documentation that the member is receiving appropriate follow-up care from the prescribing specialist

If a formulary exception is approved Kisqali will be paid for under the member's prescription drug benefit.

Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 447.0

**SECTION: Commercial Drug
SUBJECT: Kisqali**

FORMULARY ALTERNATIVES:

lbrance*

*prior authorization required

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE
STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND
FEDERAL REGULATORY ENTITIES.**

**THIS POLICY WILL BE REVISED AS NECESSARY AND
REVIEWED NO LESS THAN ANNUALLY.**

Signed: _____

Title: Director, Pharmacy Services

Date: April 6, 2022

Devised: 6/2/17
Revised: 3/1/18 – annual review, updated signature, added grandfather language, updated prescriber criteria
Revised: 11/28/18 – added pre/perimenopausal, added combo with fulvestrant, split indications to initial endocrine vs. following disease progression, added QL statement
Reviewed: 3/1/19 – annual review
Revised: 3/1/20 – annual review, added GHP Kids
Revised: 3/1/21 – annual review, updated logo, added MediSpan approval level, updated QL statement
Revised: 11/24/21 – added one-time PA to approval crit., removed auth duration & added re-auth crit.
Revised: 3/1/22 – annual review, updated referenced policies & covered LOBs, added coverage for males for initial therapy
Revised: 4/6/22 – removed ovarian ablation/suppression



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 448.0

**SECTION: Commercial Drug
SUBJECT: Topiramate Extended Release**

Applicable line of business:

Commercial	X	Medicaid	
Medicare		ACA	X
GHP Kids	X	Self-Insured	X

POLICY:

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for topiramate extended release for GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 487.0 Quantity Limit Exceptions

REQUIRED DEFINITIONS:

1. **Attachment** – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. **Exhibit** – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. **Devised** – the date the policy was implemented.
4. **Revised** – the date of every revision to the policy, including typographical and grammatical changes.
5. **Reviewed** – the date documenting the annual review if the policy has no revisions necessary.

ADDITIONAL DEFINITIONS:

1. **Formulary** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. **Non-formulary products** – those medications that are not included in the Formulary.
3. **Healthcare provider** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
4. **NCQA** – National Committee for Quality Assurance.
5. **Medically Necessary or Medical Necessity** – covered services rendered by a provider that the Health Plan determines are:



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 448.0

**SECTION: Commercial Drug
SUBJECT: Topiramate Extended Release**

- A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
- B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
- C. In accordance with current standards of medical practice;
- D. Not primarily for the convenience of the Member, or the Member's Provider; and
- E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

PROCEDURE:

New members to the plan already established on therapy may be eligible for continuity of care coverage as long as there is medical record documentation that the safety and effectiveness of use for the prescribed indication is supported by Food and Drug Administration (FDA) approval or adequate medical and scientific evidence in the medical literature.

An exception for coverage of topiramate extended release may be made for members who meet the following criteria:

Seizure Disorders

- Medical record documentation of a diagnosis of partial onset seizures, primary generalized tonic-clonic seizures, or Lennox Gastaut Syndrome **AND**
- Medical record documentation of age greater than or equal to 2 years **AND**
- Medical record documentation of therapeutic failure on, intolerance to, or contraindication three formulary alternatives, one of which must be topiramate immediate release

Migraine Headache Prophylaxis

- Medical record documentation of use for prophylaxis of migraine headaches **AND**
- Medical record documentation of age greater than or equal to 12 years **AND**
- Medical record documentation of therapeutic failure on, intolerance to, or contraindication to three formulary alternatives, one of which must be topiramate immediate release

MEDISPAN AUTHORIZATION LEVEL: GPI-12, generic only



POLICY NUMBER: 448.0

**POLICY AND PROCEDURE
PHARMACY
MANUAL**

**SECTION: Commercial Drug
SUBJECT: Topiramate Extended Release**

If an exception is made, topiramate extended release will be paid for under the member's prescription drug benefit.

Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.

FORMULARY ALTERNATIVES:

Seizure Disorders: carbamazepine, divalproex, felbamate, valproic acid, topiramate immediate release, lamotrigine, levetiracetam, oxcarbazepine, phenytoin, zonisamide, gabapentin, tiagabine, phenobarbital, pregabalin

Migraine Prophylaxis: topiramate immediate release, propranolol, timolol, divalproex delayed release, divalproex extended release, amitriptyline, atenolol, metoprolol, nadolol, venlafaxine, sodium valproate

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE
STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND
FEDERAL REGULATORY ENTITIES.**

**THIS POLICY WILL BE REVISED AS NECESSARY AND
REVIEWED NO LESS THAN ANNUALLY.**

Signed: _____

Title: Director, Pharmacy Services

Date: March 1, 2022

Devised: 6/2/17
Revised: 3/1/18 – annual review, updated signature, added grandfather language
Reviewed: 3/1/19 – annual review
Revised: 11/13/19 – updated formulary alternatives
Revised: 3/1/20 – annual review, added GHP Kids
Revised: 3/1/21 – annual review, updated logo, added MediSpan approval level
Revised: 3/1/22 – annual review, updated referenced policies & covered LOBs



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 449.0

**SECTION: Commercial Drug
SUBJECT: Sevelamer HCl
(generic Renagel)**

Applicable line of business:

Commercial	X	Medicaid	
Medicare		ACA	X
GHP Kids	X	Self-Insured	X

POLICY:

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for sevelamer HCl (generic Renagel) for GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 487.0 Quantity Limit Exceptions

REQUIRED DEFINITIONS:

1. **Attachment** – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. **Exhibit** – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. **Devised** – the date the policy was implemented.
4. **Revised** – the date of every revision to the policy, including typographical and grammatical changes.
5. **Reviewed** – the date documenting the annual review if the policy has no revisions necessary.

ADDITIONAL DEFINITIONS:

1. **Formulary** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. **Non-formulary products** – those medications that are not included in the Formulary.
3. **Healthcare provider** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
4. **NCQA** – National Committee for Quality Assurance.
5. **Medically Necessary or Medical Necessity** – covered services rendered by a provider that the Health Plan determines are:



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 449.0

**SECTION: Commercial Drug
SUBJECT: Sevelamer HCl
(generic Renagel)**

- A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
- B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
- C. In accordance with current standards of medical practice;
- D. Not primarily for the convenience of the Member, or the Member's Provider; and
- E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

PROCEDURE:

An exception for coverage of sevelamer HCl (generic Renagel) may be made for members who meet the following criteria:

- Medical record documentation of a diagnosis of chronic kidney disease (CKD) on dialysis **AND**
- Medical record documentation of a contraindication to, intolerance to, or therapeutic failure on calcium acetate **AND** sevelamer carbonate **AND** lanthanum carbonate

MEDISPAN AUTHORIZATION LEVEL: GPI-12, generic only

If an exception is made, sevelamer HCl (generic Renagel) will be paid for under the member's prescription drug benefit.

Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.

FORMULARY ALTERNATIVES:

calcium acetate, Eliphos, sevelamer carbonate, lanthanum carbonate, Fosrenol powder packet

Geisinger

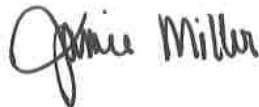
**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 449.0

**SECTION: Commercial Drug
SUBJECT: Sevelamer HCl
(generic Renagel)**

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE
STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND
FEDERAL REGULATORY ENTITIES.**

**THIS POLICY WILL BE REVISED AS NECESSARY AND
REVIEWED NO LESS THAN ANNUALLY.**



Signed: _____

Title: Director, Pharmacy Services

Date: March 1, 2022

Devised: 6/2/17
Revised: 3/1/18 – annual review, updated signature
Revised: 4/5/18 – updated FA criteria to generic products, updated FA
Reviewed: 3/1/19 – annual review
Revised: 11/21/19 – updated Renagel to generic sevelamer HCl
Revised: 3/1/20 – annual review, added GHP Kids
Revised: 3/1/21 – annual review, updated logo, added MediSpan approval level
Revised: 3/1/22 – annual review, updated referenced policies & covered LOBs



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 450.0

**SECTION: Commercial Drug
SUBJECT: Soliqua**

Applicable line of business:

Commercial	X	Medicaid	
Medicare		ACA	X
GHP Kids	X	Self-Insured	X

POLICY:

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for Soliqua for GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 487.0 Quantity Limit Exceptions

REQUIRED DEFINITIONS:

1. **Attachment** – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. **Exhibit** – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. **Devised** – the date the policy was implemented.
4. **Revised** – the date of every revision to the policy, including typographical and grammatical changes.
5. **Reviewed** – the date documenting the annual review if the policy has no revisions necessary.

ADDITIONAL DEFINITIONS:

1. **Formulary** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. **Non-formulary products** – those medications that are not included in the Formulary.
3. **Healthcare provider** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
4. **NCQA** – National Committee for Quality Assurance.
5. **Medically Necessary or Medical Necessity** – covered services rendered by a provider that the Health Plan determines are:



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 450.0

**SECTION: Commercial Drug
SUBJECT: Soliqua**

- A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
- B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
- C. In accordance with current standards of medical practice;
- D. Not primarily for the convenience of the Member, or the Member's Provider; and
- E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

PROCEDURE:

An exception for coverage of Soliqua may be made for members who meet the following criteria:

- Medical record documentation of a diagnosis of type 2 diabetes **AND**
- Medical record documentation of therapeutic failure on, intolerance to, or contraindication to Xultophy **AND**
- Medical record documentation that the dose of Soliqua is being prescribed at a minimum of 15 units (15 units insulin glargine/5 mcg lixisenatide) and no more than 60 units (60 units insulin glargine/20 mcg lixisenatide)

MEDISPAN AUTHORIZATION LEVEL: GPI-12

QUANTITY LIMIT: *No QLs need to be entered within the authorization unless the requested quantity exceeds the QL.*

- QL FOR LETTER ONLY: 0.6 mL per day

If an exception is made, Soliqua will be paid for under the member's prescription drug benefit.

Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.

FORMULARY ALTERNATIVES:

Xultophy*

*step therapy required



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 450.0

**SECTION: Commercial Drug
SUBJECT: Soliqua**

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE
STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND
FEDERAL REGULATORY ENTITIES.**

**THIS POLICY WILL BE REVISED AS NECESSARY AND
REVIEWED NO LESS THAN ANNUALLY.**

Signed: _____

Title: Director, Pharmacy Services

Date: March 1, 2022

Devised: 6/2/17
Revised: 3/1/18 – annual review, updated signature, updated FA
Revised: 3/1/19 – annual review, updated FA
Revised: 7/23/19 – added QL
Revised: 3/1/20 – annual review, added GHP Kids
Revised: 3/1/21 – annual review, updated logo, added MediSpan approval level, updated QL statement
Revised: 3/1/22 – annual review, updated referenced policies & covered LOBs



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 451.0

**SECTION: Commercial Drug
SUBJECT: Adlyxin**

Applicable line of business:

Commercial	X	Medicaid	
Medicare		ACA	X
GHP Kids	X	Self-Insured	X

POLICY:

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for Adlyxin for GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 487.0 Quantity Limit Exceptions

REQUIRED DEFINITIONS:

1. **Attachment** – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. **Exhibit** – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. **Devised** – the date the policy was implemented.
4. **Revised** – the date of every revision to the policy, including typographical and grammatical changes.
5. **Reviewed** – the date documenting the annual review if the policy has no revisions necessary.

ADDITIONAL DEFINITIONS:

1. **Formulary** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. **Non-formulary products** – those medications that are not included in the Formulary.
3. **Healthcare provider** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
4. **NCQA** – National Committee for Quality Assurance.
5. **Medically Necessary or Medical Necessity** – covered services rendered by a provider that the Health Plan determines are:



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 451.0

**SECTION: Commercial Drug
SUBJECT: Adlyxin**

- A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
- B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
- C. In accordance with current standards of medical practice;
- D. Not primarily for the convenience of the Member, or the Member's Provider; and
- E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

PROCEDURE:

An exception for coverage of Adlyxin may be made for members who meet the following criteria:

- Medical record documentation of a diagnosis of type 2 diabetes **AND**
- Medical record documentation of therapeutic failure on, intolerance to, or contraindication to metformin, Victoza **AND** either Ozempic or Rybelsus

MEDISPAN AUTHORIZATION LEVEL: GPI-10

QUANTITY LIMIT: *No QLs need to be entered within the authorization unless the requested quantity exceeds the QL.*

- QL FOR LETTER ONLY: 0.2 mL per day

If an exception is made, Adlyxin will be paid for under the member's prescription drug benefit.

Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.

FORMULARY ALTERNATIVES:

metformin, Ozempic, Victoza, Rybelsus, Trulicity

Geisinger

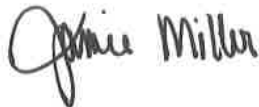
**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 451.0

**SECTION: Commercial Drug
SUBJECT: Adlyxin**

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE
STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND
FEDERAL REGULATORY ENTITIES.**

**THIS POLICY WILL BE REVISED AS NECESSARY AND
REVIEWED NO LESS THAN ANNUALLY.**



Signed: _____

Title: Director, Pharmacy Services

Date: March 1, 2022

Devised: 6/2/17

Revised: 1/17/18 – updated failure to Ozempic from Tanzeum, updated FA, updated QL to daily limit, updated signature

Revised: 3/1/18 – annual review, updated FA

Revised: 3/1/19 – annual review, added QL approval note, updated FA

Revised: 1/28/20 – added failure of Rybelsus, updated FA

Revised: 3/1/20 – annual review, added GHP Kids

Revised: 3/1/21 – annual review, updated logo, added MediSpan approval level, updated QL statement, added metformin to FA

Revised: 3/1/22 – annual review, updated referenced policies & covered LOBs, updated FA



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 452.0

**SECTION: Commercial Drug
SUBJECT: Xultophy**

Applicable line of business:

Commercial	X	Medicaid	
Medicare		ACA	X
GHP Kids	X	Self-Insured	X

POLICY:

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for Xultophy for GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 487.0 Quantity Limit Exceptions

REQUIRED DEFINITIONS:

1. **Attachment** – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. **Exhibit** – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. **Devised** – the date the policy was implemented.
4. **Revised** – the date of every revision to the policy, including typographical and grammatical changes.
5. **Reviewed** – the date documenting the annual review if the policy has no revisions necessary.

ADDITIONAL DEFINITIONS:

1. **Formulary** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. **Non-formulary products** – those medications that are not included in the Formulary.
3. **Healthcare provider** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
4. **NCQA** – National Committee for Quality Assurance.
5. **Medically Necessary or Medical Necessity** – covered services rendered by a provider that the Health Plan determines are:



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 452.0

**SECTION: Commercial Drug
SUBJECT: Xultophy**

- A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
- B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
- C. In accordance with current standards of medical practice;
- D. Not primarily for the convenience of the Member, or the Member's Provider; and
- E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

PROCEDURE:

An exception for coverage of Xultophy may be made for members who meet the following criteria:

- Electronic step therapy of on-line prescription drug claims history showing 15 days use of a formulary GLP-1 agonist **OR** a formulary long-acting basal insulin product, within the previous 180 days. If this electronic step is met, the claim will automatically adjudicate **OR**
- Medical record documentation of therapeutic failure on, intolerance to, or contraindication to one formulary GLP-1 agonist **OR** one formulary long-acting basal insulin product

MEDISPAN AUTHORIZATION LEVEL: GPI-12

QUANTITY LIMIT: *No QLs need to be entered within the authorization unless the requested quantity exceeds the QL.*

- QL FOR LETTER ONLY: 15 mL per 30 days

If an exception is made, Xultophy will be paid for under the member's prescription drug benefit.

Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.

FORMULARY ALTERNATIVES:

Ozempic, Victoza, Rybelsus, Trulicity, Lantus, Toujeo, Tresiba, Levemir



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 452.0

**SECTION: Commercial Drug
SUBJECT: Xultophy**

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE
STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND
FEDERAL REGULATORY ENTITIES.**

**THIS POLICY WILL BE REVISED AS NECESSARY AND
REVIEWED NO LESS THAN ANNUALLY.**

Signed: _____

Title: Director, Pharmacy Services

Date: March 1, 2022

Devised: 6/2/17
Revised: 3/1/18 – annual review, updated signature, added ST language, updated FA
Revised: 3/1/19 – annual review, added QL approval note, updated FA
Revised: 7/23/19 – added “long-acting” to basal insulin requirement
Revised: 3/1/20 – annual review, added GHP Kids
Revised: 3/1/21 – annual review, updated logo, added MediSpan approval level, updated QL statement,
added Rybelsus to FA
Revised: 3/1/22 – annual review, updated referenced policies & covered LOBs, updated FA



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 453.0

**SECTION: Commercial Drug
SUBJECT: Alunbrig**

Applicable line of business:

Commercial	X	Medicaid	
Medicare		ACA	X
GHP Kids	X	Self-Insured	X

POLICY:

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for Alunbrig for GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 487.0 Quantity Limit Exceptions

REQUIRED DEFINITIONS:

1. **Attachment** – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. **Exhibit** – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. **Devised** – the date the policy was implemented.
4. **Revised** – the date of every revision to the policy, including typographical and grammatical changes.
5. **Reviewed** – the date documenting the annual review if the policy has no revisions necessary.

ADDITIONAL DEFINITIONS:

1. **Formulary** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. **Non-formulary products** – those medications that are not included in the Formulary.
3. **Healthcare provider** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
4. **NCQA** – National Committee for Quality Assurance.
5. **Medically Necessary or Medical Necessity** – covered services rendered by a provider that the Health Plan determines are:



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 453.0

**SECTION: Commercial Drug
SUBJECT: Alunbrig**

- A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
- B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
- C. In accordance with current standards of medical practice;
- D. Not primarily for the convenience of the Member, or the Member's Provider; and
- E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

PROCEDURE:

New members to the plan already established on therapy may be eligible for continuity of care coverage as long as there is medical record documentation that the safety and effectiveness of use for the prescribed indication is supported by Food and Drug Administration (FDA) approval or adequate medical and scientific evidence in the medical literature.

A formulary exception for coverage of Alunbrig may be made for members who meet the following criteria:

- Medical record documentation that Alunbrig is prescribed by an oncologist **AND**
- Medical record documentation of a diagnosis of ALK-positive, metastatic non-small cell lung cancer

MEDISPAN AUTHORIZATION LEVEL: GPI-10, number of claims authorized = 1, enter for the remainder of the calendar year

QUANTITY LIMIT: *No QLs need to be entered within the authorization unless the requested quantity exceeds the QL.*

- **QL FOR LETTER ONLY:**
 - 30 mg tablet: 2 tablets per day, 30 day supply per fill
 - 90 mg, 180 mg, and Starter Pack: 1 tablet per day, 30 day supply per fill

RE-AUTHORIZATION CRITERIA: Alunbrig is configured as a prior authorization for new starts only. Alunbrig will no longer be covered if it is identified that the member is not receiving appropriate follow-up care from the prescribing specialist or if the member has greater than or equal to a 90 day break in therapy.

- Medical record documentation that the member is receiving appropriate follow-up care from the prescribing specialist



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 453.0

**SECTION: Commercial Drug
SUBJECT: Alunbrig**

If a formulary exception is approved Alunbrig will be paid for under the member's prescription drug benefit.

Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.

FORMULARY ALTERNATIVES:

Xalkori*, Zykadia*, Alecensa*

*prior authorization required

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE
STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND
FEDERAL REGULATORY ENTITIES.**

**THIS POLICY WILL BE REVISED AS NECESSARY AND
REVIEWED NO LESS THAN ANNUALLY.**

Signed: _____

Title: Director, Pharmacy Services

Date: March 1, 2022

- Devised: 8/8/17
- Revised: 3/1/18 – annual review, updated signature & prescriber criteria, added grandfather language
- Revised: 3/1/19 – annual review, added QL approval note
- Revised: 3/1/20 – annual review, added GHP Kids
- Revised: 7/29/20 – removed failure of Xalkori
- Revised: 10/12/20 – updated QL
- Revised: 3/1/21 – annual review, updated logo, added MediSpan approval level, updated QL statement
- Revised: 11/24/21 – added one-time PA to approval crit., removed auth duration & added re-auth crit.
- Revised: 3/1/22 – annual review, updated referenced policies & covered LOBs



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 454.0

**SECTION: Commercial Drug
SUBJECT: Rydapt**

Applicable line of business:

Commercial	X	Medicaid	
Medicare		ACA	X
GHP Kids	X	Self-Insured	X

POLICY:

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for Rydapt for GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 487.0 Quantity Limit Exceptions

REQUIRED DEFINITIONS:

1. **Attachment** – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. **Exhibit** – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. **Devised** – the date the policy was implemented.
4. **Revised** – the date of every revision to the policy, including typographical and grammatical changes.
5. **Reviewed** – the date documenting the annual review if the policy has no revisions necessary.

ADDITIONAL DEFINITIONS:

1. **Formulary** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. **Non-formulary products** – those medications that are not included in the Formulary.
3. **Healthcare provider** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
4. **NCQA** – National Committee for Quality Assurance.
5. **Medically Necessary or Medical Necessity** – covered services rendered by a provider that the Health Plan determines are:

- A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
- B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
- C. In accordance with current standards of medical practice;
- D. Not primarily for the convenience of the Member, or the Member's Provider; and
- E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

PROCEDURE:

New members to the plan already established on therapy may be eligible for continuity of care coverage as long as there is medical record documentation that the safety and effectiveness of use for the prescribed indication is supported by Food and Drug Administration (FDA) approval or adequate medical and scientific evidence in the medical literature.

A formulary exception for coverage of Rydapt may be made for members who meet the following criteria:

AML

- Medical record documentation that Rydapt is prescribed by a hematologist or oncologist **AND**
- Medical record documentation of age greater than or equal to 18 years **AND**
- Medical record documentation of a diagnosis of newly diagnosed acute myeloid leukemia (AML) that is FLT3 mutation positive as detected by a Food and Drug Administration (FDA)-approved test **AND**
- Medical record documentation that Rydapt will be administered in combination with standard cytarabine and daunorubicin induction and cytarabine consolidation

NOTE: Rydapt is not indicated as a single-agent induction therapy for the treatment of patients with AML.

ASM / SM-AHN / MCL

- Medical record documentation that Rydapt is prescribed by a hematologist or oncologist **AND**
- Medical record documentation of age greater than or equal to 18 years **AND**

- Medical record documentation of a diagnosis of aggressive systemic mastocytosis (ASM), systemic mastocytosis associated with hematological neoplasm (SM-AHN), or mast cell leukemia (MCL)

MEDISPAN AUTHORIZATION LEVEL: GPI-12, number of claims authorized = 1, enter for the remainder of the calendar year

QUANTITY LIMIT:

- AML
 - In PA Hub: Add ST, PA, PE, OQL, and 56 capsules per 21 days (max quantity 56, min/max day supply 21. *QL must be entered within the authorization.*)
 - QL FOR LETTER: 56 capsules per 21 days
- ASM / SM-AHN / MCL:
 - In PA Hub: Add ST, PA, and PE. *No QLs need to be entered within the authorization unless the requested quantity exceeds the QL.*
 - QL FOR LETTER: 224 capsules per 28 days

RE-AUTHORIZATION CRITERIA: Rydapt is configured as a prior authorization for new starts only. Rydapt will no longer be covered if it is identified that the member is not receiving appropriate follow-up care from the prescribing specialist or if the member has greater than or equal to a 90 day break in therapy.

- Medical record documentation that the member is receiving appropriate follow-up care from the prescribing specialist

If a formulary exception is approved Rydapt will be paid for under the member's prescription drug benefit.

Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.

FORMULARY ALTERNATIVES:

ASM: imatinib

Geisinger

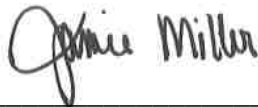
**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 454.0

**SECTION: Commercial Drug
SUBJECT: Rydapt**

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE
STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND
FEDERAL REGULATORY ENTITIES.**

**THIS POLICY WILL BE REVISED AS NECESSARY AND
REVIEWED NO LESS THAN ANNUALLY.**



Signed: _____

Title: Director, Pharmacy Services

Date: March 1, 2022

Devised: 8/8/17

Revised: 3/1/18 – annual review, updated signature, added grandfather language, updated age & prescriber criteria

Reviewed: 3/1/19 – annual review

Revised: 5/24/19 – updated ASM/SM-AHN/MCL QL

Revised: 3/1/20 – annual review, added GHP Kids

Revised: 3/1/21 – annual review, updated logo, added MediSpan approval level, updated QL statement

Revised: 12/1/21 – added one-time PA to approval crit., removed auth duration & added re-auth crit.

Revised: 3/1/22 – annual review, updated referenced policies & covered LOBs



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 455.0

**SECTION: Commercial Drug
SUBJECT: Zejula**

Applicable line of business:

Commercial	X	Medicaid	
Medicare		ACA	X
GHP Kids	X	Self-Insured	X

POLICY:

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for Zejula for GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 487.0 Quantity Limit Exceptions

REQUIRED DEFINITIONS:

1. **Attachment** – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. **Exhibit** – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. **Devised** – the date the policy was implemented.
4. **Revised** – the date of every revision to the policy, including typographical and grammatical changes.
5. **Reviewed** – the date documenting the annual review if the policy has no revisions necessary.

ADDITIONAL DEFINITIONS:

1. **Formulary** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. **Non-formulary products** – those medications that are not included in the Formulary.
3. **Healthcare provider** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
4. **NCQA** – National Committee for Quality Assurance.
5. **Medically Necessary or Medical Necessity** – covered services rendered by a provider that the Health Plan determines are:



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 455.0

**SECTION: Commercial Drug
SUBJECT: Zejula**

- A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
- B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
- C. In accordance with current standards of medical practice;
- D. Not primarily for the convenience of the Member, or the Member's Provider; and
- E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

PROCEDURE:

New members to the plan already established on therapy may be eligible for continuity of care coverage as long as there is medical record documentation that the safety and effectiveness of use for the prescribed indication is supported by Food and Drug Administration (FDA) approval or adequate medical and scientific evidence in the medical literature.

A formulary exception for coverage of Zejula may be made for members who meet the following criteria:

- Medical record documentation that Zejula is prescribed by a hematologist or oncologist **AND**
- Medical record documentation of age greater than or equal to 18 years **AND**

If the member is in complete/partial response to first-line platinum based chemotherapy:

- Medical record documentation of advanced epithelial ovarian, primary peritoneal, or fallopian tube cancer **AND**
- Medical record documentation that Zejula is being used as maintenance treatment **AND**
- Medical record documentation that member is in complete or partial response to platinum-based chemotherapy **AND**
- Medical record documentation that Zejula is being given at a dosage consistency with Food and Drug Administration (FDA)-approved labeling*

OR

If the member has failed three or more treatments:

- Medical record documentation of advanced ovarian, fallopian tube, or primary peritoneal cancer **AND**
- Medical record documentation of treatment with three or more prior chemotherapy regimens **AND**

- Medical record documentation of homologous recombination deficiency (HRD) positive status defined by either a deleterious or suspected deleterious *BRCA* mutation OR genomic instability with progression more than six months after response to last platinum-based chemotherapy

OR

If the member has platinum-sensitive recurrent disease and has completed two or more lines of platinum-based chemotherapy:

- Medical record documentation of recurrent epithelial ovarian, primary peritoneal, or fallopian tube cancer **AND**
- Medical record documentation that Zejula is being used as maintenance treatment **AND**
- Medical record documentation of a complete or partial response to platinum based chemotherapy

***NOTE:** For the first-line treatment of advanced ovarian cancer:

- For patient weight less than 77 kg (170 lbs) **OR** with a platelet count of less than 150,000/ μ L, the recommended dose is 200 mg (two 100-mg capsules taken orally once daily) .
- For patient weight greater than or equal to 77 kg (170 lbs) **AND** who have a platelet count greater than or equal to 150,000/ μ L the recommended dose is 300 mg (three 100-mg capsules) taken orally once daily.

MEDISPAN AUTHORIZATION LEVEL: GPI-12, number of claims authorized = 1, enter for the remainder of the calendar year

QUANTITY LIMIT: *No QLs need to be entered within the authorization unless the requested quantity exceeds the QL.*

- QL FOR LETTER ONLY: 3 tablets per day, 30 day supply per fill

RE-AUTHORIZATION CRITERIA: Zejula is configured as a prior authorization for new starts only. Zejula will no longer be covered if it is identified that the member is not receiving appropriate follow-up care from the prescribing specialist or if the member has greater than or equal to a 90 day break in therapy.

- Medical record documentation that the member is receiving appropriate follow-up care from the prescribing specialist

If a formulary exception is approved Zejula will be paid for under the member's prescription drug benefit.



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 455.0

**SECTION: Commercial Drug
SUBJECT: Zejula**

Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.

FORMULARY ALTERNATIVES:

Lynparza*, Rubraca*

*prior authorization required

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE
STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND
FEDERAL REGULATORY ENTITIES.**

**THIS POLICY WILL BE REVISED AS NECESSARY AND
REVIEWED NO LESS THAN ANNUALLY.**

Signed: _____

Title: Director, Pharmacy Services

Date: March 1, 2022

- Devised: 8/8/17
- Revised: 3/1/18 – annual review, updated signature, added grandfather language, updated age & prescriber criteria
- Revised: 3/1/19 – annual review, added QL approval note
- Revised: 1/28/20 – added advanced ovarian, fallopian tube, and primary peritoneal cancer indication
- Revised: 3/1/20 – annual review, added GHP Kids
- Revised: 7/29/20 – reorganized criteria for better usability, added advanced ovarian after complete/partial response to platinum therapy indication
- Revised: 3/1/21 – annual review, updated logo, added MediSpan approval level, updated QL statement
- Revised: 12/2/21 – added one-time PA to approval crit., removed auth duration & added re-auth crit.
- Revised: 3/1/22 – annual review, updated referenced policies & covered LOBs



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 456.0

**SECTION: Commercial Drug
SUBJECT: Eucrisa**

Applicable line of business:

Commercial	X	Medicaid	
Medicare		ACA	X
GHP Kids	X	Self-Insured	X

POLICY:

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for Eucrisa for GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 487.0 Quantity Limit Exceptions

REQUIRED DEFINITIONS:

1. **Attachment** – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. **Exhibit** – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. **Devised** – the date the policy was implemented.
4. **Revised** – the date of every revision to the policy, including typographical and grammatical changes.
5. **Reviewed** – the date documenting the annual review if the policy has no revisions necessary.

ADDITIONAL DEFINITIONS:

1. **Formulary** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. **Non-formulary products** – those medications that are not included in the Formulary.
3. **Healthcare provider** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
4. **NCQA** – National Committee for Quality Assurance.
5. **Medically Necessary or Medical Necessity** – covered services rendered by a provider that the Health Plan determines are:



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 456.0

**SECTION: Commercial Drug
SUBJECT: Eucrisa**

- A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
- B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
- C. In accordance with current standards of medical practice;
- D. Not primarily for the convenience of the Member, or the Member's Provider; and
- E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

PROCEDURE:

A formulary exception for coverage of Eucrisa may be made for members who meet the following criteria:

- Medical record documentation that Eucrisa is prescribed by or in consultation with a dermatologist **AND**
- Medical record documentation of a diagnosis of mild to moderate atopic dermatitis **AND**
- **For members 2 years of age and older:** Medical record documentation of contraindication to, intolerance to, or therapeutic failure on tacrolimus ointment **AND**
- Medical record documentation of contraindication to, intolerance to, or therapeutic failure on at least two (2) formulary topical corticosteroids unless deemed inadvisable due to potential risks such as (a) use on sensitive skin areas (face, axillae, or groin) or (b) member is less than 15 years of age

MEDISPAN AUTHORIZATION LEVEL: GPI-12

If a formulary exception is approved Eucrisa will be paid for under the member's prescription drug benefit.

Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 456.0

**SECTION: Commercial Drug
SUBJECT: Eucrisa**

FORMULARY ALTERNATIVES:

tacrolimus ointment

Low-potency topical corticosteroids: alclometasone dipropionate 0.5% cream and ointment (Aclovate); fluocinolone acetonide 0.01% soln. (Synalar); hydrocortisone 2.5% cream, ointment, and lotion (Hytone)

Medium-potency topical corticosteroids: betamethasone valerate 0.1% cream (Valisone); fluocinolone acetonide 0.025% cream and ointment (Synalar); fluticasone propionate 0.05% cream, ointment, and lotion (Cutivate); triamcinolone 0.1% cream, ointment and lotion (Kenalog); triamcinolone acetonide 0.025% cream, ointment and lotion (Kenalog); triamcinolone acetonide 0.147 mg/g aerosol (Kenalog Spray)

High-potency topical corticosteroids: augmented betamethasone dipropionate 0.05% cream (Diprolene AF); betamethasone valerate 0.1% ointment (Valisone); triamcinolone 0.5% cream (Kenalog); fluocinonide 0.05% cream, ointment and gel (Lidex)

Very high-potency topical corticosteroids: augmented betamethasone dipropionate 0.05% ointment, gel and lotion (Diprolene); clobetasol 0.05% cream, ointment, and scalp lotion (Temovate) diflorasone diacetate 0.05% cream and ointment (ApexiCon/Psorcon)

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE
STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND
FEDERAL REGULATORY ENTITIES.**

**THIS POLICY WILL BE REVISED AS NECESSARY AND
REVIEWED NO LESS THAN ANNUALLY.**

Signed: _____

Title: Director, Pharmacy Services

Date: March 1, 2022

Devised: 8/8/17
Revised: 3/1/18 – annual review, updated signature, updated prescriber criteria
Reviewed: 3/1/19 – annual review
Revised: 3/1/20 – annual review, added GHP Kids
Revised: 3/1/20 – annual review, added GHP Kids
Revised: 10/12/20 – removed age criteria, updated to failure of tacrolimus only if 2 years or older, removed “between 2 and” from failure of steroids
Revised: 3/1/21 – annual review, updated logo, added MediSpan approval level
Revised: 3/1/22 – annual review, updated referenced policies & covered LOBs



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 457.0

**SECTION: Commercial Drug
SUBJECT: Dupixent**

Applicable line of business:

Commercial	X	Medicaid	
Medicare		ACA	X
GHP Kids	X	Self-Insured	X

POLICY:

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for Dupixent for GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 487.0 Quantity Limit Exceptions

REQUIRED DEFINITIONS:

1. **Attachment** – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. **Exhibit** – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. **Devised** – the date the policy was implemented.
4. **Revised** – the date of every revision to the policy, including typographical and grammatical changes.
5. **Reviewed** – the date documenting the annual review if the policy has no revisions necessary.

ADDITIONAL DEFINITIONS:

1. **Formulary** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. **Non-formulary products** – those medications that are not included in the Formulary.
3. **Healthcare provider** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
4. **NCQA** – National Committee for Quality Assurance.
5. **Medically Necessary or Medical Necessity** – covered services rendered by a provider that the Health Plan determines are:

- A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
- B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
- C. In accordance with current standards of medical practice;
- D. Not primarily for the convenience of the Member, or the Member's Provider; and
- E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

PROCEDURE:

A formulary exception for coverage of Dupixent may be made for members who meet the following criteria:

Atopic Dermatitis

- Medical record documentation that Dupixent is prescribed by or in consultation with an allergist, dermatologist, or immunologist **AND**
- Medical record documentation of age greater than or equal to 6 years **AND**
- Medical record documentation of a diagnosis of moderate to severe atopic dermatitis **AND**
- Medical record documentation of one of the following:
 - Therapeutic failure* on an adequate trial of at least one medium (or higher) potency topical corticosteroid **OR**
 - For members with an intolerance or contraindication to topical corticosteroids or for members in whom topical corticosteroids are inadvisable (use on sensitive areas, age between 2 and 15 years): Therapeutic failure on, intolerance to, or contraindication to a topical calcineurin inhibitor **AND**
- Medical record documentation of contraindication to, intolerance to, or therapeutic failure on an adequate trial of phototherapy (UVA/UVB treatment) **AND**
- Medical record documentation that the member is receiving an appropriate dose[#] based on patient's age and weight

***NOTE:** Therapeutic failure is defined as an inability to achieve and maintain remission of low to mild disease activity.

AUTHORIZATION DURATION: Initial approval will be for 6 months or less if the reviewing provider feels it is medically appropriate. Subsequent approvals will be for an additional 12 months or less if the reviewing provider feels it is medically appropriate.

The medication will no longer be covered if the member experiences unacceptable toxicity or worsening of disease.

- Medical record documentation of continued disease improvement or lack of disease progression **AND**
- Medical record documentation that the member is receiving an appropriate dose[#] based on patient's age and weight

MEDISPAN AUTHORIZATION LEVEL: GPI-10

#NOTE:

Atopic Dermatitis

Dosage in Adults

- Recommended dosage is an initial dose of 600 mg (two 300 mg injections), followed by 300 mg given every other week (Q2W). (2.3)

Dosage in Pediatric Patients (6 to 17 Years of Age)

Body Weight	Initial Loading Dose	Subsequent Doses ^a
15 to less than 30 kg	600 mg (two 300 mg injections)	300 mg Q4W
30 to less than 60 kg	400 mg (two 200 mg injections)	200 mg Q2W
60 kg or more	600 mg (two 300 mg injections)	300 mg Q2W

^a Q2W – every other week; Q4W – every 4 weeks

QUANTITY LIMIT

• Initial Approval

- 600 mg once, followed by 300 mg every other week
 1. In Darwin: Add PA, OQL, OUP, DS, enter 1 in max number of claims authorized, max quantity dispensed 8, minimum day supply 42, and maximum day supply 42 with a duration of two-weeks.
 2. In PA Hub: Add PA, OQL, and max quantity dispensed 4 with a start date 1 day after the loading dose ends for the remainder of the authorization.
 - QL FOR LETTER: Loading dose: 8 mL per 42 days, Maintenance dose: 4 mL per 28 days
- 600 mg once, followed by 300 mg every four weeks
 1. In Darwin: Add PA, OQL, OUP, DS, enter 1 in max number of claims authorized, max quantity dispensed 8, minimum day supply 42, and maximum day supply 42 with a duration of two-weeks.
 2. In PA Hub: Add PA, OQL, and max quantity dispensed 2 with a start date 1 day after the loading dose ends for the remainder of the authorization.
 - QL FOR LETTER: Loading dose: 8 mL per 42 days, Maintenance dose: 2 mL per 28 days

- 400 mg once, followed by 200 mg every other week
 1. In Darwin: Add PA, OQL, OUP, DS, enter 1 in max number of claims authorized, max quantity dispensed 4.56, minimum day supply 42, and maximum day supply 42 with a duration of two-weeks.
 2. In PA Hub: Add PA, OQL, and max quantity dispensed 2.28 with a start date 1 day after the loading dose ends for the remainder of the authorization.
 - QL FOR LETTER: Loading dose: 4.56 mL per 42 days, Maintenance dose: 2.28 mL per 28 days

• Renewal –

- 300 mg every other week
 1. In PA Hub: Add PA, OQL, and max quantity dispensed 4.
 - QL FOR LETTER: 4 mL per 28 days
- 300 mg every four weeks
 1. In PA Hub: Add PA, OQL, and max quantity dispensed 2.
 - QL FOR LETTER: 2 mL per 28 days
- 200 mg every other week
 1. In PA Hub: Add PA, OQL, and max quantity dispensed 2.28.
 - QL FOR LETTER: 2.28 mL per 28 days

****Topical Corticosteroid Potency Chart:**

Potency Group	Corticosteroid	Vehicle/Form	Strength
Super-high Potency	Betamethasone dipropionate, augmented	Ointment, Lotion, Gel	0.05%
	Clobetasol propionate	Ointment, Cream, Gel, Lotion Foam, Shampoo, Solution, Spray	0.05%
	Fluocinonide	Cream	0.1%
	Halobetasol propionate	Ointment, Cream, Lotion	0.05%
High Potency	Amcinonide	Ointment	0.1%
	Betamethasone dipropionate	Ointment, Cream	0.05%
	Desoximetasone	Cream	0.05%
	Diflorasone diacetate	Cream	0.05%
	Fluocinonide	Cream	0.05%
	Fluticasone propionate	Ointment	0.005%
	Mometasone furoate	Ointment	0.1%
	Triamcinolone acetonide	Ointment, Cream	0.5%
Medium Potency	Betamethasone dipropionate	Spray	0.05%
	Clocortolone pivalate	Cream	0.1%
	Fluocinolone acetonide	Ointment	0.025%
	Flurandrenolide	Ointment	0.05%
	Hydrocortisone valerate	Ointment	0.2%
	Mometasone furoate	Cream, Lotion, Solution	0.1%
	Triamcinolone acetonide	Cream, Ointment	0.1%
		Aerosol Spray	0.2%

Lower-mid Potency	Betamethasone dipropionate	Lotion	0.05%
	Betamethasone valerate	Cream	0.1%
	Desonide	Ointment, Gel	0.05%
	Fluocinolone acetonide	Cream	0.025%
	Flurandrenolide	Cream, Lotion	0.05%
	Fluticasone propionate	Cream, Lotion	0.05%
	Hydrocortisone butyrate	Ointment, Cream, Lotion, Solution	0.1%
	Hydrocortisone probutate	Cream	0.1%
	Hydrocortisone valerate	Cream	0.2%
	Prednicarbate	Cream, Ointment	0.1%
Triamcinolone acetonide	Lotion	0.1%	
	Ointment	0.025%	
Low Potency	Alclometasone dipropionate	Ointment, Cream	0.05%
	Betamethasone valerate	Lotion	0.1%
	Desonide	Cream, Lotion, Foam	0.5%
	Fluocinolone acetonide	Cream, Solution, Shampoo, Oil	0.01%
	Triamcinolone acetonide	Cream, Lotion	0.025%
Least Potent	Hydrocortisone (base)	Ointment, Cream, Lotion, Solution, Spray, Foam	0.5%, 1%, 2%, 2.5%

FORMULARY ALTERNATIVES:

Systemic Therapies:

azathioprine, cyclosporine, methotrexate, mycophenolate

Topical Therapies:

Calcineurin Inhibitors: tacrolimus ointment, pimecrolimus cream*
Eucrisa*

Low-potency topical corticosteroids: alclometasone dipropionate 0.5% cream and ointment (Aclovate); fluocinolone acetonide 0.01% soln. (Synalar); hydrocortisone 2.5% cream, ointment, and lotion (Hytone)

Medium-potency topical corticosteroids: betamethasone valerate 0.1% cream (Valisone); fluocinolone acetonide 0.025% cream and ointment (Synalar); fluticasone propionate 0.05% cream, ointment, and lotion (Cutivate); triamcinolone 0.1% cream, ointment and lotion (Kenalog); triamcinolone acetonide 0.025% cream, ointment and lotion (Kenalog); triamcinolone acetonide 0.147 mg/g aerosol (Kenalog Spray)

High-potency topical corticosteroids: augmented betamethasone dipropionate 0.05% cream (Diprolene AF); betamethasone valerate 0.1% ointment (Valisone); triamcinolone 0.5% cream (Kenalog); fluocinolone 0.05% cream, ointment and gel (Lidex)

Very high-potency topical corticosteroids: augmented betamethasone dipropionate 0.05% ointment, gel and lotion (Diprolene); clobetasol 0.05% cream, ointment, and scalp lotion (Temovate) diflorasone diacetate 0.05% cream and ointment (ApexiCon/Psorcon)

*prior authorization required

Asthma

- Medical record documentation that Dupixent is prescribed by or in consultation with an allergist, immunologist, or pulmonologist **AND**
- Medical record documentation of age greater than or equal to 6 years **AND**
- Medical record documentation of one of the following:
 - A diagnosis of moderate to severe eosinophilic asthma **AND** a blood eosinophilic count greater than or equal to 150 cells/microL **OR**
 - A diagnosis of oral corticosteroid dependent asthma **AND**
- Medical record documentation that Dupixent will be used as an add-on maintenance treatment **AND**
- Medical record documentation of one of the following:
 - Contraindication, intolerance to, or poorly (not well) controlled symptoms despite at least a 3-month trial of: maximally tolerated inhaled corticosteroids and/or oral systemic corticosteroids plus a long-acting beta agonist **OR**
 - One exacerbation in the previous 12 months requiring additional medical treatment (oral corticosteroids, emergency department or urgent care visits, or hospitalization) despite current therapy or intolerance to inhaled corticosteroids plus a long-acting beta agonist **AND**
- Medical record documentation that Dupixent will not be used in combination with another biologic medication indicated for asthma treatment (e.g., Xolair, Fasenna, Nucala, Cinqair, or Tezspire) **AND**
- Medical record documentation that the member is receiving an appropriate dose[#] based on patient’s age and weight

Measures of Disease Severity

Measure	Not Well Controlled	Very Poorly Controlled
Symptoms	> 2 days per week	Throughout the day
Nighttime awakenings	1-3x/week	> 4x/week
Interference with normal activity	Some limitation	Extremely limited
SABA use for symptom control (not to prevent exercise-induced bronchospasm)	> 2 days/week	Several times per day
FEV1 (% predicted) or peak flow (% personal best)	60-80%	< 60%
Asthma Control Test (ACT) Score	16-19	< 15

MEDISPAN AUTHORIZATION LEVEL: GPI-10

#NOTE:

Asthma

Dosage in Adult and Pediatric Patients 12 Years and Older

Initial Loading Dose	Subsequent Dose
400 mg (two 200 mg injections)	200 mg every 2 weeks (Q2W)
or	
600 mg (two 300 mg injections)	300 mg every 2 weeks (Q2W)
Dosage for patients with oral corticosteroid-dependent asthma or with co-morbid moderate-to-severe atopic dermatitis or adults with co-morbid chronic rhinosinusitis with nasal polyposis	
600 mg (two 300 mg injections)	300 mg every 2 weeks (Q2W)

Dosage in Pediatric Patients 6 to 11 Years of Age

Body Weight	Initial Dose and Subsequent Doses
15 to less than 30 kg	100 mg every other week (Q2W) or 300 mg every four weeks (Q4W)
≥30 kg	200 mg every other week (Q2W)

QUANTITY LIMIT

• Initial Approval

- 600 mg once, followed by 300 mg every other week
 1. In Darwin: Add PA, OQL, OUP, DS, enter 1 in max number of claims authorized, max quantity dispensed 8, minimum day supply 42, and maximum day supply 42 with a duration of two-weeks.
 2. In PA Hub: Add PA, OQL, and max quantity dispensed 4 with a start date 1 day after the loading dose ends for the remainder of the authorization.
 - QL FOR LETTER: Loading dose: 8 mL per 42 days, Maintenance dose: 4 mL per 28 days
- 400 mg once, followed by 200 mg every other week
 1. In Darwin: Add PA, OQL, OUP, DS, enter 1 in max number of claims authorized, max quantity dispensed 4.56, minimum day supply 42, and maximum day supply 42 with a duration of two-weeks.
 2. In PA Hub: Add PA, OQL, and max quantity dispensed 2.28 with a start date 1 day after the loading dose ends for the remainder of the authorization.
 - QL FOR LETTER: Loading dose: 4.56 mL per 42 days, Maintenance dose: 2.28 mL per 28 days

- 300 mg every four weeks (no loading dose required)
 - 1. In PA Hub: Add PA, OQL, and max quantity dispensed 2
 - QL FOR LETTER: 2 mL per 28 days
- 100 mg every other week (no loading dose required)
 - 1. In PA Hub: Add PA, OQL, and max quantity dispensed 1.34
 - QL FOR LETTER: 1.34 mL per 28 days
- 200 mg every other week (no loading dose required)
 - 1. In PA Hub: Add PA, OQL, and max quantity dispensed 2.28
 - QL FOR LETTER: 2.28 mL per 28 days

• Renewal –

- 300 mg every other week
 - 1. In PA Hub: Add PA, OQL, and max quantity dispensed 4
 - QL FOR LETTER: 4 mL per 28 days
- 300 mg every four weeks
 - 1. In PA Hub: Add PA, OQL, and max quantity dispensed 2
 - QL FOR LETTER: 2 mL per 28 days
- 200 mg every other week
 - 1. In PA Hub: Add PA, OQL, and max quantity dispensed 2.28
 - QL FOR LETTER: 2.28 mL per 28 days
- 100 mg every other week
 - 1. In PA Hub: Add PA, OQL, and max quantity dispensed 1.34
 - QL FOR LETTER: 1.34 mL per 28 days

AUTHORIZATION DURATION: Initial approval will be for 6 months or less if the reviewing provider feels it is medically appropriate. Subsequent approvals will be for an additional 12 months or less if the reviewing provider feels it is medically appropriate. The medication will no longer be covered if the member experiences unacceptable toxicity or worsening of disease.

- Medical record documentation of continued disease improvement or lack of disease progression **AND**
- Medical record documentation that the member is receiving an appropriate dose[#] based on patient's age and weight

FORMULARY ALTERNATIVES:

Inhaled Therapies: Arnuity Ellipta, Asmanex, Flovent, Pulmicort Flexhaler, QVAR RediHaler, fluticasone/salmeterol, Breo Ellipta, Dulera

Systemic Therapies: prednisone, dexamethasone, methylprednisolone, prednisolone

Chronic Rhinosinusitis with Nasal Polyposis (CRSwNP)

- Medical record documentation that Dupixent is prescribed by or in consultation with an allergist, pulmonologist, immunologist, or otolaryngologist (ENT provider) **AND**
- Medical record documentation of age greater than or equal to 18 years **AND**
- Medical record documentation of a diagnosis of chronic rhinosinusitis with nasal polyposis (CRwNP) **AND**
- Medical record documentation that Dupixent will be used as add-on maintenance treatment **AND**
- Medical record documentation of therapeutic failure on, intolerance to, or contraindication to three (3) intranasal corticosteroids **AND**
- Medical record documentation that the member is receiving an appropriate dose[#] based on patient's age and weight

MEDISPAN AUTHORIZATION LEVEL: GPI-10

#NOTE: Recommended dosage for adult patients is 300 mg given every other week. No loading dose is required.

QUANTITY LIMIT:

- 300 mg every other week
 1. In PA Hub: Add PA, OQL, and max quantity dispensed 4.
 - QL FOR LETTER: 4 mL per 28 days

AUTHORIZATION DURATION: Initial approval will be for 6 months or less if the reviewing provider feels it is medically appropriate. Subsequent approvals will be for an additional 12 months or less if the reviewing provider feels it is medically appropriate. The medication will no longer be covered if the member experiences unacceptable toxicity or worsening of disease.

- Medical record documentation of continued disease improvement or lack of disease progression **AND**
- Medical record documentation that the member is receiving an appropriate dose[#] based on patient's age and weight

FORMULARY ALTERNATIVES:

fluticasone propionate, triamcinolone acetonide, mometasone furoate



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 457.0

**SECTION: Commercial Drug
SUBJECT: Dupixent**

If a formulary exception is approved Dupixent will be paid for under the member's prescription drug benefit.

Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE
STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND
FEDERAL REGULATORY ENTITIES.**

**THIS POLICY WILL BE REVISED AS NECESSARY AND
REVIEWED NO LESS THAN ANNUALLY.**

Signed: _____

Title: Director, Pharmacy Services

Date: June 7, 2022

- Devised: 8/8/17
- Revised: 10/4/17 – updated QL from syringes to mL's
- Revised: 3/1/18 – annual review, updated signature, updated prescriber criteria
- Revised: 10/8/18 – clarified "at least one" systemic failure, added allergist/immunologist
- Reviewed: 3/1/19 – annual review
- Revised: 3/28/19 – added asthma indication, updated FA
- Revised: 6/4/19 – added authorization parameters
- Revised: 7/12/19 – corrected 200 mg dosage typo in authorization parameters
- Revised: 7/23/19 – Atopic dermatitis: decreased age to 12, removed failure of systemic therapy, updated to failure of one steroid, tacrolimus, Eucrisa, and phototherapy
- Revised: 11/20/19 – reformatted policy, added CRSwNP indication
- Revised: 3/1/20 – annual review, added GHP Kids
- Revised: 11/17/20 – updated age requirements for atopic dermatitis, moved FA to under each indication
- Revised: 1/25/21 – updated atopic dermatitis to failure of steroid or calcineurin inhibitor, added MediSpan approval lever, updated auth duration/QL language
- Revised: 3/1/21 – annual review, updated logo, corrected QL's
- Revised: 6/15/21 – removed criteria for failure of tacrolimus and Eucrisa for atopic dermatitis. (January P&T)
- Revised: 11/23/21 – updated age for asthma to 6, updated asthma QL formatting and added 100 mg dose, updated QL for atopic dermatitis to include 400 mg EOW and 300 mg every 4 week dosing, updated QL entry to account for DS over 28
- Revised: 1/21/22 – updated to GPI-10, updated how QL's are entered, added dosage criterion, added dosing chart
- Revised: 3/1/22 – annual review, updated referenced policies & covered LOBs, updated how QL's are entered



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 457.0

**SECTION: Commercial Drug
SUBJECT: Dupixent**

Revised: 4/6/22 – added additional prescribers to CRSwNP, updated age to 6 years for asthma & atopic dermatitis.
Revised: 6/7/22 – updated concurrent biologic criterion in asthma indication



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 458.0

**SECTION: Commercial Drug
SUBJECT: Trulance**

Applicable line of business:

Commercial	X	Medicaid	
Medicare		ACA	X
GHP Kids	X	Self-Insured	X

POLICY:

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for Trulance for GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 487.0 Quantity Limit Exceptions

REQUIRED DEFINITIONS:

1. **Attachment** – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. **Exhibit** – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. **Devised** – the date the policy was implemented.
4. **Revised** – the date of every revision to the policy, including typographical and grammatical changes.
5. **Reviewed** – the date documenting the annual review if the policy has no revisions necessary.

ADDITIONAL DEFINITIONS:

1. **Formulary** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. **Non-formulary products** – those medications that are not included in the Formulary.
3. **Healthcare provider** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
4. **NCQA** – National Committee for Quality Assurance.
5. **Medically Necessary or Medical Necessity** – covered services rendered by a provider that the Health Plan determines are:

- A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
- B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
- C. In accordance with current standards of medical practice;
- D. Not primarily for the convenience of the Member, or the Member's Provider; and
- E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

PROCEDURE:

A formulary exception for coverage of Trulance may be made for members who meet the following criteria:

Chronic Idiopathic Constipation

- Medical record documentation of age greater than or equal to 18 years **AND**
- Medical record documentation of a diagnosis of chronic idiopathic constipation **AND**
- Medical record documentation of therapeutic failure on, intolerance to, or contraindication to Linzess **AND** lubiprostone

Irritable Bowel Syndrome with Constipation (IBS-C)

- Medical record documentation of age greater than or equal to 18 years **AND**
- Medical record documentation of a diagnosis of irritable bowel syndrome with constipation (IBS-C) **AND**
- Medical record documentation of therapeutic failure on, intolerance to, or contraindication to Linzess

MEDISPAN AUTHORIZATION LEVEL: GPI-12

QUANTITY LIMIT: *No QLs need to be entered within the authorization unless the requested quantity exceeds the QL.*

- **QL FOR LETTER ONLY:** 1 tablet per day

If a formulary exception is approved Trulance will be paid for under the member's prescription drug benefit.

Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.



POLICY NUMBER: 458.0

**POLICY AND PROCEDURE
PHARMACY
MANUAL**

**SECTION: Commercial Drug
SUBJECT: Trulance**

FORMULARY ALTERNATIVES:

Chronic Idiopathic Constipation: lubiprostone, Linzess
Irritable Bowel Syndrome with Constipation: Linzess

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE
STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND
FEDERAL REGULATORY ENTITIES.**

**THIS POLICY WILL BE REVISED AS NECESSARY AND
REVIEWED NO LESS THAN ANNUALLY.**

Signed: _____

Title: Director, Pharmacy Services

Date: March 1, 2022

Devised: 8/8/17
Revised: 3/1/18 – annual review, updated signature
Revised: 8/7/18 – added IBS-C indication, updated FA
Revised: 3/1/19 – annual review, added QL approval note
Revised: 3/1/20 – annual review, added GHP Kids
Revised: 11/18/20 – corrected QL typo
Revised: 3/1/21 – annual review, updated logo, added MediSpan approval level, updated QL statement
Revised: 3/1/22 – annual review, updated referenced policies & covered LOBs, updated Amitiza to generic



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 459.0

**SECTION: Commercial Drug
SUBJECT: Xermelo**

Applicable line of business:

Commercial	X	Medicaid	
Medicare		ACA	X
GHP Kids	X	Self-Insured	X

POLICY:

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for Xermelo for GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 487.0 Quantity Limit Exceptions

REQUIRED DEFINITIONS:

1. **Attachment** – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. **Exhibit** – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. **Devised** – the date the policy was implemented.
4. **Revised** – the date of every revision to the policy, including typographical and grammatical changes.
5. **Reviewed** – the date documenting the annual review if the policy has no revisions necessary.

ADDITIONAL DEFINITIONS:

1. **Formulary** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. **Non-formulary products** – those medications that are not included in the Formulary.
3. **Healthcare provider** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
4. **NCQA** – National Committee for Quality Assurance.
5. **Medically Necessary or Medical Necessity** – covered services rendered by a provider that the Health Plan determines are:



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 459.0

**SECTION: Commercial Drug
SUBJECT: Xermelo**

- A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
- B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
- C. In accordance with current standards of medical practice;
- D. Not primarily for the convenience of the Member, or the Member's Provider; and
- E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

PROCEDURE:

A formulary exception for coverage of Xermelo may be made for members who meet the following criteria:

- Medical record documentation of age greater than or equal to 18 years **AND**
- Medical record documentation of a diagnosis of carcinoid syndrome diarrhea **AND**
- Medical record documentation of an inadequate response* on a somatostatin analog monotherapy **AND**
- Medical record documentation that Xermelo will be used in combination with a somatostatin analog (i.e., octreotide, Sandostatin LAR Depot, Somatuline Depot)

***Note:** In the clinical trials, inadequate response was defined as at least 4 bowel movements per day with 3 months or more of a stable dose of a somatostatin analog.

MEDISPAN AUTHORIZATION LEVEL: GPI-12

QUANTITY LIMIT: *No QLs need to be entered within the authorization unless the requested quantity exceeds the QL.*

- **QL FOR LETTER ONLY:** 3 tablets per day

If a formulary exception is approved Xermelo will be paid for under the member's prescription drug benefit.

Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.



POLICY NUMBER: 459.0

**POLICY AND PROCEDURE
PHARMACY
MANUAL**

**SECTION: Commercial Drug
SUBJECT: Xermelo**

FORMULARY ALTERNATIVES:
octreotide, Somatuline Depot*

*prior authorization required

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE
STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND
FEDERAL REGULATORY ENTITIES.**

**THIS POLICY WILL BE REVISED AS NECESSARY AND
REVIEWED NO LESS THAN ANNUALLY.**

Signed: _____

Title: Director, Pharmacy Services

Date: March 1, 2022

Devised: 8/8/17
Revised: 3/1/18 – annual review, updated signature
Revised: 3/1/19 – annual review, added QL approval note
Revised: 3/1/20 – annual review, added GHP Kids
Revised: 3/1/21 – annual review, updated logo, added MediSpan approval level, updated QL statement
Revised: 3/1/22 – annual review, updated referenced policies & covered LOBs



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 460.0

**SECTION: Commercial Drug
SUBJECT: Vosevi**

Applicable line of business:

Commercial	X	Medicaid	
Medicare		ACA	X
GHP Kids	X	Self-Insured	X

POLICY:

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for Vosevi for GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 487.0 Quantity Limit Exceptions

REQUIRED DEFINITIONS:

1. **Attachment** – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. **Exhibit** – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. **Devised** – the date the policy was implemented.
4. **Revised** – the date of every revision to the policy, including typographical and grammatical changes.
5. **Reviewed** – the date documenting the annual review if the policy has no revisions necessary.

ADDITIONAL DEFINITIONS:

1. **Formulary** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. **Non-formulary products** – those medications that are not included in the Formulary.
3. **Healthcare provider** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
4. **NCQA** – National Committee for Quality Assurance.
5. **Medically Necessary or Medical Necessity** – covered services rendered by a provider that the Health Plan determines are:



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 460.0

**SECTION: Commercial Drug
SUBJECT: Vosevi**

- A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
 - B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
 - C. In accordance with current standards of medical practice;
 - D. Not primarily for the convenience of the Member, or the Member's Provider; and
 - E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.
6. **HBV** – Hepatitis B Virus
 7. **HCV** – Hepatitis C Virus
 8. **HIV** – Human Immunodeficiency Virus

PROCEDURE:

A formulary exception for coverage of Vosevi may be made for members who meet the following criteria:

- Medical record documentation of age greater than or equal to 18 years **AND**
- Medical record documentation of a diagnosis of hepatitis C infection **AND**
- Medical record documentation of the member's hepatitis C genotype **AND**
- Medical record documentation of a diagnosis of hepatitis C virus (HCV) genotype 1, 2, 3, 4, 5, or 6 infection **AND**
- Medical record documentation of METAVIR liver scoring **AND**
- Medical record documentation of a hepatocellular carcinoma screening in those with cirrhosis (METAVIR score F4) **AND**
- Medical record documentation that Vosevi is prescribed by a board-certified gastroenterologist, hepatologist, infectious disease specialist, or transplant specialist **AND**
- Medical record documentation of the member receiving a Food and Drug Administration (FDA) approved medication regimen that is inside the parameters of use approved by the FDA or supported in the widely used compendia available **OR**
- Medical record documentation of:
 - Genotype 1, 2, 3, 4, 5, or 6
 - As monotherapy if treatment experienced with an NS5A inhibitor (daclatasvir, elbasvir, ledipasvir, ombitasvir, or velpatasvir) **OR**
 - Genotype 1a or 3
 - As monotherapy if treatment experienced with a prior treatment regimen including sofosbuvir with or without any of the following:

peginterferon alfa/ribavirin, ribavirin, HCV NS3/4A protease inhibitor (boceprevir, simeprevir, or telaprevir) **AND**

- Medical record documentation of appropriate duration of treatment **AND**
- Medical record documentation of previous treatment and treatment response **AND**
- Medical record documentation of any potential drug interactions addressed by the prescriber (such as discontinuation of the interacting drug, dose reduction of the interacting drug, or counseling of the recipient of the risks associated with the use of both medications when they interact) **AND**
- Medical record documentation of receiving the following within the past 3 months:
 - Hepatic function panel
 - Complete blood count including differential
 - Basic metabolic panel
 - Baseline hepatitis C virus (HCV) RNA viral load **AND**
- Medical record documentation that member does not have severe renal impairment (estimated glomerular filtration rate less than 30 mL/min/1.73 m²) or end stage renal disease requiring hemodialysis **AND**
- If actively abusing alcohol or intravenous (IV) drugs, or has a history of abuse, has documentation of prescriber counseling regarding the risks of alcohol or IV drug abuse, and an offer of a referral for substance use disorder treatment **AND**
- Medical record documentation that member received pre-treatment readiness education about hepatitis C treatment expectations by a health care provider **AND**
- Medical record documentation that the member commits to the documented planned course of treatment including anticipated blood tests and visits, during and after treatment **AND**
- Medical record documentation that member does not have a limited life expectancy of less than 12 months due to non-liver related co-morbid conditions **AND**
- Medical record documentation of completed:
 - Hepatitis B immunization series **OR**
 - Hepatitis B screening (sAb/sAg and cAb/cAg) **AND** Quantitative hepatitis B virus (HBV) DNA if positive for hepatitis B sAg or cAb or cAg **AND**
 - If there is detectable hepatitis B virus (HBV) DNA, will be treated for Hepatitis B **OR**
 - If negative for hepatitis B sAb, is being vaccinated against Hepatitis B **AND**
- Medical record documentation of human immunodeficiency virus (HIV) screening (HIV Ag/Ab) and if confirmed positive by HIV-1/HIV-2 differentiation immunoassay:
 - Is being treated for human immunodeficiency virus (HIV) **OR**
 - If not being treated for human immunodeficiency virus (HIV), the medical record documents the rationale for the beneficiary not being treated **AND**
- Medical record documentation of a therapeutic failure on, intolerance to, or contraindication to Mavyret, if clinically appropriate **AND**



**POLICY AND PROCEDURE
PHARMACY
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POLICY NUMBER: 460.0

**SECTION: Commercial Drug
SUBJECT: Vosevi**

- Medical record documentation that member has been evaluated and treated by a contracted Center of Excellence in hepatitis C management

OR

- Medical record documentation of a hepatitis C negative recipient receiving a transplant from a hepatitis C positive donor **AND**
- Medical record documentation of therapeutic failure on, intolerance to, or contraindication to Mavyret, if clinically appropriate

NOTE: Center of Excellence (COE) requirements do not apply to strategic partner TPA plans (i.e., Northern Light Health).

MEDISPAN AUTHORIZATION LEVEL: GPI-12

QUANTITY LIMIT: *No QLs need to be entered within the authorization unless the requested quantity exceeds the QL.*

- **QL FOR LETTER ONLY:** one (1) tablet per day, 28 day supply per fill

AUTHORIZATION DURATION: 12 weeks **OR** medical record documentation of the member receiving a Food and Drug Administration (FDA) approved medication regimen that is inside the parameters of use approved by the FDA or supported in the widely used compendia available

If a formulary exception is approved Vosevi will be paid for under the member's prescription drug benefit.

Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.

FORMULARY ALTERNATIVES:

Mavyret*

*prior authorization required



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 460.0

**SECTION: Commercial Drug
SUBJECT: Vosevi**

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE
STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND
FEDERAL REGULATORY ENTITIES.**

**THIS POLICY WILL BE REVISED AS NECESSARY AND
REVIEWED NO LESS THAN ANNUALLY.**

Signed: _____

Title: Director, Pharmacy Services

Date: March 1, 2022

- Devised: 9/28/17
- Revised: 11/28/17 – updated failure to specifically Mavyret, updated signature
- Revised: 1/19/18 – updated age format, removed prescriber, added Hep B & HIV criteria
- Revised: 3/1/18 – annual review, updated prescriber criteria & Hep B/HIV criteria to match DHS
- Revised: 12/28/18 – added HCV positive transplant indication/FA criteria, added COE
- Revised: 3/1/19 – annual review, defined abbr.
- Revised: 7/23/19 – added TPA COE exclusion
- Revised: 3/1/20 – annual review, added GHP Kids
- Revised: 3/1/21 – annual review, updated logo, added MediSpan approval level, updated QL statement, removed Atlanticare & St Lukes
- Revised: 3/1/22 – annual review, updated referenced policies & covered LOBs



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 461.0

**SECTION: Commercial Drug
SUBJECT: Mavyret**

Applicable line of business:

Commercial	X	Medicaid	
Medicare		ACA	X
GHP Kids	X	Self-Insured	X

POLICY:

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for Mavyret for GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 487.0 Quantity Limit Exceptions

REQUIRED DEFINITIONS:

1. **Attachment** – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. **Exhibit** – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. **Devised** – the date the policy was implemented.
4. **Revised** – the date of every revision to the policy, including typographical and grammatical changes.
5. **Reviewed** – the date documenting the annual review if the policy has no revisions necessary.

ADDITIONAL DEFINITIONS:

1. **Formulary** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. **Non-formulary products** – those medications that are not included in the Formulary.
3. **Healthcare provider** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
4. **NCQA** – National Committee for Quality Assurance.
5. **Medically Necessary or Medical Necessity** – covered services rendered by a provider that the Health Plan determines are:



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 461.0

**SECTION: Commercial Drug
SUBJECT: Mavyret**

- A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
 - B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
 - C. In accordance with current standards of medical practice;
 - D. Not primarily for the convenience of the Member, or the Member's Provider; and
 - E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.
6. **HBV** – Hepatitis B Virus
 7. **HCV** – Hepatitis C Virus
 8. **HIV** – Human Immunodeficiency Virus

PROCEDURE:

A formulary exception for coverage of Mavyret may be made for members who meet the following criteria:

- Medical record documentation of age greater than or equal to 3 years **AND**
- If member is under the age of 12 years or weighs less than 45 kg, medical record documentation that proper weight-based dosing is prescribed **AND**
- Medical record documentation of a diagnosis of hepatitis C infection **AND**
- Medical record documentation of the member's hepatitis C genotype **AND**
- Medical record documentation of a diagnosis of hepatitis C virus (HCV) genotype 1, 2, 3, 4, 5, or 6 infection **AND**
- Medical record documentation of METAVIR liver scoring **AND**
- Medical record documentation of a hepatocellular carcinoma screening in those with cirrhosis (METAVIR score F4) **AND**
- Medical record documentation of the member receiving a Food and Drug Administration (FDA) approved medication regimen that is inside the parameters of use approved by the FDA or supported in the widely used compendia available **OR**
- Medical record documentation of:
 - Genotype 1, 2, 3, 4, 5, or 6 without cirrhosis or with compensated cirrhosis who are treatment naïve or experienced with peginterferon/ribavirin or Sovaldi/ribavirin +/- peginterferon **OR**
 - Genotype 1 previously treated with a regimen containing an HCV NS5A inhibitor or an NS3/4A protease inhibitor, but not both **OR**
 - Liver or kidney transplant recipients with Hepatitis C infection **AND**
- Medical record documentation of appropriate duration of treatment **AND**
- Medical record documentation of previous treatment and treatment response **AND**

- Medical record documentation of any potential drug interactions addressed by the prescriber (such as discontinuation of the interacting drug, dose reduction of the interacting drug, or counseling of the recipient of the risks associated with the use of both medications when they interact) **AND**
- Medical record documentation of receiving the following within the past 3 months:
 - Hepatic function panel
 - Complete blood count including differential
 - Basic metabolic panel
 - Baseline hepatitis C virus (HCV) RNA viral load **AND**
- If actively abusing alcohol or intravenous (IV) drugs, or has a history of abuse, has documentation of prescriber counseling regarding the risks of alcohol or IV drug abuse, and an offer of a referral for substance use disorder treatment **AND**
- Medical record documentation that member received pre-treatment readiness education about hepatitis C treatment expectations by a health care provider **AND**
- Medical record documentation that the member commits to the documented planned course of treatment including anticipated blood tests and visits, during and after treatment **AND**
- Medical record documentation that member does not have a limited life expectancy of less than 12 months due to non-liver related co-morbid conditions **AND**
- Medical record documentation of completed:
 - Hepatitis B immunization series **OR**
 - Hepatitis B screening (sAb/sAg and cAb/cAg) **AND** Quantitative hepatitis N virus (HBV) DNA if positive for hepatitis B sAg or cAb or cAg **AND**
 - If there is detectable hepatitis B virus (HBV) DNA, will be treated for Hepatitis B **OR**
 - If negative for hepatitis B sAb, is being vaccinated against Hepatitis B **AND**
- Medical record documentation of human immunodeficiency virus (HIV) screening (HIV Ag/Ab) and if confirmed positive by HIV-1/HIV-2 differentiation immunoassay:
 - Is being treated for human immunodeficiency virus (HIV) **OR**
 - If not being treated for human immunodeficiency virus (HIV), the medical record documents the rationale for the beneficiary not being treated **AND**
- Medical record documentation that member has been evaluated and treated by a contracted Center of Excellence in hepatitis C management **AND**
- If member is greater than or equal to 12 years of age or weighs greater than or equal to 45 kilograms and the request is for packets, medical record documentation of why tablets cannot be used

OR



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 461.0

**SECTION: Commercial Drug
SUBJECT: Mavyret**

- Medical record documentation of a hepatitis C negative recipient receiving a transplant from a hepatitis C positive donor

NOTE: Center of Excellence (COE) requirements do not apply to strategic partner TPA plans (i.e., Northern Light Health).

MEDISPAN AUTHORIZATION LEVEL: GPI-12

QUANTITY LIMIT: *No QLs need to be entered within the authorization unless the requested quantity exceeds the QL.*

- **QL FOR LETTER ONLY:**
 - Tablets: three (3) tablets per day, 28 day supply per fill
 - Packets: six (6) packets per day, 28 day supply per fill

AUTHORIZATION DURATION: 8, 12, or 16 weeks consistent with current AASLD/IDSA guidelines or Food and Drug Administration (FDA) recommendations

NOTE: Per the prescribing information, treatment duration for liver or kidney transplant recipients is 12 weeks. Geisinger has been treating kidney transplant recipients for 8 weeks with success.

If a formulary exception is approved Mavyret will be paid for under the member's prescription drug benefit.

Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.

FORMULARY ALTERNATIVES:

none

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE
STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND
FEDERAL REGULATORY ENTITIES.**

**THIS POLICY WILL BE REVISED AS NECESSARY AND
REVIEWED NO LESS THAN ANNUALLY.**



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 461.0

**SECTION: Commercial Drug
SUBJECT: Mavyret**

Signed: _____

Title: Director, Pharmacy Services

Date: March 1, 2022

- Devised: 9/28/17
- Revised: 1/19/18 – updated age format & sig., removed prescriber, added Hep B & HIV criteria
- Revised: 1/24/18 – added Hep B immunization series bullet
- Revised: 3/1/18 – annual review, updated Hep B/HIV criteria to match DHS
- Revised: 12/28/18 – added HCV positive transplant indication, added COE
- Revised: 2/6/19 – added liver/kidney transplant indication and corresponding note
- Revised: 3/1/19 – annual review, added QL approval note
- Revised: 7/23/19 – added TPA COE exclusion, corrected typo
- Revised: 10/1/19 – updated age to 12 years or weight greater than 45 kg
- Revised: 3/1/20 – annual review, added GHP Kids
- Revised: 3/1/21 – annual review, updated logo, added MediSpan approval level, updated QL statement, removed Atlanticare & St. Lukes
- Revised: 11/23/21 – updated age to 3 years, added proper weight based dosing, added requirement to use tablets, added QL for packets
- Revised: 3/1/22 – annual review, updated referenced policies & covered LOBs



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 462.0

**SECTION: Commercial Drug
SUBJECT: Idhifa**

Applicable line of business:

Commercial	X	Medicaid	
Medicare		ACA	X
GHP Kids	X	Self-Insured	X

POLICY:

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for Idhifa for GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 487.0 Quantity Limit Exceptions

REQUIRED DEFINITIONS:

1. **Attachment** – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. **Exhibit** – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. **Devised** – the date the policy was implemented.
4. **Revised** – the date of every revision to the policy, including typographical and grammatical changes.
5. **Reviewed** – the date documenting the annual review if the policy has no revisions necessary.

ADDITIONAL DEFINITIONS:

1. **Formulary** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. **Non-formulary products** – those medications that are not included in the Formulary.
3. **Healthcare provider** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
4. **NCQA** – National Committee for Quality Assurance.
5. **Medically Necessary or Medical Necessity** – covered services rendered by a provider that the Health Plan determines are:



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 462.0

**SECTION: Commercial Drug
SUBJECT: Idhifa**

- A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
- B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
- C. In accordance with current standards of medical practice;
- D. Not primarily for the convenience of the Member, or the Member's Provider; and
- E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

PROCEDURE:

New members to the plan already established on therapy may be eligible for continuity of care coverage as long as there is medical record documentation that the safety and effectiveness of use for the prescribed indication is supported by Food and Drug Administration (FDA) approval or adequate medical and scientific evidence in the medical literature.

A formulary exception for coverage of Idhifa may be made for members who meet the following criteria:

- Medical record documentation that Idhifa is prescribed by a hematologist or oncologist **AND**
- Medical record documentation of age greater than or equal to 18 years **AND**
- Medical record documentation of a diagnosis of relapsed or refractory acute myeloid leukemia **AND**
- Medical record documentation of an isocitrate dehydrogenase-2 (IDH2) mutation as detected by a Food and Drug Administration (FDA) approved test

MEDISPAN AUTHORIZATION LEVEL: GPI-12, number of claims authorized = 1, enter for the remainder of the calendar year

QUANTITY LIMIT: *No QLs need to be entered within the authorization unless the requested quantity exceeds the QL.*

- **QL FOR LETTER ONLY:** 1 tablet per day, 30 day supply per fill

NOTE: The Food and Drug Administration (FDA) approved test is Abbott RealTime™ IDH2 assay.



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 462.0

**SECTION: Commercial Drug
SUBJECT: Idhifa**

RE-AUTHORIZATION CRITERIA: Idhifa is configured as a prior authorization for new starts only. Idhifa will no longer be covered if it is identified that the member is not receiving appropriate follow-up care from the prescribing specialist or if the member has greater than or equal to a 90 day break in therapy.

- Medical record documentation that the member is receiving appropriate follow-up care from the prescribing specialist

If a formulary exception is approved Idhifa will be paid for under the member's prescription drug benefit.

Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.

FORMULARY ALTERNATIVES:

none

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE
STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND
FEDERAL REGULATORY ENTITIES.**

**THIS POLICY WILL BE REVISED AS NECESSARY AND
REVIEWED NO LESS THAN ANNUALLY.**

Signed: _____

Title: Director, Pharmacy Services

Date: March 1, 2022

Devised: 9/28/17

Revised: 3/1/18 – annual review, updated signature, added grandfather language, updated prescriber & age criteria

Revised: 3/1/19 – annual review, added QL approval note

Revised: 3/1/20 – annual review, added GHP Kids

Revised: 3/1/21 – annual review, updated logo, added MediSpan approval level, updated QL statement

Revised: 11/24/21 – added one-time PA to approval crit., removed auth duration & added re-auth crit.

Revised: 3/1/22 – annual review, updated referenced policies & covered LOBs

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Dev. 9/28/17

Rev.3/1/22



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 463.0

**SECTION: Commercial Drug
SUBJECT: Nerlynx**

Applicable line of business:

Commercial	X	Medicaid	
Medicare		ACA	X
GHP Kids	X	Self-Insured	X

POLICY:

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for Nerlynx for GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 487.0 Quantity Limit Exceptions

REQUIRED DEFINITIONS:

1. **Attachment** – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. **Exhibit** – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. **Devised** – the date the policy was implemented.
4. **Revised** – the date of every revision to the policy, including typographical and grammatical changes.
5. **Reviewed** – the date documenting the annual review if the policy has no revisions necessary.

ADDITIONAL DEFINITIONS:

1. **Formulary** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. **Non-formulary products** – those medications that are not included in the Formulary.
3. **Healthcare provider** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
4. **NCQA** – National Committee for Quality Assurance.
5. **Medically Necessary or Medical Necessity** – covered services rendered by a provider that the Health Plan determines are:

- A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
- B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
- C. In accordance with current standards of medical practice;
- D. Not primarily for the convenience of the Member, or the Member's Provider; and
- E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

PROCEDURE:

New members to the plan already established on therapy may be eligible for continuity of care coverage as long as there is medical record documentation that the safety and effectiveness of use for the prescribed indication is supported by Food and Drug Administration (FDA) approval or adequate medical and scientific evidence in the medical literature.

A formulary exception for coverage of Nerlynx may be made for members who meet the following criteria:

- Medical record documentation that Nerlynx is prescribed by an oncologist **AND**
 - Medical record documentation of age greater than or equal to 18 years **AND**
 - One of the following:
 - Medical record documentation of a diagnosis of early stage (stages I-IIIa) breast cancer **AND**
 - Medical record documentation of HER-2 overexpression/amplification **AND**
 - Medical record documentation of prior treatment with trastuzumab-based therapy
- OR**
- Medical record documentation of a diagnosis of advanced or metastatic HER2-positive breast cancer **AND**
 - Medical record documentation of two or more prior anti-HER2 based regimens given in the metastatic setting **AND**
 - Medical record documentation that Nerlynx will be used in combination with capecitabine

MEDISPAN AUTHORIZATION LEVEL: GPI-12

QUANTITY LIMIT: *No QLs need to be entered within the authorization unless the requested quantity exceeds the QL.*

- QL FOR LETTER ONLY: 6 tablets per day, up to a 30 day supply per fill

AUTHORIZATION DURATION:

- Early Stage Breast Cancer: One time, 12 month authorization
- Advanced or Metastatic Breast Cancer: Initial approval will be for 12 months or less if the reviewing provider feels it is medically appropriate. Subsequent approvals will be for an additional 12 months or less if the reviewing provider feels it is medically appropriate and will require medical record documentation of continued disease improvement or lack of disease progression. The medication will no longer be covered if the member experiences unacceptable toxicity or worsening of disease.

NOTE: The Food and Drug Administration (FDA) approved dosing schedule only approves the use of Nerlynx for 1 year following adjuvant trastuzumab therapy.

If a formulary exception is approved Nerlynx will be paid for under the member's prescription drug benefit.

Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.

FORMULARY ALTERNATIVES:

lapatinib*

*prior authorization required

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE
STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND
FEDERAL REGULATORY ENTITIES.**

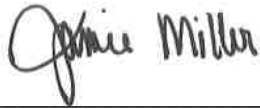
**THIS POLICY WILL BE REVISED AS NECESSARY AND
REVIEWED NO LESS THAN ANNUALLY.**

Geisinger

**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 463.0

**SECTION: Commercial Drug
SUBJECT: Nerlynx**



Signed: _____

Title: Director, Pharmacy Services

Date: March 1, 2022

Devised: 9/28/17

Revised: 3/1/18 – annual review, updated signature, added grandfather language, updated age & prescriber criteria

Revised: 3/1/19 – annual review, added QL approval note

Revised: 3/1/20 – annual review, added GHP Kids

Revised: 6/4/20 – added advanced/metastatic HER2-positive breast cancer indication

Revised: 3/1/21 – annual review, updated logo, added MediSpan approval level, updated QL statement

Revised: 3/1/22 – annual review, updated referenced policies & covered LOBs, updated FA



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 464.0

**SECTION: Commercial Drug
SUBJECT: Austedo**

Applicable line of business:

Commercial	X	Medicaid	
Medicare		ACA	X
GHP Kids	X	Self-Insured	X

POLICY:

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for Austedo for GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 487.0 Quantity Limit Exceptions

REQUIRED DEFINITIONS:

1. **Attachment** – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. **Exhibit** – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
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4. **Revised** – the date of every revision to the policy, including typographical and grammatical changes.
5. **Reviewed** – the date documenting the annual review if the policy has no revisions necessary.

ADDITIONAL DEFINITIONS:

1. **Formulary** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. **Non-formulary products** – those medications that are not included in the Formulary.
3. **Healthcare provider** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
4. **NCQA** – National Committee for Quality Assurance.
5. **Medically Necessary or Medical Necessity** – covered services rendered by a provider that the Health Plan determines are:

- A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
- B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
- C. In accordance with current standards of medical practice;
- D. Not primarily for the convenience of the Member, or the Member's Provider; and
- E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

PROCEDURE:

A formulary exception for coverage of Austedo may be made for members who meet the following criteria:

Huntington's Disease

- Medical record documentation of age greater than or equal to 18 years **AND**
- Medical record documentation that Austedo is prescribed by, or in consultation with, a neurologist or movement disorder specialist **AND**
- Medical record documentation of a diagnosis of Huntington's Disease **AND**
- Medical record documentation of symptoms of chorea **AND**
- Medical record documentation of that patient's baseline Total Maximal Chorea Score prior to initiating therapy **AND**
- One of the following:
 - If patient has a history of prior suicide attempt, bipolar disorder, or major depressive disorder: Medical record documentation that patient was evaluated and treated by a psychiatrist **OR**
 - For all others: Medical record documentation of a mental health evaluation performed by the prescriber **AND**
 - Medical record documentation of therapeutic failure on, intolerance to, or contraindication to tetrabenazine

Tardive Dyskinesia

- Medical record documentation of age greater than or equal to 18 years **AND**
- Medical record documentation that Austedo is prescribed by, or in consultation with, a psychiatrist or neurologist **AND**
- Medical record documentation of a diagnosis of tardive dyskinesia (TD) as evidenced by one of the following:
 - Moderate to severe abnormal body movement (AIMS score 3 or 4) in greater than or equal to 1 body area **OR**

- Mild abnormal body movements (AIMS score 1 or 2) in greater than or equal to 2 body areas **AND**
- Medical record documentation that the member was assessed for and determined to have no other causes of involuntary movements **AND**
- Medical record documentation of the member's baseline AIMS score prior to initiating therapy **AND**
- One of the following:
 - If patient has a history of prior suicide attempt, bipolar disorder, or major depressive disorder: Medical record documentation that patient was evaluated and treated by a psychiatrist **OR**
 - For all others: Medical record documentation of a mental health evaluation performed by the prescriber **AND**
- If member's symptoms are related to use of a first-generation antipsychotic, medical record documentation that a switch to a second-generation antipsychotic has been attempted and did not resolve tardive dyskinesia symptoms **OR** provider rationale as to why a switch to a second-generation antipsychotic would not be appropriate for the member **AND**
- Medical record documentation of therapeutic failure on, intolerance to, or contraindication to amantadine

MEDISPAN AUTHORIZATION LEVEL: GPI-12

QUANTITY LIMIT: *No QLs need to be entered within the authorization unless the requested quantity exceeds the QL.*

- **QL FOR LETTER ONLY:**
 - 6 mg tablet: 2 tablets per day, 30 day supply per fill
 - 9 mg tablet: 4 tablets per day, 30 day supply per fill
 - 12 mg tablet: 4 tablets per day, 30 day supply per fill

AUTHORIZATION DURATION: Initial approval will be for a period of one (1) year.

Reevaluation of coverage will be every one (1) year and will require documentation of:

- For patients with Huntington's disease: Medical record documentation of an improvement in chorea associated with Huntington's Disease as evidenced by a reduction in the Total Maximal Chorea Score from baseline.
- For patients with Tardive Dyskinesia: Medical record documentation of an improvement in tardive dyskinesia (TD) as evidenced by a reduction from baseline in the patient's AIMS score



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 464.0

**SECTION: Commercial Drug
SUBJECT: Austedo**

If a formulary exception is approved Austedo will be paid for under the member's prescription drug benefit.

Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.

FORMULARY ALTERNATIVES:

Huntington's Disease: tetrabenazine*
Tardive Dyskinesia: amantadine

*prior authorization required

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE
STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND
FEDERAL REGULATORY ENTITIES.**

**THIS POLICY WILL BE REVISED AS NECESSARY AND
REVIEWED NO LESS THAN ANNUALLY.**

Signed: _____

Title: Director, Pharmacy Services

Date: March 1, 2022

Devised: 9/28/17
Revised: 3/1/18 – annual review, updated signature, updated age criteria & indication headers
Revised: 3/1/19 – annual review, added QL approval note, removed all GPID note
Revised: 3/1/20 – annual review, added GHP Kids
Revised: 3/1/21 – annual review, updated logo, added MediSpan approval level, updated QL statement
Revised: 3/1/22 – annual review, updated referenced policies & covered LOBs



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 465.0

**SECTION: Commercial Drug
SUBJECT: Ingrezza**

Applicable line of business:

Commercial	X	Medicaid	
Medicare		ACA	X
GHP Kids	X	Self-Insured	X

POLICY:

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for Ingrezza for GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 487.0 Quantity Limit Exceptions

REQUIRED DEFINITIONS:

1. **Attachment** – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. **Exhibit** – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
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ADDITIONAL DEFINITIONS:

1. **Formulary** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. **Non-formulary products** – those medications that are not included in the Formulary.
3. **Healthcare provider** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
4. **NCQA** – National Committee for Quality Assurance.
5. **Medically Necessary or Medical Necessity** – covered services rendered by a provider that the Health Plan determines are:



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 465.0

**SECTION: Commercial Drug
SUBJECT: Ingrezza**

- A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
- B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
- C. In accordance with current standards of medical practice;
- D. Not primarily for the convenience of the Member, or the Member's Provider; and
- E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

PROCEDURE:

A formulary exception for coverage of Ingrezza may be made for members who meet the following criteria:

- Medical record documentation of age greater than or equal to 18 years **AND**
- Medical record documentation that Ingrezza is prescribed by, or in consultation with, a psychiatrist or neurologist **AND**
- Medical record documentation of a diagnosis of tardive dyskinesia (TD) as evidenced by one of the following:
 - Moderate to severe abnormal body movement (AIMS score 3 or 4) in greater than or equal to 1 body area **OR**
 - Mild abnormal body movements (AIMS score 1 or 2) in greater than or equal to 2 body areas **AND**
- Medical record documentation that the member was assessed for and determined to have no other causes of involuntary movements **AND**
- Medical record documentation of the member's baseline AIMS score prior to initiating therapy **AND**
- If member's symptoms are related to use of a first-generation antipsychotic, medical record documentation that a switch to a second-generation antipsychotic has been attempted and did not resolve tardive dyskinesia symptoms **OR** provider rationale as to why a switch to a second-generation antipsychotic would not be appropriate for the member **AND**
- Medical record documentation of therapeutic failure on, intolerance to, or contraindication to amantadine

MEDISPAN AUTHORIZATION LEVEL: GPI-10



POLICY NUMBER: 465.0

**POLICY AND PROCEDURE
PHARMACY
MANUAL**

**SECTION: Commercial Drug
SUBJECT: Ingrezza**

QUANTITY LIMIT: *No QLs need to be entered within the authorization unless the requested quantity exceeds the QL.*

- **QL FOR LETTER ONLY:** 1 capsule per day, 30 day supply per fill

AUTHORIZATION DURATION: Initial approval will be for a period of one (1) year. Reevaluation of coverage will be every one (1) year and will require documentation of:

- Medical record documentation of an improvement in tardive dyskinesia (TD) as evidenced by a reduction from baseline in the patient's AIMS score

If a formulary exception is approved Ingrezza will be paid for under the member's prescription drug benefit.

Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.

FORMULARY ALTERNATIVES:
amantadine

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE
STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND
FEDERAL REGULATORY ENTITIES.**

**THIS POLICY WILL BE REVISED AS NECESSARY AND
REVIEWED NO LESS THAN ANNUALLY.**

Signed: _____

Title: Director, Pharmacy Services

Date: March 1, 2022

Devised: 9/28/17
Revised: 11/27/17 – updated QL to 1/day, updated signature
Revised: 3/1/18 – annual review, updated age criteria
Revised: 3/1/19 – annual review, added QL approval note
Revised: 3/1/20 – annual review, added GHP Kids
Revised: 3/1/21 – annual review, updated logo, added MediSpan approval level, updated QL statement
Revised: 3/1/22 – annual review, updated referenced policies & covered LOBs



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 466.0

**SECTION: Commercial Drug
SUBJECT: Tetrabenazine**

Applicable line of business:

Commercial	X	Medicaid	
Medicare		ACA	X
GHP Kids	X	Self-Insured	X

POLICY:

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for tetrabenazine for GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 487.0 Quantity Limit Exceptions

REQUIRED DEFINITIONS:

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ADDITIONAL DEFINITIONS:

1. **Formulary** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. **Non-formulary products** – those medications that are not included in the Formulary.
3. **Healthcare provider** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
4. **NCQA** – National Committee for Quality Assurance.
5. **Medically Necessary or Medical Necessity** – covered services rendered by a provider that the Health Plan determines are:



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 466.0

**SECTION: Commercial Drug
SUBJECT: Tetrabenazine**

- A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
- B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
- C. In accordance with current standards of medical practice;
- D. Not primarily for the convenience of the Member, or the Member's Provider; and
- E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

PROCEDURE:

A formulary exception for coverage of tetrabenazine may be made for members who meet the following criteria:

- Medical record documentation of a diagnosis of chorea associated with Huntington's Disease

MEDISPAN AUTHORIZATION LEVEL: GPI-12, generic only

QUANTITY LIMIT: *No QLs need to be entered within the authorization unless the requested quantity exceeds the QL.*

- **QL FOR LETTER ONLY:**
 - 12.5 mg tablet: 3 tablets per day
 - 25 mg tablet: 4 tablets per day

If a formulary exception is approved tetrabenazine will be paid for under the member's prescription drug benefit.

Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.

FORMULARY ALTERNATIVES:

none

Geisinger

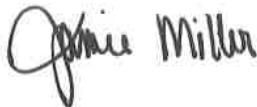
**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 466.0

**SECTION: Commercial Drug
SUBJECT: Tetrabenazine**

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE
STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND
FEDERAL REGULATORY ENTITIES.**

**THIS POLICY WILL BE REVISED AS NECESSARY AND
REVIEWED NO LESS THAN ANNUALLY.**



Signed: _____

Title: Director, Pharmacy Services

Date: March 1, 2022

Devised: 9/28/17
Revised: 3/1/18 – annual review, updated signature
Revised: 3/1/19 – annual review, added QL approval note
Revised: 3/1/20 – annual review, added GHP Kids
Revised: 3/1/21 – annual review, updated logo, added MediSpan approval level, updated QL statement
Revised: 3/1/22 – annual review, updated referenced policies & covered LOBs



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 467.0

**SECTION: Commercial Drug
SUBJECT: Tymlos**

Applicable line of business:

Commercial	X	Medicaid	
Medicare		ACA	X
GHP Kids	X	Self-Insured	X

POLICY:

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for Tymlos for GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 487.0 Quantity Limit Exceptions

REQUIRED DEFINITIONS:

1. **Attachment** – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
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ADDITIONAL DEFINITIONS:

1. **Formulary** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. **Non-formulary products** – those medications that are not included in the Formulary.
3. **Healthcare provider** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
4. **NCQA** – National Committee for Quality Assurance.
5. **Medically Necessary or Medical Necessity** – covered services rendered by a provider that the Health Plan determines are:

- A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
- B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
- C. In accordance with current standards of medical practice;
- D. Not primarily for the convenience of the Member, or the Member's Provider; and
- E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

PROCEDURE:

A formulary exception for coverage of Tymlos may be made for members who meet the following criteria:

- There is no medical record documentation of increased baseline risk of osteosarcoma [Paget's disease, open epiphyses (pediatric or young adult patients), prior radiation therapy involving the skeleton, unexplained elevations of alkaline phosphatase] **AND**
- **For women:**
 - Medical record documentation of a diagnosis of postmenopausal osteoporosis **AND**
 - Medical record documentation that member has not previously been on a parathyroid hormone analog for greater than 2 years* **AND**
 - Medical record documentation of an attempt of therapy with or contraindication to bisphosphonates **OR**
 - Medical record documentation of a previous osteoporotic fracture or high risk of fracture (T-score -2.5 or below with documented risk factors)

MEDISPAN AUTHORIZATION LEVEL: GPI-12

QUANTITY LIMIT: *No QLs need to be entered within the authorization unless the requested quantity exceeds the QL.*

- **QL FOR LETTER ONLY:** 1.56 mL per 30 days

AUTHORIZATION DURATION: Approval will be for 2 years, or less if there is medical record documentation of a previous incomplete course of therapy with a parathyroid hormone analog. Cumulative use of parathyroid hormone analogs for more than 2 years during a patient's lifetime is not recommended.

***NOTE:** Cumulative use of parathyroid hormone analogs for more than 2 years during a patient's lifetime is not recommended.

Risk Factors Included in the WHO Fracture Risk Assessment Model

- Current age
- Gender
- A prior osteoporotic fracture (including morphometric vertebral fracture)
- Femoral neck BMD
- Low body mass index (kg/m²)
- Oral glucocorticoids ≥ 5 mg/d of prednisone for ≥ 3 mo (ever)
- Rheumatoid arthritis
- Secondary osteoporosis
- Parental history of hip fracture
- Current smoking
- Alcohol intake (3 or more drinks/d)

From: WHO Technical Report.8

If a formulary exception is approved Tymlos will be paid for under the member's prescription drug benefit.

Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.

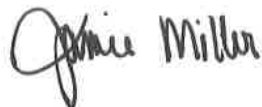
FORMULARY ALTERNATIVES:

alendronate, ibandronate, risedronate

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE
STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND
FEDERAL REGULATORY ENTITIES.**

**THIS POLICY WILL BE REVISED AS NECESSARY AND
REVIEWED NO LESS THAN ANNUALLY.**

Signed: _____



Title: Director, Pharmacy Services

Date: March 1, 2022

Devised: 9/28/17



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 467.0

**SECTION: Commercial Drug
SUBJECT: Tymlos**

- Revised: 3/1/18 – annual review, updated signature
- Revised: 3/1/19 – annual review, added QL approval note
- Revised: 3/1/20 – annual review, added GHP Kids
- Revised: 3/1/21 – annual review, updated logo, added MediSpan approval level, updated QL statement
- Revised: 3/1/22 – annual review, updated referenced policies & covered LOBs



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 468.0

**SECTION: Commercial Drug
SUBJECT: Siliq**

Applicable line of business:

Commercial	X	Medicaid	
Medicare		ACA	X
GHP Kids	X	Self-Insured	X

POLICY:

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for Siliq for GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 487.0 Quantity Limit Exceptions

REQUIRED DEFINITIONS:

1. **Attachment** – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. **Exhibit** – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. **Devised** – the date the policy was implemented.
4. **Revised** – the date of every revision to the policy, including typographical and grammatical changes.
5. **Reviewed** – the date documenting the annual review if the policy has no revisions necessary.

ADDITIONAL DEFINITIONS:

1. **Formulary** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. **Non-formulary products** – those medications that are not included in the Formulary.
3. **Healthcare provider** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
4. **NCQA** – National Committee for Quality Assurance.
5. **Medically Necessary or Medical Necessity** – covered services rendered by a provider that the Health Plan determines are:



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 468.0

**SECTION: Commercial Drug
SUBJECT: Siliq**

- A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
- B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
- C. In accordance with current standards of medical practice;
- D. Not primarily for the convenience of the Member, or the Member's Provider; and
- E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

PROCEDURE:

New members to the plan already established on therapy may be eligible for continuity of care coverage as long as there is medical record documentation that the safety and effectiveness of use for the prescribed indication is supported by Food and Drug Administration (FDA) approval or adequate medical and scientific evidence in the medical literature.

A formulary exception for coverage of Siliq may be made for members who meet the following criteria:

- Medical record documentation of age greater than or equal to 18 years **AND**
- Medical record documentation that Siliq is prescribed by a dermatologist **AND**
- Medical record documentation of a diagnosis of moderate-to-severe plaque psoriasis with greater than or equal to 5% body surface area involved **OR** disease involving crucial areas of the body such as hands, feet, face, and/or genitals **AND**
- Medical record documentation that member does not have a history of suicidal thoughts or ideations **AND**
- Medical record documentation that member does not have a history of depression **OR** medical record documentation of a concomitant diagnosis of depression and documentation that a psychiatric evaluation has been completed and member has been deemed an appropriate candidate for therapy **AND**
- Medical record documentation of a therapeutic failure on, intolerance to, or contraindication to Cosentyx* **AND** Humira* **AND**
- Medical record documentation that Siliq is not being used concurrently with a tumor necrosis factor (TNF) blocker or other biologic agent

MEDISPAN AUTHORIZATION LEVEL: GPI-12



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 468.0

**SECTION: Commercial Drug
SUBJECT: Siliq**

QUANTITY LIMIT:

- In PA Hub: Add PA, OQL, DS, max number of claims authorized 1, max quantity dispensed 6, min day supply 28, max day supply 28 with a duration of one month.
 - QL FOR LETTER: Loading dose: 6 mL per 28 days; Maintenance dose: 3 mL per 28 days

RE-AUTHORIZATION CRITERIA: Siliq is configured as a prior authorization for new starts only. Siliq will no longer be covered if it is identified that the member is not receiving appropriate follow-up care from the prescribing specialist or if the member has greater than or equal to a 90 day break in therapy.

- Medical record documentation that the member is receiving appropriate follow-up care from the prescribing specialist

If a formulary exception is approved Siliq will be paid for under the member's prescription drug benefit.

Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.

FORMULARY ALTERNATIVES:

Cosentyx*, Humira*

*prior authorization required

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE
STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND
FEDERAL REGULATORY ENTITIES.**

**THIS POLICY WILL BE REVISED AS NECESSARY AND
REVIEWED NO LESS THAN ANNUALLY.**

Signed: _____

Title: Director, Pharmacy Services

Date: March 1, 2022

HPRX02

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Dev. 10/3/17

Rev. 3/1/22



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 468.0

**SECTION: Commercial Drug
SUBJECT: Siliq**

Devised: 10/3/17
Revised: 3/1/18 – annual review, updated signature & age criteria, added grandfather language
Revised: 5/31/18 – added combination with other biologic agent, removed failure of Enbrel and added failure of Cosentyx, updated FA
Reviewed: 3/1/19 – annual review
Revised: 3/1/20 – annual review, added GHP Kids
Revised: 3/1/21 – annual review, updated logo, added MediSpan approval level, updated QL statement
Revised: 12/2/21 – added one-time PA to approval crit., removed auth duration & added re-auth crit., updated QL auth entry to account for PA NSO
Revised: 3/1/22 – annual review, updated referenced policies & covered LOBs, updated how QL is entered



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 469.0

**SECTION: Commercial Drug
SUBJECT: Statin Quantity Limit
Exception**

Applicable line of business:

Commercial	X	Medicaid	
Medicare		ACA	X
GHP Kids	X	Self-Insured	X

POLICY:

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for statin quantity limit exceptions for GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 487.0 Quantity Limit Exceptions

REQUIRED DEFINITIONS:

1. **Attachment** – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. **Exhibit** – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. **Devised** – the date the policy was implemented.
4. **Revised** – the date of every revision to the policy, including typographical and grammatical changes.
5. **Reviewed** – the date documenting the annual review if the policy has no revisions necessary.

ADDITIONAL DEFINITIONS:

1. **Formulary** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. **Non-formulary products** – those medications that are not included in the Formulary.
3. **Healthcare provider** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
4. **NCQA** – National Committee for Quality Assurance.
5. **Medically Necessary or Medical Necessity** – covered services rendered by a provider that the Health Plan determines are:



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 469.0

**SECTION: Commercial Drug
SUBJECT: Statin Quantity Limit
Exception**

- A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
- B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
- C. In accordance with current standards of medical practice;
- D. Not primarily for the convenience of the Member, or the Member's Provider; and
- E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

PROCEDURE:

A formulary exception for coverage of statin quantity limit exceptions may be made for members who meet the following criteria:

- Medical record documentation that requested dose cannot be achieved by using a formulary alternative (i.e.- use of one 10mg tablet in place of two 5mg tablets) **AND**
- Medical record documentation that prescribed dosage does not exceed those approved by the Food and Drug Administration (FDA) or accepted standards of care **AND**
- If request is for dose that exceeds Food and Drug Administration (FDA) approved labeling, medical record documentation of peer-reviewed literature citing well-designed clinical trials to indicate that the member's healthcare outcome will be improved by dosing that exceeds FDA approved labeling **AND**
- Medical record documentation that current formulary quantity limit has been ineffective in management of member's condition

MEDISPAN AUTHORIZATION LEVEL: GPI-14, consider generic only depending on drug requested.

NOTE: Approved quantity limit exceptions should indicate the approved maximum daily dosage.

If a formulary exception is approved, the statin quantity limit exception will be paid for under the member's prescription drug benefit.

Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.

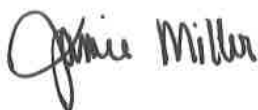
FORMULARY ALTERNATIVES:

- Atorvastatin 10 mg: 2 tablets per day
- Atorvastatin 40 mg: 1 tablet per day
- Fluvastatin 20 mg: 4 tablets per day
- Fluvastatin ER 80 mg: 1 tablet per day
- Lovastatin 20 mg: 2 tablets per day
- Livalo 1 mg: 4 tablets per day*
- Livalo 4 mg: 1 tablet per day*
- Pravastatin 20 mg: 4 tablets per day
- Pravastatin 80 mg: 1 tablet per day
- Rosuvastatin 10 mg: 1 tablet per day
- Rosuvastatin 40 mg: 1 tablet per day
- Simvastatin 10 mg: 4 tablets per day
- Simvastatin 40 mg: 1 tablet per day
- Atorvastatin 20 mg: 1 tablet per day
- Atorvastatin 80 mg: 1 tablet per day
- Fluvastatin 40 mg: 2 tablets per day
- Lovastatin 10 mg: 4 tablets per day
- Lovastatin 40 mg: 1 tablet per day
- Livalo 2 mg: 2 tablets per day*
- Pravastatin 10mg: 8 tablets per day
- Pravastatin 40 mg: 2 tablets per day
- Rosuvastatin 5 mg: 2 tablets per day
- Rosuvastatin 20 mg: 1 tablet per day
- Simvastatin 5 mg: 8 tablets per day
- Simvastatin 20 mg: 2 tablets per day
- Simvastatin 80 mg: 1 tablet per day

*prior authorization required

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE
STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND
FEDERAL REGULATORY ENTITIES.**

**THIS POLICY WILL BE REVISED AS NECESSARY AND
REVIEWED NO LESS THAN ANNUALLY.**



Signed: _____

Title: Director, Pharmacy Services

Date: March 1, 2022

Devised: 11/11/17

Revised: 3/1/18 – annual review, updated signature

Revised: 3/1/19 – annual review, defined abbr.

Revised: 3/1/20 – annual review, added GHP Kids

Revised: 3/1/21 – annual review, updated logo, added MediSpan approval level, updated note

Revised: 3/1/22 – annual review, updated referenced policies & covered LOBs, corrected typo, updated FA



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 470.0

**SECTION: Commercial Drug
SUBJECT: Xadago**

Applicable line of business:

Commercial	X	Medicaid	
Medicare		ACA	X
GHP Kids	X	Self-Insured	X

POLICY:

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for Xadago for GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 487.0 Quantity Limit Exceptions

REQUIRED DEFINITIONS:

1. **Attachment** – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. **Exhibit** – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. **Devised** – the date the policy was implemented.
4. **Revised** – the date of every revision to the policy, including typographical and grammatical changes.
5. **Reviewed** – the date documenting the annual review if the policy has no revisions necessary.

ADDITIONAL DEFINITIONS:

1. **Formulary** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. **Non-formulary products** – those medications that are not included in the Formulary.
3. **Healthcare provider** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
4. **NCQA** – National Committee for Quality Assurance.
5. **Medically Necessary or Medical Necessity** – covered services rendered by a provider that the Health Plan determines are:

- A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
- B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
- C. In accordance with current standards of medical practice;
- D. Not primarily for the convenience of the Member, or the Member's Provider; and
- E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

PROCEDURE:

A formulary exception for coverage of Xadago may be made for members who meet the following criteria:

- Medical record documentation of a diagnosis of Parkinson's disease experiencing off episodes **AND**
- Medical record documentation that Xadago is prescribed by or in consultation with a neurologist **AND**
- Medical record documentation that member is concomitantly receiving carbidopa/levodopa **AND**
- Medical record documentation of age greater than or equal to 18 years **AND**
- Medical record documentation that the member does not have severe hepatic impairment **AND**
- Medical record documentation of therapeutic failure on, intolerance to, or contraindication to three formulary alternatives, one of which must be rasagiline or selegiline

MEDISPAN AUTHORIZATION LEVEL: GPI-12

QUANTITY LIMIT: *No QLs need to be entered within the authorization unless the requested quantity exceeds the QL.*

- **QL FOR LETTER ONLY:** 1 tablet per day

If a formulary exception is approved Xadago will be paid for under the member's prescription drug benefit.

Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.

Geisinger

POLICY NUMBER: 470.0

**POLICY AND PROCEDURE
PHARMACY
MANUAL**

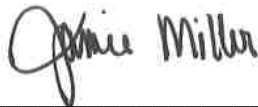
**SECTION: Commercial Drug
SUBJECT: Xadago**

FORMULARY ALTERNATIVES:

rasagiline, entacapone, pramipexole, levodopa/carbidopa/entacapone, bromocriptine, selegiline, ropinirole, ropinirole extended release, tolcapone

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE
STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND
FEDERAL REGULATORY ENTITIES.**

**THIS POLICY WILL BE REVISED AS NECESSARY AND
REVIEWED NO LESS THAN ANNUALLY.**



Signed: _____

Title: Director, Pharmacy Services

Date: March 1, 2022

Devised: 11/27/17

Reviewed: 3/18 – annual review

Revised: 3/1/19 – annual review, added QL approval note

Revised: 3/1/20 – annual review, added GHP Kids

Revised: 3/1/21 – annual review, updated logo, added MediSpan approval level, updated QL statement

Revised: 3/1/22 – annual review, updated referenced policies & covered LOBs



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 471.0

**SECTION: Commercial Drug
SUBJECT: Haegarda**

Applicable line of business:

Commercial	X	Medicaid	
Medicare		ACA	X
GHP Kids	X	Self-Insured	X

POLICY:

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for Haegarda for GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 487.0 Quantity Limit Exceptions

REQUIRED DEFINITIONS:

1. **Attachment** – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
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5. **Reviewed** – the date documenting the annual review if the policy has no revisions necessary.

ADDITIONAL DEFINITIONS:

1. **Formulary** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. **Non-formulary products** – those medications that are not included in the Formulary.
3. **Healthcare provider** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
4. **NCQA** – National Committee for Quality Assurance.
5. **Medically Necessary or Medical Necessity** – covered services rendered by a provider that the Health Plan determines are:

- A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
- B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
- C. In accordance with current standards of medical practice;
- D. Not primarily for the convenience of the Member, or the Member's Provider; and
- E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

PROCEDURE:

A formulary exception for coverage of Haegarda may be made for members who meet the following criteria:

- Medical record documentation of age greater than or equal to 12 years **AND**
- Medical record documentation that Haegarda is prescribed by an allergist, immunologist, hematologist, or dermatologist **AND**
- Medical record documentation of a diagnosis of hereditary angioedema (HAE) established and supported by documentation of:
 - Recurrent, self-limiting, non-inflammatory subcutaneous angioedema without urticaria which lasts more than 12 hours **OR**
 - Laryngeal edema **OR**
 - Recurrent, self-remitting abdominal pain which lasts more than 6 hours, without clear organic etiology **AND**
- Medical record documentation of specific abnormalities in complement proteins, in the setting of a suggestive clinical history or episodic angioedema without urticaria; supported by:
 - Medical record documentation of two (2) or more sets of complement studies, separated by one month or more, showing consistent results of:
 - Low C4 levels **AND**
 - Less than 50% of the lower limit of normal C1-INH antigenic protein levels **OR**
 - Less than 50% of the lower limit of normal C1-INH function levels **AND**
- Medical record documentation of history of more than one (1) severe event per month **OR** a history of laryngeal attacks **AND**
- Medical record documentation that Haegarda is being used as prophylactic therapy for hereditary angioedema (HAE) attacks **AND**
- Medical record documentation of therapeutic failure on, intolerance to, or contraindication to danazol

Geisinger

**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 471.0

**SECTION: Commercial Drug
SUBJECT: Haegarda**

MEDISPAN AUTHORIZATION LEVEL: GPI-14 (must enter 85802022002130 & 85802022002140)

QUANTITY LIMIT: 8 weight based doses per 28 days

AUTHORIZATION DURATION: Initial approval will be for 6 months or less if the reviewing provider feels it is medically appropriate. Subsequent approvals will be for an additional 12 months or less if the reviewing provider feels it is medically appropriate and will required medical record documentation of continued disease improvement or lack of disease progression. Haegarda will no longer be covered if the member experiences unacceptable toxicity or worsening of disease.

If a formulary exception is approved Haegarda will be paid for under the member's prescription drug benefit.

Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.

FORMULARY ALTERNATIVES:

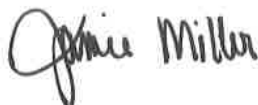
danazol, icatibant*

*prior authorization required

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE
STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND
FEDERAL REGULATORY ENTITIES.**

**THIS POLICY WILL BE REVISED AS NECESSARY AND
REVIEWED NO LESS THAN ANNUALLY.**

Signed: _____



Title: Director, Pharmacy Services

Date: March 1, 2022



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 471.0

**SECTION: Commercial Drug
SUBJECT: Haegarda**

Devised: 11/27/17
Revised: 3/1/18 – annual review, corrected typo
Reviewed: 3/1/19 – annual review
Revised: 3/1/20 – annual review, added GHP Kids
Revised: 3/1/21 – annual review, updated logo, added MediSpan approval level, updated FA
Revised: 3/1/22 – annual review, updated referenced policies & covered LOBs



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 472.0

**SECTION: Commercial Drug
SUBJECT: Kevzara**

Applicable line of business:

Commercial	X	Medicaid	
Medicare		ACA	X
GHP Kids	X	Self-Insured	X

POLICY:

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for agents to treat insomnia for GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 487.0 Quantity Limit Exceptions

REQUIRED DEFINITIONS:

1. **Attachment** – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. **Exhibit** – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
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5. **Reviewed** – the date documenting the annual review if the policy has no revisions necessary.

ADDITIONAL DEFINITIONS:

1. **Formulary** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. **Non-formulary products** – those medications that are not included in the Formulary.
3. **Healthcare provider** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
4. **NCQA** – National Committee for Quality Assurance.
5. **Medically Necessary or Medical Necessity** – covered services rendered by a provider that the Health Plan determines are:



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 472.0

**SECTION: Commercial Drug
SUBJECT: Kevzara**

- A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
- B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
- C. In accordance with current standards of medical practice;
- D. Not primarily for the convenience of the Member, or the Member's Provider; and
- E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

PROCEDURE:

New members to the plan already established on therapy may be eligible for continuity of care coverage as long as there is medical record documentation that the safety and effectiveness of use for the prescribed indication is supported by Food and Drug Administration (FDA) approval or adequate medical and scientific evidence in the medical literature.

A formulary exception for coverage of Kevzara may be made for members who meet the following criteria:

- Medical record documentation of age greater than or equal to 18 years **AND**
- Medical record documentation that Kevzara is prescribed by a rheumatologist **AND**
- Medical record documentation of a diagnosis of moderate to severe rheumatoid arthritis (RA) made in accordance with the American College of Rheumatology Criteria for the Classification and Diagnosis of RA **AND**
- Medical record documentation of therapeutic failure on, intolerance to, or contraindication to a minimum 3 month trial of Humira*, Rinvoq*, OR Xeljanz* **AND**
- Medical record documentation that Kevzara is not being used concurrently with a tumor necrosis factor (TNF) blocker or other biologic agent

MEDISPAN AUTHORIZATION LEVEL: GPI-10, number of claims authorized = 1, enter for the remainder of the calendar year

QUANTITY LIMIT: *No QLs need to be entered within the authorization unless the requested quantity exceeds the QL.*

- QL FOR LETTER ONLY: 2.28 mL per 28 days

RE-AUTHORIZATION CRITERIA: Kevzara is configured as a prior authorization for new starts only. Kevzara will no longer be covered if it is identified that the member is not



**POLICY AND PROCEDURE
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POLICY NUMBER: 472.0

**SECTION: Commercial Drug
SUBJECT: Kevzara**

receiving appropriate follow-up care from the prescribing specialist or if the member has greater than or equal to a 90 day break in therapy.

- Medical record documentation that the member is receiving appropriate follow-up care from the prescribing specialist

If a formulary exception is approved Kevzara will be paid for under the member's prescription drug benefit.

Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.

FORMULARY ALTERNATIVES:

Humira*, Rinvoq*, Xeljanz*

*prior authorization required

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE
STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND
FEDERAL REGULATORY ENTITIES.**

**THIS POLICY WILL BE REVISED AS NECESSARY AND
REVIEWED NO LESS THAN ANNUALLY.**

Signed: _____

Title: Director, Pharmacy Services

Date: March 1, 2022

- Devised: 11/27/17
Revised: 3/1/18 – annual review, added grandfather language
Revised: 10/1/18 – removed failure of Enbrel, updated FA, added concurrent biologic crit. (RA)
Revised: 3/1/19 – annual review, corrected typo, defined TNF, added QL approval note
Revised: 5/3/19 – corrected typo, defined RA
Revised: 1/28/20 – updated RA FA and added failure of Rinvoq and Xeljanz
Revised: 3/1/20 – annual review, added GHP Kids
Revised: 3/1/21 – annual review, updated logo, added MediSpan approval level, updated QL statement
Revised: 12/2/21 – added one-time PA to approval crit., removed auth duration & added re-auth crit.

HPRX02

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Dev. 11/27/17

Rev. 3/1/22



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POLICY NUMBER: 472.0

**SECTION: Commercial Drug
SUBJECT: Kevzara**

Revised: 3/1/22 – annual review, updated referenced policies & covered LOBs



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 473.0

**SECTION: Commercial Drug
SUBJECT: Verzenio**

Applicable line of business:

Commercial	X	Medicaid	
Medicare		ACA	X
GHP Kids	X	Self-Insured	X

POLICY:

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for Verzenio for GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 487.0 Quantity Limit Exceptions

REQUIRED DEFINITIONS:

1. **Attachment** – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. **Exhibit** – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. **Devised** – the date the policy was implemented.
4. **Revised** – the date of every revision to the policy, including typographical and grammatical changes.
5. **Reviewed** – the date documenting the annual review if the policy has no revisions necessary.

ADDITIONAL DEFINITIONS:

1. **Formulary** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. **Non-formulary products** – those medications that are not included in the Formulary.
3. **Healthcare provider** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
4. **NCQA** – National Committee for Quality Assurance.
5. **Medically Necessary or Medical Necessity** – covered services rendered by a provider that the Health Plan determines are:



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 473.0

**SECTION: Commercial Drug
SUBJECT: Verzenio**

- A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
- B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
- C. In accordance with current standards of medical practice;
- D. Not primarily for the convenience of the Member, or the Member's Provider; and
- E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

PROCEDURE:

New members to the plan already established on therapy may be eligible for continuity of care coverage as long as there is medical record documentation that the safety and effectiveness of use for the prescribed indication is supported by Food and Drug Administration (FDA) approval or adequate medical and scientific evidence in the medical literature.

A formulary exception for coverage of Verzenio may be made for members who meet the following criteria:

Advanced of Metastatic Breast Cancer

- Medical record documentation of age greater than or equal to 18 years **AND**
- Medical record documentation that Verzenio is prescribed by an oncologist **AND**
- Medical record documentation of a diagnosis of advanced or metastatic breast cancer that is hormone receptor positive, human epidermal growth factor receptor 2 negative (HR+/HER2-) **AND**
- One of the following:
 - Medical record documentation that Verzenio is being prescribed as initial endocrine-based therapy **AND**
 - Medical record documentation of postmenopausal status **OR** if the patient is male, that they have received a gonadotropin-releasing hormone agonist (e.g., LHRH agonist; goserelin) for at least 4 weeks prior to and will continue for the duration of Verzenio therapy **AND**
 - Medical record documentation that Verzenio will be prescribed in combination with an aromatase inhibitor (i.e. letrozole, anastrozole, etc.)

OR

- Medical record documentation that the patient experienced disease progression following prior endocrine therapy* **AND** prior chemotherapy[^] in the metastatic setting **AND**

- Medical record documentation that Verzenio is being used as monotherapy

OR

- Medical record documentation that the patient experienced disease progression following prior endocrine therapy* **AND**
- Medical record documentation that fulvestrant (Faslodex) will be administered along with Verzenio **AND**
- Medical record documentation of postmenopausal status **OR** if the patient is pre/perimenopausal, that they have received a gonadotropin-releasing hormone agonist (e.g., LHRH agonist; goserelin) for at least 4 weeks prior to and will continue for the duration of Verzenio therapy

NOTES:

*Examples of endocrine therapy include: exemestane, letrozole, anastrozole, tamoxifen, and toremifene

^Examples of preferred chemotherapy include: Anthracyclines (doxorubicin/pegylated liposomal doxorubicin), taxanes (paclitaxel), anti-metabolites (capecitabine/gemcitabine), other microtubule inhibitors (vinorelbine/eribulin). Other chemotherapy agents that can be used include: cyclophosphamide, carboplatin, docetaxel, albumin-bound paclitaxel, cisplatin, epirubicin, and ixabepilone.

Early Breast Cancer

- Medical record documentation of age greater than or equal to 18 years **AND**
- Medical record documentation that Verzenio is prescribed by an oncologist **AND**
- Medical record documentation of a diagnosis of hormone receptor (HR)-positive, human epidermal growth factor receptor 2 (HER2)-negative, node-positive, early breast cancer **AND**
- Medical record documentation that member has a high risk of recurrence[&] **AND**
- Medical record documentation of a Ki-67 score greater than or equal to 20% determined by a Food and Drug Administration (FDA) approved test[#] **AND**
- Medical record documentation that Verzenio will be used as adjuvant treatment in combination with endocrine therapy (i.e., tamoxifen or an aromatase inhibitor) **AND**
- If patient is treated with an aromatase inhibitor (i.e., letrozole, anastrozole, etc.):
 - Medical record documentation of postmenopausal status **OR** if the patient is pre/perimenopausal or male, that they have received a gonadotropin-releasing hormone agonist (e.g., LHRH agonist; goserelin) for at least 4 weeks prior to and will continue for the duration of Verzenio therapy



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**SECTION: Commercial Drug
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NOTES:

*Examples of endocrine therapy include: exemestane, letrozole, anastrozole, tamoxifen, and toremifene

&In clinical trials, high risk of recurrence was defined as either tumor involvement in one to three axillary lymph nodes with either tumor grade 3 disease or tumor size ≥ 50 mm **OR** tumor involvement of ≥ 4 axillary lymph nodes

#The FDA approved test for the measurement of Ki-67 score is the Ki-67 IHC MIB-1 pharmDx.

MEDISPAN AUTHORIZATION LEVEL: GPI-12

QUANTITY LIMIT: *No QLs need to be entered within the authorization unless the requested quantity exceeds the QL.*

- QL FOR LETTER ONLY: 2 tablets per day, 28 day supply per fill

AUTHORIZATION DURATION:

****For adjuvant treatment of hormone receptor (HR)-positive, human epidermal growth factor receptor 2 (HER2)-negative, node positive, early breast cancer:** One approval will be given for 24 months or less if the reviewing provider feels it is medically appropriate. The medication will no longer be covered if patient experiences toxicity or worsening of disease.

Authorization of Verzenio for adjuvant treatment of hormone receptor (HR)-positive, human epidermal growth factor receptor 2 (HER2)-negative, node positive, early breast cancer should not exceed the FDA-approved treatment duration of 2 year (24 months) in patients. For requests exceeding the above limit, medical record documentation of the following is required:

- Peer-reviewed literature citing well-designed clinical trials to indicate that the member's healthcare outcome will be improved by dosing beyond the FDA-approved treatment duration

For all other indications:

Initial approval will be for 24 months or less if the reviewing provider feels it is medically appropriate. Subsequent approvals will be for an additional 24 months or less if the reviewing provider feels it is medically appropriate and will require medical record documentation of continued disease improvement or lack of disease progression. The medication will no longer be covered if patient experiences toxicity or worsening of disease.



**POLICY AND PROCEDURE
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POLICY NUMBER: 473.0

**SECTION: Commercial Drug
SUBJECT: Verzenio**

If a formulary exception is approved Verzenio will be paid for under the member's prescription drug benefit.

Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.

FORMULARY ALTERNATIVES:

Ibrance*, Kisqali*

*prior authorization required

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE
STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND
FEDERAL REGULATORY ENTITIES.**

**THIS POLICY WILL BE REVISED AS NECESSARY AND
REVIEWED NO LESS THAN ANNUALLY.**

Signed: _____

Title: Director, Pharmacy Services

Date: March 1, 2022

- Devised: 11/27/17
- Revised: 3/1/18 – annual review, added grandfather language
- Revised: 4/10/18 – added combo with aromatase inhibitor, moved requirements of postmenopausal/gonadotropin agonist therapy, updated QL
- Revised: Corrected typo in note, moved OR to appropriate position in last criteria
- Revised: 3/1/19 – annual review, added QL approval note
- Revised: 3/1/20 – annual review, added GHP Kids
- Revised: 3/1/21 – annual review, updated logo, added MediSpan approval level, updated QL statement
- Revised: 12/2/21 – added one-time PA to approval crit., removed auth duration & added re-auth crit.
- Revised: 1/5/22 – added males to initial endocrine-based therapy, added early breast cancer indication, updated back to Type 1 PA, added auth duration back
- Revised: 3/1/22 – annual review, updated referenced policies & covered LOBs



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 474.0

**SECTION: Commercial Drug
SUBJECT: Basaglar**

Applicable line of business:

Commercial	X	Medicaid	
Medicare		ACA	X
GHP Kids	X	Self-Insured	X

POLICY:

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for Basaglar for GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 487.0 Quantity Limit Exceptions

REQUIRED DEFINITIONS:

1. **Attachment** – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. **Exhibit** – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. **Devised** – the date the policy was implemented.
4. **Revised** – the date of every revision to the policy, including typographical and grammatical changes.
5. **Reviewed** – the date documenting the annual review if the policy has no revisions necessary.

ADDITIONAL DEFINITIONS:

1. **Formulary** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. **Non-formulary products** – those medications that are not included in the Formulary.
3. **Healthcare provider** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
4. **NCQA** – National Committee for Quality Assurance.
5. **Medically Necessary or Medical Necessity** – covered services rendered by a provider that the Health Plan determines are:



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 474.0

**SECTION: Commercial Drug
SUBJECT: Basaglar**

- A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
- B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
- C. In accordance with current standards of medical practice;
- D. Not primarily for the convenience of the Member, or the Member's Provider; and
- E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

PROCEDURE:

A formulary exception for coverage of Basaglar may be made for members who meet the following criteria:

- Medical record documentation of therapeutic failure on, intolerance to, or contraindication to Lantus **OR** Toujeo

MEDISPAN AUTHORIZATION LEVEL: NDC-9

If a formulary exception is approved Basaglar will be paid for under the member's prescription drug benefit.

Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.

FORMULARY ALTERNATIVES:

Lantus, Toujeo, Tresiba, Levemir

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE
STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND
FEDERAL REGULATORY ENTITIES.**

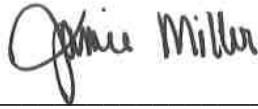
**THIS POLICY WILL BE REVISED AS NECESSARY AND
REVIEWED NO LESS THAN ANNUALLY.**

Geisinger

**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 474.0

**SECTION: Commercial Drug
SUBJECT: Basaglar**



Signed: _____

Title: Director, Pharmacy Services

Date: March 1, 2022

Devised: 11/27/17
Reviewed: 3/1/18 – annual review
Reviewed: 3/1/19 – annual review
Revised: 3/1/20 – annual review, added GHP Kids
Revised: 3/1/21 – annual review, updated logo, added MediSpan approval level
Revised: 3/1/22 – annual review, updated referenced policies & covered LOBs



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 475.0

**SECTION: Commercial Drug
SUBJECT: Benlysta for
Self-Administration**

Applicable line of business:

Commercial	X	Medicaid	
Medicare		ACA	X
GHP Kids	X	Self-Insured	X

POLICY:

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for Benlysta for self-administration for GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 487.0 Quantity Limit Exceptions

REQUIRED DEFINITIONS:

1. **Attachment** – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. **Exhibit** – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. **Devised** – the date the policy was implemented.
4. **Revised** – the date of every revision to the policy, including typographical and grammatical changes.
5. **Reviewed** – the date documenting the annual review if the policy has no revisions necessary.

ADDITIONAL DEFINITIONS:

1. **Formulary** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. **Non-formulary products** – those medications that are not included in the Formulary.
3. **Healthcare provider** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
4. **NCQA** – National Committee for Quality Assurance.
5. **Medically Necessary or Medical Necessity** – covered services rendered by a provider that the Health Plan determines are:



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 475.0

**SECTION: Commercial Drug
SUBJECT: Benlysta for
Self-Administration**

- A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
- B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
- C. In accordance with current standards of medical practice;
- D. Not primarily for the convenience of the Member, or the Member's Provider; and
- E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

PROCEDURE:

New members to the plan already established on therapy may be eligible for continuity of care coverage as long as there is medical record documentation that the safety and effectiveness of use for the prescribed indication is supported by Food and Drug Administration (FDA) approval or adequate medical and scientific evidence in the medical literature.

A formulary exception for coverage of Benlysta for self-administration may be made for members who meet the following criteria:

Systemic Lupus Erythematosus (SLE)

- Medical record documentation of age greater than or equal to 18 years **AND**
- Medical record documentation a diagnosis of active systemic lupus erythematosus **AND**
- Medical record documentation that Benlysta for self-administration is prescribed by a rheumatologist **AND**
- Medical record documentation of a positive ANA/anti-sdDNA antibody **AND**
- Medical record documentation that member is concurrently receiving a stable treatment regimen with prednisone, an NSAID, anti-malarial or immunosuppressant **AND**
- Medical record documentation of no central nervous system (CNS) involvement

SLE AUTHORIZATION DURATION: Each authorization will be for a period of 12 months. Re-review is required with medical record documentation showing a clinical benefit of one of the following:

- Improvement in functional impairment **OR**
- Decrease in the number of exacerbations since the start of Benlysta **OR**
- Decrease in the daily required dose of oral corticosteroids such as prednisone



POLICY NUMBER: 475.0

**POLICY AND PROCEDURE
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**SECTION: Commercial Drug
SUBJECT: Benlysta for
Self-Administration**

MEDISPAN AUTHORIZATION LEVEL: GPI-14 (must enter 9942201500E520 & 9942201500D520)

QUANTITY LIMIT: *No QLs need to be entered within the authorization unless the requested quantity exceeds the QL.*

- **QL FOR LETTER ONLY:** 4 mL per 28 days

Lupus Nephritis (LN)

- Medical record documentation of a diagnosis of active lupus nephritis, Class III, IV, V alone or in combination, confirmed by a kidney biopsy **AND**
- Medical record documentation of age greater than or equal to 18 years **AND**
- Medical record documentation that Benlysta for self-administration is prescribed by or in consultation with a rheumatologist or nephrologist **AND**
- Medical record documentation that Benlysta will be prescribed in combination with standard therapy (e.g., mycophenolate mofetil (MMF), corticosteroids, cyclophosphamide, azathioprine)

LN AUTHORIZATION DURATION: Initial approval will be for 12 months. Subsequent approvals will be for 12 months. Re-authorization will require the following:

- Improvement in functional impairment
- Decrease in the number of exacerbations since the start of Benlysta
- Decrease in the daily required dose of oral corticosteroids such as prednisone
- Medical record documentation of a positive clinical response to Benlysta (e.g., improvement/stabilization in UPCR, eGFR, renal-related events) **AND**
- Medical record documentation that Benlysta will be prescribed in combination with standard therapy (e.g., mycophenolate mofetil (MMF), corticosteroids, cyclophosphamide, azathioprine)

MEDISPAN AUTHORIZATION LEVEL: GPI-14 (must enter 9942201500E520 & 9942201500D520)

QUANTITY LIMIT:

- **Initial Approval** – *Two authorizations must be entered.*
 - 400 mg once weekly for 4 weeks, then 200 mg once weekly thereafter
 1. In PA Hub: Add PA only with the approved authorization duration.
 2. In Darwin: Add OQL, DS, max number of claims authorized 1, max quantity dispensed 8, min day supply 28, max day supply 28, with a duration of two weeks.
 - **QL FOR LETTER:** Loading dose: 8 mL per 28 days;
Maintenance dose: 4 mL per 28 days



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 475.0

**SECTION: Commercial Drug
SUBJECT: Benlysta for
Self-Administration**

- **Renewal** – *No QLs need to be entered within the authorization unless the requested quantity exceeds the QL.*
 - QL FOR LETTER ONLY: 4 mL per 28 days

If a formulary exception is approved Benlysta for self-administration will be paid for under the member's prescription drug benefit.

Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.

FORMULARY ALTERNATIVES:

none

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE
STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND
FEDERAL REGULATORY ENTITIES.**

**THIS POLICY WILL BE REVISED AS NECESSARY AND
REVIEWED NO LESS THAN ANNUALLY.**

Signed: _____

Title: Director, Pharmacy Services

Date: March 1, 2022

Devised: 11/27/17
Revised: 12/20/17 – updated typo in prescriber bullet
Revised: 3/1/18 – annual review, corrected typo, added grandfather language
Revised: 3/1/19 – annual review, added QL approval note
Revised: 01/28/20 – added criteria for age of at least 18 years
Revised: 3/1/20 – annual review, added GHP Kids
Revised: 3/1/21 – annual review, updated logo, added MediSpan approval level, updated QL statement
Revised: 7/23/21 – removed nephritis from SLE indication, added LN indication, updated policy title
Revised: 3/1/22 – annual review, updated referenced policies & covered LOBs, updated how QL is entered, corrected typo



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 476.0

**SECTION: Commercial Drug
SUBJECT: Non-Preferred Acne
Medications**

Applicable line of business:

Commercial	X	Medicaid	
Medicare		ACA	X
GHP Kids	X	Self-Insured	X

POLICY:

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for non-preferred acne medications for GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 487.0 Quantity Limit Exceptions

REQUIRED DEFINITIONS:

1. **Attachment** – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. **Exhibit** – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. **Devised** – the date the policy was implemented.
4. **Revised** – the date of every revision to the policy, including typographical and grammatical changes.
5. **Reviewed** – the date documenting the annual review if the policy has no revisions necessary.

ADDITIONAL DEFINITIONS:

1. **Formulary** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. **Non-formulary products** – those medications that are not included in the Formulary.
3. **Healthcare provider** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
4. **NCQA** – National Committee for Quality Assurance.
5. **Medically Necessary or Medical Necessity** – covered services rendered by a provider that the Health Plan determines are:



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 476.0

**SECTION: Commercial Drug
SUBJECT: Non-Preferred Acne
Medications**

- A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
- B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
- C. In accordance with current standards of medical practice;
- D. Not primarily for the convenience of the Member, or the Member's Provider; and
- E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

PROCEDURE:

A formulary exception for coverage of non-preferred acne medications may be made for members who meet the following criteria:

- Medical record documentation a diagnosis of acne, acne vulgaris, or adult onset acne **AND**
- Medical record documentation of therapeutic failure on, intolerance to, or contraindication to three (3) formulary alternatives

If a formulary exception is approved, the non-preferred acne medication will be paid for under the member's prescription drug benefit.

Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.

FORMULARY ALTERNATIVES:

adapalene, benzoyl peroxide, topical clindamycin, clindamycin/benzoyl peroxide, oral doxycycline, topical erythromycin, erythromycin/benzoyl peroxide, isotretinoin, oral minocycline, sulfacetamide/sulfur, topical tretinoin

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE
STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND
FEDERAL REGULATORY ENTITIES.**

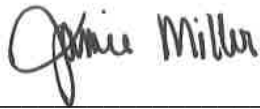
**THIS POLICY WILL BE REVISED AS NECESSARY AND
REVIEWED NO LESS THAN ANNUALLY.**

Geisinger

**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 476.0

**SECTION: Commercial Drug
SUBJECT: Non-Preferred Acne
Medications**



Signed: _____

Title: Director, Pharmacy Services

Date: March 1, 2022

Devised: 11/27/17
Reviewed: 3/1/18 – annual review
Reviewed: 3/1/19 – annual review
Revised: 3/1/20 – annual review, added GHP Kids
Revised: 3/1/21 – annual review, updated logo
Revised: 3/1/22 – annual review, updated referenced policies & covered LOBs



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 477.0

**SECTION: Commercial Drug
SUBJECT: Janumet and Janumet XR**

Applicable line of business:

Commercial	X	Medicaid	
Medicare		ACA	X
GHP Kids	X	Self-Insured	X

POLICY:

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for Janumet and Janumet XR for GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 487.0 Quantity Limit Exceptions

REQUIRED DEFINITIONS:

1. **Attachment** – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. **Exhibit** – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. **Devised** – the date the policy was implemented.
4. **Revised** – the date of every revision to the policy, including typographical and grammatical changes.
5. **Reviewed** – the date documenting the annual review if the policy has no revisions necessary.

ADDITIONAL DEFINITIONS:

1. **Formulary** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. **Non-formulary products** – those medications that are not included in the Formulary.
3. **Healthcare provider** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
4. **NCQA** – National Committee for Quality Assurance.
5. **Medically Necessary or Medical Necessity** – covered services rendered by a provider that the Health Plan determines are:



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 477.0

**SECTION: Commercial Drug
SUBJECT: Janumet and Janumet XR**

- A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
- B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
- C. In accordance with current standards of medical practice;
- D. Not primarily for the convenience of the Member, or the Member's Provider; and
- E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

PROCEDURE:

A formulary exception for coverage of Janumet or Janumet XR may be made for members who meet the following criteria:

- Medical record documentation of therapeutic failure on, intolerance to, or contraindication to Tradjenta + metformin, Jentadueto, **OR** Jentadueto XR

MEDISPAN AUTHORIZATION LEVEL: GPI-10

QUANTITY LIMIT: *No QLs need to be entered within the authorization unless the requested quantity exceeds the QL.*

- **QL FOR LETTER ONLY:**
 - Janumet: 2 tablets per day
 - Janumet XR 50-1000 mg & 50-500 mg: 2 tablets per day
 - Janumet XR 100-1000 mg: 1 tablet per day

If a formulary exception is approved, Janumet or Janumet XR will be paid for under the member's prescription drug benefit.

Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.

FORMULARY ALTERNATIVES:

metformin, Tradjenta, Jentadueto, Jentadueto XR



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 477.0

**SECTION: Commercial Drug
SUBJECT: Janumet and Janumet XR**

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE
STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND
FEDERAL REGULATORY ENTITIES.**

**THIS POLICY WILL BE REVISED AS NECESSARY AND
REVIEWED NO LESS THAN ANNUALLY.**

Signed: _____

Title: Director, Pharmacy Services

Date: March 1, 2022

Devised: 11/28/17
Revised: 2/2/18 – removed new start criteria
Reviewed: 3/1/18 – annual review
Revised: 3/1/19 – annual review, added QL approval note, updated FA
Revised: 3/1/20 – annual review, added GHP Kids
Revised: 3/1/21 – annual review, updated logo, added MediSpan approval level, updated QL statement
Revised: 3/1/22 – annual review, updated referenced policies & covered LOBs



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 480.0

**SECTION: Commercial Drug
SUBJECT: Calquence**

Applicable line of business:

Commercial	X	Medicaid	
Medicare		ACA	X
GHP Kids	X	Self-Insured	X

POLICY:

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for Calquence for GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 487.0 Quantity Limit Exceptions

REQUIRED DEFINITIONS:

1. **Attachment** – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. **Exhibit** – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. **Devised** – the date the policy was implemented.
4. **Revised** – the date of every revision to the policy, including typographical and grammatical changes.
5. **Reviewed** – the date documenting the annual review if the policy has no revisions necessary.

ADDITIONAL DEFINITIONS:

1. **Formulary** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. **Non-formulary products** – those medications that are not included in the Formulary.
3. **Healthcare provider** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
4. **NCQA** – National Committee for Quality Assurance.
5. **Medically Necessary or Medical Necessity** – covered services rendered by a provider that the Health Plan determines are:

- A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
- B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
- C. In accordance with current standards of medical practice;
- D. Not primarily for the convenience of the Member, or the Member's Provider; and
- E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

PROCEDURE:

New members to the plan already established on therapy may be eligible for continuity of care coverage as long as there is medical record documentation that the safety and effectiveness of use for the prescribed indication is supported by Food and Drug Administration (FDA) approval or adequate medical and scientific evidence in the medical literature.

A formulary exception for coverage of Calquence may be made for members who meet the following criteria:

- Medical record documentation that Calquence is prescribed by a hematologist or oncologist **AND**
- Medical record documentation of age greater than or equal to 18 years **AND**
- Medical record documentation one of the following:
 - Medical record documentation of a diagnosis of mantle cell lymphoma (MCL) **AND** therapeutic failure on, intolerance to, or contraindication to one prior therapy **OR**
 - Medical record documentation of diagnosis of chronic lymphocytic leukemia (CLL) or small lymphocytic lymphoma (SLL)
- If the requested dose is 400 mg daily: Medical record documentation that the patient is using Calquence in combination with a strong CYP3A inducer, including but not limited to carbamazepine, enzalutamide, fosphenytoin, lumacaftor, mitotane, phenytoin, rifampin, St. John's Wort

MEDISPAN AUTHORIZATION LEVEL: GPI-12, number of claims authorized = 1, enter for the remainder of the calendar year

QUANTITY LIMIT: *No QLs need to be entered within the authorization unless the requested quantity exceeds the QL.*

- **QL FOR LETTER ONLY:** 2 capsules per day, 30 day supply per fill

RE-AUTHORIZATION CRITERIA: Calquence is configured as a prior authorization for new starts only. Calquence will no longer be covered if it is identified that the member is not receiving appropriate follow-up care from the prescribing specialist or if the member has greater than or equal to a 90 day break in therapy.

- Medical record documentation that the member is receiving appropriate follow-up care from the prescribing specialist

NOTE: Acalabrutinib has not been shown to be effective for ibrutinib refractory CLL/SLL in patients with BTK C481S mutations

If a formulary exception is approved Calquence will be paid for under the member's prescription drug benefit.

Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.

FORMULARY ALTERNATIVES:

Mantle Cell Lymphoma: Imbruvica*, Brukinsa*, Revlimid*

Chronic Lymphocytic Leukemia/Small Lymphocytic Lymphoma: Imbruvica*, Venclexta*

*prior authorization required

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE
STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND
FEDERAL REGULATORY ENTITIES.**

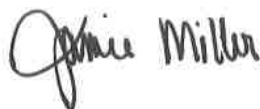
**THIS POLICY WILL BE REVISED AS NECESSARY AND
REVIEWED NO LESS THAN ANNUALLY.**

Geisinger

**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 480.0

**SECTION: Commercial Drug
SUBJECT: Calquence**



Signed: _____

Title: Director, Pharmacy Services

Date: March 1, 2022

Devised: 1/17/18
Revised: 3/1/18 – annual review, added grandfather language, updated prescriber criteria
Revised: 3/1/19 – annual review, added QL approval note
Revised: 1/28/20 – added CLL/SLL indication, updated formulary alternatives
Revised: 3/1/20 – annual review, added GHP Kids
Revised: 3/1/21 – annual review, updated logo, added MediSpan approval level, updated QL statement
Revised: 11/24/21 – added one-time PA to approval crit., removed auth duration & added re-auth crit.
Revised: 3/1/22 – annual review, updated referenced policies & covered LOBs



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 481.0

**SECTION: Commercial Drug
SUBJECT: Nityr**

Applicable line of business:

Commercial	X	Medicaid	
Medicare		ACA	X
GHP Kids	X	Self-Insured	X

POLICY:

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for Nityr for GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 487.0 Quantity Limit Exceptions

REQUIRED DEFINITIONS:

1. **Attachment** – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. **Exhibit** – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. **Devised** – the date the policy was implemented.
4. **Revised** – the date of every revision to the policy, including typographical and grammatical changes.
5. **Reviewed** – the date documenting the annual review if the policy has no revisions necessary.

ADDITIONAL DEFINITIONS:

1. **Formulary** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. **Non-formulary products** – those medications that are not included in the Formulary.
3. **Healthcare provider** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
4. **NCQA** – National Committee for Quality Assurance.
5. **Medically Necessary or Medical Necessity** – covered services rendered by a provider that the Health Plan determines are:



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 481.0

**SECTION: Commercial Drug
SUBJECT: Nityr**

- A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
- B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
- C. In accordance with current standards of medical practice;
- D. Not primarily for the convenience of the Member, or the Member's Provider; and
- E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

PROCEDURE:

A formulary exception for coverage of Nityr may be made for members who meet the following criteria:

- Medical record documentation that Nityr is prescribed by a specialist in medical genetics or metabolic diseases **AND**
- Medical record documentation of a diagnosis of hereditary tyrosinemia type 1 (HT-1) established and supported by documentation of elevated plasma or urine succinylacetone (SA) levels **AND**
- Medical record documentation that Nityr will be used in combination with dietary restriction of tyrosine and phenylalanine

MEDISPAN AUTHORIZATION LEVEL: GPI-12

AUTHORIZATION DURATION: Initial approval will be for 12 months or less if the reviewing provider feels it is medically appropriate. Subsequent approvals will be for an additional 12 months or less if the reviewing provider feels it is medically appropriate and will require medical record documentation of continued disease improvement or lack of disease progression. Nityr will no longer be covered if the member experiences unacceptable toxicity or worsening of disease.

If a formulary exception is approved Nityr will be paid for under the member's prescription drug benefit.

Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 481.0

**SECTION: Commercial Drug
SUBJECT: Nityr**

FORMULARY ALTERNATIVES:

none

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE
STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND
FEDERAL REGULATORY ENTITIES.**

**THIS POLICY WILL BE REVISED AS NECESSARY AND
REVIEWED NO LESS THAN ANNUALLY.**

Signed: _____

Title: Director, Pharmacy Services

Date: March 1, 2022

Devised: 1/17/18

Reviewed: 3/1/18 – annual review

Reviewed: 3/1/19 – annual review

Revised: 3/1/20 – annual review, added GHP Kids

Revised: 3/1/21 – annual review, updated logo, added MediSpan approval level

Revised: 3/1/22 – annual review, updated referenced policies & covered LOBs



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 482.0

**SECTION: Commercial Drug
SUBJECT: Orfadin**

Applicable line of business:

Commercial	X	Medicaid	
Medicare		ACA	X
GHP Kids	X	Self-Insured	X

POLICY:

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for Orfadin for GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 487.0 Quantity Limit Exceptions

REQUIRED DEFINITIONS:

1. **Attachment** – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. **Exhibit** – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. **Devised** – the date the policy was implemented.
4. **Revised** – the date of every revision to the policy, including typographical and grammatical changes.
5. **Reviewed** – the date documenting the annual review if the policy has no revisions necessary.

ADDITIONAL DEFINITIONS:

1. **Formulary** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. **Non-formulary products** – those medications that are not included in the Formulary.
3. **Healthcare provider** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
4. **NCQA** – National Committee for Quality Assurance.
5. **Medically Necessary or Medical Necessity** – covered services rendered by a provider that the Health Plan determines are:



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 482.0

**SECTION: Commercial Drug
SUBJECT: Orfadin**

- A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
- B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
- C. In accordance with current standards of medical practice;
- D. Not primarily for the convenience of the Member, or the Member's Provider; and
- E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

PROCEDURE:

A formulary exception for coverage of Orfadin may be made for members who meet the following criteria:

- Medical record documentation that Orfadin is prescribed by a specialist in medical genetics or metabolic diseases **AND**
- Medical record documentation of a diagnosis of hereditary tyrosinemia type 1 (HT-1) established and supported by documentation of elevated plasma or urine succinylacetone (SA) levels **AND**
- Medical record documentation that Orfadin will be used in combination with dietary restriction of tyrosine and phenylalanine **AND**
- Medical record documentation of therapeutic failure on, intolerance to, or contraindication to Nityr tablets

MEDISPAN AUTHORIZATION LEVEL: GPI-12 (must enter 309040450001 & 309040450018)

AUTHORIZATION DURATION: Initial approval will be for 12 months or less if the reviewing provider feels it is medically appropriate. Subsequent approvals will be for an additional 12 months or less if the reviewing provider feels it is medically appropriate and will require medical record documentation of continued disease improvement or lack of disease progression. Orfadin will no longer be covered if the member experiences unacceptable toxicity or worsening of disease.

If a formulary exception is approved Orfadin will be paid for under the member's prescription drug benefit.

Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.

Geisinger

**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 482.0

**SECTION: Commercial Drug
SUBJECT: Orfadin**

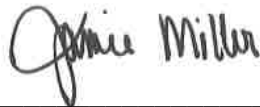
FORMULARY ALTERNATIVES:

Nityr tablets*

*prior authorization required

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE
STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND
FEDERAL REGULATORY ENTITIES.**

**THIS POLICY WILL BE REVISED AS NECESSARY AND
REVIEWED NO LESS THAN ANNUALLY.**



Signed: _____

Title: Director, Pharmacy Services

Date: March 1, 2022

Devised: 1/17/18

Reviewed: 3/1/18 – annual review

Reviewed: 3/1/19 – annual review

Revised: 3/1/20 – annual review, added GHP Kids

Revised: 3/1/21 – annual review, updated logo, added MediSpan approval level

Revised: 3/1/22 – annual review, updated referenced policies & covered LOBs



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 483.0

**SECTION: Commercial Drug
SUBJECT: Duzallo**

Applicable line of business:

Commercial	X	Medicaid	
Medicare		ACA	X
GHP Kids	X	Self-Insured	X

POLICY:

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for Duzallo for GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 487.0 Quantity Limit Exceptions

REQUIRED DEFINITIONS:

1. **Attachment** – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. **Exhibit** – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. **Devised** – the date the policy was implemented.
4. **Revised** – the date of every revision to the policy, including typographical and grammatical changes.
5. **Reviewed** – the date documenting the annual review if the policy has no revisions necessary.

ADDITIONAL DEFINITIONS:

1. **Formulary** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. **Non-formulary products** – those medications that are not included in the Formulary.
3. **Healthcare provider** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
4. **NCQA** – National Committee for Quality Assurance.
5. **Medically Necessary or Medical Necessity** – covered services rendered by a provider that the Health Plan determines are:



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 483.0

**SECTION: Commercial Drug
SUBJECT: Duzallo**

- A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
- B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
- C. In accordance with current standards of medical practice;
- D. Not primarily for the convenience of the Member, or the Member's Provider; and
- E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

PROCEDURE:

A formulary exception for coverage of Duzallo may be made for members who meet the following criteria:

- Medical record documentation of age greater than or equal to 18 years **AND**
- Medical record documentation of symptomatic hyperuricemia associated with gout **AND**
- Medical record documentation that member has been on a stable dose of allopurinol of at least 300 mg (or at least 200 mg in patients with estimated creatinine clearance less than 60 mL/min) and did not achieve target serum uric acid levels **AND**
- Medical record documentation of an estimated creatinine clearance greater than or equal to 45 mL/min **AND**
- Medical record documentation that Duzallo is not being used in tumor lysis syndrome, Lesch-Nyhan syndrome, and kidney transplant recipients **AND**
- Medical record documentation of therapeutic failure on, intolerance to, or contraindication to probenecid

MEDISPAN AUTHORIZATION LEVEL: GPI-12

QUANTITY LIMIT: *No QLs need to be entered within the authorization unless the requested quantity exceeds the QL.*

- **QL FOR LETTER ONLY:** 1 tablet per day

If a formulary exception is approved Duzallo will be paid for under the member's prescription drug benefit.

Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 483.0

**SECTION: Commercial Drug
SUBJECT: Duzallo**

FORMULARY ALTERNATIVES:

allopurinol, probenecid, febuxostat*

*prior authorization required

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE
STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND
FEDERAL REGULATORY ENTITIES.**

**THIS POLICY WILL BE REVISED AS NECESSARY AND
REVIEWED NO LESS THAN ANNUALLY.**

Signed: _____

Title: Director, Pharmacy Services

Date: March 1, 2022

Devised: 1/17/18

Reviewed: 3/1/18 – annual review

Revised: 3/1/19 – annual review, added QL approval note

Revised: 3/1/20 – annual review, added GHP Kids

Revised: 3/1/21 – annual review, updated logo, added MediSpan approval level, updated QL statement & FA

Revised: 3/1/22 – annual review, updated referenced policies & covered LOBs



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 484.0

**SECTION: Commercial Drug
SUBJECT: Tremfya**

Applicable line of business:

Commercial	X	Medicaid	
Medicare		ACA	X
GHP Kids	X	Self-Insured	X

POLICY:

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for Tremfya for GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 487.0 Quantity Limit Exceptions

REQUIRED DEFINITIONS:

1. **Attachment** – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. **Exhibit** – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. **Devised** – the date the policy was implemented.
4. **Revised** – the date of every revision to the policy, including typographical and grammatical changes.
5. **Reviewed** – the date documenting the annual review if the policy has no revisions necessary.

ADDITIONAL DEFINITIONS:

1. **Formulary** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. **Non-formulary products** – those medications that are not included in the Formulary.
3. **Healthcare provider** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
4. **NCQA** – National Committee for Quality Assurance.
5. **Medically Necessary or Medical Necessity** – covered services rendered by a provider that the Health Plan determines are:

- A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
- B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
- C. In accordance with current standards of medical practice;
- D. Not primarily for the convenience of the Member, or the Member's Provider; and
- E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

PROCEDURE:

New members to the plan already established on therapy may be eligible for continuity of care coverage as long as there is medical record documentation that the safety and effectiveness of use for the prescribed indication is supported by Food and Drug Administration (FDA) approval or adequate medical and scientific evidence in the medical literature.

A formulary exception for coverage of Tremfya may be made for members who meet the following criteria:

Psoriasis

- Medical record documentation of age greater than or equal to 18 years **AND**
- Medical record documentation that Tremfya is prescribed by a dermatologist **AND**
- Medical record documentation of a diagnosis of moderate to severe plaque psoriasis with greater than or equal to 5% body surface area involved **OR** disease involving crucial areas of the body such as hands, feet, face, and/or genitals **AND**
- Medical record documentation of therapeutic failure on, intolerance to, or contraindication to a minimum 3 month trial of Cosentyx* **AND** Humira* **AND**
- Medical record documentation that Tremfya is not being used concurrently with a tumor necrosis factor (TNF) blocker or other biologic agent

MEDISPAN AUTHORIZATION LEVEL: GPI-10

QUANTITY LIMIT: *Quantity limit must be entered in authorization.*

- 100 mg at weeks 0, 4, and then every 8 weeks thereafter
 - 1. In PA Hub: Add PA, OQL, DS, max number of claims authorized 1, max quantity dispensed 1, min day supply 28, max day supply 28, with a duration of two-weeks.



POLICY NUMBER: 484.0

**POLICY AND PROCEDURE
PHARMACY
MANUAL**

**SECTION: Commercial Drug
SUBJECT: Tremfya**

- **QL FOR LETTER:** Loading dose: 1 mL per 28 days;
Maintenance dose: 1 mL per 56 days

RE-AUTHORIZATION CRITERIA: Tremfya is configured as a prior authorization for new starts only. Tremfya will no longer be covered if it is identified that the member is not receiving appropriate follow-up care from the prescribing specialist or if the member has greater than or equal to a 90 day break in therapy.

- Medical record documentation that the member is receiving appropriate follow-up care from the prescribing specialist

Psoriatic Arthritis

- Medical record documentation of age greater than or equal to 18 years **AND**
- Medical record documentation that Tremfya is prescribed by a rheumatologist or dermatologist **AND**
- Medical record documentation of active psoriatic arthritis which must include documentation of either active psoriatic lesions or a documented history of psoriasis **AND**
- Medical record documentation of therapeutic failure on, intolerance to, or contraindication to a minimum 3 month trial of Cosentyx* **AND** Humira*

MEDISPAN AUTHORIZATION LEVEL: GPI-10

QUANTITY LIMIT: *Quantity limit must be entered in authorization.*

- 100 mg at weeks 0, 4, and then every 8 weeks thereafter
 1. In PA Hub: Add PA, OQL, DS, max number of claims authorized 1, max quantity dispensed 1, min day supply 28, max day supply 28, with a duration of two-weeks.
 - **QL FOR LETTER:** Loading dose: 1 mL per 28 days;
Maintenance dose: 1 mL per 56 days

RE-AUTHORIZATION CRITERIA: Tremfya is configured as a prior authorization for new starts only. Tremfya will no longer be covered if it is identified that the member is not receiving appropriate follow-up care from the prescribing specialist or if the member has greater than or equal to a 90 day break in therapy.

- Medical record documentation that the member is receiving appropriate follow-up care from the prescribing specialist



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 484.0

**SECTION: Commercial Drug
SUBJECT: Tremfya**

If a formulary exception is approved Tremfya will be paid for under the member's prescription drug benefit.

Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.

FORMULARY ALTERNATIVES:

Cosentyx*, Humira*

*prior authorization required

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE
STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND
FEDERAL REGULATORY ENTITIES.**

**THIS POLICY WILL BE REVISED AS NECESSARY AND
REVIEWED NO LESS THAN ANNUALLY.**

Signed: _____

Title: Director, Pharmacy Services

Date: March 1, 2022

- Devised: 1/17/18
- Revised: 3/1/18 – annual review, added grandfather language
- Revised: 4/5/18 – corrected typo in approval statement
- Revised: 5/31/18 – added combination with other biologic agents, removed failure of Enbrel and added failure of Cosentyx, updated FA, corrected typo
- Revised: 3/1/19 – annual review, defined TNF
- Revised: 6/4/19 – updated QL, added authorization parameters
- Revised: 3/1/20 – annual review, added GHP Kids
- Revised: 11/18/20 – added PsA indication, updated initial auth length to 2 weeks for PP
- Revised: 3/1/21 – annual review, updated logo, added MediSpan approval level, updated QL statement
- Revised: 12/2/21 – added one-time PA to approval crit., removed auth duration & added re-auth crit., updated QL auth entry to account for PA NSO
- Revised: 3/1/22 – annual review, updated referenced policies & covered LOBs, updated how QL is entered



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 485.0

**SECTION: Commercial Drug
SUBJECT: Bevyxxa**

Applicable line of business:

Commercial	X	Medicaid	
Medicare		ACA	X
GHP Kids	X	Self-Insured	X

POLICY:

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for Bevyxxa for GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 487.0 Quantity Limit Exceptions

REQUIRED DEFINITIONS:

1. **Attachment** – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. **Exhibit** – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
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5. **Reviewed** – the date documenting the annual review if the policy has no revisions necessary.

ADDITIONAL DEFINITIONS:

1. **Formulary** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. **Non-formulary products** – those medications that are not included in the Formulary.
3. **Healthcare provider** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
4. **NCQA** – National Committee for Quality Assurance.
5. **Medically Necessary or Medical Necessity** – covered services rendered by a provider that the Health Plan determines are:



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 485.0

**SECTION: Commercial Drug
SUBJECT: Bevyxxa**

- A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
- B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
- C. In accordance with current standards of medical practice;
- D. Not primarily for the convenience of the Member, or the Member's Provider; and
- E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

PROCEDURE:

A formulary exception for coverage of Bevyxxa may be made for members who meet the following criteria:

- Medical record documentation of age greater than or equal to 18 years **AND**
- Medical record documentation of a confirmed diagnosis of prophylaxis of venous thromboembolism (VTE) in adult patients hospitalized for an acute medical illness who are at risk for thromboembolic complications due to moderate or severe restricted mobility and other risk factors for VTE **AND**
- Medical record documentation that the member received Bevyxxa during hospitalization and will be continuing therapy following discharge from the hospital

MEDISPAN AUTHORIZATION LEVEL: GPI-12

QUANTITY LIMIT: *No QLs need to be entered within the authorization unless the requested quantity exceeds the QL.*

- **QL FOR LETTER ONLY:** 1 tablet per day

AUTHORIZATION DURATION: 42 days

If a formulary exception is approved Bevyxxa will be paid for under the member's prescription drug benefit.

Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.

FORMULARY ALTERNATIVES:

enoxaparin, fondaparinux, heparin



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 485.0

**SECTION: Commercial Drug
SUBJECT: Bevyxxa**

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE
STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND
FEDERAL REGULATORY ENTITIES.**

**THIS POLICY WILL BE REVISED AS NECESSARY AND
REVIEWED NO LESS THAN ANNUALLY.**

Signed: _____

Title: Director, Pharmacy Services

Date: March 1, 2022

Devised: 1/17/18
Reviewed: 3/1/18 – annual review
Revised: 3/1/19 – annual review, added QL approval note
Revised: 3/1/20 – annual review, added GHP Kids
Revised: 3/1/21 – annual review, updated logo, added MediSpan approval level, updated QL statement
Revised: 3/1/22 – annual review, updated referenced policies & covered LOBs



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 487.0

**SECTION: Commercial Drug
SUBJECT: Quantity Limit Exceptions**

Applicable line of business:

Commercial	X	Medicaid	
Medicare		ACA	X
GHP Kids	X	Self-Insured	X

POLICY:

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for quantity limit exceptions for GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 487.0 Quantity Limit Exceptions

REQUIRED DEFINITIONS:

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ADDITIONAL DEFINITIONS:

1. **Formulary** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. **Non-formulary products** – those medications that are not included in the Formulary.
3. **Healthcare provider** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
4. **NCQA** – National Committee for Quality Assurance.
5. **Medically Necessary or Medical Necessity** – covered services rendered by a provider that the Health Plan determines are:



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 487.0

**SECTION: Commercial Drug
SUBJECT: Quantity Limit Exceptions**

- A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
- B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
- C. In accordance with current standards of medical practice;
- D. Not primarily for the convenience of the Member, or the Member's Provider; and
- E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

PROCEDURE:

A quantity limit exception may be made for members who meet the following criteria:

- Medical record documentation that requested dose cannot be achieved by using a formulary alternative (i.e.- use of one 10mg tablet in place of two 5mg tablets) **AND**
- Medical record documentation that prescribed dosage does not exceed those approved by the Food and Drug Administration (FDA) or accepted standards of care **AND**
- If request is for dose that exceeds Food and Drug Administration (FDA) approved labeling, medical record documentation of peer-reviewed literature citing well-designed clinical trials to indicate that the member's healthcare outcome will be improved by dosing that exceeds FDA approved labeling **AND**
- Medical record documentation that current formulary quantity limit has been ineffective in management of member's condition

MEDISPAN AUTHORIZATION LEVEL: GPI-14

If a quantity limit exception is approved, the drug will be paid for under the member's prescription drug benefit.

Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.

FORMULARY ALTERNATIVES:

not applicable



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 487.0

**SECTION: Commercial Drug
SUBJECT: Quantity Limit Exceptions**

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE
STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND
FEDERAL REGULATORY ENTITIES.**

**THIS POLICY WILL BE REVISED AS NECESSARY AND
REVIEWED NO LESS THAN ANNUALLY.**

Signed: _____

Title: Director, Pharmacy Services

Date: March 1, 2022

Devised: 1/17/18
Reviewed: 3/1/18 – annual review
Revised: 8/21/18 – removed authorization duration
Revised: 3/1/19 – annual review, defined FDA
Revised: 3/1/20 – annual review, added GHP Kids
Revised: 3/1/21 – annual review, updated logo, added MediSpan approval level
Revised: 3/1/22 – annual review, updated referenced policies & covered LOBs



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 488.0

**SECTION: Commercial Drug
SUBJECT: Opioid Use**

Applicable line of business:

Commercial	X	Medicaid	
Medicare		ACA	X
GHP Kids	X	Self-Insured	X

POLICY:

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for opioid use for GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

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5. **Medically Necessary or Medical Necessity** – covered services rendered by a provider that the Health Plan determines are:



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 488.0

**SECTION: Commercial Drug
SUBJECT: Opioid Use**

- A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
 - B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
 - C. In accordance with current standards of medical practice;
 - D. Not primarily for the convenience of the Member, or the Member's Provider; and
 - E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.
6. **POS** – point of sale
 7. **MED** – morphine equivalent dose
 8. **OCDP** – opioid cumulative dosing program

POS CUMULATIVE MED EDIT PROGRAM OVERVIEW

The program encompasses five primary components:

1. A POS-level cumulative dosing edit, which calculates cumulative opioid morphine equivalent dosing (MED) and triggers soft or hard-stop edits at time of adjudication based on MED threshold values and program inclusion and exclusion parameters
 - a. Soft-stop POS Edit may be overridden by Professional Pharmacy Service (PPS) response codes or coverage determination from the Health Plan
 - b. Hard-stop POS Edit may be overridden by coverage determination from the Health Plan
2. Exceptions processing to optimize edit targeting and minimize false positives, using both automated and clinical review processes as described below
3. All clinical thresholds and triggers are reviewed by the P&T committee as needed.
4. If at any point during the member review process fraudulent activity is suspected by a pharmacy, prescriber, or member they will be referred to the fraud, waste, and abuse team in accordance with Geisinger Health Plan's Universal Policy 49.

METHODOLOGY FOR ENROLLMENT

1. Inclusion criteria:
 - a. All active, approved prescription claims meeting the following criteria will be counted for total cumulative MED for a plan beneficiary:
 - i. Opioid drug has a defined dose-normalization factor in the POS system, and
 - ii. Opioid is configured as program-eligible in the edit.
 - b. The hard-stop MED threshold, at or above which claims will hard-stop reject, will be: 90 (50 effective 7/1/19)
 - c. The minimum prescriber number threshold will be: 1



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 488.0

**SECTION: Commercial Drug
SUBJECT: Opioid Use**

2. Exclusion criteria:
 - a. Claims identified by the OCDP as overlapping refills of existing therapy will not be included in the cumulative MED calculation.
 - b. History of a prior authorization override will prevent OCDP rejections as described in the Procedure section below
 - c. Member is defined as a hospice member
 - d. Member has active claims history of cancer medication in the last 180 days
 - e. Member has a diagnosis of Sickle cell disease
3. Reject code/POS Denial Language:
 - a. POS Notification: "Cumulative morphine equivalent dose of (patient's current MED) =/exceeds threshold of (MED threshold value) per day"

DURATION OF OPIOID USE PROGRAM OVERVIEW

Any claim for a newly initiated (defined as no opioid claims history in the past 120 days) short-acting opioid greater than a 3 day supply for a child under the age of 18 years old or greater than a 5 day supply for an adult, or any claim for a long-acting opioid will block at point of sale and require prior authorization.

PROCEDURE:

Prior authorization of opioids will be made for members who meet the following criteria:

- Diagnosis of active cancer or palliative care **OR**
- Diagnosis of sickle cell disease **OR**
- Member is receiving hospice care

NOTE: Authorizations will be entered for an opioid class override for members who meet these criteria

AND For members who do not meet the above criteria:

For short-acting opioid requests to exceed an initial 3 day supply for a member under the age of 18 years or for greater than a 5 day supply for a member greater than or equal to 18 years:

- Medical record documentation of prescriber attestation that greater than a 3 day supply for members under the age of 18 or greater than a 5 days supply for members 18 years of age and older is medically necessary to treat the member's pain **OR**
- Medical record documentation that member is already established on opioid therapy

NOTE: Authorizations will be entered as a one-time override, RX count 1 for the remainder of the calendar year.

AND

For requests exceeding the MED threshold and/or for long-acting opioids, the following documentation will be required:

- Medical record documentation of therapeutic failure on, intolerance to, or contraindication to first line drug and non-drug treatments for pain **AND**
- Prescriber has assessed the member's pain, cause of pain, and documented the anticipated duration of therapy **AND**
- Medical record documentation that the member is:
 - being treated for non-cancer pain **AND**
 - the prescription is written by a Pain Management Specialist **OR** the member has been referred to a Pain Management Specialist for the same condition within the previous 24 months **OR**
 - the member has a signed pain contract in place

AND

- The prescriber will conduct urine drug screening (UDS), which includes testing for the prescribed opioid per the Centers for Disease Control (CDC) Guideline for Prescribing Opioids for Chronic Pain – United States 2016 **AND**
- Provider has evaluated member for risk of opioid use disorder using CAGE-AID, Opioid Risk Tool, or a similar screening tool upon initiation of opioids and every 3 months or as needed **AND**
- There is a plan for the tapering of benzodiazepines or rationale for continued use (if applicable) **AND**
- The prescriber has queried the State's Prescription Drug Monitoring System with every controlled substance written to ensure controlled substance history is consistent with prescribing record **AND**
- The prescriber has discussed the risks of addiction and overdose with the minor and parent, guardian or authorized adult if under the age of 18 **AND**
- If under the age of 18, the prescriber has obtained written consent for the prescription from the minor's parent/guardian/authorized adult on a standardized consent form **AND**
- There is medical record documentation that the member or parent/guardian has been educated on the potential adverse effects of opioid analgesics, including the risk for misuse, abuse and addiction **AND** the member will receive a prescription for naloxone if dose of opioid is 120 morphine equivalents (MEDs) (50 MEDs for minors) or greater and member is not being treated for end of life **OR** if the prescriber determines the member is at risk for an overdose at any MED.

AND



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 488.0

**SECTION: Commercial Drug
SUBJECT: Opioid Use**

For a long-acting opioid:

- Medical record documentation of therapeutic failure on, intolerance to, or contraindication to a short-acting opioid.

OR if the above criteria is not met:

- The Plan will work with the prescriber and provide authorization for the requested medication during a period of tapering in accordance with accepted standards of care. During this tapering process, referral will be made to case management to offer assistance to the member during the transition process.

AND for non-preferred opioids:

For non-preferred short-acting opioids:

- Medical record documentation of a therapeutic failure on, intolerance to or contraindication to three preferred short-acting formulary alternatives, one of which must be oxycodone **OR**
- If the request is for an abuse-deterrent formulation (RoxyBond), medical record documentation that the patient is at high risk of abusing opioids (e.g., past history of abuse, untreated psychiatric disorders, social or family environments that encourage misuse, or positive CAGE-AID screen).

For fentanyl citrate oral lozenge (generic Actiq)

- Medical record documentation of age greater than or equal to 16 years **AND**
- Medical record documentation that the member has a diagnosis of cancer and is receiving scheduled opioid therapy **AND**
- Medical record documentation of therapeutic failure on, intolerance to, or contraindication to immediate-release morphine sulfate **OR** immediate-release oxycodone

For Abstral, Lazanda, Fentora, Subsys

- Medical record documentation of age greater than or equal to 18 years **AND**
- Medical record documentation that the member has a diagnosis of cancer and is receiving scheduled opioid therapy **AND**
- Medical record documentation of therapeutic failure on, intolerance to, or contraindication to fentanyl lozenges* (generic Actiq) **AND** immediate-release morphine sulfate **OR** immediate-release oxycodone



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 488.0

**SECTION: Commercial Drug
SUBJECT: Opioid Use**

For non-preferred long acting opioids:

- Medical record documentation of a therapeutic failure on, intolerance to or contraindication to three preferred long-acting opioid formulary alternatives, one of which must be morphine sulfate ER **OR**
- If the request is for an abuse-deterrent formulation (see table below), medical record documentation that the patient is at high risk of abusing opioids (e.g., past history of abuse, untreated psychiatric disorders, social or family environments that encourage misuse, or positive CAGE-AID screen).

For Nucynta ER for neuropathic pain:

- Medical record documentation of a therapeutic failure on, intolerance to or contraindication to three preferred long-acting opioid formulary alternatives, one of which must be morphine sulfate ER **AND** Lyrica **AND** duloxetine

For oxycodone ER or OxyContin:

- Medical record documentation of a therapeutic failure on, intolerance to or contraindication to three preferred long-acting opioid formulary alternatives, one of which must be morphine ER **OR**
- Medical record documentation that the patient is 11 to < 18 years of age **OR**
- For Oxycontin (brand) – Medical record documentation that the patient is at high risk of abusing opioids (e.g., past history of abuse, untreated psychiatric disorders, social or family environments that encourage misuse, or positive CAGE-AID screen)

MEDISPAN AUTHORIZATION LEVEL: GPI-14

AUTHORIZATION DURATION:

- For chronic non-cancer pain, active cancer or palliative care, and hospice care: 1 year
- For sickle cell disease: lifetime
- For stabilization of an acute medical condition: stated duration of treatment
- For initial day supply exceeding 3 (member <18 years of age) or 5 days (members 18 years of age and older): one-time override, RX count 1 for remainder of calendar year
- For tapering the member off opioids: 1 year or the time requested by the prescriber for tapering, whichever is less



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 488.0

**SECTION: Commercial Drug
SUBJECT: Opioid Use**

Reference Table: Abuse-Deterrent Opioids and Routes of Abuse Each is Intended to Deter

Drug	Drug Deters Abuse Via These Routes		
	IV/injection	Intranasal	Oral
Arymo ER	X		
Embeda		X	X
Hysingla ER	X	X	X
MorphaBond ER	X	X	
OxyContin (oxycodone ER)	X	X	
Troxyca ER		X	X
Xtampza ER	X	X	X
RoxyBond	X	X	

If an exception is made, the opioid will be paid for under the member's prescription drug benefit.

Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.

FORMULARY ALTERNATIVES:

NSAIDs: celecoxib, choline magnesium salicylate, diclofenac, diclofenac extended release, diflunisal, etodolac, etodolac extended release, fenoprofen, flurbiprofen, ibuprofen, indomethacin, indomethacin sustained-release, ketoprofen, ketorolac[^], meclufenamate, meloxicam, nabumetone, naproxen, naproxen sodium, naproxen ec, oxaprozin, piroxicam, salsalate, sulindac, tolmetin

Short-acting opioids: acetaminophen/codeine, butorphanol nasal spray*, codeine solution, codeine tablets, hydrocodone/acetaminophen, hydrocodone/ibuprofen, hydromorphone liquid, hydromorphone tablet, levorphanol*, meperidine, morphine solution, morphine tablet, oxycodone acetaminophen solution, oxycodone/acetaminophen tablet, oxycodone/aspirin, oxycodone/ibuprofen, oxycodone capsule, oxycodone tablet, oxycodone solution, oxymorphone, pentazocine/naloxone*, Roxicodone, tramadol, tramadol/acetaminophen

Long-acting opioids: buprenorphine transdermal patch*[^], fentanyl transdermal patch*, methadone tablets*, morphine ER tablet*, morphine ER capsules*, oxycodone ER*, tramadol ER capsule*, tramadol ER tablet

Additional Alternatives for Nucynta ER: Lyrica, duloxetine

Additional Alternatives for Abstral, Lazanda, Fentora, Subsys: fentanyl lozenges*

* prior authorization required

[^] quantity limits apply



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 488.0

**SECTION: Commercial Drug
SUBJECT: Opioid Use**

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE
STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND
FEDERAL REGULATORY ENTITIES.**

**THIS POLICY WILL BE REVISED AS NECESSARY AND
REVIEWED NO LESS THAN ANNUALLY.**

Signed: _____

Title: Director, Pharmacy Services

Date: March 1, 2022

- Devised: 2/15/18
- Reviewed: 3/1/18 – annual review
- Revised: 8/20/18 – removed cough/cold from calculation, removed soft stop, updated hard stop to 90 MED, added duration of opioid use program, updated non-opioid criteria, added assessment of therapy duration criteria, added day supply criteria, updated UDS to CDC guidelines, added LA opioid criteria, added NP opioid criteria
- Revised: 8/28/18 – added non-preferred LA opioid/Nucynta ER for neuropathic pain/oxycodone ER criteria, added abuse deterrent reference tablet, added FA
- Revised: 3/1/19 – annual review, defined abbr.
- Revised: 6/4/19 – updated MED limit, added newly initiated to duration of use overview, added duration of use criteria for initial fills, updated description for all other criteria, removed requirement of chronic pain, removed stabilization of acute medication condition/taper
- Revised: 7/24/19 – added auth duration to initial day supply reviews
- Revised: 3/1/20 – annual review, added GHP Kids
- Revised: 6/9/20 – corrected typo
- Revised: 3/1/21 – annual review, updated logo, added MediSpan approval level, deleted note
- Revised: 3/1/22 – annual review, updated referenced policies & covered LOBs



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 489.0

**SECTION: Commercial Drug
SUBJECT: Auryxia**

Applicable line of business:

Commercial	X	Medicaid	
Medicare		ACA	X
GHP Kids	X	Self-Insured	X

POLICY:

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for Auryxia for GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 487.0 Quantity Limit Exceptions

REQUIRED DEFINITIONS:

1. **Attachment** – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. **Exhibit** – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. **Devised** – the date the policy was implemented.
4. **Revised** – the date of every revision to the policy, including typographical and grammatical changes.
5. **Reviewed** – the date documenting the annual review if the policy has no revisions necessary.

ADDITIONAL DEFINITIONS:

1. **Formulary** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. **Non-formulary products** – those medications that are not included in the Formulary.
3. **Healthcare provider** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
4. **NCQA** – National Committee for Quality Assurance.
5. **Medically Necessary or Medical Necessity** – covered services rendered by a provider that the Health Plan determines are:

- A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
- B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
- C. In accordance with current standards of medical practice;
- D. Not primarily for the convenience of the Member, or the Member's Provider; and
- E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

PROCEDURE:

A formulary exception for coverage of Auryxia may be made for members who meet the following criteria:

Hyperphosphatemia

- Medical record documentation of age greater than or equal to 18 years **AND**
- Medical record documentation that Auryxia is prescribed by a nephrologist **AND**
- Medical record documentation of a diagnosis of chronic kidney disease (CKD) on dialysis **AND**
- Medical record documentation that Auryxia is being used to control serum phosphorus levels **AND**
- Medical record documentation of therapeutic failure on, intolerance to, or contraindication to calcium acetate **AND** sevelamer carbonate **AND** lanthanum carbonate

Iron Deficiency Anemia

- Medical record documentation of age greater than or equal to 18 years **AND**
- Medical record documentation that Auryxia is prescribed by a nephrologist **AND**
- Medical record documentation of a diagnosis of iron deficiency anemia and chronic kidney disease **AND**
- Medical record documentation that the member is not receiving dialysis

MEDISPAN AUTHORIZATION LEVEL: GPI-12

QUANTITY LIMIT: *No QLs need to be entered within the authorization unless the requested quantity exceeds the QL.*

- **QL FOR LETTER ONLY: 12 tablets per day**



POLICY NUMBER: 489.0

**POLICY AND PROCEDURE
PHARMACY
MANUAL**

**SECTION: Commercial Drug
SUBJECT: Auryxia**

If a formulary exception is approved Auryxia will be paid for under the member's prescription drug benefit.

Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.

FORMULARY ALTERNATIVES:

calcium acetate, Eliphos, sevelamer carbonate, lanthanum carbonate, Fosrenol powder packet

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE
STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND
FEDERAL REGULATORY ENTITIES.**

**THIS POLICY WILL BE REVISED AS NECESSARY AND
REVIEWED NO LESS THAN ANNUALLY.**

Signed: _____

Title: Director, Pharmacy Services

Date: March 1, 2022

Devised: 4/5/18
Revised: 3/1/19 – annual review, added QL approval note
Revised: 3/1/20 – annual review, added GHP Kids
Revised: 3/1/21 – annual review, updated logo, added MediSpan approval level, updated QL statement
Revised: 3/1/22 – annual review, updated referenced policies & covered LOBs



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 490.0

**SECTION: Commercial Drug
SUBJECT: Cotempla XR-ODT**

Applicable line of business:

Commercial	X	Medicaid	
Medicare		ACA	X
GHP Kids	X	Self-Insured	X

POLICY:

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for Cotempla XR-ODT for GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 487.0 Quantity Limit Exceptions

REQUIRED DEFINITIONS:

1. **Attachment** – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. **Exhibit** – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. **Devised** – the date the policy was implemented.
4. **Revised** – the date of every revision to the policy, including typographical and grammatical changes.
5. **Reviewed** – the date documenting the annual review if the policy has no revisions necessary.

ADDITIONAL DEFINITIONS:

1. **Formulary** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. **Non-formulary products** – those medications that are not included in the Formulary.
3. **Healthcare provider** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
4. **NCQA** – National Committee for Quality Assurance.
5. **Medically Necessary or Medical Necessity** – covered services rendered by a provider that the Health Plan determines are:

- A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
- B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
- C. In accordance with current standards of medical practice;
- D. Not primarily for the convenience of the Member, or the Member's Provider; and
- E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

PROCEDURE:

New members to the plan already established on therapy may be eligible for continuity of care coverage as long as there is medical record documentation that the safety and effectiveness of use for the prescribed indication is supported by Food and Drug Administration (FDA) approval or adequate medical and scientific evidence in the medical literature.

A formulary exception for coverage of Cotempla XR-ODT may be made for members who meet the following criteria:

- Medical record documentation of age greater than or equal to 6 years **AND**
- Medical record documentation of a diagnosis of attention deficit hyperactivity disorder (ADHD) **AND**
- Medical record documentation of therapeutic failure on, intolerance to, or contraindication to methylphenidate CD (generic Metadate CD) **AND** amphetamine/dextroamphetamine SR combination

MEDISPAN AUTHORIZATION LEVEL: GPI-12

QUANTITY LIMIT: *No QLs need to be entered within the authorization unless the requested quantity exceeds the QL.*

- **QL FOR LETTER ONLY:**
 - 8.6 mg and 17.3 mg tablets: 1 tablet per day
 - 25.9 mg tablets: 2 tablets per day

Notes:

Per the Metadate CD prescribing information: "Metadate CD may be swallowed whole with the aid of liquids, or alternately, the capsule may be opened and the capsule contents sprinkled onto a small amount (tablespoon) of applesauce and given immediately, and not stored for future use. Drinking some fluids e.g., water, should follow

the intake of the sprinkles with applesauce. The capsules and the capsule contents must not be crushed or chewed.”

Per the Adderall XR prescribing information: “The capsules may be taken whole or the contents of the capsule may be sprinkled on applesauce. If using the sprinkle method, the applesauce should be consumed immediately and swallowed without chewing. The dose of a single capsule should not be divided and the contents of the entire capsule should be taken.”

If a formulary exception is approved Cotempla XR-ODT will be paid for under the member’s prescription drug benefit.

Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.

FORMULARY ALTERNATIVES:

dextroamphetamine, dextroamphetamine/amphetamine combination, dextroamphetamine/amphetamine SR combination, methylphenidate, methylphenidate sustained-release, methylphenidate extended-release, methylphenidate CD

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE
STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND
FEDERAL REGULATORY ENTITIES.**

**THIS POLICY WILL BE REVISED AS NECESSARY AND
REVIEWED NO LESS THAN ANNUALLY.**

Signed:  _____

Title: Director, Pharmacy Services

Date: March 1, 2022

Devised: 4/5/18

Revised: 3/1/19 – annual review, added QL approval note

Revised: 3/1/20 – annual review, added GHP Kids

Revised: 3/1/21 – annual review, updated logo, added MediSpan approval level, updated QL statement

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Dev. 4/5/18

Rev. 3/1/22



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 490.0

**SECTION: Commercial Drug
SUBJECT: Cotelpla XR-ODT**

Revised: 3/1/22 – annual review, updated referenced policies & covered LOBs



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 491.0

**SECTION: Commercial Drug
SUBJECT: Mydayis**

Applicable line of business:

Commercial	X	Medicaid	
Medicare		ACA	X
GHP Kids	X	Self-Insured	X

POLICY:

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for Mydayis for GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 487.0 Quantity Limit Exceptions

REQUIRED DEFINITIONS:

1. **Attachment** – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. **Exhibit** – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. **Devised** – the date the policy was implemented.
4. **Revised** – the date of every revision to the policy, including typographical and grammatical changes.
5. **Reviewed** – the date documenting the annual review if the policy has no revisions necessary.

ADDITIONAL DEFINITIONS:

1. **Formulary** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. **Non-formulary products** – those medications that are not included in the Formulary.
3. **Healthcare provider** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
4. **NCQA** – National Committee for Quality Assurance.
5. **Medically Necessary or Medical Necessity** – covered services rendered by a provider that the Health Plan determines are:



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 491.0

**SECTION: Commercial Drug
SUBJECT: Mydayis**

- A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
- B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
- C. In accordance with current standards of medical practice;
- D. Not primarily for the convenience of the Member, or the Member's Provider; and
- E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

PROCEDURE:

New members to the plan already established on therapy may be eligible for continuity of care coverage as long as there is medical record documentation that the safety and effectiveness of use for the prescribed indication is supported by Food and Drug Administration (FDA) approval or adequate medical and scientific evidence in the medical literature.

A formulary exception for coverage of Mydayis may be made for members who meet the following criteria:

- Medical record documentation of age greater than or equal to 13 years **AND**
- Medical record documentation of a diagnosis of attention deficit hyperactivity disorder (ADHD) **AND**
- Medical record documentation of therapeutic failure on, intolerance to, or contraindication to methylphenidate CD (generic Metadate CD) **AND** amphetamine/dextroamphetamine SR combination

MEDISPAN AUTHORIZATION LEVEL: GPI-12

QUANTITY LIMIT: *No QLs need to be entered within the authorization unless the requested quantity exceeds the QL.*

- **QL FOR LETTER ONLY:** 1 tablet per day

If a formulary exception is approved Mydayis will be paid for under the member's prescription drug benefit.

Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.

Geisinger

**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 491.0

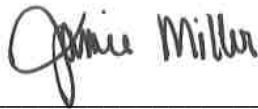
**SECTION: Commercial Drug
SUBJECT: Mydayis**

FORMULARY ALTERNATIVES:

dextroamphetamine, dextroamphetamine/amphetamine combination,
dextroamphetamine/amphetamine SR combination, methylphenidate, methylphenidate
sustained-release, methylphenidate extended-release, methylphenidate CD

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE
STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND
FEDERAL REGULATORY ENTITIES.**

**THIS POLICY WILL BE REVISED AS NECESSARY AND
REVIEWED NO LESS THAN ANNUALLY.**



Signed: _____

Title: Director, Pharmacy Services

Date: March 1, 2022

Devised: 4/6/18

Revised: 3/1/19 – annual review, added QL approval note

Revised: 3/1/20 – annual review, added GHP Kids

Revised: 3/1/21 – annual review, updated logo, added MediSpan approval level, updated QL statement

Revised: 3/1/22 – annual review, updated referenced policies & covered LOBs



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 492.0

**SECTION: Commercial Drug
SUBJECT: Symproic**

Applicable line of business:

Commercial	X	Medicaid	
Medicare		ACA	X
GHP Kids	X	Self-Insured	X

POLICY:

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for Symproic for GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 487.0 Quantity Limit Exceptions

REQUIRED DEFINITIONS:

1. **Attachment** – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. **Exhibit** – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. **Devised** – the date the policy was implemented.
4. **Revised** – the date of every revision to the policy, including typographical and grammatical changes.
5. **Reviewed** – the date documenting the annual review if the policy has no revisions necessary.

ADDITIONAL DEFINITIONS:

1. **Formulary** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. **Non-formulary products** – those medications that are not included in the Formulary.
3. **Healthcare provider** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
4. **NCQA** – National Committee for Quality Assurance.
5. **Medically Necessary or Medical Necessity** – covered services rendered by a provider that the Health Plan determines are:



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 492.0

**SECTION: Commercial Drug
SUBJECT: Symproic**

- A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
- B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
- C. In accordance with current standards of medical practice;
- D. Not primarily for the convenience of the Member, or the Member's Provider; and
- E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

PROCEDURE:

A formulary exception for coverage of Symproic may be made for members who meet the following criteria:

- Medical record documentation of age greater than or equal to 18 years **AND**
- Medical record documentation of use for opioid-induced constipation associated with chronic non-cancer pain, including patients with chronic pain related to prior cancer or it's treatment **AND**
- Medical record documentation current use of an opioid medication for greater than or equal to 4 weeks **AND**
- Medical record documentation of therapeutic failure on, intolerance to, or contraindication to one stimulant laxative **AND** one osmotic laxative **AND** Movantik **AND** lubiprostone

MEDISPAN AUTHORIZATION LEVEL: GPI-12

QUANTITY LIMIT: *No QLs need to be entered within the authorization unless the requested quantity exceeds the QL.*

- **QL FOR LETTER ONLY:** 1 tablet per day

If a formulary exception is approved Symproic will be paid for under the member's prescription drug benefit.

Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 492.0

**SECTION: Commercial Drug
SUBJECT: Symproic**

FORMULARY ALTERNATIVES:
lubiprostone, Movantik

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE
STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND
FEDERAL REGULATORY ENTITIES.**

**THIS POLICY WILL BE REVISED AS NECESSARY AND
REVIEWED NO LESS THAN ANNUALLY.**

Signed: _____

Title: Director, Pharmacy Services

Date: March 1, 2022

Devised: 4/6/18
Revised: 3/1/19 – annual review, added QL approval note
Revised: 3/1/20 – annual review, added GHP Kids
Revised: 3/1/21 – annual review, updated logo, added MediSpan approval level, updated QL statement,
updated Amitiza to generic
Revised: 3/1/22 – annual review, updated referenced policies & covered LOBs



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 493.0

**SECTION: Commercial Drug
SUBJECT: Benznidazole**

Applicable line of business:

Commercial	X	Medicaid	
Medicare		ACA	X
GHP Kids	X	Self-Insured	X

POLICY:

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for Benznidazole for GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 487.0 Quantity Limit Exceptions

REQUIRED DEFINITIONS:

1. **Attachment** – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. **Exhibit** – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. **Devised** – the date the policy was implemented.
4. **Revised** – the date of every revision to the policy, including typographical and grammatical changes.
5. **Reviewed** – the date documenting the annual review if the policy has no revisions necessary.

ADDITIONAL DEFINITIONS:

1. **Formulary** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. **Non-formulary products** – those medications that are not included in the Formulary.
3. **Healthcare provider** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
4. **NCQA** – National Committee for Quality Assurance.
5. **Medically Necessary or Medical Necessity** – covered services rendered by a provider that the Health Plan determines are:

- A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
- B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
- C. In accordance with current standards of medical practice;
- D. Not primarily for the convenience of the Member, or the Member's Provider; and
- E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

PROCEDURE:

A formulary exception for coverage of Benznidazole may be made for members who meet the following criteria:

- Medical record documentation of age greater than or equal to 2 years and less than or equal to 12 years **AND**
- Medical record documentation that Benznidazole is prescribed by or in consultation with an infectious disease specialist **AND**
- Medical record documentation of a diagnosis of Chagas disease confirmed by one of the following diagnostic tests:
 - Detection of circulating *Trypanosoma cruzi* trypomastigotes on microscopy **OR**
 - Detection of *T. cruzi* DNA by polymerase chain reaction assay **OR**
 - Two positive diagnostic serologic tests using different techniques (ex. enzyme-linked immunoassay (ELISA), indirect fluorescent antibody (IFA)) and antigens (ex. whole-parasite lysate, recombinant antigens) showing IgG antibodies to *T. cruzi*

MEDISPAN AUTHORIZATION LEVEL: GPI-12

QUANTITY LIMIT: *No QLs need to be entered within the authorization unless the requested quantity exceeds the QL.*

- **QL FOR LETTER ONLY:**
 - 100 mg tablets: 4 tablets per day, 30 day supply per fill
 - 12.5 mg tablets: 2 tablets per day, 30 day supply per fill

AUTHORIZATION DURATION: 60 days, RX count 2



POLICY NUMBER: 493.0

**POLICY AND PROCEDURE
PHARMACY
MANUAL**

**SECTION: Commercial Drug
SUBJECT: Benznidazole**

If a formulary exception is approved Benznidazole will be paid for under the member's prescription drug benefit.

Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.

FORMULARY ALTERNATIVES:

none

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE
STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND
FEDERAL REGULATORY ENTITIES.**

**THIS POLICY WILL BE REVISED AS NECESSARY AND
REVIEWED NO LESS THAN ANNUALLY.**

Signed: _____

Title: Director, Pharmacy Services

Date: March 1, 2022

Devised: 4/6/18
Revised: 3/1/19 – annual review, added QL approval note
Revised: 3/1/20 – annual review, added GHP Kids
Revised: 3/1/21 – annual review, updated logo, added MediSpan approval level, updated QL statement
Revised: 3/1/22 – annual review, updated referenced policies & covered LOBs



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 494.0

**SECTION: Commercial Drug
SUBJECT: Baxdela Tablets**

Applicable line of business:

Commercial	X	Medicaid	
Medicare		ACA	X
GHP Kids	X	Self-Insured	X

POLICY:

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for Baxdela tablets for GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 487.0 Quantity Limit Exceptions

REQUIRED DEFINITIONS:

1. **Attachment** – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. **Exhibit** – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. **Devised** – the date the policy was implemented.
4. **Revised** – the date of every revision to the policy, including typographical and grammatical changes.
5. **Reviewed** – the date documenting the annual review if the policy has no revisions necessary.

ADDITIONAL DEFINITIONS:

1. **Formulary** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. **Non-formulary products** – those medications that are not included in the Formulary.
3. **Healthcare provider** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
4. **NCQA** – National Committee for Quality Assurance.
5. **Medically Necessary or Medical Necessity** – covered services rendered by a provider that the Health Plan determines are:

- A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
- B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
- C. In accordance with current standards of medical practice;
- D. Not primarily for the convenience of the Member, or the Member's Provider; and
- E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

PROCEDURE:

A formulary exception for coverage of Baxdela tablets may be made for members who meet the following criteria:

- Medical record documentation of age greater than or equal to 18 years **AND**
- Medical record documentation that Baxdela is prescribed by or in consultation with infectious disease **AND**
- Medical record documentation of one of the following:
 - Diagnosis of acute bacterial skin and skin structure infections (ABSSSI)* caused by susceptible isolates of the following: *Staphylococcus aureus* (including methicillin-resistant [MRSA] and methicillin-susceptible [MSSA] isolates), *Staphylococcus haemolyticus*, *Staphylococcus lugdunensis*, *Streptococcus agalactiae*, *Streptococcus anginosus Group* (including *Streptococcus anginosus*, *Streptococcus intermedius*, and *Streptococcus constellatus*), *Streptococcus pyogenes*, *Enterococcus faecalis*, *Escherichia coli*, *Enterobacter cloacae*, *Klebsiella pneumoniae*, or *Pseudomonas aeruginosa* **OR**
 - Diagnosis of community-acquired bacterial pneumonia (CABP) caused by the following susceptible microorganisms: *Streptococcus pneumoniae*, *Staphylococcus aureus* (methicillin susceptible [MSSA] isolates only), *Klebsiella pneumoniae*, *Escherichia coli*, *Pseudomonas aeruginosa*, *Haemophilus influenzae*, *Haemophilus parainfluenzae*, *Chlamydia pneumoniae*, *Legionella pneumophila*, and *Mycoplasma pneumoniae* **AND**
- Medical record documentation of culture and sensitivity showing the patient's infection is not susceptible to alternative antibiotic treatments **OR** a documented history of previous intolerance to or contraindication to other antibiotics shown to be susceptible on the culture and sensitivity **OR**
- Medical record documentation that Baxdela therapy was started during an inpatient setting



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 494.0

**SECTION: Commercial Drug
SUBJECT: Baxdela Tablets**

MEDISPAN AUTHORIZATION LEVEL: GPI-12

QUANTITY LIMIT: *No QLs need to be entered within the authorization unless the requested quantity exceeds the QL.*

- **QL FOR LETTER ONLY:** 2 tablets per day

AUTHORIZATION DURATION:

- **ABSSSI:** one-time, 14-day authorization
- **CABP:** one-time, 10-day authorization

Note: ABSSSI is defined as a skin infection with a lesion surface area of at least 75 cm² and includes the three following types of infection: (1) cellulitis/erysipelas, (2) wound infections, and (3) major cutaneous abscesses.

If a formulary exception is approved Baxdela will be paid for under the member's prescription drug benefit.

Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.

FORMULARY ALTERNATIVES:

ciprofloxacin, clindamycin, doxycycline, levofloxacin, linezolid, minocycline, moxifloxacin, ofloxacin, sulfamethoxazole/TMP

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE
STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND
FEDERAL REGULATORY ENTITIES.**

**THIS POLICY WILL BE REVISED AS NECESSARY AND
REVIEWED NO LESS THAN ANNUALLY.**

Signed: _____

Title: Director, Pharmacy Services

Date: March 1, 2022

HPRX02

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Dev. 4/6/18

Rev. 3/1/22



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 494.0

**SECTION: Commercial Drug
SUBJECT: Baxdela Tablets**

Devised: 4/6/18
Revised: 3/1/19 – annual review, added QL approval note
Revised: 3/1/20 – annual review, added GHP Kids
Revised: 4/21/20 – added CABP indication
Revised: 3/1/21 – annual review, updated logo, added MediSpan approval level, updated QL statement
Revised: 3/1/22 – annual review, updated referenced policies & covered LOBs



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 495.0

**SECTION: Commercial Drug
SUBJECT: Qtern**

Applicable line of business:

Commercial	X	Medicaid	
Medicare		ACA	X
GHP Kids	X	Self-Insured	X

POLICY:

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for Qtern for GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 487.0 Quantity Limit Exceptions

REQUIRED DEFINITIONS:

1. **Attachment** – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. **Exhibit** – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. **Devised** – the date the policy was implemented.
4. **Revised** – the date of every revision to the policy, including typographical and grammatical changes.
5. **Reviewed** – the date documenting the annual review if the policy has no revisions necessary.

ADDITIONAL DEFINITIONS:

1. **Formulary** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. **Non-formulary products** – those medications that are not included in the Formulary.
3. **Healthcare provider** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
4. **NCQA** – National Committee for Quality Assurance.
5. **Medically Necessary or Medical Necessity** – covered services rendered by a provider that the Health Plan determines are:



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 495.0

**SECTION: Commercial Drug
SUBJECT: Qtern**

- A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
- B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
- C. In accordance with current standards of medical practice;
- D. Not primarily for the convenience of the Member, or the Member's Provider; and
- E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

PROCEDURE:

A formulary exception for coverage of Qtern may be made for members who meet the following criteria:

- Medical record documentation of age greater than or equal to 18 years **AND**
- Medical record documentation of a diagnosis of type II diabetes mellitus **AND**
- Medical record documentation of therapeutic failure on, intolerance to, or contraindication to Glyxambi **OR**
- Medical record documentation of therapeutic failure on, intolerance to, or contraindication to Tradjenta **AND** one formulary SGLT2 inhibitor

MEDISPAN AUTHORIZATION LEVEL: GPI-12

QUANTITY LIMIT: *No QLs need to be entered within the authorization unless the requested quantity exceeds the QL.*

- **QL FOR LETTER ONLY:** 1 tablet per day

If a formulary exception is approved Qtern will be paid for under the member's prescription drug benefit.

Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.

FORMULARY ALTERNATIVES:

Glyxambi, Invokana, Invokamet, Jardiance, Tradjenta, Jentadueto

Geisinger

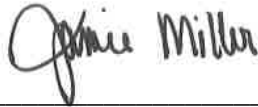
**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 495.0

**SECTION: Commercial Drug
SUBJECT: Qtern**

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE
STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND
FEDERAL REGULATORY ENTITIES.**

**THIS POLICY WILL BE REVISED AS NECESSARY AND
REVIEWED NO LESS THAN ANNUALLY.**



Signed: _____

Title: Director, Pharmacy Services

Date: March 1, 2022

Devised: 4/6/18
Revised: 5/3/18 – added QL as approved at 3/18 P&T
Revised: 5/30/18 – updated failure to Glyxambi OR Tradjenta/SGLT2 inhibitor, updated FA
Revised: 3/1/19 – annual review, added QL approval note, updated FA
Revised: 3/1/20 – annual review, added GHP Kids
Revised: 3/1/21 – annual review, updated logo, added MediSpan approval level, updated QL statement
Revised: 3/1/22 – annual review, updated referenced policies & covered LOBs



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 497.0

**SECTION: Commercial Drug
SUBJECT: Endari**

Applicable line of business:

Commercial	X	Medicaid	
Medicare		ACA	X
GHP Kids	X	Self-Insured	X

POLICY:

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for Endari for GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 487.0 Quantity Limit Exceptions

REQUIRED DEFINITIONS:

1. **Attachment** – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. **Exhibit** – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. **Devised** – the date the policy was implemented.
4. **Revised** – the date of every revision to the policy, including typographical and grammatical changes.
5. **Reviewed** – the date documenting the annual review if the policy has no revisions necessary.

ADDITIONAL DEFINITIONS:

1. **Formulary** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. **Non-formulary products** – those medications that are not included in the Formulary.
3. **Healthcare provider** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
4. **NCQA** – National Committee for Quality Assurance.
5. **Medically Necessary or Medical Necessity** – covered services rendered by a provider that the Health Plan determines are:



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 497.0

**SECTION: Commercial Drug
SUBJECT: Endari**

- A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
- B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
- C. In accordance with current standards of medical practice;
- D. Not primarily for the convenience of the Member, or the Member's Provider; and
- E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

PROCEDURE:

A formulary exception for coverage of Endari may be made for members who meet the following criteria:

- Medical record documentation of age greater than or equal to 5 years **AND**
- Medical record documentation that Endari is prescribed by or in consultation with a hematologist **AND**
- Medical record documentation of a diagnosis of sickle cell disease **AND**
- Medical record documentation of Endari being used to reduce the acute complication of sickle cell disease* **AND**
- Medical record documentation intolerance to, or contraindication to, or therapeutic failure on a minimum 3 month trial of generic hydroxyurea

MEDISPAN AUTHORIZATION LEVEL: GPI-12

QUANTITY LIMIT: *No QLs need to be entered within the authorization unless the requested quantity exceeds the QL.*

- QL FOR LETTER ONLY: 6 packets per day, 30 day supply per fill

AUTHORIZATION DURATION: Each treatment period will be defined as 12 months. Re-review will occur every 12 months. The following criteria is required for reauthorization:

- Medical record documentation of continued or sustained improvement in the acute complications of sickle cell disease (i.e., number of sickle cell crises, hospitalizations, and number of ACS occurrences)

***Notes:** In clinical trials, patients were included if they had two or more painful crises within the previous 12 months.



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 497.0

**SECTION: Commercial Drug
SUBJECT: Endari**

If a formulary exception is approved Endari will be paid for under the member's prescription drug benefit.

Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.

FORMULARY ALTERNATIVES:

hydroxyurea

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE
STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND
FEDERAL REGULATORY ENTITIES.**

**THIS POLICY WILL BE REVISED AS NECESSARY AND
REVIEWED NO LESS THAN ANNUALLY.**

Signed: _____

Title: Director, Pharmacy Services

Date: March 1, 2022

Devised: 4/6/18

Revised: 5/29/18 – corrected typo in title, removed references to Tremfya

Revised: 3/1/19 – annual review, added QL approval note

Revised: 01/17/20 – added minimum 3 month trial on hydroxyurea, removed note on NHLBI guidelines

Revised: 3/1/20 – annual review, added GHP Kids

Revised: 3/1/21 – annual review, updated logo, added MediSpan approval level, updated QL statement

Revised: 3/1/22 – annual review, updated referenced policies & covered LOBs



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 498.0

**SECTION: Commercial Drug
SUBJECT: Erleada**

Applicable line of business:

Commercial	X	Medicaid	
Medicare		ACA	X
GHP Kids	X	Self-Insured	X

POLICY:

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for Erleada for GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 487.0 Quantity Limit Exceptions

REQUIRED DEFINITIONS:

1. **Attachment** – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. **Exhibit** – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. **Devised** – the date the policy was implemented.
4. **Revised** – the date of every revision to the policy, including typographical and grammatical changes.
5. **Reviewed** – the date documenting the annual review if the policy has no revisions necessary.

ADDITIONAL DEFINITIONS:

1. **Formulary** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. **Non-formulary products** – those medications that are not included in the Formulary.
3. **Healthcare provider** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
4. **NCQA** – National Committee for Quality Assurance.
5. **Medically Necessary or Medical Necessity** – covered services rendered by a provider that the Health Plan determines are:



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 498.0

**SECTION: Commercial Drug
SUBJECT: Erleada**

- A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
- B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
- C. In accordance with current standards of medical practice;
- D. Not primarily for the convenience of the Member, or the Member's Provider; and
- E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

PROCEDURE:

New members to the plan already established on therapy may be eligible for continuity of care coverage as long as there is medical record documentation that the safety and effectiveness of use for the prescribed indication is supported by Food and Drug Administration (FDA) approval or adequate medical and scientific evidence in the medical literature.

A formulary exception for coverage of Erleada may be made for members who meet the following criteria:

- Medical record documentation that Erleada is prescribed by an oncologist or urologist **AND**
- Medical record documentation of one of the following:
 - Medical record documentation of a diagnosis of prostate cancer with evidence of metastatic castration-sensitive disease **OR**
 - Medical record documentation of a diagnosis of prostate cancer with evidence of non-metastatic disease **AND** member is no longer responding to castration or is hormone resistant **AND**
- Medical record documentation that a gonadotropin-releasing hormone (GnRH) analog will be used concurrently **OR** member has had bilateral orchiectomy

MEDISPAN AUTHORIZATION LEVEL: GPI-12, number of claims authorized = 1, enter for the remainder of the calendar year

QUANTITY LIMIT: *No QLs need to be entered within the authorization unless the requested quantity exceeds the QL.*

- **QL FOR LETTER ONLY:** 4 tablets per day, 30 day supply per fill



POLICY NUMBER: 498.0

**POLICY AND PROCEDURE
PHARMACY
MANUAL**

**SECTION: Commercial Drug
SUBJECT: Erleada**

RE-AUTHORIZATION CRITERIA: Erleada is configured as a prior authorization for new starts only. Erleada will no longer be covered if it is identified that the member is not receiving appropriate follow-up care from the prescribing specialist or if the member has greater than or equal to a 90 day break in therapy.

- Medical record documentation that the member is receiving appropriate follow-up care from the prescribing specialist

If a formulary exception is approved Erleada will be paid for under the member's prescription drug benefit.

Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.

FORMULARY ALTERNATIVES:

none

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE
STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND
FEDERAL REGULATORY ENTITIES.**

**THIS POLICY WILL BE REVISED AS NECESSARY AND
REVIEWED NO LESS THAN ANNUALLY.**

Signed: _____

Title: Director, Pharmacy Services

Date: March 1, 2022

Devised: 5/29/18
Revised: 6/11/18 – removed Zytiga and Xtandi from formulary alternatives
Revised: 8/21/18 – added bilateral orchiectomy to GnRH criteria
Revised: 3/1/19 – annual review, added QL approval note
Revised: 11/20/19 – added castration-sensitive indication
Revised: 3/1/20 – annual review, added GHP Kids
Revised: 3/1/21 – annual review, updated logo, added MediSpan approval level, updated QL statement
Revised: 11/24/21 – added one-time PA to approval crit., removed auth duration & added re-auth crit.
Revised: 3/1/22 – annual review, updated referenced policies & covered LOBs

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Dev. 5/29/18

Rev. 3/1/22



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 499.0

**SECTION: Commercial Drug
SUBJECT: Gocovri**

Applicable line of business:

Commercial	X	Medicaid	
Medicare		ACA	X
GHP Kids	X	Self-Insured	X

POLICY:

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for Gocovri for GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 487.0 Quantity Limit Exceptions

REQUIRED DEFINITIONS:

1. **Attachment** – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. **Exhibit** – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. **Devised** – the date the policy was implemented.
4. **Revised** – the date of every revision to the policy, including typographical and grammatical changes.
5. **Reviewed** – the date documenting the annual review if the policy has no revisions necessary.

ADDITIONAL DEFINITIONS:

1. **Formulary** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. **Non-formulary products** – those medications that are not included in the Formulary.
3. **Healthcare provider** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
4. **NCQA** – National Committee for Quality Assurance.
5. **Medically Necessary or Medical Necessity** – covered services rendered by a provider that the Health Plan determines are:



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 499.0

**SECTION: Commercial Drug
SUBJECT: Gocovri**

- A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
- B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
- C. In accordance with current standards of medical practice;
- D. Not primarily for the convenience of the Member, or the Member's Provider; and
- E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

PROCEDURE:

A formulary exception for coverage of Gocovri may be made for members who meet the following criteria:

Dyskinesia with Parkinson's Disease

- Medical record documentation of dyskinesia with a diagnosis of Parkinson's disease **AND**
- Medical record documentation that the member is currently receiving and will continue levodopa-based therapy with the addition of Gocovri **AND**
- Medical record documentation of therapeutic failure on, intolerance to, or contraindication to immediate-release amantadine

Off Episodes with Parkinson's Disease

- Medical record documentation of "off episodes" with a diagnosis of Parkinson's disease **AND**
- Medical record documentation that Gocovri will be used as adjunctive treatment to levodopa/carbidopa

MEDISPAN AUTHORIZATION LEVEL: GPI-12

QUANTITY LIMIT: *No QLs need to be entered within the authorization unless the requested quantity exceeds the QL.*

- **QL FOR LETTER ONLY:**
 - 68.5 mg capsule: 1 capsule per day
 - 137 mg capsule: 2 capsules per day



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 499.0

**SECTION: Commercial Drug
SUBJECT: Gocovri**

If a formulary exception is approved Gocovri will be paid for under the member's prescription drug benefit.

Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.

FORMULARY ALTERNATIVES:

immediate release amantadine, benztropine, trihexyphenidyl, carbidopa/levodopa

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE
STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND
FEDERAL REGULATORY ENTITIES.**

**THIS POLICY WILL BE REVISED AS NECESSARY AND
REVIEWED NO LESS THAN ANNUALLY.**

Signed: _____

Title: Director, Pharmacy Services

Date: March 1, 2022

Devised: 5/29/18
Revised: 3/1/19 – annual review, added QL approval note
Revised: 3/1/20 – annual review, added GHP Kids
Revised: 3/1/21 – annual review, updated logo, added MediSpan approval level, updated QL statement
Revised: 7/23/21 – added off-episodes with PD indication, updated FA
Revised: 3/1/22 – annual review, updated referenced policies & covered LOBs



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 500.0

**SECTION: Commercial Drug
SUBJECT: Odactra**

Applicable line of business:

Commercial	X	Medicaid	
Medicare		ACA	X
GHP Kids	X	Self-Insured	X

POLICY:

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for Odactra for GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 487.0 Quantity Limit Exceptions

REQUIRED DEFINITIONS:

1. **Attachment** – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. **Exhibit** – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. **Devised** – the date the policy was implemented.
4. **Revised** – the date of every revision to the policy, including typographical and grammatical changes.
5. **Reviewed** – the date documenting the annual review if the policy has no revisions necessary.

ADDITIONAL DEFINITIONS:

1. **Formulary** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. **Non-formulary products** – those medications that are not included in the Formulary.
3. **Healthcare provider** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
4. **NCQA** – National Committee for Quality Assurance.
5. **Medically Necessary or Medical Necessity** – covered services rendered by a provider that the Health Plan determines are:



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 500.0

**SECTION: Commercial Drug
SUBJECT: Odactra**

- A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
- B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
- C. In accordance with current standards of medical practice;
- D. Not primarily for the convenience of the Member, or the Member's Provider; and
- E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

PROCEDURE:

A formulary exception for coverage of Odactra may be made for members who meet the following criteria:

- Medical record documentation that Odactra is prescribed by or in consultation with an allergist, immunologist, or other physician qualified to prescribe allergy immunotherapy **AND**
- Medical record documentation of age greater than or equal to 18 years and less than or equal to 65 years **AND**
- Medical record documentation of house dust mite-induced allergic rhinitis confirmed by *in vitro* testing for IgE antibodies to *Dematophagoides farinae* or *Dematophagoides pteronyssinus* house dust mites **OR** skin testing to licensed house dust mite allergen extracts **AND**
- Medical record documentation that the member has (or will receive) a prescription for an epinephrine auto-injector **AND**
- Medical record documentation that the member does not have severe, unstable, or uncontrolled asthma **AND**
- Medical record documentation that member will no longer be receiving subcutaneous immunotherapy **AND**
- Medical record documentation that Odactra will not be used in combination with sublingual immunotherapy (e.g., Grastek, Oralair, and Ragwitek) **AND**
- Medical record documentation of therapeutic failure on, intolerance to, or contraindication to three (3) formulary alternatives, one of which must be an intranasal glucocorticoid

MEDISPAN AUTHORIZATION LEVEL: GPI-12

QUANTITY LIMIT: *No QLs need to be entered within the authorization unless the requested quantity exceeds the QL.*

- QL FOR LETTER ONLY: 1 tablet per day

AUTHORIZATION DURATION: Initial approval will be for 12 months or less if the reviewing provider feels it is medically appropriate. Subsequent approvals will be for an additional 12 months or less if the reviewing provider feels it is medically appropriate. The following criteria is required for reauthorization:

- Medical record documentation of sustained improvement in allergic rhinitis symptoms **AND**
- Medical record documentation that the member is tolerating Odactra

If a formulary exception is approved Odactra will be paid for under the member's prescription drug benefit.

Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.

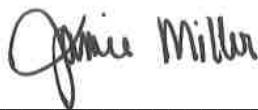
FORMULARY ALTERNATIVES:

fluticasone propionate, triamcinolone acetonide, budesonide, mometasone furoate, levocetirizine tablets, desloratadine tablets, montelukast

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE
STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND
FEDERAL REGULATORY ENTITIES.**

**THIS POLICY WILL BE REVISED AS NECESSARY AND
REVIEWED NO LESS THAN ANNUALLY.**

Signed: _____



Title: Director, Pharmacy Services

Date: March 1, 2022

Devised: 5/29/18

HPRX02

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Dev. 5/29/18

Rev. 3/1/22



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 500.0

**SECTION: Commercial Drug
SUBJECT: Odactra**

- Revised: 3/1/19 – annual review, added QL approval note
- Revised: 3/1/20 – annual review, added GHP Kids
- Revised: 3/1/21 – annual review, updated logo, added MediSpan approval level, updated QL statement
- Revised: 3/1/22 – annual review, updated referenced policies & covered LOBs



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 501.0

**SECTION: Commercial Drug
SUBJECT: Solosec**

Applicable line of business:

Commercial	X	Medicaid	
Medicare		ACA	X
GHP Kids	X	Self-Insured	X

POLICY:

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for Solosec for GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 487.0 Quantity Limit Exceptions

REQUIRED DEFINITIONS:

1. **Attachment** – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. **Exhibit** – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. **Devised** – the date the policy was implemented.
4. **Revised** – the date of every revision to the policy, including typographical and grammatical changes.
5. **Reviewed** – the date documenting the annual review if the policy has no revisions necessary.

ADDITIONAL DEFINITIONS:

1. **Formulary** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. **Non-formulary products** – those medications that are not included in the Formulary.
3. **Healthcare provider** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
4. **NCQA** – National Committee for Quality Assurance.
5. **Medically Necessary or Medical Necessity** – covered services rendered by a provider that the Health Plan determines are:



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 501.0

**SECTION: Commercial Drug
SUBJECT: Solosec**

- A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
- B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
- C. In accordance with current standards of medical practice;
- D. Not primarily for the convenience of the Member, or the Member's Provider; and
- E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

PROCEDURE:

A formulary exception for coverage of Solosec may be made for members who meet the following criteria:

Bacterial Vaginosis

- Medical record documentation of a diagnosis of bacterial vaginosis **AND**
- Medical record documentation of age greater than or equal to 18 years **AND**
- Medical record documentation of therapeutic failure on, intolerance to, or contraindication to metronidazole **AND** clindamycin **AND** tinidazole

Trichomoniasis

- Medical record documentation of trichomoniasis caused by *Trichomonas vaginalis* **AND**
- Medical record documentation of age greater than or equal to 18 years **AND**
- Medical record documentation of therapeutic failure on, intolerance to, or contraindication to oral metronidazole **AND** tinidazole

MEDISPAN AUTHORIZATION LEVEL: GPI-12

QUANTITY LIMIT: *No QLs need to be entered within the authorization unless the requested quantity exceeds the QL.*

- **QL FOR LETTER ONLY:** 1 packet per 30 days

If a formulary exception is approved, Solosec will be paid for under the member's prescription drug benefit.

Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 501.0

**SECTION: Commercial Drug
SUBJECT: Solosec**

FORMULARY ALTERNATIVES:

Bacterial vaginosis: clindamycin 2% vaginal cream, Clindesse 2% extended release vaginal cream, Cleocin 100 mg vaginal suppository, metronidazole 0.75% vaginal gel, tinidazole tablets

Trichomoniasis: oral metronidazole, tinidazole tablets

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE
STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND
FEDERAL REGULATORY ENTITIES.**

**THIS POLICY WILL BE REVISED AS NECESSARY AND
REVIEWED NO LESS THAN ANNUALLY.**

Signed: _____

Title: Director, Pharmacy Services

Date: March 1, 2022

Devised: 5/30/18
Revised: 3/1/19 – annual review, added QL approval note
Revised: 3/1/20 – annual review, added GHP Kids
Revised: 3/1/21 – annual review, updated logo, added MediSpan approval level, updated QL statement
Revised: 1/5/22 – added trichomoniasis indication
Revised: 3/1/22 – annual review, updated referenced policies & covered LOBs



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 502.0

**SECTION: Commercial Drug
SUBJECT: Steglatro**

Applicable line of business:

Commercial	X	Medicaid	
Medicare		ACA	X
GHP Kids	X	Self-Insured	X

POLICY:

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for Steglatro for GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 487.0 Quantity Limit Exceptions

REQUIRED DEFINITIONS:

1. **Attachment** – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. **Exhibit** – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. **Devised** – the date the policy was implemented.
4. **Revised** – the date of every revision to the policy, including typographical and grammatical changes.
5. **Reviewed** – the date documenting the annual review if the policy has no revisions necessary.

ADDITIONAL DEFINITIONS:

1. **Formulary** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. **Non-formulary products** – those medications that are not included in the Formulary.
3. **Healthcare provider** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
4. **NCQA** – National Committee for Quality Assurance.
5. **Medically Necessary or Medical Necessity** – covered services rendered by a provider that the Health Plan determines are:



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 502.0

**SECTION: Commercial Drug
SUBJECT: Steglatro**

- A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
- B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
- C. In accordance with current standards of medical practice;
- D. Not primarily for the convenience of the Member, or the Member's Provider; and
- E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

PROCEDURE:

A formulary exception for coverage of Steglatro may be made for members who meet the following criteria:

- Medical record documentation of a diagnosis of type II diabetes mellitus **AND**
- Medical record documentation of age greater than or equal to 18 years **AND**
- Medical record documentation of therapeutic failure on, intolerance to, or contraindication to Invokana **AND** Jardiance

MEDISPAN AUTHORIZATION LEVEL: GPI-12

QUANTITY LIMIT: *No QLs need to be entered within the authorization unless the requested quantity exceeds the QL.*

- **QL FOR LETTER ONLY:** 1 tablet per day

If a formulary exception is approved, Steglatro will be paid for under the member's prescription drug benefit.

Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.

FORMULARY ALTERNATIVES:

Invokana, Invokamet, Jardiance, Synjardy, Glyxambi

Geisinger

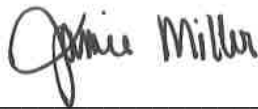
**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 502.0

**SECTION: Commercial Drug
SUBJECT: Steglatro**

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE
STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND
FEDERAL REGULATORY ENTITIES.**

**THIS POLICY WILL BE REVISED AS NECESSARY AND
REVIEWED NO LESS THAN ANNUALLY.**



Signed: _____

Title: Director, Pharmacy Services

Date: March 1, 2022

Devised: 5/30/18
Revised: 3/1/19 – annual review, added QL approval note, updated FA
Revised: 3/1/20 – annual review, added GHP Kids
Revised: 3/1/21 – annual review, updated logo, added MediSpan approval level, updated QL statement
Revised: 3/1/22 – annual review, updated referenced policies & covered LOBs



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 503.0

**SECTION: Commercial Drug
SUBJECT: Steglujan**

Applicable line of business:

Commercial	X	Medicaid	
Medicare		ACA	X
GHP Kids	X	Self-Insured	X

POLICY:

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for Steglujan for GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 487.0 Quantity Limit Exceptions

REQUIRED DEFINITIONS:

1. **Attachment** – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. **Exhibit** – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. **Devised** – the date the policy was implemented.
4. **Revised** – the date of every revision to the policy, including typographical and grammatical changes.
5. **Reviewed** – the date documenting the annual review if the policy has no revisions necessary.

ADDITIONAL DEFINITIONS:

1. **Formulary** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. **Non-formulary products** – those medications that are not included in the Formulary.
3. **Healthcare provider** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
4. **NCQA** – National Committee for Quality Assurance.
5. **Medically Necessary or Medical Necessity** – covered services rendered by a provider that the Health Plan determines are:



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 503.0

**SECTION: Commercial Drug
SUBJECT: Steglujan**

- A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
- B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
- C. In accordance with current standards of medical practice;
- D. Not primarily for the convenience of the Member, or the Member's Provider; and
- E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

PROCEDURE:

A formulary exception for coverage of Steglujan may be made for members who meet the following criteria:

- Medical record documentation of a diagnosis of type II diabetes mellitus **AND**
- Medical record documentation of age greater than or equal to 18 years **AND**
- Medical record documentation of therapeutic failure on, intolerance to, or contraindication to Glyxambi **OR**
- Medical record documentation of therapeutic failure on, intolerance to, or contraindication to Tradjenta **AND** one formulary SGLT2 inhibitor

MEDISPAN AUTHORIZATION LEVEL: GPI-12

QUANTITY LIMIT: *No QLs need to be entered within the authorization unless the requested quantity exceeds the QL.*

- QL FOR LETTER ONLY: 1 tablet per day

If a formulary exception is approved, Steglujan will be paid for under the member's prescription drug benefit.

Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.

FORMULARY ALTERNATIVES:

Glyxambi, Invokana, Invokamet, Jardiance, Synjardy, Tradjenta, Jentadueto



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 503.0

**SECTION: Commercial Drug
SUBJECT: Steglujan**

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE
STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND
FEDERAL REGULATORY ENTITIES.**

**THIS POLICY WILL BE REVISED AS NECESSARY AND
REVIEWED NO LESS THAN ANNUALLY.**

Signed: _____

Title: Director, Pharmacy Services

Date: March 1, 2022

Devised: 5/30/18
Revised: 3/1/20 – annual review, added GHP Kids
Revised: 3/1/19 – annual review, added QL approval note, updated FA
Revised: 3/1/21 – annual review, updated logo, added MediSpan approval level, updated QL statement
Revised: 3/1/22 – annual review, updated referenced policies & covered LOBs



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 504.0

**SECTION: Commercial Drug
SUBJECT: Segluromet**

Applicable line of business:

Commercial	X	Medicaid	
Medicare		ACA	X
GHP Kids	X	Self-Insured	X

POLICY:

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for Segluromet for GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 487.0 Quantity Limit Exceptions

REQUIRED DEFINITIONS:

1. **Attachment** – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. **Exhibit** – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. **Devised** – the date the policy was implemented.
4. **Revised** – the date of every revision to the policy, including typographical and grammatical changes.
5. **Reviewed** – the date documenting the annual review if the policy has no revisions necessary.

ADDITIONAL DEFINITIONS:

1. **Formulary** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. **Non-formulary products** – those medications that are not included in the Formulary.
3. **Healthcare provider** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
4. **NCQA** – National Committee for Quality Assurance.
5. **Medically Necessary or Medical Necessity** – covered services rendered by a provider that the Health Plan determines are:



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 504.0

**SECTION: Commercial Drug
SUBJECT: Segluromet**

- A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
- B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
- C. In accordance with current standards of medical practice;
- D. Not primarily for the convenience of the Member, or the Member's Provider; and
- E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

PROCEDURE:

A formulary exception for coverage of Segluromet may be made for members who meet the following criteria:

- Medical record documentation of a diagnosis of type II diabetes mellitus **AND**
- Medical record documentation of age greater than or equal to 18 years **AND**
- Medical record documentation of therapeutic failure on, intolerance to, or contraindication to Jardiance in combination with metformin, Synjardy **OR** Synjardy XR **AND**
- Medical record documentation of therapeutic failure on, intolerance to, or contraindication to Invokana in combination with metformin, Invokamet, **OR** Invokamet XR

MEDISPAN AUTHORIZATION LEVEL: GPI-12

QUANTITY LIMIT: *No QLs need to be entered within the authorization unless the requested quantity exceeds the QL.*

- **QL FOR LETTER ONLY:** 2 tablets per day

If a formulary exception is approved, Segluromet will be paid for under the member's prescription drug benefit.

Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.

FORMULARY ALTERNATIVES:

metformin, Invokana, Invokamet, Jardiance, Synjardy, Glyxambi

Geisinger

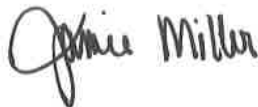
**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 504.0

**SECTION: Commercial Drug
SUBJECT: Segluromet**

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE
STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND
FEDERAL REGULATORY ENTITIES.**

**THIS POLICY WILL BE REVISED AS NECESSARY AND
REVIEWED NO LESS THAN ANNUALLY.**



Signed: _____

Title: Director, Pharmacy Services

Date: March 1, 2022

Devised: 5/30/18

Revised: 3/1/19 – annual review, added QL approval note, updated FA

Revised: 3/1/20 – annual review, added GHP Kids

Revised: 3/1/21 – annual review, updated logo, added MediSpan approval level, updated QL statement

Revised: 3/1/22 – annual review, updated referenced policies & covered LOBs



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 505.0

**SECTION: Commercial Drug
SUBJECT: Prevymis**

Applicable line of business:

Commercial	X	Medicaid	
Medicare		ACA	X
GHP Kids	X	Self-Insured	X

POLICY:

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for Prevymis for GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 487.0 Quantity Limit Exceptions

REQUIRED DEFINITIONS:

1. **Attachment** – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. **Exhibit** – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. **Devised** – the date the policy was implemented.
4. **Revised** – the date of every revision to the policy, including typographical and grammatical changes.
5. **Reviewed** – the date documenting the annual review if the policy has no revisions necessary.

ADDITIONAL DEFINITIONS:

1. **Formulary** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. **Non-formulary products** – those medications that are not included in the Formulary.
3. **Healthcare provider** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
4. **NCQA** – National Committee for Quality Assurance.
5. **Medically Necessary or Medical Necessity** – covered services rendered by a provider that the Health Plan determines are:



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 505.0

**SECTION: Commercial Drug
SUBJECT: Prevyomis**

- A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
- B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
- C. In accordance with current standards of medical practice;
- D. Not primarily for the convenience of the Member, or the Member's Provider; and
- E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

PROCEDURE:

A formulary exception for coverage of Prevyomis may be made for members who meet the following criteria:

- Medical record documentation that Prevyomis is prescribed by or in consultation with a hematologist/oncologist, infectious disease, and/or transplant specialist **AND**
- Medical record documentation of age greater than or equal to 18 years **AND**
- Medical record documentation that member is a recipient of an allogeneic hematopoietic stem cell transplant **AND**
- Medical record documentation that member is a confirmed cytomegalovirus (CMV) seropositive recipient (R+) **AND**
- Medical record documentation that Prevyomis is being used for cytomegalovirus (CMV) prophylaxis **AND**
- Medical record documentation that Prevyomis is being initiated between Day 0 and Day 28 post-transplantation **AND**
- Medical record documentation that Prevyomis is not being used in combination with pimozide, ergot alkaloids (ergotamine and dihydroergotamine), and/or pitavastatin and simvastatin (if co-administered with cyclosporine)

MEDISPAN AUTHORIZATION LEVEL: GPI-12

QUANTITY LIMIT: *No QLs need to be entered within the authorization unless the requested quantity exceeds the QL.*

- **QL FOR LETTER ONLY:** 1 tablet per day

AUTHORIZATION DURATION: 100 days



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 505.0

**SECTION: Commercial Drug
SUBJECT: Prevymis**

If a formulary exception is approved Prevymis will be paid for under the member's prescription drug benefit.

Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.

FORMULARY ALTERNATIVES:

valganciclovir

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE
STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND
FEDERAL REGULATORY ENTITIES.**

**THIS POLICY WILL BE REVISED AS NECESSARY AND
REVIEWED NO LESS THAN ANNUALLY.**

Signed: _____

Title: Director, Pharmacy Services

Date: March 1, 2022

Devised: 5/30/18
Revised: 8/7/18 – updated authorization duration, corrected 2 typos
Revised: 3/1/19 – annual review, added QL approval note, defined CMV
Revised: 3/1/20 – annual review, added GHP Kids
Revised: 3/1/21 – annual review, updated logo, added MediSpan approval level, updated QL statement
Revised: 3/1/22 – annual review, updated referenced policies & covered LOBs



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 506.0

**SECTION: Commercial Drug
SUBJECT: Vyzulta**

Applicable line of business:

Commercial	X	Medicaid	
Medicare		ACA	X
GHP Kids	X	Self-Insured	X

POLICY:

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for Vyzulta for GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 487.0 Quantity Limit Exceptions

REQUIRED DEFINITIONS:

1. **Attachment** – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. **Exhibit** – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. **Devised** – the date the policy was implemented.
4. **Revised** – the date of every revision to the policy, including typographical and grammatical changes.
5. **Reviewed** – the date documenting the annual review if the policy has no revisions necessary.

ADDITIONAL DEFINITIONS:

1. **Formulary** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. **Non-formulary products** – those medications that are not included in the Formulary.
3. **Healthcare provider** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
4. **NCQA** – National Committee for Quality Assurance.
5. **Medically Necessary or Medical Necessity** – covered services rendered by a provider that the Health Plan determines are:



POLICY NUMBER: 506.0

**POLICY AND PROCEDURE
PHARMACY
MANUAL**

**SECTION: Commercial Drug
SUBJECT: Vyzulta**

- A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
- B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
- C. In accordance with current standards of medical practice;
- D. Not primarily for the convenience of the Member, or the Member's Provider; and
- E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

PROCEDURE:

A formulary exception for coverage of Vyzulta may be made for members who meet the following criteria:

- Electronic step therapy of on-line prescription drug claims history showing 15 days use of latanoprost (generic Xalatan), Zioptan, **AND** travoprost within the previous 180 days. If this electronic step is met, the claim will automatically adjudicate **OR**
- Medical record documentation of intolerance to, contraindication to, or therapeutic failure on latanoprost (generic Xalatan), Zioptan, **AND** travoprost

MEDISPAN AUTHORIZATION LEVEL: GPI-12

If a formulary exception is approved, Vyzulta will be paid for under the member's prescription drug benefit.

Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.

FORMULARY ALTERNATIVES:

latanoprost (generic Xalatan), travoprost, Zioptan

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE
STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND
FEDERAL REGULATORY ENTITIES.**

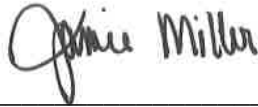
**THIS POLICY WILL BE REVISED AS NECESSARY AND
REVIEWED NO LESS THAN ANNUALLY.**

Geisinger

**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 506.0

**SECTION: Commercial Drug
SUBJECT: Vyzulta**



Signed: _____

Title: Director, Pharmacy Services

Date: March 1, 2022

Devised: 5/30/18
Revised: 8/21/18 – updated to step, added failure of Zioptan, updated FA
Reviewed: 3/1/19 – annual review
Revised: 3/1/20 – annual review, added GHP Kids
Revised: 3/1/21 – annual review, updated logo, added MediSpan approval level, updated FA
Revised: 3/1/22 – annual review, updated referenced policies, covered LOBs, & Travatan Z to travoprost



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 507.0

**SECTION: Commercial Drug
SUBJECT: Afinitor Disperz**

Applicable line of business:

Commercial	X	Medicaid	
Medicare		ACA	X
GHP Kids	X	Self-Insured	X

POLICY:

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for Afinitor Disperz for GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 487.0 Quantity Limit Exceptions

REQUIRED DEFINITIONS:

1. **Attachment** – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. **Exhibit** – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. **Devised** – the date the policy was implemented.
4. **Revised** – the date of every revision to the policy, including typographical and grammatical changes.
5. **Reviewed** – the date documenting the annual review if the policy has no revisions necessary.

ADDITIONAL DEFINITIONS:

1. **Formulary** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. **Non-formulary products** – those medications that are not included in the Formulary.
3. **Healthcare provider** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
4. **NCQA** – National Committee for Quality Assurance.
5. **Medically Necessary or Medical Necessity** – covered services rendered by a provider that the Health Plan determines are:



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 507.0

**SECTION: Commercial Drug
SUBJECT: Afinitor Disperz**

- A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
- B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
- C. In accordance with current standards of medical practice;
- D. Not primarily for the convenience of the Member, or the Member's Provider; and
- E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

PROCEDURE:

New members to the plan already established on therapy may be eligible for continuity of care coverage as long as there is medical record documentation that the safety and effectiveness of use for the prescribed indication is supported by Food and Drug Administration (FDA) approval or adequate medical and scientific evidence in the medical literature.

An exception for coverage of Afinitor Disperz may be made for members who meet the following criteria:

Tuberous sclerosis complex (TSC)-associated subependymal giant cell astrocytoma

- Medical record documentation that Afinitor Disperz is prescribed by an oncologist **AND**
- Medical record documentation of a diagnosis of subependymal giant cell astrocytoma (SEGA) associated with tuberous sclerosis (TS) who require therapeutic intervention but are not candidates for curative surgical resection

Tuberous sclerosis complex (TSC)-associated partial-onset seizures

- Medical record documentation of adjunctive treatment for adult **OR** pediatric patients aged 2 years and older with tuberous sclerosis complex (TSC)-associated partial-onset seizures **AND**
- Medical record documentation of therapeutic failure on, intolerance to, or contraindication to at least two (2) anti-epileptic drug (AED) regimens

MEDISPAN AUTHORIZATION LEVEL: GPI-12, number of claims authorized = 1, enter for the remainder of the calendar year



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 507.0

**SECTION: Commercial Drug
SUBJECT: Afinitor Disperz**

QUANTITY LIMIT (ALL INDICATIONS): *No QLs need to be entered within the authorization unless the requested quantity exceeds the QL.*

- **QL FOR LETTER ONLY:** 1 tablet per day, 28 day supply per fill

RE-AUTHORIZATION CRITERIA: Afinitor Disperz is configured as a prior authorization for new starts only. Afinitor Disperz will no longer be covered if it is identified that the member is not receiving appropriate follow-up care from the prescribing specialist or if the member has greater than or equal to a 90 day break in therapy.

- Medical record documentation that the member is receiving appropriate follow-up care from the prescribing specialist

If a formulary exception is approved, Afinitor Disperz will be paid for under the member's prescription drug benefit.

Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.

FORMULARY ALTERNATIVES:

Partial Onset Seizures –

Age 2 and older: carbamazepine, lamotrigine immediate release, levetiracetam immediate release, oxcarbazepine, phenobarbital, phenytoin, topiramate immediate release

Age 3 and older: carbamazepine, gabapentin, lamotrigine immediate release, levetiracetam immediate release, oxcarbazepine, phenobarbital, phenytoin, topiramate immediate release

Age 10 and older: carbamazepine, divalproex, gabapentin, lamotrigine immediate release, levetiracetam immediate release, oxcarbazepine, phenobarbital, phenytoin, topiramate immediate release

Age 12 and older: carbamazepine, divalproex, gabapentin, lamotrigine immediate release, levetiracetam immediate release, levetiracetam extended release, oxcarbazepine, phenobarbital, phenytoin, tiagabine, topiramate immediate release

Age 13 and older: carbamazepine, divalproex, gabapentin, lamotrigine extended release, lamotrigine immediate release, levetiracetam immediate release, levetiracetam extended release, oxcarbazepine, phenobarbital, phenytoin, tiagabine, topiramate immediate release



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 507.0

**SECTION: Commercial Drug
SUBJECT: Afinitor Disperz**

Age 14 and older: carbamazepine, divalproex, felbamate, gabapentin, lamotrigine extended release, lamotrigine immediate release, levetiracetam immediate release, levetiracetam extended release, oxcarbazepine, phenobarbital, phenytoin, tiagabine, topiramate immediate release

Age 16 and older: carbamazepine, divalproex, felbamate, gabapentin, lamotrigine extended release, lamotrigine immediate release, levetiracetam immediate release, levetiracetam extended release, oxcarbazepine, phenobarbital, phenytoin, tiagabine, topiramate immediate release, zonisamide

Age 18 and older: carbamazepine, divalproex, felbamate, gabapentin, lamotrigine extended release, lamotrigine immediate release, levetiracetam immediate release, levetiracetam extended release, Lyrica, oxcarbazepine, phenobarbital, phenytoin, tiagabine, topiramate immediate release, zonisamide

* prior authorization required

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE
STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND
FEDERAL REGULATORY ENTITIES.**

**THIS POLICY WILL BE REVISED AS NECESSARY AND
REVIEWED NO LESS THAN ANNUALLY.**

Signed: _____

Title: Director, Pharmacy Services

Date: March 1, 2022

Devised: 5/30/18
Revised: 3/1/19 – annual review, added QL approval note
Revised: 3/1/20 – annual review, added GHP Kids
Revised: 3/1/21 – annual review, updated logo, added MediSpan approval level, updated QL statement
Revised: 11/24/21 – added one-time PA to approval crit., removed auth duration & added re-auth crit.
Revised: 3/1/22 – annual review, updated referenced policies & covered LOBs



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 508.0

**SECTION: Commercial Drug
SUBJECT: Auvi-Q 0.1 mg**

Applicable line of business:

Commercial	X	Medicaid	
Medicare		ACA	X
GHP Kids	X	Self-Insured	X

POLICY:

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for Auvi-Q 0.1 mg for GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 487.0 Quantity Limit Exceptions

REQUIRED DEFINITIONS:

1. **Attachment** – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. **Exhibit** – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. **Devised** – the date the policy was implemented.
4. **Revised** – the date of every revision to the policy, including typographical and grammatical changes.
5. **Reviewed** – the date documenting the annual review if the policy has no revisions necessary.

ADDITIONAL DEFINITIONS:

1. **Formulary** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. **Non-formulary products** – those medications that are not included in the Formulary.
3. **Healthcare provider** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
4. **NCQA** – National Committee for Quality Assurance.
5. **Medically Necessary or Medical Necessity** – covered services rendered by a provider that the Health Plan determines are:



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 508.0

**SECTION: Commercial Drug
SUBJECT: Auvi-Q 0.1 mg**

- A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
- B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
- C. In accordance with current standards of medical practice;
- D. Not primarily for the convenience of the Member, or the Member's Provider; and
- E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

PROCEDURE:

An exception for coverage of Auvi-Q 0.1 mg may be made for members who meet the following criteria:

- Medical record documentation of weight greater than or equal to 7.5 kg (16.5 lbs.) and less than or equal to 15 kg (33 lbs.)

MEDISPAN AUTHORIZATION LEVEL: GPI-14

QUANTITY LIMIT: *No QLs need to be entered within the authorization unless the requested quantity exceeds the QL.*

- **QL FOR LETTER ONLY:** 2 auto-injectors per fill

If a formulary exception is approved, Auvi-Q 0.1 mg will be paid for under the member's prescription drug benefit.

Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.

FORMULARY ALTERNATIVES:

none

Geisinger

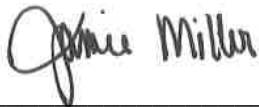
**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 508.0

**SECTION: Commercial Drug
SUBJECT: Auvi-Q 0.1 mg**

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE
STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND
FEDERAL REGULATORY ENTITIES.**

**THIS POLICY WILL BE REVISED AS NECESSARY AND
REVIEWED NO LESS THAN ANNUALLY.**



Signed: _____

Title: Director, Pharmacy Services

Date: March 1, 2022

Devised: 5/30/18

Revised: 3/1/19 – annual review, added QL approval note

Revised: 3/1/20 – annual review, added GHP Kids

Revised: 3/1/21 – annual review, updated logo, added MediSpan approval level, updated QL statement

Revised: 3/1/22 – annual review, updated referenced policies & covered LOBs



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 509.0

**SECTION: Commercial Drug
SUBJECT: Fiasp**

Applicable line of business:

Commercial	X	Medicaid	
Medicare		ACA	X
GHP Kids	X	Self-Insured	X

POLICY:

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for Fiasp for GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 487.0 Quantity Limit Exceptions

REQUIRED DEFINITIONS:

1. **Attachment** – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. **Exhibit** – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. **Devised** – the date the policy was implemented.
4. **Revised** – the date of every revision to the policy, including typographical and grammatical changes.
5. **Reviewed** – the date documenting the annual review if the policy has no revisions necessary.

ADDITIONAL DEFINITIONS:

1. **Formulary** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. **Non-formulary products** – those medications that are not included in the Formulary.
3. **Healthcare provider** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
4. **NCQA** – National Committee for Quality Assurance.
5. **Medically Necessary or Medical Necessity** – covered services rendered by a provider that the Health Plan determines are:



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 509.0

**SECTION: Commercial Drug
SUBJECT: Fiasp**

- A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
- B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
- C. In accordance with current standards of medical practice;
- D. Not primarily for the convenience of the Member, or the Member's Provider; and
- E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

PROCEDURE:

An exception for coverage of Fiasp may be made for members who meet the following criteria:

- Medical record documentation of therapeutic failure on, intolerance to, or contraindication to Novolog

MEDISPAN AUTHORIZATION LEVEL: GPI-10

If a formulary exception is approved, Fiasp will be paid for under the member's prescription drug benefit.

Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.

FORMULARY ALTERNATIVES:

Novolog, insulin aspart

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE
STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND
FEDERAL REGULATORY ENTITIES.**

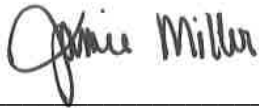
**THIS POLICY WILL BE REVISED AS NECESSARY AND
REVIEWED NO LESS THAN ANNUALLY.**

Geisinger

**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 509.0

**SECTION: Commercial Drug
SUBJECT: Fiasp**



Signed: _____

Title: Director, Pharmacy Services

Date: March 1, 2022

Devised: 7/20/18

Reviewed: 3/1/19 – annual review

Revised: 3/1/20 – annual review, added GHP Kids

Revised: 6/4/20 – removed age restriction

Revised: 3/1/21 – annual review, updated logo, added MediSpan approval level, updated FA

Revised: 3/1/22 – annual review, updated referenced policies & covered LOBs



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 510.0

**SECTION: Commercial Drug
SUBJECT: Admelog**

Applicable line of business:

Commercial	X	Medicaid	
Medicare		ACA	X
GHP Kids	X	Self-Insured	X

POLICY:

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for Admelog for GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 487.0 Quantity Limit Exceptions

REQUIRED DEFINITIONS:

1. **Attachment** – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. **Exhibit** – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. **Devised** – the date the policy was implemented.
4. **Revised** – the date of every revision to the policy, including typographical and grammatical changes.
5. **Reviewed** – the date documenting the annual review if the policy has no revisions necessary.

ADDITIONAL DEFINITIONS:

1. **Formulary** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. **Non-formulary products** – those medications that are not included in the Formulary.
3. **Healthcare provider** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
4. **NCQA** – National Committee for Quality Assurance.
5. **Medically Necessary or Medical Necessity** – covered services rendered by a provider that the Health Plan determines are:



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 510.0

**SECTION: Commercial Drug
SUBJECT: Admelog**

- A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
- B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
- C. In accordance with current standards of medical practice;
- D. Not primarily for the convenience of the Member, or the Member's Provider; and
- E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

PROCEDURE:

An exception for coverage of Admelog may be made for members who meet the following criteria:

- Medical record documentation of therapeutic failure on, intolerance to, or contraindication to comparable Novo Nordisk brand insulin **OR**
- Medical record documentation that the requested insulin require dilution

MEDISPAN AUTHORIZATION LEVEL: GPI-14 (must enter 2710400500D222 & 27104005002020)

If a formulary exception is approved, Admelog will be paid for under the member's prescription drug benefit.

Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.

FORMULARY ALTERNATIVES:

Novolog, insulin aspart

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE
STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND
FEDERAL REGULATORY ENTITIES.**

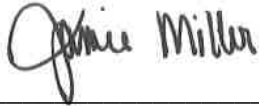
**THIS POLICY WILL BE REVISED AS NECESSARY AND
REVIEWED NO LESS THAN ANNUALLY.**

Geisinger

**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 510.0

**SECTION: Commercial Drug
SUBJECT: Admelog**



Signed: _____

Title: Director, Pharmacy Services

Date: March 1, 2022

Devised: 7/20/18

Reviewed: 3/1/19 – annual review

Revised: 3/1/20 – annual review, added GHP Kids

Revised: 3/1/21 – annual review, updated logo, added MediSpan approval level, updated FA

Revised: 3/1/22 – annual review, updated referenced policies & covered LOBs, corrected typo



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 511.0

**SECTION: Commercial Drug
SUBJECT: Aimovig**

Applicable line of business:

Commercial	X	Medicaid	
Medicare		ACA	X
GHP Kids	X	Self-Insured	X

POLICY:

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for Aimovig for GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 487.0 Quantity Limit Exceptions

REQUIRED DEFINITIONS:

1. **Attachment** – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. **Exhibit** – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. **Devised** – the date the policy was implemented.
4. **Revised** – the date of every revision to the policy, including typographical and grammatical changes.
5. **Reviewed** – the date documenting the annual review if the policy has no revisions necessary.

ADDITIONAL DEFINITIONS:

1. **Formulary** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. **Non-formulary products** – those medications that are not included in the Formulary.
3. **Healthcare provider** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
4. **NCQA** – National Committee for Quality Assurance.
5. **Medically Necessary or Medical Necessity** – covered services rendered by a provider that the Health Plan determines are:

- A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
- B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
- C. In accordance with current standards of medical practice;
- D. Not primarily for the convenience of the Member, or the Member's Provider; and
- E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

PROCEDURE:

An exception for coverage of Aimovig may be made for members who meet the following criteria:

- Medical record documentation that Aimovig is prescribed by or in consultation with a neurologist or headache specialist **AND**
- Medical record documentation of age greater than or equal to 18 years **AND**
- Medical record documentation of a diagnosis of migraine with or without aura, based on the ICHD-III diagnostic criteria **AND**
- Medical record documentation of number of baseline migraine or headache days per month **AND**
- Medical record documentation of therapeutic failure on, intolerance to, or contraindication to at least two (2) of the following:
 - One (1) beta blocker (metoprolol, propranolol, timolol, atenolol, nadolol)
 - Topiramate
 - Divalproex/sodium valproate
 - Amitriptyline
 - Venlafaxine **AND**
- Medical record documentation that Aimovig will not be used concomitantly with another calcitonin gene-related peptide (CGRP) receptor antagonist indicated for the preventive treatment of migraine (e.g., Ajoovy, Emgality, Vyepti) **AND**
- Medical record documentation that Aimovig will not be used in combination with botulinum toxin **OR**
- If the request is for use in combination with Botox, all of the following must be met:
 - Medical record documentation of a therapeutic failure on a minimum 3 month trial of at least one CGRP antagonists without the concomitant use of Botox **AND**
 - Medical record documentation of therapeutic failure on a minimum 6 month trial of Botox without the concomitant use of a CGRP antagonist

AUTHORIZATION DURATION: Initial approval will be for six (6) months and subsequent approvals will be for twelve (12) months. Requests for continuation of coverage will be approved for members who meet the following criteria:

- Medical record documentation of continued or sustained reduction in migraine or headache frequency or has experienced a decrease in severity or duration of migraine **AND**
- Medical record documentation that Aimovig will not be used concomitantly with another calcitonin gene-related peptide (CGRP) receptor antagonist indicated for the preventive treatment of migraine (e.g., Ajovy, Emgality, Vyepti) **AND**
- One of the following:
 - Medical record documentation that Aimovig is not being used concurrently with botulinum toxin **OR**
 - If the request is for use in combination with Botox, all of the following must be met:
 - Medical record documentation of a therapeutic failure on a minimum 3 month trial of at least one CGRP antagonists without the concomitant use of Botox **AND**
 - Medical record documentation of therapeutic failure on a minimum 6 month trial of Botox without the concomitant use of a CGRP antagonist

MEDISPAN AUTHORIZATION LEVEL: GPI-12

QUANTITY LIMIT: *No QLs need to be entered within the authorization unless the requested quantity exceeds the QL.*

- QL FOR LETTER ONLY: 1 mL per 30 days

ICHD-III Diagnostic Criteria³	
Migraine without Aura:	Migraine with Aura:
A) At least five (5) attacks fulfilling criteria B through D below:	A) At least two (2) attacks fulfilling criteria B through C below:
B) Headache lasting 4 to 72 hours (untreated or unsuccessfully treated)	B) One (1) or more of the following fully reversible aura symptoms: <ul style="list-style-type: none"> ○ Visual ○ Sensory ○ Speech and/or language ○ Motor ○ Brainstem ○ Retinal
C) Headache with at least two (2) of the following characteristics: <ul style="list-style-type: none"> ○ unilateral location ○ pulsating quality ○ moderate to severe pain intensity 	C) At least three (3) of the following: <ul style="list-style-type: none"> ○ at least one (1) aura symptom spreads over 5 or more minutes ○ two (2) or more aura symptoms occur in succession

Geisinger

POLICY AND PROCEDURE PHARMACY MANUAL

POLICY NUMBER: 511.0

SECTION: Commercial Drug
SUBJECT: Aimovig

<ul style="list-style-type: none">○ aggravation by or causing avoidance of routine physical activity (e.g. walking or climbing stairs)	<ul style="list-style-type: none">○ each individual aura symptom lasts 5 to 60 minutes¹○ at least one (1) aura symptom is unilateral²○ at least one (1) aura symptom is positive³○ the aura is accompanied, or followed within 60 minutes, by a headache
D) At least one of the following during the headache: <ul style="list-style-type: none">○ nausea and/or vomiting○ photophobia and phonophobia	D) Not better accounted for by another ICHD-3 diagnosis
E) Not better accounted for by another ICHD-3 diagnosis	

1. Example, if three symptoms occur during an aura, the acceptable maximal duration is 3 x 60 minutes. Motor symptoms may last up to 72 hours.
2. Aphasia (impairment of language) is always a unilateral symptom; dysarthria (slurred or slowed speech) may or may not be.
3. Scintillations (flash of light) and pins and needles are positive symptoms of aura

If a formulary exception is approved, Aimovig will be paid for under the member's prescription drug benefit.

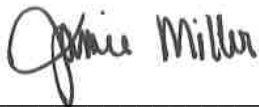
Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.

FORMULARY ALTERNATIVES:

metoprolol, propranolol, timolol, atenolol, nadolol, topiramate, divalproex, sodium valproate, amitriptyline, venlafaxine

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE
STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND
FEDERAL REGULATORY ENTITIES.**

**THIS POLICY WILL BE REVISED AS NECESSARY AND
REVIEWED NO LESS THAN ANNUALLY.**



Signed: _____

Title: Director, Pharmacy Services

Date: March 1, 2022

Devised: 7/20/18

Revised: 12/28/18 – updated prescriber to include by/in consultation with headache specialist, updated QL

HPRX02

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Dev. 7/20/18

Rev: 3/1/22



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 511.0

**SECTION: Commercial Drug
SUBJECT: Aimovig**

Reviewed: 3/1/19 – annual review
Revised: 3/28/19 – updated initial & renewal Botox criteria, added decrease in severity to renewal criteria
Revised: 5/3/19 – added missing ‘will not be used in combination with Botox’ criteria
Revised: 5/29/19 – updated QL based on new package size
Revised: 3/1/20 – annual review, added GHP Kids
Revised: 6/9/20 – updated to failure of 2 alternatives
Revised: 10/5/20 – added concomitant use with other preventive CGRP to initial/renewal criteria
Revised: 3/1/21 – annual review, updated logo, added MediSpan approval level, updated QL statement
Revised: 3/1/22 – annual review, updated referenced policies & covered LOBs



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 512.0

**SECTION: Commercial Drug
SUBJECT: Lonhala Magnair**

Applicable line of business:

Commercial	X	Medicaid	
Medicare		ACA	X
GHP Kids	X	Self-Insured	X

POLICY:

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for Lonhala Magnair for GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 487.0 Quantity Limit Exceptions

REQUIRED DEFINITIONS:

1. **Attachment** – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. **Exhibit** – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
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4. **Revised** – the date of every revision to the policy, including typographical and grammatical changes.
5. **Reviewed** – the date documenting the annual review if the policy has no revisions necessary.

ADDITIONAL DEFINITIONS:

1. **Formulary** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. **Non-formulary products** – those medications that are not included in the Formulary.
3. **Healthcare provider** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
4. **NCQA** – National Committee for Quality Assurance.
5. **Medically Necessary or Medical Necessity** – covered services rendered by a provider that the Health Plan determines are:



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 512.0

**SECTION: Commercial Drug
SUBJECT: Lonhala Magnair**

- A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
- B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
- C. In accordance with current standards of medical practice;
- D. Not primarily for the convenience of the Member, or the Member's Provider; and
- E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

PROCEDURE:

An exception for coverage of Lonhala Magnair may be made for members who meet the following criteria:

- Medical record documentation of a diagnosis of chronic obstructive pulmonary disease (COPD) **AND**
- Medical record documentation of age greater than or equal to 18 years **AND**
- Medical record documentation of therapeutic failure on, intolerance to, or contraindication to Spiriva **AND** Incruse Ellipta **OR**
- Medical record documentation of inability to perform proper inhaler technique

MEDISPAN AUTHORIZATION LEVEL: GPI-12

QUANTITY LIMIT: *No QLs need to be entered within the authorization unless the requested quantity exceeds the QL.*

- QL FOR LETTER ONLY: 2 vials per day

If a formulary exception is approved, Lonhala Magnair will be paid for under the member's prescription drug benefit.

Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.

FORMULARY ALTERNATIVES:

Spiriva, Incruse Ellipta

Geisinger

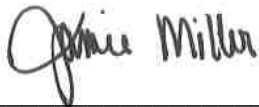
**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 512.0

**SECTION: Commercial Drug
SUBJECT: Lonhala Magnair**

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE
STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND
FEDERAL REGULATORY ENTITIES.**

**THIS POLICY WILL BE REVISED AS NECESSARY AND
REVIEWED NO LESS THAN ANNUALLY.**



Signed: _____

Title: Director, Pharmacy Services

Date: March 1, 2022

Devised: 7/20/18

Revised: 3/1/19 – annual review, added QL approval note

Revised: 3/1/20 – annual review, added GHP Kids

Revised: 3/1/21 – annual review, updated logo, added MediSpan approval level, updated QL statement

Revised: 3/1/22 – annual review, updated referenced policies & covered LOBs



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 513.0

**SECTION: Commercial Drug
SUBJECT: Hemlibra**

Applicable line of business:

Commercial	X	Medicaid	
Medicare		ACA	X
GHP Kids	X	Self-Insured	X

POLICY:

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for Hemlibra for GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 487.0 Quantity Limit Exceptions

REQUIRED DEFINITIONS:

1. **Attachment** – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. **Exhibit** – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. **Devised** – the date the policy was implemented.
4. **Revised** – the date of every revision to the policy, including typographical and grammatical changes.
5. **Reviewed** – the date documenting the annual review if the policy has no revisions necessary.

ADDITIONAL DEFINITIONS:

1. **Formulary** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. **Non-formulary products** – those medications that are not included in the Formulary.
3. **Healthcare provider** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
4. **NCQA** – National Committee for Quality Assurance.
5. **Medically Necessary or Medical Necessity** – covered services rendered by a provider that the Health Plan determines are:



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 513.0

**SECTION: Commercial Drug
SUBJECT: Hemlibra**

- A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
- B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
- C. In accordance with current standards of medical practice;
- D. Not primarily for the convenience of the Member, or the Member's Provider; and
- E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

PROCEDURE:

An exception for coverage of Hemlibra may be made for members who meet the following criteria:

- Medical record documentation of a diagnosis of hemophilia A (a documented Factor VIII deficiency **AND**
- Medical record documentation that Hemlibra is being used for routine prophylaxis **AND**
- Medical record documentation that Hemlibra will be for outpatient use

MEDISPAN AUTHORIZATION LEVEL: GPI-12

If a formulary exception is approved, Hemlibra will be paid for under the member's prescription drug benefit.

Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.

FORMULARY ALTERNATIVES:

none

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE
STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND
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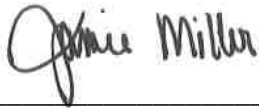
**THIS POLICY WILL BE REVISED AS NECESSARY AND
REVIEWED NO LESS THAN ANNUALLY.**

Geisinger

**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 513.0

**SECTION: Commercial Drug
SUBJECT: Hemlibra**



Signed: _____

Title: Director, Pharmacy Services

Date: March 1, 2022

Devised: 7/20/18
Reviewed: 3/1/19 – annual review
Revised: 3/28/19 – removed inhibitor requirement
Revised: 3/1/20 – annual review, added GHP Kids
Revised: 3/1/21 – annual review, updated logo, added MediSpan approval level
Revised: 3/1/22 – annual review, updated referenced policies & covered LOBs



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 514.0

**SECTION: Commercial Drug
SUBJECT: Antihemophilic Agents for
Hemophilia A**

Applicable line of business:

Commercial	X	Medicaid	
Medicare		ACA	X
GHP Kids	X	Self-Insured	X

POLICY:

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for antihemophilic agents for hemophilia A for GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 487.0 Quantity Limit Exceptions

REQUIRED DEFINITIONS:

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4. **Revised** – the date of every revision to the policy, including typographical and grammatical changes.
5. **Reviewed** – the date documenting the annual review if the policy has no revisions necessary.

ADDITIONAL DEFINITIONS:

1. **Formulary** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. **Non-formulary products** – those medications that are not included in the Formulary.
3. **Healthcare provider** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
4. **NCQA** – National Committee for Quality Assurance.
5. **Medically Necessary or Medical Necessity** – covered services rendered by a provider that the Health Plan determines are:

- A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
- B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
- C. In accordance with current standards of medical practice;
- D. Not primarily for the convenience of the Member, or the Member's Provider; and
- E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

PROCEDURE:

An exception for coverage of self-administered antihemophilic agents for hemophilia A may be made for members who meet all of the following criteria:

- Medical record documentation of a diagnosis of hemophilia A (a documented Factor VIII deficiency) **AND**
- Medical record documentation that the antihemophilic agent will be for outpatient use **AND**
- Medical record documentation that the antihemophilic agent will be used appropriately for routine prophylaxis, on-demand treatment/control of bleeding episodes, **OR** perioperative management of bleeding **AND**
- If the request is for Jivi:
 - Medical record documentation of age greater than or equal to 12 years **AND**
 - Medical record documentation that the member has previously received treatment for hemophilia A with a Factor VIII product

MEDISPAN AUTHORIZATION LEVEL: GPI-12

	Routine Prophylaxis	On-Demand/ Perioperative
Advate	X	X
Adynovate	X	X
Afstyla	X	X
Eloctate	X	X
Esperoct	X	X
Helixate FS	X	X
Hemofil M		X
Jivi	X	X
Koate/Koate-DVI		X
Kogenate FS	X	X



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 514.0

**SECTION: Commercial Drug
SUBJECT: Antihemophilic Agents for
Hemophilia A**

Kovaltry	X	X
Monoclate-P		X
Novoeight	X	X
Nuwiq	X	X
Obizur		X
Recombinate		X
Xyntha/Xyntha Solofuse		X

NOTE: Obizur is indicated for adult patients with acquired hemophilia A.

If an exception is made, the antihemophilic agent for hemophilia A will be paid for under the member's prescription drug benefit.

Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.

FORMULARY ALTERNATIVES:

none

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE
STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND
FEDERAL REGULATORY ENTITIES.**

**THIS POLICY WILL BE REVISED AS NECESSARY AND
REVIEWED NO LESS THAN ANNUALLY.**

Signed: _____

Title: Director, Pharmacy Services

Date: March 1, 2022

- Devised: 7/20/18
- Revised: 10/8/18 – removed Tretten
- Reviewed: 3/1/19 – annual review
- Revised: 3/28/19 – corrected two typos, added Jivi to policy, added Obizur note
- Revised: 3/1/20 – annual review, added GHP Kids
- Revised: 5/29/20 – added Esperoct to policy



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 514.0

**SECTION: Commercial Drug
SUBJECT: Antihemophilic Agents for
Hemophilia A**

Revised: 3/1/21 – annual review, updated logo, added MediSpan approval level

Revised: 3/1/22 – annual review, updated referenced policies & covered LOBs



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 515.0

**SECTION: Commercial Drug
SUBJECT: Novoseven**

Applicable line of business:

Commercial	X	Medicaid	
Medicare		ACA	X
GHP Kids	X	Self-Insured	X

POLICY:

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for Novoseven for GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 487.0 Quantity Limit Exceptions

REQUIRED DEFINITIONS:

1. **Attachment** – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. **Exhibit** – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
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4. **Revised** – the date of every revision to the policy, including typographical and grammatical changes.
5. **Reviewed** – the date documenting the annual review if the policy has no revisions necessary.

ADDITIONAL DEFINITIONS:

1. **Formulary** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. **Non-formulary products** – those medications that are not included in the Formulary.
3. **Healthcare provider** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
4. **NCQA** – National Committee for Quality Assurance.
5. **Medically Necessary or Medical Necessity** – covered services rendered by a provider that the Health Plan determines are:



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 515.0

**SECTION: Commercial Drug
SUBJECT: Novoseven**

- A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
- B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
- C. In accordance with current standards of medical practice;
- D. Not primarily for the convenience of the Member, or the Member's Provider; and
- E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

PROCEDURE:

An exception for coverage of Novoseven may be made for members who meet all of the following criteria:

- Medical record documentation of a diagnosis of hemophilia A or B with inhibitors, congenital Factor VII deficiency, **OR** Glanzmann's thrombasthenia with refractoriness to platelet transfusions, with or without antibodies to platelets **AND**
- Medical record documentation that the antihemophilic agent will be for outpatient use **AND**
- Medical record documentation that the antihemophilic agent will be used for on-demand treatment/control of bleeding episodes **OR** perioperative management of bleeding

AND

- For hemophilia A or B with inhibitors, medical record documentation that the member has factor inhibitors (neutralizing antibodies), confirmed by laboratory testing (ie. Bethesda assay)

AND

- For hemophilia A with inhibitors, medical record documentation of therapeutic failure on, intolerance to, or contraindication to Feiba

MEDISPAN AUTHORIZATION LEVEL: GPI-12

If an exception is made, Novoseven will be paid for under the member's prescription drug benefit.

Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.

Geisinger

**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 515.0

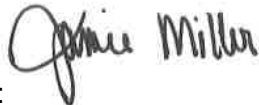
**SECTION: Commercial Drug
SUBJECT: Novoseven**

FORMULARY ALTERNATIVES:

none

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE
STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND
FEDERAL REGULATORY ENTITIES.**

**THIS POLICY WILL BE REVISED AS NECESSARY AND
REVIEWED NO LESS THAN ANNUALLY.**



Signed: _____

Title: Director, Pharmacy Services

Date: March 1, 2022

Devised: 7/20/18
Reviewed: 3/1/19 – annual review
Revised: 3/1/20 – annual review, added GHP Kids
Revised: 3/1/21 – annual review, updated logo, added MediSpan approval level
Revised: 3/1/22 – annual review, updated referenced policies & covered LOBs



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 516.0

**SECTION: Commercial Drug
SUBJECT: Feiba**

Applicable line of business:

Commercial	X	Medicaid	
Medicare		ACA	X
GHP Kids	X	Self-Insured	X

POLICY:

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for Feiba for GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 487.0 Quantity Limit Exceptions

REQUIRED DEFINITIONS:

1. **Attachment** – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. **Exhibit** – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. **Devised** – the date the policy was implemented.
4. **Revised** – the date of every revision to the policy, including typographical and grammatical changes.
5. **Reviewed** – the date documenting the annual review if the policy has no revisions necessary.

ADDITIONAL DEFINITIONS:

1. **Formulary** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. **Non-formulary products** – those medications that are not included in the Formulary.
3. **Healthcare provider** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
4. **NCQA** – National Committee for Quality Assurance.
5. **Medically Necessary or Medical Necessity** – covered services rendered by a provider that the Health Plan determines are:



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 516.0

**SECTION: Commercial Drug
SUBJECT: Feiba**

- A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
- B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
- C. In accordance with current standards of medical practice;
- D. Not primarily for the convenience of the Member, or the Member's Provider; and
- E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

PROCEDURE:

An exception for coverage of Feiba may be made for members who meet all of the following criteria:

- Medical record documentation of a diagnosis of hemophilia A (a documented Factor VIII deficiency) or hemophilia B (a documented Factor IX deficiency) **AND**
 - Medical record documentation that the antihemophilic agent will be for outpatient use **AND**
 - Medical record documentation that the member has factor inhibitors (neutralizing antibodies), confirmed by laboratory testing (i.e., Bethesda assay) **AND**
 - Medical record documentation that the antihemophilic agent will be used for on-demand treatment or perioperative management of bleeds
- OR**
- Medical record documentation that the antihemophilic agent will be used for routine prophylaxis **AND** if being used for hemophilia A: medical record documentation of therapeutic failure on, intolerance to, or contraindication to Hemlibra

MEDISPAN AUTHORIZATION LEVEL: GPI-12

If an exception is made, Feiba will be paid for under the member's prescription drug benefit.

Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.

FORMULARY ALTERNATIVES:

none



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 516.0

**SECTION: Commercial Drug
SUBJECT: Feiba**

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE
STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND
FEDERAL REGULATORY ENTITIES.**

**THIS POLICY WILL BE REVISED AS NECESSARY AND
REVIEWED NO LESS THAN ANNUALLY.**

Signed: _____

Title: Director, Pharmacy Services

Date: March 1, 2022

Devised: 7/20/18
Revised: 10/8/18 – added hemophilia B indication, clarified failure of Hemlibra for hemophilia A
Reviewed: 3/1/19 – annual review
Revised: 3/1/20 – annual review, added GHP Kids
Revised: 3/1/21 – annual review, updated logo, added MediSpan approval level
Revised: 3/1/22 – annual review, updated referenced policies & covered LOBs



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 517.0

**SECTION: Commercial Drug
SUBJECT: Noctiva and Nocdurna**

Applicable line of business:

Commercial	X	Medicaid	
Medicare		ACA	X
GHP Kids	X	Self-Insured	X

POLICY:

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for Noctiva and Nocdurna for GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 487.0 Quantity Limit Exceptions

REQUIRED DEFINITIONS:

1. **Attachment** – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. **Exhibit** – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. **Devised** – the date the policy was implemented.
4. **Revised** – the date of every revision to the policy, including typographical and grammatical changes.
5. **Reviewed** – the date documenting the annual review if the policy has no revisions necessary.

ADDITIONAL DEFINITIONS:

1. **Formulary** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. **Non-formulary products** – those medications that are not included in the Formulary.
3. **Healthcare provider** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
4. **NCQA** – National Committee for Quality Assurance.
5. **Medically Necessary or Medical Necessity** – covered services rendered by a provider that the Health Plan determines are:

- A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
- B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
- C. In accordance with current standards of medical practice;
- D. Not primarily for the convenience of the Member, or the Member's Provider; and
- E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

PROCEDURE:

An exception for coverage of Noctiva or Nocdurna may be made for members who meet the following criteria:

- **For Noctiva:** Medical record documentation of age greater than or equal to 50 years **OR**
- **For Nocdurna:** Medical record documentation of age greater than or equal to 18 years **AND**
- Medical record documentation of a diagnosis of nocturia due to nocturnal polyuria, as defined by a night-time urine production exceeding one-third of the 24-hour urine production confirmed with a 24-hour urine frequency/volume chart **AND**
- Medical record documentation that the member is waking at least 2 times per night to void **AND**
- Medical record documentation that the member is not currently hyponatremic (serum sodium < 135 meq/L) and does not have a history of hyponatremia **AND**
- Medical record documentation of an estimated glomerular filtration rate (eGFR) greater than or equal to 50 mL/min/1.73 m² **AND**
- Medical record documentation that the member has no diagnosis of syndrome of inappropriate antidiuretic hormone (SIADH) secretion, New York Heart Association (NYHA) class II-IV congestive heart failure, or uncontrolled hypertension **AND**
- Medical record documentation that Noctiva is not being used in combination with a loop diuretic or systemic or inhaled glucocorticoids

NOTE: the usual dosage for Nocdurna

- Females: 27.7 mcg once daily sublingually, one hour before bedtime (lower dose for women due to the higher risk of hyponatremia)
- Males: 55.3 mcg once daily sublingually, one hour before bedtime

AUTHORIZATION DURATION: Initial and subsequent approvals will be for six (6) months. Requests for continuation of coverage will be approved for members who meet the following criteria:

- Medical record documentation that the member is experiencing clinical benefit from the use of Noctiva or Nocdurna **AND**
- Medical record documentation that the member is not currently hyponatremic (serum sodium < 135 meq/L) and does not have a history of hyponatremia **AND**
- Medical record documentation of an estimated glomerular filtration rate (eGFR) greater than 50 mL/min/1.73m² **AND**
- Medical record documentation that the member has no diagnosis of syndrome of inappropriate antidiuretic hormone (SIADH) secretion, New York Heart Association (NYHA) class II-IV congestive heart failure, or uncontrolled hypertension **AND**
- Medical record documentation that Noctiva or Nocdurna is not being used in combination with a loop diuretic or systemic or inhaled glucocorticoids

MEDISPAN AUTHORIZATION LEVEL:

- Noctiva: GPI-12
- Nocdurna: GPI-14

QUANTITY LIMIT: *No QLs need to be entered within the authorization unless the requested quantity exceeds the QL.*

- **QL FOR LETTER ONLY:**
 - Noctiva: 3.8 grams per 30 days
 - Nocdurna: 1 tablet per day

If a formulary exception is approved, Noctiva or Nocdurna will be paid for under the member's prescription drug benefit.

Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.

FORMULARY ALTERNATIVES:

none

Geisinger

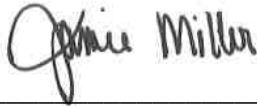
**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 517.0

**SECTION: Commercial Drug
SUBJECT: Noctiva and Nocdurna**

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE
STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND
FEDERAL REGULATORY ENTITIES.**

**THIS POLICY WILL BE REVISED AS NECESSARY AND
REVIEWED NO LESS THAN ANNUALLY.**



Signed: _____

Title: Director, Pharmacy Services

Date: March 1, 2022

Devised: 7/27/18
Revised: 3/1/19 – annual review, added QL approval note
Revised: 5/24/19 – added Nocdurna to policy
Revised: 3/1/20 – annual review, added GHP Kids
Revised: 3/1/21 – annual review, updated logo, added MediSpan approval level, updated QL statement
Revised: 3/1/22 – annual review, updated referenced policies & covered LOBs



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 518.0

**SECTION: Commercial Drug
SUBJECT: Symdeko**

Applicable line of business:

Commercial	X	Medicaid	
Medicare		ACA	X
GHP Kids	X	Self-Insured	X

POLICY:

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for Symdeko for GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 487.0 Quantity Limit Exceptions

REQUIRED DEFINITIONS:

1. **Attachment** – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. **Exhibit** – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. **Devised** – the date the policy was implemented.
4. **Revised** – the date of every revision to the policy, including typographical and grammatical changes.
5. **Reviewed** – the date documenting the annual review if the policy has no revisions necessary.

ADDITIONAL DEFINITIONS:

1. **Formulary** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. **Non-formulary products** – those medications that are not included in the Formulary.
3. **Healthcare provider** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
4. **NCQA** – National Committee for Quality Assurance.
5. **Medically Necessary or Medical Necessity** – covered services rendered by a provider that the Health Plan determines are:

- A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
- B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
- C. In accordance with current standards of medical practice;
- D. Not primarily for the convenience of the Member, or the Member's Provider; and
- E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

PROCEDURE:

An exception for coverage of Symdeko may be made for members who meet the following criteria:

- Medical record documentation that Symdeko is prescribed by a pulmonologist or cystic fibrosis specialist **AND**
- Medical record documentation of age greater than or equal to 6 years **AND**
- Medical record documentation of a diagnosis of cystic fibrosis (CF) **AND**
- Medical record documentation of one of the following, as detected by a Food and Drug Administration (FDA) cleared cystic fibrosis (CF) mutation test:
 - Medical record documentation that the member is homozygous for the *F508del* CFTR mutation **OR**
 - Medical record documentation that the member has at least one mutation in the CFTR gene that is responsive to tezacaftor/ivacaftor per product labeling

NOTE: List of CFTR gene mutations that are responsive to Symdeko:

<i>E56K</i>	<i>R117C</i>	<i>A455E</i>	<i>S977F</i>	<i>F1074L</i>	<i>3849+10kbC→T</i>
<i>P67L</i>	<i>E193K</i>	<i>D579G</i>	<i>F1052V</i>	<i>D1152H</i>	
<i>R74W</i>	<i>L206W</i>	<i>711+3A→G</i>	<i>K1060T</i>	<i>D1270N</i>	
<i>D110E</i>	<i>R347H</i>	<i>E831X</i>	<i>A1067T</i>	<i>2789+5G→A</i>	
<i>D110H</i>	<i>R352Q</i>	<i>S945L</i>	<i>R1070W</i>	<i>3272-26A→G</i>	

MEDISPAN AUTHORIZATION LEVEL: GPI-12

QUANTITY LIMIT: *No QLs need to be entered within the authorization unless the requested quantity exceeds the QL.*

- **QL FOR LETTER ONLY:** 2 tablets per day, 28 day supply per fill



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 518.0

**SECTION: Commercial Drug
SUBJECT: Symdeko**

AUTHORIZATION DURATION: Initial approval will be for four (4) months and subsequent approvals will be for twelve (12) months. Additional authorizations will require medical record documentation of improvement or stabilization in the signs and symptoms of cystic fibrosis. The medication will no longer be covered if the member experiences worsening of disease.

If a formulary exception is approved, Symdeko will be paid for under the member's prescription drug benefit.

Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.

FORMULARY ALTERNATIVES:

none

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE
STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND
FEDERAL REGULATORY ENTITIES.**

**THIS POLICY WILL BE REVISED AS NECESSARY AND
REVIEWED NO LESS THAN ANNUALLY.**

Signed: _____

Title: Director, Pharmacy Services

Date: March 1, 2022

Devised: 7/27/18
Revised: 3/1/19 – annual review, added QL approval note
Revised: 11/20/19 – updated age criteria to 6 years and older
Revised: 3/1/20 – annual review, added GHP Kids
Revised: 3/1/21 – annual review, updated logo, added MediSpan approval level, updated QL statement
Revised: 3/1/22 – annual review, updated referenced policies & covered LOBs



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 519.0

**SECTION: Commercial Drug
SUBJECT: Yonsa**

Applicable line of business:

Commercial	X	Medicaid	
Medicare		ACA	X
GHP Kids	X	Self-Insured	X

POLICY:

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for Yonsa for GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 487.0 Quantity Limit Exceptions

REQUIRED DEFINITIONS:

1. **Attachment** – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. **Exhibit** – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. **Devised** – the date the policy was implemented.
4. **Revised** – the date of every revision to the policy, including typographical and grammatical changes.
5. **Reviewed** – the date documenting the annual review if the policy has no revisions necessary.

ADDITIONAL DEFINITIONS:

1. **Formulary** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. **Non-formulary products** – those medications that are not included in the Formulary.
3. **Healthcare provider** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
4. **NCQA** – National Committee for Quality Assurance.
5. **Medically Necessary or Medical Necessity** – covered services rendered by a provider that the Health Plan determines are:



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 519.0

**SECTION: Commercial Drug
SUBJECT: Yonsa**

- A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
- B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
- C. In accordance with current standards of medical practice;
- D. Not primarily for the convenience of the Member, or the Member's Provider; and
- E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

PROCEDURE:

New members to the plan already established on therapy may be eligible for continuity of care coverage as long as there is medical record documentation that the safety and effectiveness of use for the prescribed indication is supported by Food and Drug Administration (FDA) approval or adequate medical and scientific evidence in the medical literature.

An exception for coverage of Yonsa may be made for members who meet the following criteria:

- Medical record documentation that Yonsa is prescribed by an oncologist or urologist **AND**
- Medical record documentation of a diagnosis of prostate cancer with evidence of metastatic disease **AND**
- Medical record documentation that the member is no longer responding to castration or is hormone resistant **AND**
- Medical record documentation that methylprednisolone will be administered concomitantly with Yonsa

MEDISPAN AUTHORIZATION LEVEL: GPI-14, number of claims authorized = 1, enter for the remainder of the calendar year

QUANTITY LIMIT: *No QLs need to be entered within the authorization unless the requested quantity exceeds the QL.*

- **QL FOR LETTER ONLY:** 4 tablets per day, 30 day supply per fill



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 519.0

**SECTION: Commercial Drug
SUBJECT: Yonsa**

RE-AUTHORIZATION CRITERIA: Yonsa is configured as a prior authorization for new starts only. Yonsa will no longer be covered if it is identified that the member is not receiving appropriate follow-up care from the prescribing specialist or if the member has greater than or equal to a 90 day break in therapy.

- Medical record documentation that the member is receiving appropriate follow-up care from the prescribing specialist

If a formulary exception is approved, Yonsa will be paid for under the member's prescription drug benefit.

Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.

FORMULARY ALTERNATIVES:

Xtandi*, Zytiga*, abiraterone acetate*

*prior authorization required

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE
STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND
FEDERAL REGULATORY ENTITIES.**

**THIS POLICY WILL BE REVISED AS NECESSARY AND
REVIEWED NO LESS THAN ANNUALLY.**

Signed: _____

Title: Director, Pharmacy Services

Date: March 1, 2022

- Devised: 8/7/18
Revised: 3/1/19 – annual review, added QL approval note, updated FA
Revised: 3/1/20 – annual review, added GHP Kids
Revised: 3/1/21 – annual review, updated logo, added MediSpan approval level, updated QL statement
Revised: 12/2/21 – added one-time PA to approval crit., removed auth duration & added re-auth crit.
Revised: 3/1/22 – annual review, updated referenced policies & covered LOBs

Applicable line of business:

Commercial	X	Medicaid	
Medicare		ACA	X
GHP Kids	X	Self-Insured	X

POLICY:

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for Lucemyra for GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 487.0 Quantity Limit Exceptions

REQUIRED DEFINITIONS:

1. **Attachment** – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. **Exhibit** – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. **Devised** – the date the policy was implemented.
4. **Revised** – the date of every revision to the policy, including typographical and grammatical changes.
5. **Reviewed** – the date documenting the annual review if the policy has no revisions necessary.

ADDITIONAL DEFINITIONS:

1. **Formulary** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. **Non-formulary products** – those medications that are not included in the Formulary.
3. **Healthcare provider** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
4. **NCQA** – National Committee for Quality Assurance.
5. **Medically Necessary or Medical Necessity** – covered services rendered by a provider that the Health Plan determines are:



POLICY NUMBER: 520.0

**POLICY AND PROCEDURE
PHARMACY
MANUAL**

**SECTION: Commercial Drug
SUBJECT: Lucemyra**

- A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
- B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
- C. In accordance with current standards of medical practice;
- D. Not primarily for the convenience of the Member, or the Member's Provider; and
- E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

PROCEDURE:

An exception for coverage of Lucemyra may be made for members who meet the following criteria:

- Medical record documentation of a diagnosis of use to mitigate opioid withdrawal symptoms in patients abruptly discontinuing opioids **AND**
- Medical record documentation of a Clinical Opiate Withdrawal Scale (COWS) score greater than or equal to 5 **AND**
- Medical record documentation of age greater than or equal to 18 years **AND**
- Medical record documentation of therapeutic failure on, intolerance to, or contraindication to clonidine

MEDISPAN AUTHORIZATION LEVEL: GPI-12

QUANTITY LIMIT: *No QLs need to be entered within the authorization unless the requested quantity exceeds the QL.*

- **QL FOR LETTER ONLY:** 16 tablets per day, 7 day supply per fill

AUTHORIZATION DURATION: 14 days, number of claims authorized 2

If a formulary exception is approved, Lucemyra will be paid for under the member's prescription drug benefit.

Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.

Geisinger

**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 520.0

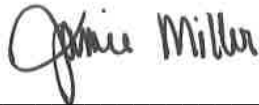
**SECTION: Commercial Drug
SUBJECT: Lucemyra**

FORMULARY ALTERNATIVES:

oral clonidine, clonidine transdermal patch

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE
STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND
FEDERAL REGULATORY ENTITIES.**

**THIS POLICY WILL BE REVISED AS NECESSARY AND
REVIEWED NO LESS THAN ANNUALLY.**



Signed: _____

Title: Director, Pharmacy Services

Date: March 1, 2022

Devised: 10/1/18

Revised: 3/1/19 – annual review, added QL approval note

Revised: 3/1/20 – annual review, added GHP Kids

Revised: 3/1/21 – annual review, updated logo, added MediSpan approval level, updated QL & auth duration

Revised: 3/1/22 – annual review, updated referenced policies & covered LOBs



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 521.0

**SECTION: Commercial Drug
SUBJECT: Xhance**

Applicable line of business:

Commercial	X	Medicaid	
Medicare		ACA	X
GHP Kids	X	Self-Insured	X

POLICY:

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for Xhance for GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 487.0 Quantity Limit Exceptions

REQUIRED DEFINITIONS:

1. **Attachment** – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. **Exhibit** – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. **Devised** – the date the policy was implemented.
4. **Revised** – the date of every revision to the policy, including typographical and grammatical changes.
5. **Reviewed** – the date documenting the annual review if the policy has no revisions necessary.

ADDITIONAL DEFINITIONS:

1. **Formulary** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. **Non-formulary products** – those medications that are not included in the Formulary.
3. **Healthcare provider** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
4. **NCQA** – National Committee for Quality Assurance.
5. **Medically Necessary or Medical Necessity** – covered services rendered by a provider that the Health Plan determines are:



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 521.0

**SECTION: Commercial Drug
SUBJECT: Xhance**

- A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
- B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
- C. In accordance with current standards of medical practice;
- D. Not primarily for the convenience of the Member, or the Member's Provider; and
- E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

PROCEDURE:

An exception for coverage of Xhance may be made for members who meet the following criteria:

- Medical record documentation of age greater than or equal to 18 years **AND**
- Medical record documentation of a diagnosis of nasal polyps **AND**
- Medical record documentation of therapeutic failure on, intolerance to, or contraindication to mometasone furoate **AND** Beconase AQ

MEDISPAN AUTHORIZATION LEVEL: GPI-12

If a formulary exception is approved, Xhance will be paid for under the member's prescription drug benefit.

Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.

FORMULARY ALTERNATIVES:

mometasone furoate, Beconase AQ*

*prior authorization required



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 521.0

**SECTION: Commercial Drug
SUBJECT: Xhance**

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE
STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND
FEDERAL REGULATORY ENTITIES.**

**THIS POLICY WILL BE REVISED AS NECESSARY AND
REVIEWED NO LESS THAN ANNUALLY.**

Signed: _____

Title: Director, Pharmacy Services

Date: March 1, 2022

Devised: 10/1/18
Reviewed: 3/1/19 – annual review
Revised: 3/1/20 – annual review, added GHP Kids
Revised: 3/1/21 – annual review, updated logo, added MediSpan approval level
Revised: 3/1/22 – annual review, updated referenced policies & covered LOBs



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 522.0

**SECTION: Commercial Drug
SUBJECT: Zypitamag**

Applicable line of business:

Commercial	X	Medicaid	
Medicare		ACA	X
GHP Kids	X	Self-Insured	X

POLICY:

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for agents to treat insomnia for GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 487.0 Quantity Limit Exceptions
- Policy 469.0 Statin Quantity Limit Exceptions

REQUIRED DEFINITIONS:

1. **Attachment** – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. **Exhibit** – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. **Devised** – the date the policy was implemented.
4. **Revised** – the date of every revision to the policy, including typographical and grammatical changes.
5. **Reviewed** – the date documenting the annual review if the policy has no revisions necessary.

ADDITIONAL DEFINITIONS:

1. **Formulary** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. **Non-formulary products** – those medications that are not included in the Formulary.
3. **Healthcare provider** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
4. **NCQA** – National Committee for Quality Assurance.

5. **Medically Necessary or Medical Necessity** – covered services rendered by a provider that the Health Plan determines are:
- A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
 - B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
 - C. In accordance with current standards of medical practice;
 - D. Not primarily for the convenience of the Member, or the Member's Provider; and
 - E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

PROCEDURE:

An exception for coverage of Zypitamag may be made for members who meet the following criteria:

- Medical record documentation of therapeutic failure on (including up-to-date laboratory values), intolerance to, or contraindication to reach goal LDL (per NCEP guidelines) after titration to tolerated doses of simvastatin **AND** atorvastatin **AND** rosuvastatin

MEDISPAN AUTHORIZATION LEVEL: GPI-12

QUANTITY LIMIT: *No QLs need to be entered within the authorization unless the requested quantity exceeds the QL.*

- QL FOR LETTER ONLY: 1 tablet per day

If a formulary exception is approved, Zypitamag will be paid for under the member's prescription drug benefit.

Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.

FORMULARY ALTERNATIVES:

atorvastatin, rosuvastatin, simvastatin, fluvastatin, lovastatin, pravastatin



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 522.0

**SECTION: Commercial Drug
SUBJECT: Zypitamag**

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE
STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND
FEDERAL REGULATORY ENTITIES.**

**THIS POLICY WILL BE REVISED AS NECESSARY AND
REVIEWED NO LESS THAN ANNUALLY.**

Signed: _____

Title: Director, Pharmacy Services

Date: March 1, 2022

Devised: 10/1/18
Revised: 3/1/19 – annual review, added QL approval note
Revised: 3/1/20 – annual review, added GHP Kids
Revised: 3/1/21 – annual review, updated logo, added MediSpan approval level, updated QL statement
Revised: 3/1/22 – annual review, updated referenced policies & covered LOBs



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 523.0

**SECTION: Commercial Drug
SUBJECT: Rhopressa**

Applicable line of business:

Commercial	X	Medicaid	
Medicare		ACA	X
GHP Kids	X	Self-Insured	X

POLICY:

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for Rhopressa for GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 487.0 Quantity Limit Exceptions

REQUIRED DEFINITIONS:

1. **Attachment** – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. **Exhibit** – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. **Devised** – the date the policy was implemented.
4. **Revised** – the date of every revision to the policy, including typographical and grammatical changes.
5. **Reviewed** – the date documenting the annual review if the policy has no revisions necessary.

ADDITIONAL DEFINITIONS:

1. **Formulary** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. **Non-formulary products** – those medications that are not included in the Formulary.
3. **Healthcare provider** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
4. **NCQA** – National Committee for Quality Assurance.
5. **Medically Necessary or Medical Necessity** – covered services rendered by a provider that the Health Plan determines are:



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 523.0

**SECTION: Commercial Drug
SUBJECT: Rhopressa**

- A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
- B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
- C. In accordance with current standards of medical practice;
- D. Not primarily for the convenience of the Member, or the Member's Provider; and
- E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

PROCEDURE:

An exception for coverage of Rhopressa may be made for members who meet the following criteria:

- Medical record documentation of therapeutic failure on, intolerance to, or contraindication to three (3) formulary alternatives, one of which must be a prostaglandin analog

MEDISPAN AUTHORIZATION LEVEL: GPI-12

QUANTITY LIMIT: *No QLs need to be entered within the authorization unless the requested quantity exceeds the QL.*

- QL FOR LETTER ONLY: 0.17 mL per day

NOTE: There are certain ocular inflammatory conditions including iritis and uveitis which do not warrant the use of Prostaglandin eye drops as first line therapy.

If a formulary exception is approved, Rhopressa will be paid for under the member's prescription drug benefit.

Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.

FORMULARY ALTERNATIVES:

brimonidine, latanoprost, Zioptan*, travoprost, Alphagan P, Azopt, Vyzulta*, Lumigan*, Simbrinza, Combigan

*prior authorization or step therapy required



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 523.0

**SECTION: Commercial Drug
SUBJECT: Rhopressa**

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE
STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND
FEDERAL REGULATORY ENTITIES.**

**THIS POLICY WILL BE REVISED AS NECESSARY AND
REVIEWED NO LESS THAN ANNUALLY.**

Signed: _____

Title: Director, Pharmacy Services

Date: March 1, 2022

Devised: 10/1/18
Revised: 12/28/18 – added note
Revised: 3/1/19 – annual review, added QL approval note
Revised: 3/1/20 – annual review, added GHP Kids
Revised: 3/1/21 – annual review, updated logo, added MediSpan approval level, updated QL statement,
updated FA
Revised: 3/1/22 – annual review, updated referenced policies & covered LOBs



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 524.0

**SECTION: Commercial Drug
SUBJECT: Tavalisse**

Applicable line of business:

Commercial	X	Medicaid	
Medicare		ACA	X
GHP Kids	X	Self-Insured	X

POLICY:

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for Tavalisse for GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 487.0 Quantity Limit Exceptions

REQUIRED DEFINITIONS:

1. **Attachment** – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. **Exhibit** – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. **Devised** – the date the policy was implemented.
4. **Revised** – the date of every revision to the policy, including typographical and grammatical changes.
5. **Reviewed** – the date documenting the annual review if the policy has no revisions necessary.

ADDITIONAL DEFINITIONS:

1. **Formulary** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. **Non-formulary products** – those medications that are not included in the Formulary.
3. **Healthcare provider** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
4. **NCQA** – National Committee for Quality Assurance.
5. **Medically Necessary or Medical Necessity** – covered services rendered by a provider that the Health Plan determines are:



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 524.0

**SECTION: Commercial Drug
SUBJECT: Tavalisse**

- A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
- B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
- C. In accordance with current standards of medical practice;
- D. Not primarily for the convenience of the Member, or the Member's Provider; and
- E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

PROCEDURE:

An exception for coverage of Tavalisse may be made for members who meet the following criteria:

- Medical record documentation that Tavalisse is prescribed by or in consultation with a hematologist **AND**
- Medical record documentation of age greater than or equal to 18 years **AND**
- Medical record documentation of a diagnosis of chronic immune thrombocytopenia (cITP) **AND**
- Medical record documentation of symptomatic immune thrombocytopenia (ITP) with bleeding symptoms and platelet count less than 30,000/microL and bleeding symptoms **OR** a platelet count less than 30,000/microL and a documented history of significant bleeding **OR** a platelet count of less than 20,000/microL **AND**
- Medical record documentation of therapeutic failure on, intolerance to, or contraindication to three (3) of the following:
 - Corticosteroids
 - Intravenous Immunoglobulin (IVIG)*
 - Rhogam (if RhD-positive and spleen intact)
 - Rituximab*
 - Splenectomy
 - Promacta*/Nplate*/Doptelet*

MEDISPAN AUTHORIZATION LEVEL: GPI-12

QUANTITY LIMIT: *No QLs need to be entered within the authorization unless the requested quantity exceeds the QL.*

- **QL FOR LETTER ONLY:** 2 tablets per day, 30 day supply per fill



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 524.0

**SECTION: Commercial Drug
SUBJECT: Tavalisse**

AUTHORIZATION DURATION: Initial approval will be for three (3) months and subsequent approvals will be for twelve (12) months. Continued coverage will require:

- Medical record documentation of platelet count greater than or equal to 50,000/microL and continued or sustained reduction in bleeding events.

If a formulary exception is approved, Tavalisse will be paid for under the member's prescription drug benefit.

Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.

FORMULARY ALTERNATIVES:

prednisone, dexamethasone, Promacta*, Doptelet*

*prior authorization required

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE
STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND
FEDERAL REGULATORY ENTITIES.**

**THIS POLICY WILL BE REVISED AS NECESSARY AND
REVIEWED NO LESS THAN ANNUALLY.**

Signed: _____

Title: Director, Pharmacy Services

Date: June 7, 2022

Devised: 10/1/18
Revised: 3/1/19 – annual review, added QL approval note
Revised: 3/1/20 – annual review, added GHP Kids
Revised: 3/1/21 – annual review, updated logo, added MediSpan approval level, updated QL statement
Revised: 3/1/22 – annual review, updated referenced policies & covered LOBs
Revised: 6/7/22 – upd. platelet count criterion, corrected typos, upd. Rituxan to rituximab, added Doptelet



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 525.0

**SECTION: Commercial Drug
SUBJECT: Braftovi**

Applicable line of business:

Commercial	X	Medicaid	
Medicare		ACA	X
GHP Kids	X	Self-Insured	X

POLICY:

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for Braftovi for GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 487.0 Quantity Limit Exceptions

REQUIRED DEFINITIONS:

1. **Attachment** – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. **Exhibit** – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. **Devised** – the date the policy was implemented.
4. **Revised** – the date of every revision to the policy, including typographical and grammatical changes.
5. **Reviewed** – the date documenting the annual review if the policy has no revisions necessary.

ADDITIONAL DEFINITIONS:

1. **Formulary** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. **Non-formulary products** – those medications that are not included in the Formulary.
3. **Healthcare provider** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
4. **NCQA** – National Committee for Quality Assurance.
5. **Medically Necessary or Medical Necessity** – covered services rendered by a provider that the Health Plan determines are:



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 525.0

**SECTION: Commercial Drug
SUBJECT: Braftovi**

- A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
- B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
- C. In accordance with current standards of medical practice;
- D. Not primarily for the convenience of the Member, or the Member's Provider; and
- E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

PROCEDURE:

New members to the plan already established on therapy may be eligible for continuity of care coverage as long as there is medical record documentation that the safety and effectiveness of use for the prescribed indication is supported by Food and Drug Administration (FDA) approval or adequate medical and scientific evidence in the medical literature.

An exception for coverage of Braftovi may be made for members who meet the following criteria:

Melanoma

- Medical record documentation that Braftovi is prescribed by a hematologist, oncologist, or dermatologist **AND**
- Medical record documentation of a diagnosis of unresectable or metastatic melanoma **AND**
- Medical record documentation of a BRAF V600E or V600K mutation as detected by a Food and Drug Administration (FDA)-approved test **AND**
- Medical record documentation that Braftovi is being prescribed in combination with Mektovi*

NOTE: Braftovi may be temporarily used as monotherapy if Mektovi must be held for any reason. If Mektovi is to be discontinued permanently, Braftovi should also be discontinued.

Colorectal Cancer

- Medical record documentation that Braftovi is prescribed by a hematologist, oncologist, or dermatologist **AND**
- Medical record documentation of a diagnosis of metastatic colorectal cancer **AND**



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 525.0

**SECTION: Commercial Drug
SUBJECT: Braftovi**

- Medical record documentation of a BRAF V600E mutation as detected by a Food and Drug Administration (FDA)-approved test **AND**
- Medical record documentation that member has had progression on at least one prior therapy **AND**
- Medical record documentation that Braftovi is being prescribed in combination with cetuximab

MEDISPAN AUTHORIZATION LEVEL: GPI-12

QUANTITY LIMIT:

- Melanoma - *No QLs need to be entered within the authorization unless the requested quantity exceeds the QL.*
 - In PA Hub: Add PA, max number of claims authorized 1, enter for the remainder of the calendar year.
 - **QL FOR LETTER ONLY:** 6 tablets per day, 30 day supply per fill
- Colorectal Cancer – *QL must be entered within the authorization*
 - In PA Hub: Add PA, max number of claims authorized 1, enter for the remainder of the calendar year.
 - In Darwin: Add OQL, and max daily dose 4, min/max day supply 30.
 - **QL FOR LETTER:** 4 tablets per day, 30 day supply per fill

RE-AUTHORIZATION CRITERIA: Braftovi is configured as a prior authorization for new starts only. Braftovi will no longer be covered if it is identified that the member is not receiving appropriate follow-up care from the prescribing specialist or if the member has greater than or equal to a 90 day break in therapy.

- Medical record documentation that the member is receiving appropriate follow-up care from the prescribing specialist

If a formulary exception is approved, Braftovi will be paid for under the member's prescription drug benefit.

Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.

FORMULARY ALTERNATIVES:

Melanoma: Tafinlar*, Zelboraf*

*prior authorization required

Geisinger

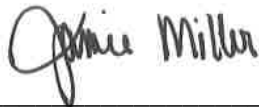
**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 525.0

**SECTION: Commercial Drug
SUBJECT: Braftovi**

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE
STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND
FEDERAL REGULATORY ENTITIES.**

**THIS POLICY WILL BE REVISED AS NECESSARY AND
REVIEWED NO LESS THAN ANNUALLY.**



Signed: _____

Title: Director, Pharmacy Services

Date: March 1, 2022

Devised: 10/1/18
Revised: 3/1/19 – annual review, added QL approval note
Revised: 3/1/20 – annual review, added GHP Kids
Revised: 6/4/20 – added colorectal cancer indication
Revised: 3/1/21 – annual review, updated logo, added MediSpan approval level, updated QL statement,
removed 50 mg QL due to D/C
Revised: 11/24/21 – added one-time PA to approval crit., removed auth duration & added re-auth crit.
Revised: 3/1/22 – annual review, updated referenced policies & covered LOBs, updated how auth is entered



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 526.0

**SECTION: Commercial Drug
SUBJECT: Mektovi**

Applicable line of business:

Commercial	X	Medicaid	
Medicare		ACA	X
GHP Kids	X	Self-Insured	X

POLICY:

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for Mektovi for GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 487.0 Quantity Limit Exceptions

REQUIRED DEFINITIONS:

1. **Attachment** – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. **Exhibit** – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. **Devised** – the date the policy was implemented.
4. **Revised** – the date of every revision to the policy, including typographical and grammatical changes.
5. **Reviewed** – the date documenting the annual review if the policy has no revisions necessary.

ADDITIONAL DEFINITIONS:

1. **Formulary** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. **Non-formulary products** – those medications that are not included in the Formulary.
3. **Healthcare provider** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
4. **NCQA** – National Committee for Quality Assurance.
5. **Medically Necessary or Medical Necessity** – covered services rendered by a provider that the Health Plan determines are:



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 526.0

**SECTION: Commercial Drug
SUBJECT: Mektovi**

- A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
- B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
- C. In accordance with current standards of medical practice;
- D. Not primarily for the convenience of the Member, or the Member's Provider; and
- E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

PROCEDURE:

New members to the plan already established on therapy may be eligible for continuity of care coverage as long as there is medical record documentation that the safety and effectiveness of use for the prescribed indication is supported by Food and Drug Administration (FDA) approval or adequate medical and scientific evidence in the medical literature.

An exception for coverage of Mektovi may be made for members who meet the following criteria:

- Medical record documentation that Mektovi is prescribed by a hematologist, oncologist, or dermatologist **AND**
- Medical record documentation of a diagnosis of unresectable or metastatic melanoma **AND**
- Medical record documentation of a BRAF V600E or V600K mutation as detected by a Food and Drug Administration (FDA)-approved test **AND**
- Medical record documentation that Mektovi is being prescribed in combination with Braftovi

MEDISPAN AUTHORIZATION LEVEL: GPI-12, number of claims authorized = 1, enter for the remainder of the calendar year

QUANTITY LIMIT: *No QLs need to be entered within the authorization unless the requested quantity exceeds the QL.*

- **QL FOR LETTER ONLY:** 6 tablets per day, 30 day supply per fill



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 526.0

**SECTION: Commercial Drug
SUBJECT: Mektovi**

RE-AUTHORIZATION CRITERIA: Mektovi is configured as a prior authorization for new starts only. Mektovi will no longer be covered if it is identified that the member is not receiving appropriate follow-up care from the prescribing specialist or if the member has greater than or equal to a 90 day break in therapy.

- Medical record documentation that the member is receiving appropriate follow-up care from the prescribing specialist

If a formulary exception is approved, Mektovi will be paid for under the member's prescription drug benefit.

Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.

FORMULARY ALTERNATIVES:

Mekinist*, Cotellic*

*prior authorization required

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE
STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND
FEDERAL REGULATORY ENTITIES.**

**THIS POLICY WILL BE REVISED AS NECESSARY AND
REVIEWED NO LESS THAN ANNUALLY.**

Signed: _____

Title: Director, Pharmacy Services

Date: March 1, 2022

Devised: 10/1/18
Revised: 3/1/19 – annual review, added QL approval note
Revised: 3/1/20 – annual review, added GHP Kids
Revised: 3/1/21 – annual review, updated logo, added MediSpan approval level, updated QL statement
Revised: 11/30/21 – added one-time PA to approval crit., removed auth duration & added re-auth crit.
Revised: 3/1/22 – annual review, updated referenced policies & covered LOBs



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 527.0

**SECTION: Commercial Drug
SUBJECT: Jynarque**

Applicable line of business:

Commercial	X	Medicaid	
Medicare		ACA	X
GHP Kids	X	Self-Insured	X

POLICY:

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for Jynarque for GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 487.0 Quantity Limit Exceptions

REQUIRED DEFINITIONS:

1. **Attachment** – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. **Exhibit** – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. **Devised** – the date the policy was implemented.
4. **Revised** – the date of every revision to the policy, including typographical and grammatical changes.
5. **Reviewed** – the date documenting the annual review if the policy has no revisions necessary.

ADDITIONAL DEFINITIONS:

1. **Formulary** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. **Non-formulary products** – those medications that are not included in the Formulary.
3. **Healthcare provider** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
4. **NCQA** – National Committee for Quality Assurance.
5. **Medically Necessary or Medical Necessity** – covered services rendered by a provider that the Health Plan determines are:



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 527.0

**SECTION: Commercial Drug
SUBJECT: Jynarque**

- A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
- B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
- C. In accordance with current standards of medical practice;
- D. Not primarily for the convenience of the Member, or the Member's Provider; and
- E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

PROCEDURE:

An exception for coverage of Jynarque may be made for members who meet the following criteria:

- Medical record documentation that Jynarque is prescribed by a nephrologist **AND**
- Medical record documentation of age greater than or equal to 18 years **AND**
- Medical record documentation of a diagnosis of Autosomal Dominant Polycystic Kidney Disease (ADPKD) as confirmed by cysts and family history or genetic testing **AND**
- Medical record documentation of an estimated glomerular filtration rate (eGFR) greater than or equal to 25 mL/min **AND**
- Medical record documentation the member is at risk for rapidly progressing Autosomal Dominant Polycystic Kidney Disease (ADPKD) as documented by one of the following:
 - Mayo classification class 1C, 1D, or 1E
 - Total Kidney Volume greater than 750 mL
 - PROPKD score greater than 6
 - Kidney length greater than 16.5 cm as measured by ultrasound (if CT and MRI contraindicated)

NOTE: Per nephrology at Geisinger, the diagnosis of ADPKD should be established through genetic testing or modified Pei-Ravine criteria:

- With family history: several cysts per kidney (3 if by sonography; 5 if by CT or MRI)
- Without family history: 10 cysts per kidney (by any radiologic method, above) and exclusion of other cystic kidney diseases

MEDISPAN AUTHORIZATION LEVEL: Must enter GPI-12 3045406000B7, NDC-9 591480082, NDC-9 591480083



POLICY NUMBER: 527.0

**POLICY AND PROCEDURE
PHARMACY
MANUAL**

**SECTION: Commercial Drug
SUBJECT: Jynarque**

QUANTITY LIMIT: *No QLs need to be entered within the authorization unless the requested quantity exceeds the QL.*

- **QL FOR LETTER ONLY:** 2 tablets per day, 28 day supply per fill

AUTHORIZATION DURATION: Initial approval will be for 12 months or less if the reviewing provider feels it is medically appropriate. Subsequent approvals will be for an additional 12 months or less if the reviewing provider feels it is medically appropriate. The medication will no longer be covered if the member progresses to end-stage renal disease (ESRD).

If a formulary exception is approved, Jynarque will be paid for under the member's prescription drug benefit.

Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.

FORMULARY ALTERNATIVES:

none

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE
STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND
FEDERAL REGULATORY ENTITIES.**

**THIS POLICY WILL BE REVISED AS NECESSARY AND
REVIEWED NO LESS THAN ANNUALLY.**

Signed: _____

Title: Director, Pharmacy Services

Date: March 1, 2022

Devised: 10/1/18
Revised: 12/28/18 – added diagnosis confirmation, eGFR, definition of high risk, note
Revised: 3/1/19 – annual review, added QL approval note, defined abbr.
Revised: 5/3/19 – removed asterisk following genetic testing criteria
Revised: 3/1/20 – annual review, added GHP Kids



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 527.0

**SECTION: Commercial Drug
SUBJECT: Jynarque**

Revised: 3/1/21 – annual review, updated logo, added MediSpan approval level, updated QL statement
Revised: 3/1/22 – annual review, updated referenced policies & covered LOBs



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 528.0

**SECTION: Commercial Drug
SUBJECT: Tibsovo**

Applicable line of business:

Commercial	X	Medicaid	
Medicare		ACA	X
GHP Kids	X	Self-Insured	X

POLICY:

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for Tibsovo for GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 487.0 Quantity Limit Exceptions

REQUIRED DEFINITIONS:

1. **Attachment** – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. **Exhibit** – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. **Devised** – the date the policy was implemented.
4. **Revised** – the date of every revision to the policy, including typographical and grammatical changes.
5. **Reviewed** – the date documenting the annual review if the policy has no revisions necessary.

ADDITIONAL DEFINITIONS:

1. **Formulary** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. **Non-formulary products** – those medications that are not included in the Formulary.
3. **Healthcare provider** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
4. **NCQA** – National Committee for Quality Assurance.
5. **Medically Necessary or Medical Necessity** – covered services rendered by a provider that the Health Plan determines are:

- A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
- B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
- C. In accordance with current standards of medical practice;
- D. Not primarily for the convenience of the Member, or the Member's Provider; and
- E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

PROCEDURE:

New members to the plan already established on therapy may be eligible for continuity of care coverage as long as there is medical record documentation that the safety and effectiveness of use for the prescribed indication is supported by Food and Drug Administration (FDA) approval or adequate medical and scientific evidence in the medical literature.

An exception for coverage of Tibsovo may be made for members who meet the following criteria:

Newly Diagnosed AML

- Medical record documentation that Tibsovo is prescribed by a hematologist or oncologist **AND**
- Medical record documentation of newly diagnosed acute myeloid leukemia **AND**
- Medical record documentation of an isocitrate dehydrogenase-1 (IDH1) mutation as detected by a Food and Drug Administration (FDA)-approved test **AND**
- Medical record documentation of one of the following:
 - Medical record documentation of age greater than or equal to 75 years **OR**
 - Medical record documentation of age greater than or equal to 18 years **AND** comorbidities[†] that preclude the use of intensive induction chemotherapy

Relapsed or Refractory AML

- Medical record documentation that Tibsovo is prescribed by a hematologist or oncologist **AND**
- Medical record documentation of age greater than or equal to 18 years **AND**
- Medical record documentation of a diagnosis of relapsed or refractory acute myeloid leukemia **AND**
- Medical record documentation of an isocitrate dehydrogenase-1 (IDH1) mutation as detected by a Food and Drug Administration (FDA)-approved test



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 528.0

**SECTION: Commercial Drug
SUBJECT: Tibsovo**

NOTES: †In the clinical trials, comorbidities that precluded the use of intensive induction chemotherapy included at least one of the following criteria: baseline ECOG performance status of ≥ 2 , severe cardiac or pulmonary disease, hepatic impairment with bilirubin $> 1.5 \times \text{ULN}$, or creatinine clearance $< 45 \text{ mL/min}$. The FDA approved test for IDH1 is the Abbott RealTime IDH1 Assay.

Locally Advanced or Metastatic Cholangiocarcinoma

- Medical record documentation that Tibsovo is prescribed by a hematologist or oncologist **AND**
- Medical record documentation of age greater than or equal to 18 years **AND**
- Medical record documentation of locally advanced or metastatic cholangiocarcinoma **AND**
- Medical record documentation of an isocitrate dehydrogenase-1 (IDH1) mutation as detected by a Food and Drug Administration (FDA)-approved test **AND**
- Medical record documentation that member has been previously treated with at least one prior therapy

MEDISPAN AUTHORIZATION LEVEL: GPI-12, number of claims authorized = 1, enter for the remainder of the calendar year

QUANTITY LIMIT: *No QLs need to be entered within the authorization unless the requested quantity exceeds the QL.*

- QL FOR LETTER ONLY: 2 tablets per day, 30 day supply per fill

RE-AUTHORIZATION CRITERIA: Tibsovo is configured as a prior authorization for new starts only. Tibsovo will no longer be covered if it is identified that the member is not receiving appropriate follow-up care from the prescribing specialist or if the member has greater than or equal to a 90 day break in therapy.

- Medical record documentation that the member is receiving appropriate follow-up care from the prescribing specialist

If a formulary exception is approved, Tibsovo will be paid for under the member's prescription drug benefit.

Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.

FORMULARY ALTERNATIVES:

none



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 528.0

**SECTION: Commercial Drug
SUBJECT: Tibsovo**

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE
STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND
FEDERAL REGULATORY ENTITIES.**

**THIS POLICY WILL BE REVISED AS NECESSARY AND
REVIEWED NO LESS THAN ANNUALLY.**

Signed: _____

Title: Director, Pharmacy Services

Date: March 1, 2022

- Devised: 10/1/18
- Revised: 11/26/18 – removed Mektovi typo
- Revised: 3/1/19 – annual review, added QL approval note
- Revised: Added newly diagnosed AML, added headers
- Revised: 3/1/20 – annual review, added GHP Kids
- Revised: 3/1/21 – annual review, updated logo, added MediSpan approval level, updated QL statement
- Revised: 11/24/21 – added cholangiocarcinoma indication, added one-time PA language to approval criteria, removed auth duration & added re-auth criteria
- Revised: 3/1/22 – annual review, updated referenced policies & covered LOBs



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 529.0

**SECTION: Commercial Drug
SUBJECT: Pregabalin ER**

Applicable line of business:

Commercial	X	Medicaid	
Medicare		ACA	X
GHP Kids	X	Self-Insured	X

POLICY:

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for pregabalin ER for GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 487.0 Quantity Limit Exceptions

REQUIRED DEFINITIONS:

1. **Attachment** – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. **Exhibit** – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. **Devised** – the date the policy was implemented.
4. **Revised** – the date of every revision to the policy, including typographical and grammatical changes.
5. **Reviewed** – the date documenting the annual review if the policy has no revisions necessary.

ADDITIONAL DEFINITIONS:

1. **Formulary** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. **Non-formulary products** – those medications that are not included in the Formulary.
3. **Healthcare provider** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
4. **NCQA** – National Committee for Quality Assurance.
5. **Medically Necessary or Medical Necessity** – covered services rendered by a provider that the Health Plan determines are:



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 529.0

**SECTION: Commercial Drug
SUBJECT: Pregabalin ER**

- A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
- B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
- C. In accordance with current standards of medical practice;
- D. Not primarily for the convenience of the Member, or the Member's Provider; and
- E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

PROCEDURE:

An exception for coverage of pregabalin ER may be made for members who meet the following criteria:

Diabetic Peripheral Neuropathy

- Medical record documentation of neuropathic pain associated with diabetic peripheral neuropathy **AND**
- Medical record documentation of therapeutic failure on, intolerance to, or contraindication to duloxetine **AND** pregabalin

Postherpetic Neuralgia

- Medical record documentation of postherpetic neuralgia **AND**
- Medical record documentation of therapeutic failure on, intolerance to, or contraindication to gabapentin **AND** pregabalin

MEDISPAN AUTHORIZATION LEVEL: GPI-12

QUANTITY LIMIT: *No QLs need to be entered within the authorization unless the requested quantity exceeds the QL.*

- **QL FOR LETTER ONLY:**
 - 82.5 and 165 mg tablets: 3 tablets per day
 - 330 mg tablets: 2 tablets per day

If a formulary exception is approved, pregabalin ER will be paid for under the member's prescription drug benefit.

Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 529.0

**SECTION: Commercial Drug
SUBJECT: Pregabalin ER**

FORMULARY ALTERNATIVES:

Diabetic Peripheral Neuropathy: duloxetine, pregabalin
Postherpetic Neuralgia: gabapentin, pregabalin

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE
STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND
FEDERAL REGULATORY ENTITIES.**

**THIS POLICY WILL BE REVISED AS NECESSARY AND
REVIEWED NO LESS THAN ANNUALLY.**

Signed: _____

Title: Director, Pharmacy Services

Date: March 1, 2022

Devised: 11/26/18
Revised: 3/1/19 – annual review, updated QL approval note
Revised: 3/1/20 – annual review, added GHP Kids
Revised: 3/1/21 – annual review, updated logo, added MediSpan approval level, updated QL statement, updated FA
Revised: 3/1/22 – annual review, updated referenced policies, covered LOBs, & Lyrica/Lyrica CR to generic



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 530.0

**SECTION: Commercial Drug
SUBJECT: Olumiant**

Applicable line of business:

Commercial	X	Medicaid	
Medicare		ACA	X
GHP Kids	X	Self-Insured	X

POLICY:

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for Olumiant for GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 487.0 Quantity Limit Exceptions

REQUIRED DEFINITIONS:

1. **Attachment** – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. **Exhibit** – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. **Devised** – the date the policy was implemented.
4. **Revised** – the date of every revision to the policy, including typographical and grammatical changes.
5. **Reviewed** – the date documenting the annual review if the policy has no revisions necessary.

ADDITIONAL DEFINITIONS:

1. **Formulary** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. **Non-formulary products** – those medications that are not included in the Formulary.
3. **Healthcare provider** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
4. **NCQA** – National Committee for Quality Assurance.
5. **Medically Necessary or Medical Necessity** – covered services rendered by a provider that the Health Plan determines are:



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 530.0

**SECTION: Commercial Drug
SUBJECT: Olumiant**

- A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
 - B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
 - C. In accordance with current standards of medical practice;
 - D. Not primarily for the convenience of the Member, or the Member's Provider; and
 - E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.
6. **DMARD** – disease modifying anti-rheumatic drug

PROCEDURE:

New members to the plan already established on therapy may be eligible for continuity of care coverage as long as there is medical record documentation that the safety and effectiveness of use for the prescribed indication is supported by Food and Drug Administration (FDA) approval or adequate medical and scientific evidence in the medical literature.

For treatment of rheumatoid arthritis

An exception for coverage of Olumiant may be made for members who meet the following criteria:

- Medical record documentation of a diagnosis of moderate to severe rheumatoid arthritis (made in accordance with the American College of Rheumatology Criteria for the Classification and Diagnosis of Rheumatoid Arthritis) **AND**
- Medical record documentation that Olumiant is prescribed by a rheumatologist **AND**
- Medical record documentation of age greater than or equal to 18 years **AND**
- Medical record documentation of therapeutic failure on, intolerance to, or contraindication to a minimum 3 month trial of Humira*, Rinvoq*, OR Xeljanz* **AND**
- Medical record documentation that Olumiant is not being used concurrently with a tumor necrosis factor (TNF) blocker or other biologic agent

MEDISPAN AUTHORIZATION LEVEL: GPI-12, number of claims authorized = 1, enter for the remainder of the calendar year

QUANTITY LIMIT: *No QLs need to be entered within the authorization unless the requested quantity exceeds the QL.*

- **QL FOR LETTER ONLY:** 1 tablet per day, 30 day supply per fill



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 530.0

**SECTION: Commercial Drug
SUBJECT: Olumiant**

RE-AUTHORIZATION CRITERIA: Olumiant is configured as a prior authorization for new starts only. Olumiant will no longer be covered if it is identified that the member is not receiving appropriate follow-up care from the prescribing specialist or if the member has greater than or equal to a 90 day break in therapy.

- Medical record documentation that the member is receiving appropriate follow-up care from the prescribing specialist

For treatment of COVID-19

If Olumiant is being prescribed for COVID-19, see the FDA website for Emergency Use Authorizations at <https://www.fda.gov/emergency-preparedness-and-response/mcm-legal-regulatory-and-policy-framework/emergency-use-authorization#coviddrugs> for current FDA authorized use. At this time, Olumiant is authorized for inpatient use only for COVID-19 and would not be covered for outpatient use.

If an exception is made, Olumiant will be paid for under the member's prescription drug benefit.

Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.

FORMULARY ALTERNATIVES:

Humira*, Rinvoq*, Xeljanz*

*prior authorization required

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE
STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND
FEDERAL REGULATORY ENTITIES.**

**THIS POLICY WILL BE REVISED AS NECESSARY AND
REVIEWED NO LESS THAN ANNUALLY.**

Signed:  _____

Title: Director, Pharmacy Services



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 530.0

**SECTION: Commercial Drug
SUBJECT: Olumiant**

Date: March 1, 2022

Devised: 11/26/18
Revised: 3/1/19 – annual review, added QL approval note
Revised: 1/28/20 – updated RA FA and added failure of Rinvoq and Xeljanz
Revised: 3/1/20 – annual review, added GHP Kids
Revised: 3/1/21 – annual review, updated logo, added MediSpan approval level, updated QL statement
Revised: 12/2/21 – added one-time PA to approval crit., removed auth duration & added re-auth crit.
Revised: 3/1/22 – annual review, updated referenced policies & covered LOBs, added COVID note



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 531.0

**SECTION: Commercial Drug
SUBJECT: Copiktra**

Applicable line of business:

Commercial	X	Medicaid	
Medicare		ACA	X
GHP Kids	X	Self-Insured	X

POLICY:

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for Copiktra for GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 487.0 Quantity Limit Exceptions

REQUIRED DEFINITIONS:

1. **Attachment** – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. **Exhibit** – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. **Devised** – the date the policy was implemented.
4. **Revised** – the date of every revision to the policy, including typographical and grammatical changes.
5. **Reviewed** – the date documenting the annual review if the policy has no revisions necessary.

ADDITIONAL DEFINITIONS:

1. **Formulary** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. **Non-formulary products** – those medications that are not included in the Formulary.
3. **Healthcare provider** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
4. **NCQA** – National Committee for Quality Assurance.
5. **Medically Necessary or Medical Necessity** – covered services rendered by a provider that the Health Plan determines are:



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**SECTION: Commercial Drug
SUBJECT: Copiktra**

- A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
- B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
- C. In accordance with current standards of medical practice;
- D. Not primarily for the convenience of the Member, or the Member's Provider; and
- E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

PROCEDURE:

New members to the plan already established on therapy may be eligible for continuity of care coverage as long as there is medical record documentation that the safety and effectiveness of use for the prescribed indication is supported by Food and Drug Administration (FDA) approval or adequate medical and scientific evidence in the medical literature.

An exception for coverage of Copiktra may be made for members who meet the following criteria:

- Medical record documentation that Copiktra is prescribed by a hematologist or oncologist **AND**
- Medical record documentation of age greater than or equal to 18 years **AND**
- Medical record documentation of a diagnosis of either:
 - Relapsed or refractory chronic lymphocytic leukemia (CLL) or small lymphocytic lymphoma (SLL) **OR**
 - Relapsed or refractory follicular lymphoma (FL)
- Medical record documentation of therapeutic failure on, intolerance to, or contraindication to at least two (2) prior therapies

MEDISPAN AUTHORIZATION LEVEL: GPI-12, number of claims authorized = 1, enter for the remainder of the calendar year

QUANTITY LIMIT: *No QLs need to be entered within the authorization unless the requested quantity exceeds the QL.*

- **QL FOR LETTER ONLY:** 2 tablets per day, 30 day supply per fill



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**SECTION: Commercial Drug
SUBJECT: Copiktra**

RE-AUTHORIZATION CRITERIA: Copiktra is configured as a prior authorization for new starts only. Copiktra will no longer be covered if it is identified that the member is not receiving appropriate follow-up care from the prescribing specialist or if the member has greater than or equal to a 90 day break in therapy.

- Medical record documentation that the member is receiving appropriate follow-up care from the prescribing specialist

If a formulary exception is approved, Copiktra will be paid for under the member's prescription drug benefit.

Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.

FORMULARY ALTERNATIVES:

CLL/SLL: Imbruvica*, Venclexta*, Zydelig*
FL: Zydelig*

*prior authorization required

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE
STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND
FEDERAL REGULATORY ENTITIES.**

**THIS POLICY WILL BE REVISED AS NECESSARY AND
REVIEWED NO LESS THAN ANNUALLY.**

Signed: _____

Title: Director, Pharmacy Services

Date: March 1, 2022

Devised: 11/26/18
Revised: 3/1/19 – annual review, added QL approval note
Revised: 3/1/20 – annual review, added GHP Kids
Revised: 3/1/21 – annual review, updated logo, added MediSpan approval level, updated QL statement
Revised: 11/24/21 – added one-time PA to approval crit., removed auth duration & added re-auth crit.



**POLICY AND PROCEDURE
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POLICY NUMBER: 531.0

**SECTION: Commercial Drug
SUBJECT: Copiktra**

Revised: 3/1/22 – annual review, updated referenced policies & covered LOBs



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 532.0

**SECTION: Commercial Drug
SUBJECT: Ajoyv**

Applicable line of business:

Commercial	X	Medicaid	
Medicare		ACA	X
GHP Kids	X	Self-Insured	X

POLICY:

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for Ajoyv for GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 487.0 Quantity Limit Exceptions

REQUIRED DEFINITIONS:

1. **Attachment** – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. **Exhibit** – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. **Devised** – the date the policy was implemented.
4. **Revised** – the date of every revision to the policy, including typographical and grammatical changes.
5. **Reviewed** – the date documenting the annual review if the policy has no revisions necessary.

ADDITIONAL DEFINITIONS:

1. **Formulary** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. **Non-formulary products** – those medications that are not included in the Formulary.
3. **Healthcare provider** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
4. **NCQA** – National Committee for Quality Assurance.
5. **Medically Necessary or Medical Necessity** – covered services rendered by a provider that the Health Plan determines are:

- A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
- B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
- C. In accordance with current standards of medical practice;
- D. Not primarily for the convenience of the Member, or the Member's Provider; and
- E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

PROCEDURE:

An exception for coverage of Ajovy may be made for members who meet the following criteria:

- Medical record documentation that Ajovy is prescribed by or in consultation with a neurologist or headache specialist **AND**
- Medical record documentation of age greater than or equal to 18 years **AND**
- Medical record documentation of a diagnosis of migraine with or without aura, based on the ICHD-III diagnostic criteria **AND**
- Medical record documentation of number of baseline migraine or headache days per month **AND**
- Medical record documentation of therapeutic failure on, intolerance to, or contraindication to at least three (3) of the following:
 - One (1) beta blocker (metoprolol, propranolol, timolol, atenolol, nadolol)
 - Topiramate
 - Divalproex/sodium valproate
 - Amitriptyline
 - Venlafaxine **AND**
- Medical record documentation of therapeutic failure on, intolerance to, or contraindication to Aimovig **AND** Emgality **AND**
- Medical record documentation that Ajovy will not be used concomitantly with another calcitonin gene-related peptide (CGRP) receptor antagonist indicated for the preventive treatment of migraine (e.g., Aimovig, Emgality, Vyepti) **AND**
- Medical record documentation that Ajovy will not be used in combination with botulinum toxin **OR**
- If the request is for use in combination with Botox, all of the following must be met:
 - Medical record documentation of a therapeutic failure on a minimum 3 month trial of at least one CGRP antagonists without the concomitant use of Botox **AND**

- Medical record documentation of therapeutic failure on a minimum 6 month trial of Botox without the concomitant use of a CGRP antagonist

AUTHORIZATION DURATION: Initial approval will be for six (6) months and subsequent approvals will be for twelve (12) months. Requests for continuation of coverage will be approved for members who meet the following criteria:

- Medical record documentation of continued or sustained reduction in migraine or headache frequency or has experienced a decrease in severity or duration of migraine **AND**
- Medical record documentation that Ajoxy will not be used concomitantly with another calcitonin gene-related peptide (CGRP) receptor antagonist indicated for the preventive treatment of migraine (e.g., Aimovig, Emgality, Vyepti) **AND**
- One of the following:
 - Medical record documentation that Ajoxy is not being used concurrently with botulinum toxin **OR**
 - If the request is for use in combination with Botox, all of the following must be met:
 - Medical record documentation of a therapeutic failure on a minimum 3 month trial of at least one CGRP antagonists without the concomitant use of Botox **AND**
 - Medical record documentation of therapeutic failure on a minimum 6 month trial of Botox without the concomitant use of a CGRP antagonist

MEDISPAN AUTHORIZATION LEVEL: GPI-10

QUANTITY LIMIT: *No QLs need to be entered within the authorization unless the requested quantity exceeds the QL.*

- QL FOR LETTER ONLY: 4.5 mL per 90 days

ICHD-III Diagnostic Criteria³

Migraine without Aura:	Migraine with Aura:
A) At least five (5) attacks fulfilling criteria B through D below:	A) At least two (2) attacks fulfilling criteria B through C below:
B) Headache lasting 4 to 72 hours (untreated or unsuccessfully treated)	B) One (1) or more of the following fully reversible aura symptoms: <ul style="list-style-type: none"> ○ Visual ○ Sensory ○ Speech and/or language ○ Motor ○ Brainstem ○ Retinal



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**SECTION: Commercial Drug
SUBJECT: Ajovy**

<p>C) Headache with at least two (2) of the following characteristics:</p> <ul style="list-style-type: none"> o unilateral location o pulsating quality o moderate to severe pain intensity o aggravation by or causing avoidance of routine physical activity (e.g. walking or climbing stairs) 	<p>C) At least three (3) of the following:</p> <ul style="list-style-type: none"> o at least one (1) aura symptom spreads over 5 or more minutes o two (2) or more aura symptoms occur in succession o each individual aura symptom lasts 5 to 60 minutes¹ o at least one (1) aura symptom is unilateral² o at least one (1) aura symptom is positive³ o the aura is accompanied, or followed within 60 minutes, by a headache
<p>D) At least one of the following during the headache:</p> <ul style="list-style-type: none"> o nausea and/or vomiting o photophobia and phonophobia 	<p>D) Not better accounted for by another ICHD-3 diagnosis</p>
<p>E) Not better accounted for by another ICHD-3 diagnosis</p>	
<ol style="list-style-type: none"> 1. Example, if three symptoms occur during an aura, the acceptable maximal duration is 3 x 60 minutes. Motor symptoms may last up to 72 hours. 2. Aphasia (impairment of language) is always a unilateral symptom; dysarthria (slurred or slowed speech) may or may not be. 3. Scintillations (flash of light) and pins and needles are positive symptoms of aura 	

If a formulary exception is approved, Ajovy will be paid for under the member's prescription drug benefit.

Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.

FORMULARY ALTERNATIVES:

metoprolol, propranolol, timolol, atenolol, nadolol, topiramate, divalproex, sodium valproate, amitriptyline, venlafaxine, Aimovig*, Emgality*

*prior authorization required

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE
STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND
FEDERAL REGULATORY ENTITIES.**

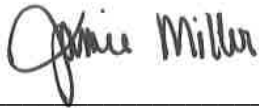
**THIS POLICY WILL BE REVISED AS NECESSARY AND
REVIEWED NO LESS THAN ANNUALLY.**

Geisinger

**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 532.0

**SECTION: Commercial Drug
SUBJECT: Ajoyv**



Signed: _____

Title: Director, Pharmacy Services

Date: March 1, 2022

Devised: 11/26/18
Revised: 3/1/19 – annual review, added QL approval note
Revised: 3/28/19 – updated initial & renewal Botox criteria, added decrease in severity to renewal criteria
Revised: 5/3/19 – added missing 'will not be used in combination with Botox' criteria
Revised: 7/23/19 – corrected Aimovig typo
Revised: 3/1/20 – annual review, added GHP Kids
Revised: 6/9/20 – added failure of Aimovig & Emgality
Revised: 10/5/20 – added concomitant use with other preventive CGRP to initial/renewal crit., updated FA
Revised: 3/1/21 – annual review, updated logo, added MediSpan approval level, updated QL statement
Revised: 3/1/22 – annual review, updated referenced policies & covered LOBs



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 533.0

**SECTION: Commercial Drug
SUBJECT: Emgality**

Applicable line of business:

Commercial	X	Medicaid	
Medicare		ACA	X
GHP Kids	X	Self-Insured	X

POLICY:

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for Emgality for GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 487.0 Quantity Limit Exceptions

REQUIRED DEFINITIONS:

1. **Attachment** – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
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5. **Reviewed** – the date documenting the annual review if the policy has no revisions necessary.

ADDITIONAL DEFINITIONS:

1. **Formulary** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. **Non-formulary products** – those medications that are not included in the Formulary.
3. **Healthcare provider** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
4. **NCQA** – National Committee for Quality Assurance.
5. **Medically Necessary or Medical Necessity** – covered services rendered by a provider that the Health Plan determines are:

- A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
- B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
- C. In accordance with current standards of medical practice;
- D. Not primarily for the convenience of the Member, or the Member's Provider; and
- E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

PROCEDURE:

An exception for coverage of Emgality may be made for members who meet the following criteria:

Migraine

- Medical record documentation that Emgality is prescribed by or in consultation with a neurologist or headache specialist **AND**
- Medical record documentation of age greater than or equal to 18 years **AND**
- Medical record documentation of a diagnosis of migraine with or without aura, based on the ICHD-III diagnostic criteria **AND**
- Medical record documentation of number of baseline migraine or headache days per month **AND**
- Medical record documentation of therapeutic failure on, intolerance to, or contraindication to at least two (2) of the following:
 - One (1) beta blocker (metoprolol, propranolol, timolol, atenolol, nadolol)
 - Topiramate
 - Divalproex/sodium valproate
 - Amitriptyline
 - Venlafaxine **AND**
- Medical record documentation that Emgality will not be used concomitantly with another calcitonin gene-related peptide (CGRP) receptor antagonist indicated for the preventive treatment of migraine (e.g., Ajovy, Aimovig, Vyepti) **AND**
- Medical record documentation that Emgality will not be used in combination with botulinum toxin **OR**
- If the request is for use in combination with Botox, all of the following must be met:
 - Medical record documentation of a therapeutic failure on a minimum 3 month trial of at least one CGRP antagonists without the concomitant use of Botox **AND**

- Medical record documentation of therapeutic failure on a minimum 6 month trial of Botox without the concomitant use of a CGRP antagonist

AUTHORIZATION DURATION: Initial approval will be for six (6) months and subsequent approvals will be for twelve (12) months. Requests for continuation of coverage will be approved for members who meet the following criteria:

- Medical record documentation of continued or sustained reduction in migraine or headache frequency or has experienced a decrease in severity or duration of migraine **AND**
- Medical record documentation that Emgality will not be used concomitantly with another calcitonin gene-related peptide (CGRP) receptor antagonist indicated for the preventive treatment of migraine (e.g., Ajovy, Aimovig, Vyepti) **AND**
- One of the following:
 - Medical record documentation that Emgality is not being used concurrently with botulinum toxin **OR**
 - If the request is for use in combination with Botox, all of the following must be met:
 - Medical record documentation of a therapeutic failure on a minimum 3 month trial of at least one CGRP antagonists without the concomitant use of Botox **AND**
 - Medical record documentation of therapeutic failure on a minimum 6 month trial of Botox without the concomitant use of a CGRP antagonist

MEDISPAN AUTHORIZATION LEVEL: GPI-14 (must enter 6770203530D520 & 6770203530E520)

QUANTITY LIMIT:

- **Initial Approval** – *Two authorizations must be entered.*
 - 240 mg once, then 120 mg once monthly
 1. In PA Hub: Add PA only.
 2. In Darwin: Add OQL, DS, max number of claims authorized 1, max quantity dispensed 2, min day supply 30, max day supply 30, with a duration of two weeks.
 - **QL FOR LETTER:** Loading dose: 2 mL per 30 days;
Maintenance dose: 1 mL per 30 days
- **Renewal**
 - 120 mg once monthly – *No QLs need to be entered within the authorization unless the requested quantity exceeds the QL.*
 - **QL FOR LETTER:** 1 mL per 30 days



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 533.0

**SECTION: Commercial Drug
SUBJECT: Emgality**

ICHD-III Diagnostic Criteria

Migraine without Aura:	Migraine with Aura:
A) At least five (5) attacks fulfilling criteria B through D below:	A) At least two (2) attacks fulfilling criteria B through C below:
B) Headache lasting 4 to 72 hours (untreated or unsuccessfully treated)	B) One (1) or more of the following fully reversible aura symptoms: <ul style="list-style-type: none"> o Visual o Sensory o Speech and/or language o Motor o Brainstem o Retinal
C) Headache with at least two (2) of the following characteristics: <ul style="list-style-type: none"> o unilateral location o pulsating quality o moderate to severe pain intensity o aggravation by or causing avoidance of routine physical activity (e.g. walking or climbing stairs) 	C) At least three (3) of the following: <ul style="list-style-type: none"> o at least one (1) aura symptom spreads over 5 or more minutes o two (2) or more aura symptoms occur in succession o each individual aura symptom lasts 5 to 60 minutes¹ o at least one (1) aura symptom is unilateral² o at least one (1) aura symptom is positive³ o the aura is accompanied, or followed within 60 minutes, by a headache
D) At least one of the following during the headache: <ul style="list-style-type: none"> o nausea and/or vomiting o photophobia and phonophobia 	D) Not better accounted for by another ICHD-3 diagnosis
E) Not better accounted for by another ICHD-3 diagnosis	

1. Example, if three symptoms occur during an aura, the acceptable maximal duration is 3 x 60 minutes. Motor symptoms may last up to 72 hours.
2. Aphasia (impairment of language) is always a unilateral symptom; dysarthria (slurred or slowed speech) may or may not be.
3. Scintillations (flash of light) and pins and needles are positive symptoms of aura



POLICY NUMBER: 533.0

**POLICY AND PROCEDURE
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**SECTION: Commercial Drug
SUBJECT: Emgality**

Episodic Cluster Headache

- Medical record documentation that Emgality is prescribed by or in consultation with a neurologist or headache specialist **AND**
- Medical record documentation of age greater than or equal to 18 years **AND**
- Medical record documentation of a diagnosis of episodic cluster headache, based on the ICHD-III diagnostic criteria **AND**
- Medical record documentation of baseline cluster headache attack frequency (e.g. weekly headache attack frequency) **AND**
- Medical record documentation the member is currently experiencing a cluster headache period (period of recurrent attacks) **AND**
- Medical record documentation of therapeutic failure on, intolerance to, or contraindication to suboccipital steroid injections **AND**
- Medical record documentation of therapeutic failure on, intolerance to, or contraindication to verapamil

AUTHORIZATION DURATION: Initial approval will be for six (6) months and subsequent approvals will be for six (6) months. Requests for continuation of coverage will be approved for members who meet the following criteria:

- Medical record documentation of a diagnosis of episodic cluster headache, based on the ICHD-III diagnostic criteria **AND**
- Medical record documentation the member is currently experiencing a cluster headache period (period of recurrent attacks) **AND**
- Medical record documentation of continued or sustained reduction in cluster headache attack frequency

MEDISPAN AUTHORIZATION LEVEL: GPI-14

QUANTITY LIMIT: *No QLs need to be entered within the authorization unless the requested quantity exceeds the QL.*

- **QL FOR LETTER ONLY:** 3 mL per 30 days



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 533.0

**SECTION: Commercial Drug
SUBJECT: Emgality**

ICHD-III Diagnostic Criteria

Diagnosis of Cluster Headache	Diagnosis of Episodic Cluster Headache
At least <u>5 attacks</u> fulfilling the following criteria:	Diagnosis of Cluster Headache fulfilling occurring in bouts (cluster periods) the following criteria:
<ul style="list-style-type: none"> Severe or very severe unilateral orbital, supraorbital and/or temporal pain lasting 15-180 minutes (when untreated) <i>During part (but less than half) of the active time-course attacks may be less severe and/or of shorter or longer duration.</i> 	At least two cluster periods lasting from 7 days to 1 year (when untreated) and separated by pain-free remission periods of ≥ 3 months.
One or both of the following: <ul style="list-style-type: none"> At least one of the following symptoms or signs, ipsilateral to the headache: <ul style="list-style-type: none"> Conjunctival injection and/or lacrimation Nasal congestion and/or rhinorrhea Eyelid edema Forehead and facial sweating Miosis and/or ptosis A sense of restlessness or agitation 	
Occurring with a frequency between one every other day and 8 per day <i>During part (but less than half) of the active time-course attacks may be less frequent</i>	
Not better accounted for by another ICHD-3 another ICHD-3 diagnosis	

If a formulary exception is approved, Emgality will be paid for under the member's prescription drug benefit.

Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.

FORMULARY ALTERNATIVES:

Migraine: metoprolol, propranolol, timolol, atenolol, nadolol, topiramate, divalproex, sodium valproate, amitriptyline, venlafaxine

Episodic Cluster Headache: verapamil

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE
STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND
FEDERAL REGULATORY ENTITIES.**

**THIS POLICY WILL BE REVISED AS NECESSARY AND
REVIEWED NO LESS THAN ANNUALLY.**



POLICY NUMBER: 533.0

**POLICY AND PROCEDURE
PHARMACY
MANUAL**

**SECTION: Commercial Drug
SUBJECT: Emgality**

Signed: _____

Title: Director, Pharmacy Services

Date: March 1, 2022

- Devised: 11/26/18
- Reviewed: 3/1/19 – annual review
- Revised: 3/28/19 – updated initial & renewal Botox criteria, added decrease in severity to renewal criteria
- Revised: 5/3/19 – added missing 'will not be used in combination with Botox criteria
- Revised: 6/4/19 – corrected Aimovig typo, added authorization parameters
- Revised: 7/23/19 – added cluster headache indication
- Revised: 3/1/20 – annual review, added GHP Kids
- Revised: 6/9/20 – updated to failure of 2 alternatives for migraine
- Revised: 10/5/20 – added concomitant use with other preventive CGRP to initial/renewal criteria
- Revised: 3/1/21 – annual review, updated logo, added MediSpan approval level, updated QL statement
- Revised: 3/1/22 – annual review, updated referenced policies & covered LOBs, updated how QL is entered



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 534.0

**SECTION: Commercial Drug
SUBJECT: Palynziq**

Applicable line of business:

Commercial	X	Medicaid	
Medicare		ACA	X
GHP Kids	X	Self-Insured	X

POLICY:

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for Palynziq for GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 487.0 Quantity Limit Exceptions

REQUIRED DEFINITIONS:

1. **Attachment** – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. **Exhibit** – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. **Devised** – the date the policy was implemented.
4. **Revised** – the date of every revision to the policy, including typographical and grammatical changes.
5. **Reviewed** – the date documenting the annual review if the policy has no revisions necessary.

ADDITIONAL DEFINITIONS:

1. **Formulary** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. **Non-formulary products** – those medications that are not included in the Formulary.
3. **Healthcare provider** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
4. **NCQA** – National Committee for Quality Assurance.
5. **Medically Necessary or Medical Necessity** – covered services rendered by a provider that the Health Plan determines are:

- A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
- B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
- C. In accordance with current standards of medical practice;
- D. Not primarily for the convenience of the Member, or the Member's Provider; and
- E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

PROCEDURE:

An exception for coverage of Palynziq may be made for members who meet the following criteria:

- Medical record documentation that Palynziq is prescribed by a metabolic specialist **AND**
- Medical record documentation of age greater than or equal to 18 years **AND**
- Medical record documentation of a diagnosis of phenylketonuria (PKU) **AND**
- Medical record documentation of phenylalanine (Phe) concentrations greater than 600 micromol/L on existing management (e.g., dietary restriction of Phe and protein intake, use of medical foods, and/or Kuvan) **AND**
- Medical record documentation that the member has (or will receive) a prescription for epinephrine auto-injector **AND**
- Medical record documentation of therapeutic failure on, intolerance to, or contraindication to Kuvan **AND**
- Medical record documentation that Palynziq will not be used in combination with Kuvan

MEDISPAN AUTHORIZATION LEVEL: GPI-12

QUANTITY LIMIT: *No QLs need to be entered within the authorization unless the requested quantity exceeds the QL.*

- **QL FOR LETTER ONLY:**
 - 2.5mg/0.5 mL syringe: 4 mL per 28 days
 - 10 mg/0.5 mL syringe: 14 mL per 28 days
 - 20 mg/mL syringe: 84 mL per 28 days

AUTHORIZATION DURATION: Initial and subsequent approvals will be for twelve (12) months. Requests for continuation of coverage will be approved for members who meet the following criteria:

- Medical record documentation of a 20% reduction in phenylalanine concentration from baseline or a blood phenylalanine concentration less than or equal to 600 micromol/L **OR**
- Medical record documentation of improvement in neuropsychiatric symptoms or an increase in phenylalanine tolerance

If a formulary exception is approved, Palynziq will be paid for under the member's prescription drug benefit.

Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.

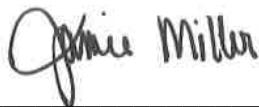
FORMULARY ALTERNATIVES:

Kuvan*

*prior authorization required

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE
STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND
FEDERAL REGULATORY ENTITIES.**

**THIS POLICY WILL BE REVISED AS NECESSARY AND
REVIEWED NO LESS THAN ANNUALLY.**



Signed: _____

Title: Director, Pharmacy Services

Date: March 1, 2022

Devised: 11/26/18

Reviewed: 3/1/19 – annual review

Revised: 3/1/20 – annual review, added GHP Kids

Revised: 3/1/21 – annual review, updated logo, added MediSpan approval level, updated QL statement

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Dev. 11/26/18

Rev. 3/1/22



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 534.0

**SECTION: Commercial Drug
SUBJECT: Palynziq**

Revised: 3/26/21 – updated QL for 20 mg syringe to 84 mL per 28 days
Revised: 3/1/22 – annual review, updated referenced policies & covered LOBs



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 535.0

**SECTION: Commercial Drug
SUBJECT: Orilissa**

Applicable line of business:

Commercial	X	Medicaid	
Medicare		ACA	X
GHP Kids	X	Self-Insured	X

POLICY:

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for Orilissa for GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 487.0 Quantity Limit Exceptions

REQUIRED DEFINITIONS:

1. **Attachment** – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. **Exhibit** – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. **Devised** – the date the policy was implemented.
4. **Revised** – the date of every revision to the policy, including typographical and grammatical changes.
5. **Reviewed** – the date documenting the annual review if the policy has no revisions necessary.

ADDITIONAL DEFINITIONS:

1. **Formulary** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. **Non-formulary products** – those medications that are not included in the Formulary.
3. **Healthcare provider** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
4. **NCQA** – National Committee for Quality Assurance.
5. **Medically Necessary or Medical Necessity** – covered services rendered by a provider that the Health Plan determines are:



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 535.0

**SECTION: Commercial Drug
SUBJECT: Orilissa**

- A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
- B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
- C. In accordance with current standards of medical practice;
- D. Not primarily for the convenience of the Member, or the Member's Provider; and
- E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

PROCEDURE:

An exception for coverage of Orilissa may be made for members who meet the following criteria:

- Medical record documentation that Orilissa is prescribed by a gynecologist **AND**
- Medical record documentation of age greater than or equal to 18 years **AND**
- Medical record documentation of a diagnosis of moderate to severe pain associated with endometriosis **AND**
- Medical record documentation of a therapeutic failure on, intolerance to, or contraindication to one formulary extended-cycle contraceptive **AND**
- Medical record documentation of a therapeutic failure on, intolerance to, or contraindication to two formulary nonsteroidal anti-inflammatory drugs (NSAIDs)

NOTE: Available extended-cycle contraceptives include: Amethia, Amethia Lo, Amethyst, Ashlyna, Camrese, Camrese Lo, Daysee, Fayosim, Introvale, Jaimiess, Jolessa, LoSeasonique, Quasense, Quartette, Rivelasa, Seasonique, Simpesse, Seasonale, Setlakin, Medroxyprogesterone Acetate, and the intrauterine devices: Mirena, Liletta, Kyleena, Skyla, and ParaGard.

MEDISPAN AUTHORIZATION LEVEL: GPI-14

QUANTITY LIMIT: *No QLs need to be entered within the authorization unless the requested quantity exceeds the QL.*

- **QL FOR LETTER ONLY:**
 - 150 mg tablet: 30 tablets per 30 days
 - 200 mg tablet: 60 tablets per 30 days



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 535.0

**SECTION: Commercial Drug
SUBJECT: Orilissa**

AUTHORIZATION DURATION:

- **Orilissa 150mg tablets:** Initial approval will be for 24 months (or less if there is medical record documentation of a previous incomplete course of therapy with Orilissa 150 mg tablets).
- **Orilissa 200mg tablets:** Initial approval will be for 6 months (or less if there is medical record documentation of a previous incomplete course of therapy with Orilissa 200 mg tablets).

REAUTHORIZATION: Medical record documentation that the patient has not been treated for more than a total of 24 months with Orilissa 150 mg once daily OR more than a total of 6 months with Orilissa 200 mg twice daily OR documentation of medical or scientific literature to support the use of this agent beyond the FDA-approved treatment duration.

If a formulary exception is approved, Orilissa will be paid for under the member's prescription drug benefit.

Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.

FORMULARY ALTERNATIVES:

NSAIDs: celecoxib, choline magnesium salicylate, diclofenac, diclofenac extended release, diflunisal, etodolac, etodolac extended release, fenoprofen, flurbiprofen, ibuprofen, indomethacin, indomethacin sustained-release, ketoprofen, ketorolac**, meclofenamate, meloxicam, nabumetone, naproxen, naproxen sodium, naproxen ec, oxaprozin, piroxicam, salsalate, sulindac, tolmetin

Extended Cycle Contraceptives: Amethia, Amethia Lo, Amethyst, Ashlyna, Camrese, Camrese Lo, Daysee, Fayosim, Introvale, Jaimiess, Jolessa, LoSeasonique, Quasense, Quartette, Rivelasa, Seasonique, Simpesse, Seasonale, Setlakin, Medroxyprogesterone Acetate

**quantity limit applies

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE
STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND
FEDERAL REGULATORY ENTITIES.**

**THIS POLICY WILL BE REVISED AS NECESSARY AND
REVIEWED NO LESS THAN ANNUALLY.**



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 535.0

**SECTION: Commercial Drug
SUBJECT: Orilissa**

Signed: _____

Title: Director, Pharmacy Services

Date: March 1, 2022

- Devised: 11/26/18
- Revised: 3/1/19 – annual review, defined NSAIDs
- Revised: 3/28/19 – removed 200 mg requirement
- Revised: 7/12/19 – updated and defined ketorolac QL indicator
- Revised: 3/1/20 – annual review, added GHP Kids
- Revised: 3/1/21 – annual review, updated logo, added MediSpan approval level, updated QL statement
- Revised: 6/7/21 – updated authorization duration criteria, updated GPI level
- Revised: 3/1/22 – annual review, updated referenced policies & covered LOBs, corrected typo



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 536.0

**SECTION: Commercial Drug
SUBJECT: Doptelet**

Applicable line of business:

Commercial	X	Medicaid	
Medicare		ACA	X
GHP Kids	X	Self-Insured	X

POLICY:

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.00T Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for Doptelet for GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 487.0 Quantity Limit Exceptions

REQUIRED DEFINITIONS:

1. **Attachment** – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. **Exhibit** – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
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5. **Reviewed** – the date documenting the annual review if the policy has no revisions necessary.

ADDITIONAL DEFINITIONS:

1. **Formulary** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. **Non-formulary products** – those medications that are not included in the Formulary.
3. **Healthcare provider** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
4. **NCQA** – National Committee for Quality Assurance.
5. **Medically Necessary or Medical Necessity** – covered services rendered by a provider that the Health Plan determines are:

- A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
- B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
- C. In accordance with current standards of medical practice;
- D. Not primarily for the convenience of the Member, or the Member's Provider; and
- E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

PROCEDURE:

An exception for coverage of Doptelet may be made for members who meet the following criteria:

Thrombocytopenia in Members with Chronic Liver Disease Undergoing Procedure

- Medical record documentation that Doptelet is prescribed by or in consultation with a hematologist, gastroenterologist, hepatologist, immunologist, transplant specialist, interventional radiologist, or endocrinologist **AND**
- Medical record documentation of age greater than or equal to 18 years **AND**
- Medical record documentation of thrombocytopenia in adult patients with chronic liver disease **AND**
- Medical record documentation of a platelet count of less than $50 \times 10^9/L$ measured within the past 30 days **AND**
- Medical record documentation of a planned invasive procedure to be performed 10-13 days after initiation date for Doptelet treatment **AND**
- Medical record documentation that the member is not receiving other thrombopoietin receptor agonists (TPO-Ras) (Nplate/romiplostim, Promacta/eltrombopag) **AND**
- Medical record documentation of the correct dose being used (Platelet count 40,000 to less than 50,000 $\times 10^9/L$ - 40 mg once daily for 5 consecutive days **OR** for platelet count less than 40,000 $\times 10^9/L$ - 60 mg once daily for 5 consecutive days)

MEDISPAN AUTHORIZATION LEVEL: GPI-12

QUANTITY LIMIT: *No QLs need to be entered within the authorization unless the requested quantity exceeds the QL.*

- **QL FOR LETTER ONLY:**
 - Platelet count 40,000 to less than 50,000 $\times 10^9/L$: 10 tablets per fill
 - Platelet count less than 40,000 $\times 10^9/L$: 15 tablets per fill

AUTHORIZATION DURATION: 30 days, RX count 1

Chronic Immune Thrombocytopenia

- Medical record documentation that Doptelet is prescribed by or in consultation with a hematologist **AND**
- Medical record documentation of age greater than or equal to 18 years **AND**
- Medical record documentation of a diagnosis of chronic immune thrombocytopenia (cITP) **AND**
- Medical record documentation of symptomatic ITP with bleeding symptoms and platelet count of less than $30 \times 10^9/L$ **OR** a documented history of significant bleeding and platelet count less than $30 \times 10^9/L$ **OR** platelet count of less than $20 \times 10^9/L$ **AND**
- Medical record documentation that the member is not receiving other thrombopoietin receptor agonists (TPO-Ras) (Nplate/romiplostim, Promacta/eltrombopag) **AND**
- Medical record documentation of therapeutic failure on, intolerance to, or contraindication to three (3) previous treatments, including, but not limited to:
 - Corticosteroids
 - IVIG*
 - Rhogam (if RhD-positive and spleen intact)
 - Rituximab*
 - Splenectomy
 - Promacta*/Nplate*

MEDISPAN AUTHORIZATION LEVEL: GPI-12

QUANTITY LIMIT: *No QLs need to be entered within the authorization unless the requested quantity exceeds the QL.*

- **QL FOR LETTER ONLY:** 2 tablets per day, 30 day supply per fill

AUTHORIZATION DURATION: Initial approval will be for three (3) months and subsequent approvals will be for twelve (12) months.

Reauthorization criteria:

- Medical record documentation of platelet count greater than or equal to $50 \times 10^9/L$ and continued or sustained reduction in bleeding events **AND**
- One of the following:
 - Medical record documentation that the platelet count does not exceed $400 \times 10^9/L$ **OR**
 - If the platelet count does exceed $400 \times 10^9/L$, medical record documentation that the dose will be adjusted **AND** documentation that the member has not been on 20 mg once weekly for 2 weeks



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 536.0

**SECTION: Commercial Drug
SUBJECT: Doptelet**

If a formulary exception is approved, Doptelet will be paid for under the member's prescription drug benefit.

Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.

FORMULARY ALTERNATIVES:

Chronic Liver Disease: Promacta*, Mulpleta*

cITP: Promacta*

*prior authorization required

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE
STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND
FEDERAL REGULATORY ENTITIES.**

**THIS POLICY WILL BE REVISED AS NECESSARY AND
REVIEWED NO LESS THAN ANNUALLY.**

Signed: _____

Title: Director, Pharmacy Services

Date: June 7, 2022

Devised: 11/27/18
Revised: 2/5/19 – added failure of Mulpleta, updated FA
Revised: 3/1/19 – annual review, defined TPO-Ras
Revised: 3/21/19 – added interventional radiologist to prescriber criteria
Revised: 11/20/19 – removed failure of Mulpleta for liver disease, added cITP indication
Revised: 3/1/20 – annual review, added GHP Kids
Revised: 3/1/21 – annual review, updated logo, added MediSpan approval level, updated QL statement
Revised: 3/1/22 – annual review, updated referenced policies & covered LOBs
Revised: 6/7/22 – added history of bleeding and platelets < 30, removed increased risk of bleeding for platelets < 20, corrected typo in cITP



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 537.0

**SECTION: Commercial Drug
SUBJECT: Vizimpro**

Applicable line of business:

Commercial	X	Medicaid	
Medicare		ACA	X
GHP Kids	X	Self-Insured	X

POLICY:

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for Vizimpro for GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 487.0 Quantity Limit Exceptions

REQUIRED DEFINITIONS:

1. **Attachment** – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. **Exhibit** – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
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4. **Revised** – the date of every revision to the policy, including typographical and grammatical changes.
5. **Reviewed** – the date documenting the annual review if the policy has no revisions necessary.

ADDITIONAL DEFINITIONS:

1. **Formulary** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. **Non-formulary products** – those medications that are not included in the Formulary.
3. **Healthcare provider** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
4. **NCQA** – National Committee for Quality Assurance.
5. **Medically Necessary or Medical Necessity** – covered services rendered by a provider that the Health Plan determines are:



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 537.0

**SECTION: Commercial Drug
SUBJECT: Vizimpro**

- A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
- B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
- C. In accordance with current standards of medical practice;
- D. Not primarily for the convenience of the Member, or the Member's Provider; and
- E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

PROCEDURE:

New members to the plan already established on therapy may be eligible for continuity of care coverage as long as there is medical record documentation that the safety and effectiveness of use for the prescribed indication is supported by Food and Drug Administration (FDA) approval or adequate medical and scientific evidence in the medical literature.

An exception for coverage of Vizimpro may be made for members who meet the following criteria:

- Medical record documentation that Vizimpro is prescribed by a hematologist or oncologist **AND**
- Medical record documentation of age greater than or equal to 18 years **AND**
- Medical record documentation of a diagnosis of metastatic non-small cell lung cancer (NSCLC) with epidermal growth factor receptor (EGFR) exon 19 deletion of exon 21 L858R substitution mutations as detected by a Food and Drug Administration (FDA)-approved test

MEDISPAN AUTHORIZATION LEVEL: GPI-12, number of claims authorized = 1, enter for the remainder of the calendar year

QUANTITY LIMIT: *No QLs need to be entered within the authorization unless the requested quantity exceeds the QL.*

- **QL FOR LETTER ONLY:** 1 tablet per day, 30 day supply per fill



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 537.0

**SECTION: Commercial Drug
SUBJECT: Vizimpro**

RE-AUTHORIZATION CRITERIA: Vizimpro is configured as a prior authorization for new starts only. Vizimpro will no longer be covered if it is identified that the member is not receiving appropriate follow-up care from the prescribing specialist or if the member has greater than or equal to a 90 day break in therapy.

- Medical record documentation that the member is receiving appropriate follow-up care from the prescribing specialist

If a formulary exception is approved, Vizimpro will be paid for under the member's prescription drug benefit.

Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.

FORMULARY ALTERNATIVES:

Gilotrif*, Iressa*, Tagrisso*, erlotinib*

*prior authorization required

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE
STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND
FEDERAL REGULATORY ENTITIES.**

**THIS POLICY WILL BE REVISED AS NECESSARY AND
REVIEWED NO LESS THAN ANNUALLY.**

Signed: _____

Title: Director, Pharmacy Services

Date: March 1, 2022

Devised: 11/28/18
Reviewed: 3/1/19 – annual review
Revised: 3/1/20 – annual review, added GHP Kids
Revised: 3/1/21 – annual review, updated logo, added MediSpan approval level, updated QL statement, updated FA
Revised: 12/1/21 – added one-time PA to approval crit., removed auth duration & added re-auth crit.



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 537.0

**SECTION: Commercial Drug
SUBJECT: Vizimpro**

Revised: 3/1/22 – annual review, updated referenced policies & covered LOBs



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 538.0

**SECTION: Commercial Drug
SUBJECT: Epidiolex**

Applicable line of business:

Commercial	X	Medicaid	
Medicare		ACA	X
GHP Kids	X	Self-Insured	X

POLICY:

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for Epidiolex for GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 487.0 Quantity Limit Exceptions

REQUIRED DEFINITIONS:

1. **Attachment** – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. **Exhibit** – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
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ADDITIONAL DEFINITIONS:

1. **Formulary** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. **Non-formulary products** – those medications that are not included in the Formulary.
3. **Healthcare provider** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
4. **NCQA** – National Committee for Quality Assurance.
5. **Medically Necessary or Medical Necessity** – covered services rendered by a provider that the Health Plan determines are:



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 538.0

**SECTION: Commercial Drug
SUBJECT: Epidiolex**

- A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
- B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
- C. In accordance with current standards of medical practice;
- D. Not primarily for the convenience of the Member, or the Member's Provider; and
- E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

PROCEDURE:

New members to the plan already established on therapy may be eligible for continuity of care coverage as long as there is medical record documentation that the safety and effectiveness of use for the prescribed indication is supported by Food and Drug Administration (FDA) approval or adequate medical and scientific evidence in the medical literature.

An exception for coverage of Epidiolex may be made for members who meet the following criteria:

- Medical record documentation that Epidiolex is prescribed by a neurologist **AND**
- Medical record documentation of age greater than or equal to 1 year **AND**
- Medical record documentation of a diagnosis of either Lennox-Gastaut syndrome or Dravet syndrome **AND**
- **For Lennox-Gastaut syndrome:** Medical record documentation of therapeutic failure on, intolerance to, or contraindication to two (2) generic formulary alternatives **OR** member age between 1 and 2 years

MEDISPAN AUTHORIZATION LEVEL: GPI-12

If a formulary exception is approved, Epidiolex will be paid for under the member's prescription drug benefit.

Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 538.0

**SECTION: Commercial Drug
SUBJECT: Epidiolex**

FORMULARY ALTERNATIVES:

For patients > 2 years of age: clonazepam, felbamate, lamotrigine, topiramate, topiramate ER*, rufinamide*, clobazam

*prior authorization required

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE
STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND
FEDERAL REGULATORY ENTITIES.**

**THIS POLICY WILL BE REVISED AS NECESSARY AND
REVIEWED NO LESS THAN ANNUALLY.**

Signed: _____

Title: Director, Pharmacy Services

Date: March 1, 2022

Devised: 12/27/18
Reviewed: 3/1/19 – annual review
Revised: 3/1/20 – annual review, added GHP Kids
Revised: 10/12/20 – updated age to 1 year, added age criteria for Lennox Gastaut alternative criteria
Revised: 3/1/21 – annual review, updated logo, added MediSpan approval level, updated FA
Revised: 3/1/22 – annual review, updated referenced policies & covered LOBs, updated FA



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 539.0

**SECTION: Commercial Drug
SUBJECT: Lorbrena**

Applicable line of business:

Commercial	X	Medicaid	
Medicare		ACA	X
GHP Kids	X	Self-Insured	X

POLICY:

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for Lorbrena for GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 487.0 Quantity Limit Exceptions

REQUIRED DEFINITIONS:

1. **Attachment** – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. **Exhibit** – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. **Devised** – the date the policy was implemented.
4. **Revised** – the date of every revision to the policy, including typographical and grammatical changes.
5. **Reviewed** – the date documenting the annual review if the policy has no revisions necessary.

ADDITIONAL DEFINITIONS:

1. **Formulary** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. **Non-formulary products** – those medications that are not included in the Formulary.
3. **Healthcare provider** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
4. **NCQA** – National Committee for Quality Assurance.
5. **Medically Necessary or Medical Necessity** – covered services rendered by a provider that the Health Plan determines are:



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 539.0

**SECTION: Commercial Drug
SUBJECT: Lorbrena**

- A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
- B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
- C. In accordance with current standards of medical practice;
- D. Not primarily for the convenience of the Member, or the Member's Provider; and
- E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

PROCEDURE:

New members to the plan already established on therapy may be eligible for continuity of care coverage as long as there is medical record documentation that the safety and effectiveness of use for the prescribed indication is supported by Food and Drug Administration (FDA) approval or adequate medical and scientific evidence in the medical literature.

An exception for coverage of Lorbrena may be made for members who meet the following criteria:

- Medical record documentation that Lorbrena is prescribed by or in consultation with a hematologist or oncologist **AND**
- Medical record documentation of age greater than or equal to 18 years **AND**
- Medical record documentation of anaplastic lymphoma kinase (ALK)-positive metastatic non-small cell lung cancer (NSCLC)

MEDISPAN AUTHORIZATION LEVEL: GPI-12, number of claims authorized = 1, enter for the remainder of the calendar year

QUANTITY LIMIT: *No QLs need to be entered within the authorization unless the requested quantity exceeds the QL.*

- **QL FOR LETTER ONLY:**
 - 25 mg tablet: 3 tablets per day, 30 day supply per fill
 - 100 mg tablet: 1 tablet per day, 30 day supply per fill



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 539.0

**SECTION: Commercial Drug
SUBJECT: Lorbrena**

RE-AUTHORIZATION CRITERIA: Lorbrena is configured as a prior authorization for new starts only. Lorbrena will no longer be covered if it is identified that the member is not receiving appropriate follow-up care from the prescribing specialist or if the member has greater than or equal to a 90 day break in therapy.

- Medical record documentation that the member is receiving appropriate follow-up care from the prescribing specialist

If a formulary exception is approved, Lorbrena will be paid for under the member's prescription drug benefit.

Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.

FORMULARY ALTERNATIVES:

Xalkori*, Zykadia*, Alecensa*, Alunbrig*

*prior authorization required

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE
STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND
FEDERAL REGULATORY ENTITIES.**

**THIS POLICY WILL BE REVISED AS NECESSARY AND
REVIEWED NO LESS THAN ANNUALLY.**

Signed: _____

Title: Director, Pharmacy Services

Date: March 1, 2022

Devised: 2/5/19
Revised: 3/1/19 – annual review, defined ALK
Revised: 3/1/20 – annual review, added GHP Kids
Revised: 3/1/21 – annual review, updated logo, added MediSpan approval level, updated QL statement
Revised: 6/7/21 – removed failure of prior agents
Revised: 11/29/21 – added one-time PA to approval crit., removed auth duration & added re-auth crit.



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 539.0

**SECTION: Commercial Drug
SUBJECT: Lorbrena**

Revised: 3/1/22 – annual review, updated referenced policies & covered LOBs



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 540.0

**SECTION: Commercial Drug
SUBJECT: Lokelma**

Applicable line of business:

Commercial	X	Medicaid	
Medicare		ACA	X
GHP Kids	X	Self-Insured	X

POLICY:

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for Lokelma for GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 487.0 Quantity Limit Exceptions

REQUIRED DEFINITIONS:

1. **Attachment** – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. **Exhibit** – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. **Devised** – the date the policy was implemented.
4. **Revised** – the date of every revision to the policy, including typographical and grammatical changes.
5. **Reviewed** – the date documenting the annual review if the policy has no revisions necessary.

ADDITIONAL DEFINITIONS:

1. **Formulary** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. **Non-formulary products** – those medications that are not included in the Formulary.
3. **Healthcare provider** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
4. **NCQA** – National Committee for Quality Assurance.
5. **Medically Necessary or Medical Necessity** – covered services rendered by a provider that the Health Plan determines are:



POLICY NUMBER: 540.0

**POLICY AND PROCEDURE
PHARMACY
MANUAL**

**SECTION: Commercial Drug
SUBJECT: Lokelma**

- A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
- B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
- C. In accordance with current standards of medical practice;
- D. Not primarily for the convenience of the Member, or the Member's Provider; and
- E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

PROCEDURE:

A formulary exception for coverage of Lokelma may be made for members who meet the following criteria:

- Medical record documentation of a diagnosis of hyperkalemia **AND**
- Medical record documentation of age greater than or equal to 18 years **AND**
- Medical record documentation that attempt has been made to identify and correct the underlying cause of the patient's hyperkalemia **OR** rationale as to why the underlying cause cannot be corrected **AND**
- For mild hyperkalemia (serum potassium greater than or equal to 5.1 mEq/L and less than 5.5 mEq/L): Medical record documentation that a low potassium diet has been tried and was unsuccessful at controlling the patient's serum potassium level **AND**
- Medical record documentation of a therapeutic failure on, intolerance to, or contraindication to loop diuretic or thiazide diuretic therapy

MEDISPAN AUTHORIZATION LEVEL: GPI-12

QUANTITY LIMIT: *No QLs need to be entered within the authorization unless the requested quantity exceeds the QL.*

- **QL FOR LETTER ONLY:**
 - 5 g packet: 1 packet per day
 - 10 g packet: 1.14 packets per day

If a formulary exception is approved Lokelma will be paid for under the member's prescription drug benefit.

Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 540.0

**SECTION: Commercial Drug
SUBJECT: Lokelma**

FORMULARY ALTERNATIVES:
sodium polystyrene sulfonate

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE
STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND
FEDERAL REGULATORY ENTITIES.**

**THIS POLICY WILL BE REVISED AS NECESSARY AND
REVIEWED NO LESS THAN ANNUALLY.**

Signed: _____

Title: Director, Pharmacy Services

Date: March 1, 2022

Devised: 2/5/19
Reviewed: 3/1/19 – annual review
Revised: 3/28/19 – removed mild/moderate & lab requirement
Revised: 3/1/20 – annual review, added GHP Kids
Revised: 3/1/21 – annual review, updated logo, added MediSpan approval level, updated QL statement
Revised: 3/1/22 – annual review, updated referenced policies & covered LOBs



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 541.0

**SECTION: Commercial Drug
SUBJECT: Mulpleta**

Applicable line of business:

Commercial	X	Medicaid	
Medicare		ACA	X
GHP Kids	X	Self-Insured	X

POLICY:

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for Mulpleta for GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 487.0 Quantity Limit Exceptions

REQUIRED DEFINITIONS:

1. **Attachment** – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. **Exhibit** – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. **Devised** – the date the policy was implemented.
4. **Revised** – the date of every revision to the policy, including typographical and grammatical changes.
5. **Reviewed** – the date documenting the annual review if the policy has no revisions necessary.

ADDITIONAL DEFINITIONS:

1. **Formulary** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. **Non-formulary products** – those medications that are not included in the Formulary.
3. **Healthcare provider** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
4. **NCQA** – National Committee for Quality Assurance.
5. **Medically Necessary or Medical Necessity** – covered services rendered by a provider that the Health Plan determines are:



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 541.0

**SECTION: Commercial Drug
SUBJECT: Mulpleta**

- A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
- B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
- C. In accordance with current standards of medical practice;
- D. Not primarily for the convenience of the Member, or the Member's Provider; and
- E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

PROCEDURE:

An exception for coverage of Mulpleta may be made for members who meet the following criteria:

- Medical record documentation that Mulpleta is prescribed by or in consultation with a hematologist, gastroenterologist, hepatologist, immunologist, transplant specialist, interventional radiologist, or endocrinologist **AND**
- Medical record documentation of age greater than or equal to 18 years **AND**
- Medical record documentation of thrombocytopenia in adult patients with chronic liver disease **AND**
- Medical record documentation of a platelet count of less than $50 \times 10^9/L$ measured within the past 30 days **AND**
- Medical record documentation of a planned invasive procedure to be performed 8-14 days after initiation date for Mulpleta treatment **AND**
- Medical record documentation that the member is not receiving other thrombopoietin receptor agonists (TPO-Ras) (Nplate/romiplostim, Promacta/eltrombopag) **AND**
- Medical record documentation of the correct dose being used (3 mg orally once daily for 7 days) **AND**
- Medical record documentation of therapeutic failure on, intolerance to, or contraindication to Doptelet

MEDISPAN AUTHORIZATION LEVEL: GPI-12

QUANTITY LIMIT: *No QLs need to be entered within the authorization unless the requested quantity exceeds the QL.*

- **QL FOR LETTER ONLY:** 7 tablets per fill

AUTHORIZATION DURATION: 30 days, RX count 1



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 541.0

**SECTION: Commercial Drug
SUBJECT: Mulpleta**

If a formulary exception is approved, Mulpleta will be paid for under the member's prescription drug benefit.

Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.

FORMULARY ALTERNATIVES:

Promacta*, Doptelet*

*prior authorization required

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE
STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND
FEDERAL REGULATORY ENTITIES.**

**THIS POLICY WILL BE REVISED AS NECESSARY AND
REVIEWED NO LESS THAN ANNUALLY.**

Signed: _____

Title: Director, Pharmacy Services

Date: March 1, 2022

- Devised: 2/5/19
- Revised: 3/1/19 – annual review, defined TPO-Ras
- Revised: 3/21/19 – added interventional radiologist to prescriber criteria
- Revised: 11/20/19 – added failure of Doptelet
- Revised: 3/1/20 – annual review, added GHP Kids
- Revised: 3/1/21 – annual review, updated logo, added MediSpan approval level, updated QL statement
- Revised: 3/1/22 – annual review, updated referenced policies & covered LOBs



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 542.0

**SECTION: Commercial Drug
SUBJECT: Galafold**

Applicable line of business:

Commercial	X	Medicaid	
Medicare		ACA	X
GHP Kids	X	Self-Insured	X

POLICY:

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for Galafold for GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 487.0 Quantity Limit Exceptions

REQUIRED DEFINITIONS:

1. **Attachment** – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. **Exhibit** – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. **Devised** – the date the policy was implemented.
4. **Revised** – the date of every revision to the policy, including typographical and grammatical changes.
5. **Reviewed** – the date documenting the annual review if the policy has no revisions necessary.

ADDITIONAL DEFINITIONS:

1. **Formulary** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. **Non-formulary products** – those medications that are not included in the Formulary.
3. **Healthcare provider** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
4. **NCQA** – National Committee for Quality Assurance.
5. **Medically Necessary or Medical Necessity** – covered services rendered by a provider that the Health Plan determines are:



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 542.0

**SECTION: Commercial Drug
SUBJECT: Galafold**

- A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
- B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
- C. In accordance with current standards of medical practice;
- D. Not primarily for the convenience of the Member, or the Member's Provider; and
- E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

PROCEDURE:

An exception for coverage of Galafold may be made for members who meet the following criteria:

- Medical record documentation that Lorbrena is prescribed by or in consultation with a geneticist, nephrologist, cardiologist, or a physician who specializes in the treatment of Fabry disease **AND**
- Medical record documentation of age greater than or equal to 18 years **AND**
- Medical record documentation of a diagnosis of Fabry disease as confirmed by one of the following:
 - Enzyme assay indicating deficiency of Alpha Gal-a (if male) **OR**
 - Genetic test documenting galactosidase alpha gene mutation **AND**
- Medical record documentation of in vitro assay data confirming the presence of an amenable galactosidase alpha gene (GLA) variant, in accordance with the Food and Drug administration (FDA)-approved prescribing information **AND**
- Medical record documentation that Galafold will not be used concurrently with enzyme replacement therapy intended for the treatment of Fabry disease, such as agalsidase beta (Fabrazyme)

MEDISPAN AUTHORIZATION LEVEL: GPI-12

QUANTITY LIMIT: *No QLs need to be entered within the authorization unless the requested quantity exceeds the QL.*

- **QL FOR LETTER ONLY:** 14 capsules per 28 days

AUTHORIZATION DURATION: Initial approval will be for a duration of **six (6) months**. For continuation of coverage, medical record documentation of clinical improvement or lack of progression in signs and symptoms of Fabry disease on six (6) months of migalastat is required. After the initial six (6) month approval, **subsequent approvals** for coverage will be for a duration of **one (1) year**. Reevaluation of coverage will be every one (1) year requiring medical record documentation of clinical improvement or lack of progression in signs and symptoms of Fabry disease while on migalastat therapy.

Note: Examples of disease improvement may include:

- Decreased symptoms of Fabry disease (e.g., pain, hypohidrosis/anhidrosis, exercise intolerance, GI symptoms, angiokeratomas, abnormal cornea, tinnitus/hearing loss)
- Imaging (brain/cardiac MRI, DEXA, renal ultrasound)
- Laboratory testing (e.g., GL-3 in plasma/urine) or histological tests (e.g., renal biopsy)

If a formulary exception is approved, Galafold will be paid for under the member's prescription drug benefit.

Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.

FORMULARY ALTERNATIVES:

none

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE
STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND
FEDERAL REGULATORY ENTITIES.**

**THIS POLICY WILL BE REVISED AS NECESSARY AND
REVIEWED NO LESS THAN ANNUALLY.**

Signed:  _____

Title: Director, Pharmacy Services



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 542.0

**SECTION: Commercial Drug
SUBJECT: Galafold**

Date: March 1, 2022

Devised: 2/5/19

Reviewed: 3/1/19 – annual review

Revised: 3/1/20 – annual review, added GHP Kids

Revised: 3/1/21 – annual review, updated logo, added MediSpan approval level, updated QL statement

Revised: 3/1/22 – annual review, updated referenced policies & covered LOBs



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 543.0

**SECTION: Commercial Drug
SUBJECT: Takhzyro**

Applicable line of business:

Commercial	X	Medicaid	
Medicare		ACA	X
GHP Kids	X	Self-Insured	X

POLICY:

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for Takhzyro for GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 487.0 Quantity Limit Exceptions

REQUIRED DEFINITIONS:

1. **Attachment** – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. **Exhibit** – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. **Devised** – the date the policy was implemented.
4. **Revised** – the date of every revision to the policy, including typographical and grammatical changes.
5. **Reviewed** – the date documenting the annual review if the policy has no revisions necessary.

ADDITIONAL DEFINITIONS:

1. **Formulary** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. **Non-formulary products** – those medications that are not included in the Formulary.
3. **Healthcare provider** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
4. **NCQA** – National Committee for Quality Assurance.
5. **Medically Necessary or Medical Necessity** – covered services rendered by a provider that the Health Plan determines are:



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 543.0

**SECTION: Commercial Drug
SUBJECT: Takhzyro**

- A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
- B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
- C. In accordance with current standards of medical practice;
- D. Not primarily for the convenience of the Member, or the Member's Provider; and
- E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

PROCEDURE:

An exception for coverage of Takhzyro may be made for members who meet the following criteria:

- Medical record documentation of age greater than or equal to 12 years **AND**
- Medical record documentation that Takhzyro is prescribed by an allergist, immunologist, hematologist, or dermatologist **AND**
- Medical record documentation of a diagnosis of hereditary angioedema (HAE) established and supported by documentation of:
 - Recurrent, self-limiting, non-inflammatory subcutaneous angioedema without urticaria which lasts more than 12 hours **OR**
 - Laryngeal edema **OR**
 - Recurrent, self-remitting abdominal pain which lasts more than 6 hours, without clear organic etiology **AND**
- Medical record documentation of specific abnormalities in complement proteins, in the setting of a suggestive clinical history or episodic angioedema without urticaria; supported by:
 - Medical record documentation of two (2) or more sets of complement studies, separated by one month or more, showing consistent results of:
 - Low C4 levels **AND**
 - Less than 50% of the lower limit of normal C1-INH antigenic protein levels **OR**
 - Less than 50% of the lower limit of normal C1-INH functions levels **AND**
- Medical record documentation of history of more than one (1) severe event per month **OR** a history of laryngeal attacks **AND**
- Medical record documentation that Takhzyro is being used as prophylactic therapy for hereditary angioedema (HAE) attacks **AND**



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 543.0

**SECTION: Commercial Drug
SUBJECT: Takhzyro**

- Medical record documentation of therapeutic failure on, intolerance to, or contraindication to danazol

MEDISPAN AUTHORIZATION LEVEL: GPI-12

QUANTITY LIMIT: *No QLs need to be entered within the authorization unless the requested quantity exceeds the QL.*

- QL FOR LETTER ONLY: 4 mL per 28 days

AUTHORIZATION DURATION: Initial approval will be for 6 months or less if the reviewing provider feels it is medically appropriate. Subsequent approvals will be for an additional 12 months or less if the reviewing provider feels it is medically appropriate and will required medical record documentation of continued disease improvement or lack of disease progression. Takhzyro will no longer be covered if the member experiences unacceptable toxicity or worsening of disease.

If a formulary exception is approved, Takhzyro will be paid for under the member's prescription drug benefit.

Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.

FORMULARY ALTERNATIVES:

Danazol, Haegarda*

*prior authorization required

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE
STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND
FEDERAL REGULATORY ENTITIES.**

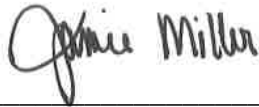
**THIS POLICY WILL BE REVISED AS NECESSARY AND
REVIEWED NO LESS THAN ANNUALLY.**

Geisinger

**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 543.0

**SECTION: Commercial Drug
SUBJECT: Takhzyro**



Signed: _____

Title: Director, Pharmacy Services

Date: March 1, 2022

Devised: 2/6/19

Reviewed: 3/1/19 – annual review

Revised: 3/1/20 – annual review, added GHP Kids

Revised: 3/1/21 – annual review, updated logo, added MediSpan approval level, updated QL statement

Revised: 3/1/22 – annual review, updated referenced policies & covered LOBs



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 544.0

**SECTION: Commercial Drug
SUBJECT: Talzenna**

Applicable line of business:

Commercial	X	Medicaid	
Medicare		ACA	X
GHP Kids	X	Self-Insured	X

POLICY:

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for Talzenna for GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 487.0 Quantity Limit Exceptions

REQUIRED DEFINITIONS:

1. **Attachment** – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. **Exhibit** – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. **Devised** – the date the policy was implemented.
4. **Revised** – the date of every revision to the policy, including typographical and grammatical changes.
5. **Reviewed** – the date documenting the annual review if the policy has no revisions necessary.

ADDITIONAL DEFINITIONS:

1. **Formulary** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. **Non-formulary products** – those medications that are not included in the Formulary.
3. **Healthcare provider** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
4. **NCQA** – National Committee for Quality Assurance.
5. **Medically Necessary or Medical Necessity** – covered services rendered by a provider that the Health Plan determines are:



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 544.0

**SECTION: Commercial Drug
SUBJECT: Talzenna**

- A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
- B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
- C. In accordance with current standards of medical practice;
- D. Not primarily for the convenience of the Member, or the Member's Provider; and
- E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

PROCEDURE:

New members to the plan already established on therapy may be eligible for continuity of care coverage as long as there is medical record documentation that the safety and effectiveness of use for the prescribed indication is supported by Food and Drug Administration (FDA) approval or adequate medical and scientific evidence in the medical literature.

An exception for coverage of Talzenna may be made for members who meet the following criteria:

- Medical record documentation that Talzenna is prescribed by or in consultation with a hematologist or oncologist **AND**
- Medical record documentation of age greater than or equal to 18 years **AND**
- Medical record documentation of deleterious or suspected deleterious germline BRCA-mutated (gBRCAm) HER2-negative advanced or metastatic breast cancer as verified by a Food and Drug Administration (FDA)-approved test

MEDISPAN AUTHORIZATION LEVEL: GPI-12, number of claims authorized = 1, enter for the remainder of the calendar year

QUANTITY LIMIT: *No QLs need to be entered within the authorization unless the requested quantity exceeds the QL.*

- **QL FOR LETTER ONLY:**
 - 1 capsule per day, 30 day supply per fill

NOTE: Information on the FDA-approved test for the detection of BRCA mutations is available at <http://www.fda.gov/companiondiagnostics>



POLICY NUMBER: 544.0

**POLICY AND PROCEDURE
PHARMACY
MANUAL**

**SECTION: Commercial Drug
SUBJECT: Talzenna**

RE-AUTHORIZATION CRITERIA: Talzenna is configured as a prior authorization for new starts only. Talzenna will no longer be covered if it is identified that the member is not receiving appropriate follow-up care from the prescribing specialist or if the member has greater than or equal to a 90 day break in therapy.

- Medical record documentation that the member is receiving appropriate follow-up care from the prescribing specialist

If a formulary exception is approved, Talzenna will be paid for under the member's prescription drug benefit.

Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.

FORMULARY ALTERNATIVES:

Lynparza*, Zejula*, Rubraca*

*prior authorization required

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE
STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND
FEDERAL REGULATORY ENTITIES.**

**THIS POLICY WILL BE REVISED AS NECESSARY AND
REVIEWED NO LESS THAN ANNUALLY.**

Signed: _____

Title: Director, Pharmacy Services

Date: April 6, 2022

Devised: 2/6/19
Reviewed: 3/1/19 – annual review
Revised: 3/1/20 – annual review, added GHP Kids
Revised: 3/1/21 – annual review, updated logo, added MediSpan approval level, updated QL statement
Revised: 12/1/21 – added one-time PA to approval crit., removed auth duration & added re-auth crit.
Revised: 3/1/22 – annual review, updated referenced policies & covered LOBs



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 544.0

**SECTION: Commercial Drug
SUBJECT: Talzenna**

Revised: 4/6/22 – updated QL for all strengths to 1 capsule per day



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 545.0

**SECTION: Commercial Drug
SUBJECT: Qbrexza**

Applicable line of business:

Commercial	X	Medicaid	
Medicare		ACA	X
GHP Kids	X	Self-Insured	X

POLICY:

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for Qbrexza for GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 487.0 Quantity Limit Exceptions

REQUIRED DEFINITIONS:

1. **Attachment** – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. **Exhibit** – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. **Devised** – the date the policy was implemented.
4. **Revised** – the date of every revision to the policy, including typographical and grammatical changes.
5. **Reviewed** – the date documenting the annual review if the policy has no revisions necessary.

ADDITIONAL DEFINITIONS:

1. **Formulary** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. **Non-formulary products** – those medications that are not included in the Formulary.
3. **Healthcare provider** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
4. **NCQA** – National Committee for Quality Assurance.
5. **Medically Necessary or Medical Necessity** – covered services rendered by a provider that the Health Plan determines are:



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 545.0

**SECTION: Commercial Drug
SUBJECT: Qbrexza**

- A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
- B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
- C. In accordance with current standards of medical practice;
- D. Not primarily for the convenience of the Member, or the Member's Provider; and
- E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

PROCEDURE:

An exception for coverage of Qbrexza may be made for members who meet the following criteria:

- Medical record documentation of age greater than or equal to 9 years **AND**
- Medical record documentation of a diagnosis of primary axillary hyperhidrosis **AND**
- Medical record documentation of therapeutic failure on, intolerance to, or contraindication to at least one prescription antiperspirant (aluminum chloride hexahydrate 6.25% [Xerac AC], 20% [Drysol])

MEDISPAN AUTHORIZATION LEVEL: GPI-12

QUANTITY LIMIT: *No QLs need to be entered within the authorization unless the requested quantity exceeds the QL.*

- **QL FOR LETTER ONLY:** 1 per day

If a formulary exception is approved, Qbrexza will be paid for under the member's prescription drug benefit.

Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.

FORMULARY ALTERNATIVES:

Xerac AC, Drysol



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 545.0

**SECTION: Commercial Drug
SUBJECT: Qbrexza**

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE
STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND
FEDERAL REGULATORY ENTITIES.**

**THIS POLICY WILL BE REVISED AS NECESSARY AND
REVIEWED NO LESS THAN ANNUALLY.**

Signed: _____

Title: Director, Pharmacy Services

Date: March 1, 2022

Devised: 2/6/19
Reviewed: 3/1/19 – annual review
Revised: 3/1/20 – annual review, added GHP Kids
Revised: 3/1/21 – annual review, updated logo, added MediSpan approval level, updated QL statement
Revised: 3/1/22 – annual review, updated referenced policies & covered LOBs



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 546.0

**SECTION: Commercial Drug
SUBJECT: Nuversa**

Applicable line of business:

Commercial	X	Medicaid	
Medicare		ACA	X
GHP Kids	X	Self-Insured	X

POLICY:

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for Nuversa for GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 487.0 Quantity Limit Exceptions

REQUIRED DEFINITIONS:

1. **Attachment** – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. **Exhibit** – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. **Devised** – the date the policy was implemented.
4. **Revised** – the date of every revision to the policy, including typographical and grammatical changes.
5. **Reviewed** – the date documenting the annual review if the policy has no revisions necessary.

ADDITIONAL DEFINITIONS:

1. **Formulary** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. **Non-formulary products** – those medications that are not included in the Formulary.
3. **Healthcare provider** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
4. **NCQA** – National Committee for Quality Assurance.
5. **Medically Necessary or Medical Necessity** – covered services rendered by a provider that the Health Plan determines are:



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 546.0

**SECTION: Commercial Drug
SUBJECT: Nuversa**

- A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
- B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
- C. In accordance with current standards of medical practice;
- D. Not primarily for the convenience of the Member, or the Member's Provider; and
- E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

PROCEDURE:

An exception for coverage of Nuversa may be made for members who meet the following criteria:

- For members 18 years of age and older: Medical record documentation of therapeutic failure on, intolerance to, or contraindication to clindamycin 2% vaginal cream **AND** metronidazole 0.75% vaginal gel
- For members age 12 to less than 18 years of age: Medical record documentation of therapeutic failure on, intolerance to, or contraindication to clindamycin 2% vaginal cream

NOTE: Pediatric dosing is based on adult dosing for clindamycin phosphate 2% vaginal cream **ONLY** in postmenarchal female pediatric patients. Safety and effectiveness in premenarchal females have not been established.

MEDISPAN AUTHORIZATION LEVEL: GPI-14

If a formulary exception is approved, Nuversa will be paid for under the member's prescription drug benefit.

Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.

FORMULARY ALTERNATIVES:

clindamycin 2% vaginal cream, metronidazole 0.75% vaginal gel



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 546.0

**SECTION: Commercial Drug
SUBJECT: Nuversa**

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE
STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND
FEDERAL REGULATORY ENTITIES.**

**THIS POLICY WILL BE REVISED AS NECESSARY AND
REVIEWED NO LESS THAN ANNUALLY.**

Signed: _____

Title: Director, Pharmacy Services

Date: March 1, 2022

Devised: 2/6/19
Reviewed: 3/1/19 – annual review
Revised: 3/1/20 – annual review, added GHP Kids
Revised: 3/1/21 – annual review, updated logo, added MediSpan approval level
Revised: 3/1/22 – annual review, updated referenced policies & covered LOBs



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 547.0

**SECTION: Commercial Drug
SUBJECT: Alvesco and ArmonAir**

Applicable line of business:

Commercial	X	Medicaid	
Medicare		ACA	X
GHP Kids	X	Self-Insured	X

POLICY:

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for Alvesco and ArmonAir for GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 487.0 Quantity Limit Exceptions

REQUIRED DEFINITIONS:

1. **Attachment** – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. **Exhibit** – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. **Devised** – the date the policy was implemented.
4. **Revised** – the date of every revision to the policy, including typographical and grammatical changes.
5. **Reviewed** – the date documenting the annual review if the policy has no revisions necessary.

ADDITIONAL DEFINITIONS:

1. **Formulary** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. **Non-formulary products** – those medications that are not included in the Formulary.
3. **Healthcare provider** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
4. **NCQA** – National Committee for Quality Assurance.
5. **Medically Necessary or Medical Necessity** – covered services rendered by a provider that the Health Plan determines are:



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 547.0

**SECTION: Commercial Drug
SUBJECT: Alvesco and ArmonAir**

- A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
- B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
- C. In accordance with current standards of medical practice;
- D. Not primarily for the convenience of the Member, or the Member's Provider; and
- E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

PROCEDURE:

An exception for coverage of Alvesco or ArmonAir may be made for members who meet the following criteria:

- Medical record documentation of failure on, intolerance to, or contraindication to Arnuity Ellipta **AND** QVAR RediHaler **AND** one additional formulary agent

NOTE: Alvesco and QVAR RediHaler are both small particle inhalers. It has been believed that the smaller particle size distribution is an advantage of these agents however there is no concrete evidence to indicate that this is clinically justified. Currently, per the guidelines, there is not one ICS inhaler preferred over the other.

MEDISPAN AUTHORIZATION LEVEL: GPI-12

If a formulary exception is approved, Alvesco or ArmonAir will be paid for under the member's prescription drug benefit.

Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.

FORMULARY ALTERNATIVES:

Arnuity Ellipta, Asmanex, Flovent, Pulmicort Flexhaler, QVAR RediHaler



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 547.0

**SECTION: Commercial Drug
SUBJECT: Alvesco and ArmonAir**

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE
STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND
FEDERAL REGULATORY ENTITIES.**

**THIS POLICY WILL BE REVISED AS NECESSARY AND
REVIEWED NO LESS THAN ANNUALLY.**

Signed: _____

Title: Director, Pharmacy Services

Date: March 1, 2022

Devised: 2/6/19
Reviewed: 3/1/19 – annual review
Revised: 3/1/20 – annual review, added GHP Kids
Revised: 3/1/21 – annual review, updated logo, added MediSpan approval level
Revised: 3/1/22 – annual review, updated referenced policies & covered LOBs



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 548.0

**SECTION: Commercial Drug
SUBJECT: Daurismo**

Applicable line of business:

Commercial	X	Medicaid	
Medicare		ACA	X
GHP Kids	X	Self-Insured	X

POLICY:

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for Daurismo for GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 487.0 Quantity Limit Exceptions

REQUIRED DEFINITIONS:

1. **Attachment** – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. **Exhibit** – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. **Devised** – the date the policy was implemented.
4. **Revised** – the date of every revision to the policy, including typographical and grammatical changes.
5. **Reviewed** – the date documenting the annual review if the policy has no revisions necessary.

ADDITIONAL DEFINITIONS:

1. **Formulary** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. **Non-formulary products** – those medications that are not included in the Formulary.
3. **Healthcare provider** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
4. **NCQA** – National Committee for Quality Assurance.
5. **Medically Necessary or Medical Necessity** – covered services rendered by a provider that the Health Plan determines are:

- A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
- B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
- C. In accordance with current standards of medical practice;
- D. Not primarily for the convenience of the Member, or the Member's Provider; and
- E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

PROCEDURE:

New members to the plan already established on therapy may be eligible for continuity of care coverage as long as there is medical record documentation that the safety and effectiveness of use for the prescribed indication is supported by Food and Drug Administration (FDA) approval or adequate medical and scientific evidence in the medical literature.

An exception for coverage of Daurismo may be made for members who meet the following criteria:

- Medical record documentation that Daurismo is prescribed by a hematologist or oncologist **AND**
- Medical record documentation of newly-diagnosed acute myeloid leukemia (AML) **AND**
- Medical record documentation of age 75 years or older **OR** medical record documentation of the presence of comorbidities that preclude use of intensive induction chemotherapy **AND**
- Medical record documentation that Daurismo is being used in combination with low-dose cytarabine

MEDISPAN AUTHORIZATION LEVEL: GPI-12, number of claims authorized = 1, enter for the remainder of the calendar year

QUANTITY LIMIT: *No QLs need to be entered within the authorization unless the requested quantity exceeds the QL.*

- **QL FOR LETTER ONLY:**
 - 100 mg tablet: 1 tablet per day, 30 day supply per fill
 - 25 mg tablet: 2 tablets per day, 30 day supply per fill

RE-AUTHORIZATION CRITERIA: Daurismo is configured as a prior authorization for new starts only. Daurismo will no longer be covered if it is identified that the member is not receiving appropriate follow-up care from the prescribing specialist or if the member has greater than or equal to a 90 day break in therapy.

- Medical record documentation that the member is receiving appropriate follow-up care from the prescribing specialist

If a formulary exception is approved, Daurismo will be paid for under the member's prescription drug benefit.

Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.

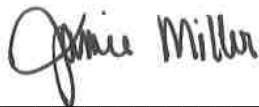
FORMULARY ALTERNATIVES:

Idhifa*, Tibsovo*, Venclexta*

*prior authorization required

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE
STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND
FEDERAL REGULATORY ENTITIES.**

**THIS POLICY WILL BE REVISED AS NECESSARY AND
REVIEWED NO LESS THAN ANNUALLY.**



Signed: _____

Title: Director, Pharmacy Services

Date: March 1, 2022

- Devised: 3/21/19
Revised: 3/1/20 – annual review, added GHP Kids
Revised: 3/1/21 – annual review, updated logo, added MediSpan approval level, updated QL statement
Revised: 11/24/21 – added one-time PA to approval crit., removed auth duration & added re-auth crit.
Revised: 3/1/22 – annual review, updated referenced policies & covered LOBs



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 549.0

**SECTION: Commercial Drug
SUBJECT: Vitrakvi**

Applicable line of business:

Commercial	X	Medicaid	
Medicare		ACA	X
GHP Kids	X	Self-Insured	X

POLICY:

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for Vitrakvi for GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 487.0 Quantity Limit Exceptions

REQUIRED DEFINITIONS:

1. **Attachment** – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. **Exhibit** – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. **Devised** – the date the policy was implemented.
4. **Revised** – the date of every revision to the policy, including typographical and grammatical changes.
5. **Reviewed** – the date documenting the annual review if the policy has no revisions necessary.

ADDITIONAL DEFINITIONS:

1. **Formulary** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. **Non-formulary products** – those medications that are not included in the Formulary.
3. **Healthcare provider** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
4. **NCQA** – National Committee for Quality Assurance.
5. **Medically Necessary or Medical Necessity** – covered services rendered by a provider that the Health Plan determines are:



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 549.0

**SECTION: Commercial Drug
SUBJECT: Vitrakvi**

- A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
- B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
- C. In accordance with current standards of medical practice;
- D. Not primarily for the convenience of the Member, or the Member's Provider; and
- E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

PROCEDURE:

New members to the plan already established on therapy may be eligible for continuity of care coverage as long as there is medical record documentation that the safety and effectiveness of use for the prescribed indication is supported by Food and Drug Administration (FDA) approval or adequate medical and scientific evidence in the medical literature.

An exception for coverage of Vitrakvi may be made for members who meet the following criteria:

- Medical record documentation that Vitrakvi is prescribed by or in consultation with an oncologist or hematologist **AND**
- Medical record documentation of unresectable or metastatic solid tumors with a neurotrophic receptor tyrosine kinase (NTRK) gene fusion without a known acquired resistance mutation **AND**
- One of the following:
 - Medical record documentation that the member must have progressed following treatment **OR**
 - Member must have no satisfactory alternative treatments

NOTE: There is currently no FDA-approved test for the detection of NTRK gene fusions. Testing can currently be completed via next-generation sequencing (NGS) assay and fluorescence in situ hybridization (FISH).

MEDISPAN AUTHORIZATION LEVEL: GPI-10, number of claims authorized = 1, enter for the remainder of the calendar year

Geisinger

**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 549.0

**SECTION: Commercial Drug
SUBJECT: Vitrakvi**

QUANTITY LIMIT: *No QLs need to be entered within the authorization unless the requested quantity exceeds the QL.*

- **QL FOR LETTER ONLY:**
 - 25 mg capsule: 6 capsules per day, 30 day supply per fill
 - 100 mg capsule: 2 capsules per day, 30 day supply per fill
 - 20 mg/mL solution: 10 mL per day, 30 day supply per fill

RE-AUTHORIZATION CRITERIA: Vitrakvi is configured as a prior authorization for new starts only. Vitrakvi will no longer be covered if it is identified that the member is not receiving appropriate follow-up care from the prescribing specialist or if the member has greater than or equal to a 90 day break in therapy.

- Medical record documentation that the member is receiving appropriate follow-up care from the prescribing specialist

If a formulary exception is approved, Vitrakvi will be paid for under the member's prescription drug benefit.

Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.

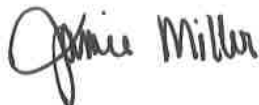
FORMULARY ALTERNATIVES:

none

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE
STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND
FEDERAL REGULATORY ENTITIES.**

**THIS POLICY WILL BE REVISED AS NECESSARY AND
REVIEWED NO LESS THAN ANNUALLY.**

Signed: _____



Title: Director, Pharmacy Services

Date: March 1, 2022



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 549.0

**SECTION: Commercial Drug
SUBJECT: Vitrakvi**

Devised: 3/21/19
Revised: 3/1/20 – annual review, added GHP Kids
Revised: 3/1/21 – annual review, updated logo, added MediSpan approval level, updated QL statement
Revised: 11/30/21 – added one-time PA to approval crit., removed auth duration & added re-auth crit.
Revised: 3/1/22 – annual review, updated referenced policies & covered LOBs



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 550.0

**SECTION: Commercial Drug
SUBJECT: Xospata**

Applicable line of business:

Commercial	X	Medicaid	
Medicare		ACA	X
GHP Kids	X	Self-Insured	X

POLICY:

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for Xospata for GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 487.0 Quantity Limit Exceptions

REQUIRED DEFINITIONS:

1. **Attachment** – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. **Exhibit** – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. **Devised** – the date the policy was implemented.
4. **Revised** – the date of every revision to the policy, including typographical and grammatical changes.
5. **Reviewed** – the date documenting the annual review if the policy has no revisions necessary.

ADDITIONAL DEFINITIONS:

1. **Formulary** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. **Non-formulary products** – those medications that are not included in the Formulary.
3. **Healthcare provider** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
4. **NCQA** – National Committee for Quality Assurance.
5. **Medically Necessary or Medical Necessity** – covered services rendered by a provider that the Health Plan determines are:

- A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
- B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
- C. In accordance with current standards of medical practice;
- D. Not primarily for the convenience of the Member, or the Member's Provider; and
- E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

PROCEDURE:

New members to the plan already established on therapy may be eligible for continuity of care coverage as long as there is medical record documentation that the safety and effectiveness of use for the prescribed indication is supported by Food and Drug Administration (FDA) approval or adequate medical and scientific evidence in the medical literature.

An exception for coverage of Xospata may be made for members who meet the following criteria:

- Medical record documentation that Xospata is prescribed by an oncologist or hematologist **AND**
- Medical record documentation of age greater than or equal to 18 years **AND**
- Medical record documentation of a diagnosis of relapsed or refractory acute myeloid leukemia (AML) **AND**
- Medical record documentation of a FMS-like tyrosine kinase 3 (FLT3) mutation as detected by a Food and Drug Administration (FDA)-approved test

NOTE: Information regarding the FDA approved test for FLT3 mutations can be found at: https://www.accessdata.fda.gov/cdrh_docs/pdf16/P160040C.pdf

MEDISPAN AUTHORIZATION LEVEL: GPI-12, number of claims authorized = 1, enter for the remainder of the calendar year



POLICY NUMBER: 550.0

**POLICY AND PROCEDURE
PHARMACY
MANUAL**

**SECTION: Commercial Drug
SUBJECT: Xospata**

RE-AUTHORIZATION CRITERIA: Xospata is configured as a prior authorization for new starts only. Xospata will no longer be covered if it is identified that the member is not receiving appropriate follow-up care from the prescribing specialist or if the member has greater than or equal to a 90 day break in therapy.

- Medical record documentation that the member is receiving appropriate follow-up care from the prescribing specialist

If a formulary exception is approved, Xospata will be paid for under the member's prescription drug benefit.

Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.

FORMULARY ALTERNATIVES:

Nexavar*

*prior authorization required

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE
STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND
FEDERAL REGULATORY ENTITIES.**

**THIS POLICY WILL BE REVISED AS NECESSARY AND
REVIEWED NO LESS THAN ANNUALLY.**

Signed: _____

Title: Director, Pharmacy Services

Date: March 1, 2022

- Devised: 3/21/19
Revised: 3/1/20 – annual review, added GHP Kids
Revised: 3/1/21 – annual review, updated logo, added MediSpan approval level
Revised: 12/2/21 – added one-time PA to approval crit., removed auth duration & added re-auth crit.
Revised: 3/1/22 – annual review, updated referenced policies & covered LOBs



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 551.0

**SECTION: Commercial Drug
SUBJECT: Arakoda**

Applicable line of business:

Commercial	X	Medicaid	
Medicare		ACA	X
GHP Kids	X	Self-Insured	X

POLICY:

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for Arakoda for GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 487.0 Quantity Limit Exceptions

REQUIRED DEFINITIONS:

1. **Attachment** – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. **Exhibit** – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. **Devised** – the date the policy was implemented.
4. **Revised** – the date of every revision to the policy, including typographical and grammatical changes.
5. **Reviewed** – the date documenting the annual review if the policy has no revisions necessary.

ADDITIONAL DEFINITIONS:

1. **Formulary** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. **Non-formulary products** – those medications that are not included in the Formulary.
3. **Healthcare provider** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
4. **NCQA** – National Committee for Quality Assurance.
5. **Medically Necessary or Medical Necessity** – covered services rendered by a provider that the Health Plan determines are:



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 551.0

**SECTION: Commercial Drug
SUBJECT: Arakoda**

- A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
- B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
- C. In accordance with current standards of medical practice;
- D. Not primarily for the convenience of the Member, or the Member's Provider; and
- E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

PROCEDURE:

An exception for coverage of Arakoda may be made for members who meet the following criteria:

- Medical record documentation of age greater than or equal to 18 years **AND**
- Medical record documentation that Arakoda is being prescribed for prophylaxis of malaria **AND**
- Medical record documentation of G6PD deficiency testing with documented normal levels of G6PD **AND**
- Medical record documentation of therapeutic failure on, intolerance to, or contraindication to three (3) formulary alternatives

MEDISPAN AUTHORIZATION LEVEL: GPI-14

AUTHORIZATION DURATION: 6 months

If a formulary exception is approved, Arakoda will be paid for under the member's prescription drug benefit.

Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.

FORMULARY ALTERNATIVES:

atovaquone/proguanil, chloroquine, doxycycline, mefloquine



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 551.0

**SECTION: Commercial Drug
SUBJECT: Arakoda**

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE
STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND
FEDERAL REGULATORY ENTITIES.**

**THIS POLICY WILL BE REVISED AS NECESSARY AND
REVIEWED NO LESS THAN ANNUALLY.**

Signed: _____

Title: Director, Pharmacy Services

Date: March 1, 2022

Devised: 3/21/19
Revised: 3/1/20 – annual review, added GHP Kids
Revised: 3/1/21 – annual review, updated logo, added MediSpan approval level
Revised: 3/1/22 – annual review, updated referenced policies & covered LOBs



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 552.0

**SECTION: Commercial Drug
SUBJECT: Xepi**

Applicable line of business:

Commercial	X	Medicaid	
Medicare		ACA	X
GHP Kids	X	Self-Insured	X

POLICY:

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for Xepi for GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 487.0 Quantity Limit Exceptions

REQUIRED DEFINITIONS:

1. **Attachment** – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. **Exhibit** – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. **Devised** – the date the policy was implemented.
4. **Revised** – the date of every revision to the policy, including typographical and grammatical changes.
5. **Reviewed** – the date documenting the annual review if the policy has no revisions necessary.

ADDITIONAL DEFINITIONS:

1. **Formulary** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. **Non-formulary products** – those medications that are not included in the Formulary.
3. **Healthcare provider** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
4. **NCQA** – National Committee for Quality Assurance.
5. **Medically Necessary or Medical Necessity** – covered services rendered by a provider that the Health Plan determines are:



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 552.0

**SECTION: Commercial Drug
SUBJECT: Xepi**

- A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
- B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
- C. In accordance with current standards of medical practice;
- D. Not primarily for the convenience of the Member, or the Member's Provider; and
- E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

PROCEDURE:

An exception for coverage of Xepi may be made for members who meet the following criteria:

- Medical record documentation of age greater than or equal to 2 months **AND**
- Medical record documentation of a diagnosis of impetigo **AND**
- Medical record documentation of therapeutic failure on, intolerance to, or contraindication to mupirocin ointment **AND** oral antibiotic therapy

MEDISPAN AUTHORIZATION LEVEL: GPI-12

AUTHORIZATION DURATION: 5 days, RX count 1

If a formulary exception is approved, Xepi will be paid for under the member's prescription drug benefit.

Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.

FORMULARY ALTERNATIVES:

mupirocin ointment, Altabax*, cephalexin, dicloxacillin, erythromycin, clarithromycin, clindamycin, sulfamethoxazole/trimethoprim, doxycycline

*prior authorization required

Geisinger

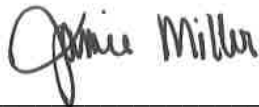
**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 552.0

**SECTION: Commercial Drug
SUBJECT: Xepi**

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE
STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND
FEDERAL REGULATORY ENTITIES.**

**THIS POLICY WILL BE REVISED AS NECESSARY AND
REVIEWED NO LESS THAN ANNUALLY.**



Signed: _____

Title: Director, Pharmacy Services

Date: March 1, 2022

Devised: 3/21/19

Revised: 3/1/20 – annual review, added GHP Kids

Revised: 3/1/21 – annual review, updated logo, added MediSpan approval level

Revised: 3/1/22 – annual review, updated referenced policies & covered LOBs



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 553.0

**SECTION: Commercial Drug
SUBJECT: Tegsedi**

licable line of business:

Commercial	X	Medicaid	
Medicare		ACA	X
GHP Kids	X	Self-Insured	X

POLICY:

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for Tegsedi for GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 487.0 Quantity Limit Exceptions

REQUIRED DEFINITIONS:

1. **Attachment** – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. **Exhibit** – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. **Devised** – the date the policy was implemented.
4. **Revised** – the date of every revision to the policy, including typographical and grammatical changes.
5. **Reviewed** – the date documenting the annual review if the policy has no revisions necessary.

ADDITIONAL DEFINITIONS:

1. **Formulary** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. **Non-formulary products** – those medications that are not included in the Formulary.
3. **Healthcare provider** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
4. **NCQA** – National Committee for Quality Assurance.
5. **Medically Necessary or Medical Necessity** – covered services rendered by a provider that the Health Plan determines are:



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 553.0

**SECTION: Commercial Drug
SUBJECT: Tegsedi**

- A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
- B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
- C. In accordance with current standards of medical practice;
- D. Not primarily for the convenience of the Member, or the Member's Provider; and
- E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

PROCEDURE:

An exception for coverage of Tegsedi may be made for members who meet the following criteria:

- Medical record documentation that Tegsedi is prescribed by or in consultation with a neurologist, geneticist, or specialist with experience in the treatment of hereditary transthyretin-mediated amyloidosis (hATTR) **AND**
- Medical record documentation of age greater than or equal to 18 years **AND**
- Medical record documentation of a diagnosis of hereditary transthyretin-mediated amyloidosis as confirmed by generic testing to confirm a pathogenic mutation in TTR **AND** one of the following:
 - Biopsy of tissue/organ to confirm amyloid presence **OR**
 - A clinical manifestation typical of hATTR (neuropathy and/or congestive heart failure) without a better alternative explanation **AND**
- Medical record documentation that Tegsedi will be used to treat polyneuropathy **AND**
- Medical record documentation of familial amyloid polyneuropathy (FAP) stage 1-2 and/or polyneuropathy disability score (PND) indicating the patient is not wheelchair bound or bedridden **AND**
- Medical record documentation that Tegsedi will not be used in combination with other RNA interference treatment **AND**
- Medical record documentation that member has been evaluated and treated by a contracted Center of Excellence in amyloidosis management

NOTE: Center of Excellence (COE) requirements do not apply to strategic partner TPA plans (i.e., Northern Light Health).

MEDISPAN AUTHORIZATION LEVEL: GPI-12



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 553.0

**SECTION: Commercial Drug
SUBJECT: Tegsedi**

QUANTITY LIMIT: *No QLs need to be entered within the authorization unless the requested quantity exceeds the QL.*

- QL FOR LETTER ONLY: 6 mL per 28 days

AUTHORIZATION DURATION: Initial approval will be for 12 months or less if the reviewing provider feels it is medically appropriate. Subsequent approvals will be for an additional 12 months or less if the reviewing provider feels it is medically appropriate. The medication will no longer be covered if the member progresses to FAP stage 3 and/or polyneuropathy disability score indicating the patient is wheelchair-bound or bedridden.

NOTE:

FAP stage:

- 1-unimpairment ambulation
- 2- assistance with ambulation
- 3- wheelchair-bound or bedridden

Polyneuropathy disability score:

- I- preserved walking, sensory disturbances
- II- impaired walking without need for stick/crutches
- IIIa- walking with 1 stick/crutch
- IIIb- walking with 2 sticks/crutches
- IV-wheelchair-bound or bedridden

Polyneuropathy disability score (used in Neuro-TTR trial):

- I- preserved walking, sensory disturbances
- II- impaired walking without need for stick/crutches
- III- walking with 1 stick/crutch
- IV- walking with 2 sticks/crutches
- V-wheelchair-bound or bedridden

If a formulary exception is approved, Tegsedi will be paid for under the member's prescription drug benefit.

Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.

FORMULARY ALTERNATIVES:

none

Geisinger

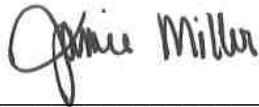
**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 553.0

**SECTION: Commercial Drug
SUBJECT: Tegsedi**

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE
STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND
FEDERAL REGULATORY ENTITIES.**

**THIS POLICY WILL BE REVISED AS NECESSARY AND
REVIEWED NO LESS THAN ANNUALLY.**



Signed: _____

Title: Director, Pharmacy Services

Date: March 1, 2022

Devised: 3/28/19
Revised: 3/1/20 – annual review, added GHP Kids
Revised: 3/1/21 – annual review, updated logo, added MediSpan approval level, updated QL statement
Revised: 1/5/22 – added COE criterion and note
Revised: 3/1/22 – annual review, updated referenced policies & covered LOBs



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 554.0

**SECTION: Commercial Drug
SUBJECT: Firdapse**

Applicable line of business:

Commercial	X	Medicaid	
Medicare		ACA	X
GHP Kids	X	Self-Insured	X

POLICY:

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for Firdapse for GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 487.0 Quantity Limit Exceptions

REQUIRED DEFINITIONS:

1. **Attachment** – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. **Exhibit** – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. **Devised** – the date the policy was implemented.
4. **Revised** – the date of every revision to the policy, including typographical and grammatical changes.
5. **Reviewed** – the date documenting the annual review if the policy has no revisions necessary.

ADDITIONAL DEFINITIONS:

1. **Formulary** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. **Non-formulary products** – those medications that are not included in the Formulary.
3. **Healthcare provider** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
4. **NCQA** – National Committee for Quality Assurance.
5. **Medically Necessary or Medical Necessity** – covered services rendered by a provider that the Health Plan determines are:



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 554.0

**SECTION: Commercial Drug
SUBJECT: Firdapse**

- A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
- B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
- C. In accordance with current standards of medical practice;
- D. Not primarily for the convenience of the Member, or the Member's Provider; and
- E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

PROCEDURE:

An exception for coverage of Firdapse may be made for members who meet the following criteria:

- Medical record documentation of age greater than or equal to 18 years **AND**
- Medical record documentation that Firdapse is prescribed by a neurologist **AND**
- Medical record documentation of a diagnosis of Lambert-Eaton myasthenic syndrome confirmed by one of the following:
 - Medical record documentation of post-exercise facilitation test showing increase in compound muscle action potential (CMAP) amplitude of at least 60% compared to pre-exercise baseline value **OR**
 - Medical record documentation of high-frequency repetitive nerve stimulation (RNS) showing increase in compound muscle action potential (CMAP) of at least 60% **OR**
 - Medical record documentation of positive anti-P/Q voltage-gated calcium channel antibody test **AND**
- Medical record documentation of therapeutic failure on, intolerance to, or contraindication to pyridostigmine

MEDISPAN AUTHORIZATION LEVEL: GPI-12

QUANTITY LIMIT: *No QLs need to be entered within the authorization unless the requested quantity exceeds the QL.*

- **QL FOR LETTER ONLY:** 8 tablets per day, 30 day supply per fill

AUTHORIZATION DURATION: Initial approval will be for 6 months. Subsequent authorizations will be for 12 months and will require:

- Medical record documentation of clinical improvement or lack of progression in signs and symptoms of Lambert-Eaton Myasthenic Syndrome **OR**



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 554.0

**SECTION: Commercial Drug
SUBJECT: Firdapse**

- Medical record documentation of prescriber attestation that the member will benefit from continued therapy with Firdapse and that Firdapse treatment continues to be medically necessary

If a formulary exception is approved, Firdapse will be paid for under the member's prescription drug benefit.

Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.

FORMULARY ALTERNATIVES:

pyridostigmine, guanidine

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE
STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND
FEDERAL REGULATORY ENTITIES.**

**THIS POLICY WILL BE REVISED AS NECESSARY AND
REVIEWED NO LESS THAN ANNUALLY.**

Signed: _____

Title: Director, Pharmacy Services

Date: March 1, 2022

Devised: 5/24/19

Revised: 3/1/20 – annual review, added GHP Kids

Revised: 3/1/21 – annual review, updated logo, added MediSpan approval level, updated QL statement

Revised: 3/1/22 – annual review, updated referenced policies & covered LOBs



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 555.0

**SECTION: Commercial Drug
SUBJECT: Yupelri**

Applicable line of business:

Commercial	X	Medicaid	
Medicare		ACA	X
GHP Kids	X	Self-Insured	X

POLICY:

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for Yupelri for GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 487.0 Quantity Limit Exceptions

REQUIRED DEFINITIONS:

1. **Attachment** – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. **Exhibit** – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. **Devised** – the date the policy was implemented.
4. **Revised** – the date of every revision to the policy, including typographical and grammatical changes.
5. **Reviewed** – the date documenting the annual review if the policy has no revisions necessary.

ADDITIONAL DEFINITIONS:

1. **Formulary** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. **Non-formulary products** – those medications that are not included in the Formulary.
3. **Healthcare provider** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
4. **NCQA** – National Committee for Quality Assurance.
5. **Medically Necessary or Medical Necessity** – covered services rendered by a provider that the Health Plan determines are:



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 555.0

**SECTION: Commercial Drug
SUBJECT: Yupelri**

- A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
- B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
- C. In accordance with current standards of medical practice;
- D. Not primarily for the convenience of the Member, or the Member's Provider; and
- E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

PROCEDURE:

An exception for coverage of Yupelri may be made for members who meet the following criteria:

- Medical record documentation of age greater than or equal to 18 years **AND**
- Medical record documentation of use for maintenance of moderate to severe chronic obstructive pulmonary disease (COPD) **AND**
- Medical record documentation of therapeutic failure on, intolerance to, or contraindication to Spiriva **AND** Incruse Ellipta **OR**
- Medical record documentation of inability to perform proper inhaler technique

MEDISPAN AUTHORIZATION LEVEL: GPI-12

QUANTITY LIMIT: *No QLs need to be entered within the authorization unless the requested quantity exceeds the QL.*

- QL FOR LETTER ONLY: 3 mL per day

If a formulary exception is approved, Yupelri will be paid for under the member's prescription drug benefit.

Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.

FORMULARY ALTERNATIVES:

Spiriva Handihaler, Spiriva Respimat, Incruse Ellipta

Geisinger

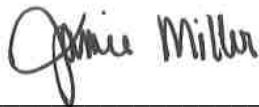
**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 555.0

**SECTION: Commercial Drug
SUBJECT: Yupelri**

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE
STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND
FEDERAL REGULATORY ENTITIES.**

**THIS POLICY WILL BE REVISED AS NECESSARY AND
REVIEWED NO LESS THAN ANNUALLY.**



Signed: _____

Title: Director, Pharmacy Services

Date: March 1, 2022

Devised: 5/24/19

Revised: 3/1/20 – annual review, added GHP Kids

Revised: 3/1/21 – annual review, updated logo, added MediSpan approval level, updated QL statement

Revised: 3/1/22 – annual review, updated referenced policies & covered LOBs



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 556.0

**SECTION: Commercial Drug
SUBJECT: Tiglutik**

Applicable line of business:

Commercial	X	Medicaid	
Medicare		ACA	X
GHP Kids	X	Self-Insured	X

POLICY:

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for Tiglutik for GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 487.0 Quantity Limit Exceptions

REQUIRED DEFINITIONS:

1. **Attachment** – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. **Exhibit** – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. **Devised** – the date the policy was implemented.
4. **Revised** – the date of every revision to the policy, including typographical and grammatical changes.
5. **Reviewed** – the date documenting the annual review if the policy has no revisions necessary.

ADDITIONAL DEFINITIONS:

1. **Formulary** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. **Non-formulary products** – those medications that are not included in the Formulary.
3. **Healthcare provider** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
4. **NCQA** – National Committee for Quality Assurance.
5. **Medically Necessary or Medical Necessity** – covered services rendered by a provider that the Health Plan determines are:

- A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
- B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
- C. In accordance with current standards of medical practice;
- D. Not primarily for the convenience of the Member, or the Member's Provider; and
- E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

PROCEDURE:

An exception for coverage of Tiglutik may be made for members who meet the following criteria:

- Medical record documentation of age greater than or equal to 18 years **AND**
- Medical record documentation that Tiglutik is prescribed by or in consultation with a neurologist **AND**
- Medical record documentation of a diagnosis of amyotrophic lateral sclerosis (ALS) **AND**
- Medical record documentation of therapeutic failure on, intolerance to, or contraindication to riluzole tablets **OR**
- Medical record documentation that member has dysphagia or is unable to swallow tablets

MEDISPAN AUTHORIZATION LEVEL: GPI-12

QUANTITY LIMIT: *No QLs need to be entered within the authorization unless the requested quantity exceeds the QL.*

- **QL FOR LETTER ONLY:** 600 mL per 30 days

If a formulary exception is approved, Tiglutik will be paid for under the member's prescription drug benefit.

Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.

Geisinger

**POLICY AND PROCEDURE
PHARMACY
MANUAL**

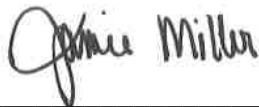
POLICY NUMBER: 556.0

**SECTION: Commercial Drug
SUBJECT: Tiglutik**

FORMULARY ALTERNATIVES:
riluzole tablets

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE
STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND
FEDERAL REGULATORY ENTITIES.**

**THIS POLICY WILL BE REVISED AS NECESSARY AND
REVIEWED NO LESS THAN ANNUALLY.**



Signed: _____

Title: Director, Pharmacy Services

Date: March 1, 2022

Devised: 5/24/19

Revised: 3/1/20 – annual review, added GHP Kids

Revised: 3/1/21 – annual review, updated logo, added MediSpan approval level, updated QL statement

Revised: 3/1/22 – annual review, updated referenced policies & covered LOBs



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 557.0

**SECTION: Commercial Drug
SUBJECT: Oxtellar XR**

Applicable line of business:

Commercial	X	Medicaid	
Medicare		ACA	X
GHP Kids	X	Self-Insured	X

POLICY:

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for Oxtellar XR for GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 487.0 Quantity Limit Exceptions

REQUIRED DEFINITIONS:

1. **Attachment** – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. **Exhibit** – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. **Devised** – the date the policy was implemented.
4. **Revised** – the date of every revision to the policy, including typographical and grammatical changes.
5. **Reviewed** – the date documenting the annual review if the policy has no revisions necessary.

ADDITIONAL DEFINITIONS:

1. **Formulary** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. **Non-formulary products** – those medications that are not included in the Formulary.
3. **Healthcare provider** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
4. **NCQA** – National Committee for Quality Assurance.
5. **Medically Necessary or Medical Necessity** – covered services rendered by a provider that the Health Plan determines are:



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 557.0

**SECTION: Commercial Drug
SUBJECT: Oxtellar XR**

- A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
- B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
- C. In accordance with current standards of medical practice;
- D. Not primarily for the convenience of the Member, or the Member's Provider; and
- E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

PROCEDURE:

An exception for coverage of Oxtellar XR may be made for members who meet the following criteria:

- Medical record documentation of a of partial-onset seizures **AND**
- Medical record documentation of age greater than or equal to 6 years **AND**
- Medical record documentation of therapeutic failure on, intolerance to, or contraindication to three (3) formulary alternatives, one of which must be oxcarbazepine

MEDISPAN AUTHORIZATION LEVEL: GPI-12

If a formulary exception is approved, Oxtellar XR will be paid for under the member's prescription drug benefit.

Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.

FORMULARY ALTERNATIVES:

For patients ≥ 6 years of age: carbamazepine, gabapentin, lamotrigine IR, levetiracetam IR, oxcarbazepine, phenobarbital, phenytoin, topiramate IR, topiramate ER*, and Lyrica

Additional formulary alternatives for patients over certain ages: Divalproex (10+), levetiracetam ER (12+), tiagabine (12+), lamotrigine ER (13+), felbamate (14+), and zonisamide (16+)

*prior authorization required

Geisinger

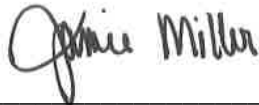
**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 557.0

**SECTION: Commercial Drug
SUBJECT: Oxtellar XR**

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE
STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND
FEDERAL REGULATORY ENTITIES.**

**THIS POLICY WILL BE REVISED AS NECESSARY AND
REVIEWED NO LESS THAN ANNUALLY.**



Signed: _____

Title: Director, Pharmacy Services

Date: March 1, 2022

Devised: 5/24/19

Revised: 3/1/20 – annual review, added GHP Kids

Revised: 3/1/21 – annual review, updated logo, added MediSpan approval level, added LOB table

Revised: 3/1/22 – annual review, updated referenced policies & covered LOBs



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 558.0

**SECTION: Commercial Drug
SUBJECT: Aemcolo**

Applicable line of business:

Commercial	X	Medicaid	
Medicare		ACA	X
GHP Kids	X	Self-Insured	X

POLICY:

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for Aemcolo for GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 487.0 Quantity Limit Exceptions

REQUIRED DEFINITIONS:

1. **Attachment** – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. **Exhibit** – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. **Devised** – the date the policy was implemented.
4. **Revised** – the date of every revision to the policy, including typographical and grammatical changes.
5. **Reviewed** – the date documenting the annual review if the policy has no revisions necessary.

ADDITIONAL DEFINITIONS:

1. **Formulary** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. **Non-formulary products** – those medications that are not included in the Formulary.
3. **Healthcare provider** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
4. **NCQA** – National Committee for Quality Assurance.
5. **Medically Necessary or Medical Necessity** – covered services rendered by a provider that the Health Plan determines are:



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 558.0

**SECTION: Commercial Drug
SUBJECT: Aemcolo**

- A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
- B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
- C. In accordance with current standards of medical practice;
- D. Not primarily for the convenience of the Member, or the Member's Provider; and
- E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

PROCEDURE:

An exception for coverage of Aemcolo may be made for members who meet the following criteria:

- Medical record documentation of age greater than or equal to 18 years **AND**
- Medical record documentation of a diagnosis of travelers' diarrhea **AND**
- Medical record documentation of therapeutic failure on, intolerance to, or contraindication to azithromycin **AND** one oral fluoroquinolone

MEDISPAN AUTHORIZATION LEVEL: GPI-12

QUANTITY LIMIT: *No QLs need to be entered within the authorization unless the requested quantity exceeds the QL.*

- QL FOR LETTER ONLY: 4 tablets per day

AUTHORIZATION DURATION: 3 days, RX count 1

If a formulary exception is approved, Aemcolo will be paid for under the member's prescription drug benefit.

Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.

FORMULARY ALTERNATIVES:

azithromycin, ciprofloxacin, levofloxacin

Geisinger

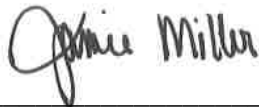
**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 558.0

**SECTION: Commercial Drug
SUBJECT: Aemcolo**

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE
STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND
FEDERAL REGULATORY ENTITIES.**

**THIS POLICY WILL BE REVISED AS NECESSARY AND
REVIEWED NO LESS THAN ANNUALLY.**



Signed: _____

Title: Director, Pharmacy Services

Date: March 1, 2022

Devised: 5/24/19

Revised: 3/1/20 – annual review, added GHP Kids

Revised: 3/1/21 – annual review, updated logo, added MediSpan approval level, updated QL statement

Revised: 3/1/22 – annual review, updated referenced policies & covered LOBs



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 559.0

**SECTION: Commercial Drug
SUBJECT: Copaxone**

Applicable line of business:

Commercial	X	Medicaid	
Medicare		ACA	X
GHP Kids	X	Self-Insured	X

POLICY:

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for Copaxone for GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 487.0 Quantity Limit Exceptions

REQUIRED DEFINITIONS:

1. **Attachment** – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. **Exhibit** – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. **Devised** – the date the policy was implemented.
4. **Revised** – the date of every revision to the policy, including typographical and grammatical changes.
5. **Reviewed** – the date documenting the annual review if the policy has no revisions necessary.

ADDITIONAL DEFINITIONS:

1. **Formulary** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. **Non-formulary products** – those medications that are not included in the Formulary.
3. **Healthcare provider** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
4. **NCQA** – National Committee for Quality Assurance.
5. **Medically Necessary or Medical Necessity** – covered services rendered by a provider that the Health Plan determines are:



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 559.0

**SECTION: Commercial Drug
SUBJECT: Copaxone**

- A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
- B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
- C. In accordance with current standards of medical practice;
- D. Not primarily for the convenience of the Member, or the Member's Provider; and
- E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

PROCEDURE:

An exception for coverage of Copaxone may be made for members who meet the following criteria:

- Medical record documentation of therapeutic failure on, intolerance to, or contraindication to glatiramer acetate

MEDISPAN AUTHORIZATION LEVEL: GPI-12

QUANTITY LIMIT: *No QLs need to be entered within the authorization unless the requested quantity exceeds the QL.*

- **QL FOR LETTER ONLY:**
 - Copaxone 20 mg/mL: 30 mL per 30 days
 - Copaxone 40 mg/mL: 12 mL per 28 days

If a formulary exception is approved, Copaxone will be paid for under the member's prescription drug benefit.

Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.

FORMULARY ALTERNATIVES:

glatiramer acetate, Gilenya, dimethyl fumarate, Betaseron, Plegridy, Extavia, Aubagio 14 mg, Avonex, Rebif, Mayzent



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 559.0

**SECTION: Commercial Drug
SUBJECT: Copaxone**

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE
STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND
FEDERAL REGULATORY ENTITIES.**

**THIS POLICY WILL BE REVISED AS NECESSARY AND
REVIEWED NO LESS THAN ANNUALLY.**

Signed: _____

Title: Director, Pharmacy Services

Date: March 7, 2022

Devised: 5/24/19
Revised: 3/1/20 – annual review, added GHP Kids
Revised: 3/1/21 – annual review, updated logo, added MediSpan approval level, updated QL statement & FA
Revised: 3/1/22 – annual review, updated referenced policies & covered LOBs
Revised: 3/7/22 – corrected policy number typo



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 560.0

**SECTION: Commercial Drug
SUBJECT: Astagraf XL**

Applicable line of business:

Commercial	X	Medicaid	
Medicare		ACA	X
GHP Kids	X	Self-Insured	X

POLICY:

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for Astagraf XL for GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 487.0 Quantity Limit Exceptions

REQUIRED DEFINITIONS:

1. **Attachment** – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. **Exhibit** – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. **Devised** – the date the policy was implemented.
4. **Revised** – the date of every revision to the policy, including typographical and grammatical changes.
5. **Reviewed** – the date documenting the annual review if the policy has no revisions necessary.

ADDITIONAL DEFINITIONS:

1. **Formulary** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. **Non-formulary products** – those medications that are not included in the Formulary.
3. **Healthcare provider** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
4. **NCQA** – National Committee for Quality Assurance.
5. **Medically Necessary or Medical Necessity** – covered services rendered by a provider that the Health Plan determines are:



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 560.0

**SECTION: Commercial Drug
SUBJECT: Astagraf XL**

- A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
- B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
- C. In accordance with current standards of medical practice;
- D. Not primarily for the convenience of the Member, or the Member's Provider; and
- E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

PROCEDURE:

New members to the plan already established on therapy may be eligible for continuity of care coverage as long as there is medical record documentation that the safety and effectiveness of use for the prescribed indication is supported by Food and Drug Administration (FDA) approval or adequate medical and scientific evidence in the medical literature.

A formulary exception for coverage of Astagraf XL may be made for members who meet the following criteria:

- Medical record documentation that Astagraf XL is prescribed by a physician experienced in immunosuppressive therapy and management of transplant patients **AND**
- Medical record documentation of kidney transplant **AND**
- Medical record documentation of age greater than or equal to 4 years **AND**
- **If 18 years of age and older:** Medical record documentation of rationale for not using Envarsus XR if clinically appropriate

MEDISPAN AUTHORIZATION LEVEL: GPI-12

If a formulary exception is approved Astagraf XL will be paid for under the member's prescription drug benefit.

Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.

Geisinger

**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 560.0

**SECTION: Commercial Drug
SUBJECT: Astagraf XL**

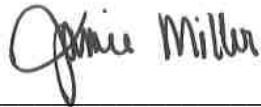
FORMULARY ALTERNATIVES:

tacrolimus, sirolimus*, Envarsus XR, Zortress*

*prior authorization required

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE
STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND
FEDERAL REGULATORY ENTITIES.**

**THIS POLICY WILL BE REVISED AS NECESSARY AND
REVIEWED NO LESS THAN ANNUALLY.**



Signed: _____

Title: Director, Pharmacy Services

Date: March 1, 2022

Devised: 5/24/19

Revised: 3/1/20 – annual review, added GHP Kids

Revised: 3/1/21 – annual review, updated logo, added MediSpan approval level

Revised: 3/1/22 – annual review, updated referenced policies & covered LOBs



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 561.0

**SECTION: Commercial Drug
SUBJECT: Pyrimethamine**

Applicable line of business:

Commercial	X	Medicaid	
Medicare		ACA	X
GHP Kids	X	Self-Insured	X

POLICY:

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for pyrimethamine for GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 487.0 Quantity Limit Exceptions

REQUIRED DEFINITIONS:

1. **Attachment** – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. **Exhibit** – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. **Devised** – the date the policy was implemented.
4. **Revised** – the date of every revision to the policy, including typographical and grammatical changes.
5. **Reviewed** – the date documenting the annual review if the policy has no revisions necessary.

ADDITIONAL DEFINITIONS:

1. **Formulary** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. **Non-formulary products** – those medications that are not included in the Formulary.
3. **Healthcare provider** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
4. **NCQA** – National Committee for Quality Assurance.
5. **Medically Necessary or Medical Necessity** – covered services rendered by a provider that the Health Plan determines are:

- A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
- B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
- C. In accordance with current standards of medical practice;
- D. Not primarily for the convenience of the Member, or the Member's Provider; and
- E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

PROCEDURE:

An exception for coverage of pyrimethamine may be made for members who meet the following criteria:

Treatment of Toxoplasmosis

- Medical record documentation that pyrimethamine is prescribed by or in consultation with an infectious disease specialist **AND**
- Medical record documentation of diagnosis of toxoplasmosis **AND**
- Medical record documentation that pyrimethamine will be used in combination with leucovorin and a sulfonamide **OR** therapeutic failure on, intolerance to, or contraindication to a sulfonamide

AUTHORIZATION DURATION: Initial approval will be for six (6) weeks and subsequent approval will be for six (6) months. Requests for continuation of coverage will be approved for members who meet the following criteria:

- Medical record documentation of clinical syndrome (e.g. headache and/or other neurologic symptoms) **OR**
- Medical record documentation of persistent radiographic disease **OR**
- If HIV positive, medical record documentation of CD4 count less than 200 cells/microL **AND** medical record documentation that the member is taking anti-retroviral therapy (ART)

Primary Prophylaxis of Toxoplasmosis with HIV

- Medical record documentation that pyrimethamine is prescribed by or in consultation with an infectious disease specialist **AND**
- Medical record documentation of diagnosis of human immunodeficiency virus (HIV) **AND**
- Medical record documentation of CD4 count less than 200 cells/microL

- Medical record documentation of therapeutic failure on, intolerance to, or contraindication to trimethoprim-sulfamethoxazole

MEDISPAN AUTHORIZATION LEVEL: GPI-12, generic only

AUTHORIZATION DURATION: Initial approval will be for three (3) months and subsequent approval will be for six (6) months. Requests for continuation of coverage will be approved for members who meet the following criteria:

- Medical record documentation of CD4 count less than 200 cells/microL **AND**
- Medical record documentation that the member is taking anti-retroviral therapy (ART)

NOTE:

Recommended Dose:

- Immunocompetent patients: The recommended dose of pyrimethamine is 100 mg loading dose followed by 25 to 50 mg daily (25 mg daily for those with ocular disease).
- HIV-Treatment: The recommended initial dose of pyrimethamine 200 mg loading dose followed by 50 mg daily (<60 kg) or 75 mg daily (≥60 kg). The recommended chronic maintenance dose of pyrimethamine is 25 to 50 mg daily.
- HIV-Primary Prophylaxis: The recommended dose is 50 to 75 mg once weekly in combination with dapsone and leucovorin; or 25 mg once daily in combination with atovaquone and leucovorin.
- Congenital: The recommended dose of pyrimethamine is 2 mg/kg (maximum 50 mg/dose) once daily for two days; then 1 mg/kg (maximum 25 mg/dose) once daily for 6 months; then 1 mg/kg (maximum 25 mg/dose) three times per week for 12 months.
- Pregnancy: The recommended dose of pyrimethamine 100 mg/day orally divided into two doses for two days followed by 50 mg orally daily.

Treatment Duration:

- Immunocompetent patients with ocular disease: Minimum of 6 weeks
- HIV-Treatment: Initial- 6 weeks; chronic maintenance- 6 months or more
- HIV- Primary Prophylaxis: 3 months or more
- Congenital: 12 months
- Pregnancy: 18 weeks or after gestation and may be up administered until delivery

If a formulary exception is approved, pyrimethamine will be paid for under the member's prescription drug benefit.

Geisinger

**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 561.0

**SECTION: Commercial Drug
SUBJECT: Pyrimethamine**

Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.

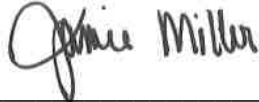
FORMULARY ALTERNATIVES:

Treatment: none

Prophylaxis: trimethoprim-sulfamethoxazole

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE
STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND
FEDERAL REGULATORY ENTITIES.**

**THIS POLICY WILL BE REVISED AS NECESSARY AND
REVIEWED NO LESS THAN ANNUALLY.**



Signed: _____

Title: Director, Pharmacy Services

Date: March 1, 2022

Devised: 5/29/19

Revised: 3/1/20 – annual review, added GHP Kids

Revised: 3/1/21 – annual review, updated logo, added MediSpan approval level, updated Daraprim to generic

Revised: 3/1/22 – annual review, updated referenced policies & covered LOBs



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 562.0

**SECTION: Commercial Drug
SUBJECT: Cablivi**

Applicable line of business:

Commercial	X	Medicaid	
Medicare		ACA	X
GHP Kids	X	Self-Insured	X

POLICY:

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for Cablivi for GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 487.0 Quantity Limit Exceptions

REQUIRED DEFINITIONS:

1. **Attachment** – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. **Exhibit** – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
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4. **Revised** – the date of every revision to the policy, including typographical and grammatical changes.
5. **Reviewed** – the date documenting the annual review if the policy has no revisions necessary.

ADDITIONAL DEFINITIONS:

1. **Formulary** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. **Non-formulary products** – those medications that are not included in the Formulary.
3. **Healthcare provider** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
4. **NCQA** – National Committee for Quality Assurance.
5. **Medically Necessary or Medical Necessity** – covered services rendered by a provider that the Health Plan determines are:



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 562.0

**SECTION: Commercial Drug
SUBJECT: Cablivi**

- A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
- B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
- C. In accordance with current standards of medical practice;
- D. Not primarily for the convenience of the Member, or the Member's Provider; and
- E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

PROCEDURE:

An exception for coverage of Cablivi may be made for members who meet the following criteria:

Currently on PEX Therapy

- Medical record documentation that Cablivi is prescribed by or in consultation with a hematologist **AND**
- Medical record documentation of age greater than or equal to 18 years **AND**
- Medical record documentation of diagnosis of acquired thrombotic thrombocytopenic purpura (aTTP) **AND**
- Medical record documentation that Cablivi will be used in combination with daily plasma exchange and immunosuppressive therapy (e.g. glucocorticoids, rituximab) **AND**
- Medical record documentation that the member has not experienced more than two recurrences of aTTP while on Cablivi

Completed PEX

- Medical record documentation that Cablivi is prescribed by or in consultation with a hematologist **AND**
- Medical record documentation of age greater than or equal to 18 years **AND**
- Medical record documentation of diagnosis of acquired thrombotic thrombocytopenic purpura (aTTP) **AND**
- Medical record documentation that the member previously received daily plasma exchange, immunosuppressive therapy, and Cablivi within the inpatient setting **AND**
- Medical record documentation of the date of the last plasma exchange **AND**
 - Medical record documentation of one of the following:
 - The date of plasma exchange is within 30 days of the request date **OR**
 - If the date of plasma exchange is > 30 days of the request date, medical record documentation sign(s) of persistent underlying disease

(e.g., suppressed ADAMTS13 activity levels remain present) and medical record documentation that the member has not exceeded the maximum treatment duration of Cablivi (30 days post PEX and up to 28 days of extended treatment) **AND**

- Medical record documentation that the member has not experienced more than two recurrences of aTTP while on Cablivi

MEDISPAN AUTHORIZATION LEVEL: GPI-12

QUANTITY LIMIT: *No QLs need to be entered within the authorization unless the requested quantity exceeds the QL.*

- QL FOR LETTER ONLY: 1 kit per day

AUTHORIZATION DURATION: Initial approval will be for 30 days or less if the reviewing provider feels it is medically necessary. Subsequent approvals will be for an additional 30 days or less if the reviewing provider feels it is medically necessary. Requests for continuation of coverage will be approved for members who meet the following criteria:

Currently on PEX Therapy

- Medical record documentation that the member is still receiving daily plasma exchange therapy and Cablivi will be used in combination with plasma exchange and immunosuppressive therapy (e.g. glucocorticoids, rituximab) **AND**
- Medical record documentation that the member has not experienced more than two recurrences of aTTP while on Cablivi

Completed PEX within 30 days

- Medical record documentation that the member previously received daily plasma exchange and immunosuppressive therapy **AND**
- Medical record documentation of the date of last plasma exchange **AND**
- The date of plasma exchange is within 30 days of the request date **AND**
- Medical record documentation that the member has not experienced more than two recurrences of aTTP while on Cablivi

Completed PEX greater than 30 days

- Medical record documentation sign(s) of persistent underlying disease (e.g. suppressed ADAMTS13 activity levels remain present) **AND**
- Medical record documentation of the date of last plasma exchange **AND**
- Medical record documentation that the member has not exceeded the maximum treatment duration of Cablivi (30 days post PEX and up to 28 days of extended treatment) **AND**



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 562.0

**SECTION: Commercial Drug
SUBJECT: Cablivi**

- Medical record documentation that the member has not experienced more than two recurrences of aTTP while on Cablivi

NOTE: Cablivi should be administered upon initiation of PEX therapy, during daily PEX, and continued daily for 30 days following last daily PEX. If necessary, treatment can be extended for a maximum of 28 days.

If a formulary exception is approved, Cablivi will be paid for under the member's prescription drug benefit.

Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.

FORMULARY ALTERNATIVES:

none

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE
STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND
FEDERAL REGULATORY ENTITIES.**

**THIS POLICY WILL BE REVISED AS NECESSARY AND
REVIEWED NO LESS THAN ANNUALLY.**

Signed: _____

Title: Director, Pharmacy Services

Date: March 1, 2022

Devised: 7/23/19
Revised: 3/1/20 – annual review, added GHP Kids
Revised: 3/1/21 – annual review, updated logo, added MediSpan approval level, updated QL statement
Revised: 3/1/22 – annual review, updated referenced policies & covered LOBs



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 563.0

**SECTION: Commercial Drug
SUBJECT: Balversa**

Applicable line of business:

Commercial	X	Medicaid	
Medicare		ACA	X
GHP Kids	X	Self-Insured	X

POLICY:

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for Balversa for GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 487.0 Quantity Limit Exceptions

REQUIRED DEFINITIONS:

1. **Attachment** – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. **Exhibit** – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. **Devised** – the date the policy was implemented.
4. **Revised** – the date of every revision to the policy, including typographical and grammatical changes.
5. **Reviewed** – the date documenting the annual review if the policy has no revisions necessary.

ADDITIONAL DEFINITIONS:

1. **Formulary** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. **Non-formulary products** – those medications that are not included in the Formulary.
3. **Healthcare provider** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
4. **NCQA** – National Committee for Quality Assurance.
5. **Medically Necessary or Medical Necessity** – covered services rendered by a provider that the Health Plan determines are:

- A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
- B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
- C. In accordance with current standards of medical practice;
- D. Not primarily for the convenience of the Member, or the Member's Provider; and
- E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

PROCEDURE:

New members to the plan already established on therapy may be eligible for continuity of care coverage as long as there is medical record documentation that the safety and effectiveness of use for the prescribed indication is supported by Food and Drug Administration (FDA) approval or adequate medical and scientific evidence in the medical literature.

An exception for coverage of Balversa may be made for members who meet the following criteria:

- Medical record documentation that Balversa is prescribed by an oncologist **AND**
- Medical record documentation of age greater than or equal to 18 years **AND**
- Medical record documentation of a diagnosis of locally advanced or metastatic urothelial carcinoma **AND**
- Medical record documentation of an FGFR3 or FGFR2 genetic alteration determined using a Food and Drug Administration (FDA) approved test **AND**
- Medical record documentation of therapeutic failure on platinum-containing chemotherapy

NOTE: The FDA-approved test is the *therascreen*® FGFR RGQ RT-PCR Kit

MEDISPAN AUTHORIZATION LEVEL: GPI-12, number of claims authorized = 1, enter for the remainder of the calendar year

QUANTITY LIMIT: *No QLs need to be entered within the authorization unless the requested quantity exceeds the QL.*

- **QL FOR LETTER ONLY:**
 - 3 mg tablet – 3 tablets per day, 28 day supply per fill
 - 4 mg tablet – 2 tablets per day, 28 day supply per fill

- 5 mg tablet – 1 tablet per day, 28 day supply per fill

RE-AUTHORIZATION CRITERIA: Balversa is configured as a prior authorization for new starts only. Balversa will no longer be covered if it is identified that the member is not receiving appropriate follow-up care from the prescribing specialist or if the member has greater than or equal to a 90 day break in therapy.

- Medical record documentation that the member is receiving appropriate follow-up care from the prescribing specialist

If a formulary exception is approved, Balversa will be paid for under the member's prescription drug benefit.

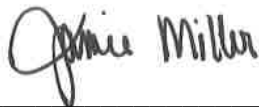
Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.

FORMULARY ALTERNATIVES:

none

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE
STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND
FEDERAL REGULATORY ENTITIES.**

**THIS POLICY WILL BE REVISED AS NECESSARY AND
REVIEWED NO LESS THAN ANNUALLY.**



Signed: _____

Title: Director, Pharmacy Services

Date: March 1, 2022

Devised: 7/23/19

Revised: 3/1/20 – annual review, added GHP Kids

Revised: 3/1/21 – annual review, updated logo, added MediSpan approval level, updated QL statement

Revised: 11/24/21 – added one-time PA to approval crit., removed auth duration & added re-auth crit.

Revised: 3/1/22 – annual review, updated referenced policies & covered LOBs



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 564.0

**SECTION: Commercial Drug
SUBJECT: Symjepi**

Applicable line of business:

Commercial	X	Medicaid	
Medicare		ACA	X
GHP Kids	X	Self-Insured	X

POLICY:

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for Symjepi for GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 487.0 Quantity Limit Exceptions

REQUIRED DEFINITIONS:

1. **Attachment** – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. **Exhibit** – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. **Devised** – the date the policy was implemented.
4. **Revised** – the date of every revision to the policy, including typographical and grammatical changes.
5. **Reviewed** – the date documenting the annual review if the policy has no revisions necessary.

ADDITIONAL DEFINITIONS:

1. **Formulary** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. **Non-formulary products** – those medications that are not included in the Formulary.
3. **Healthcare provider** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
4. **NCQA** – National Committee for Quality Assurance.
5. **Medically Necessary or Medical Necessity** – covered services rendered by a provider that the Health Plan determines are:



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 564.0

**SECTION: Commercial Drug
SUBJECT: Symjepi**

- A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
- B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
- C. In accordance with current standards of medical practice;
- D. Not primarily for the convenience of the Member, or the Member's Provider; and
- E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

PROCEDURE:

An exception for coverage of Symjepi may be made for members who meet the following criteria:

- Medical record documentation that the patient has shown the inability to properly use the generic EpiPen device

MEDISPAN AUTHORIZATION LEVEL: GPI-12

QUANTITY LIMIT: *No QLs need to be entered within the authorization unless the requested quantity exceeds the QL.*

- **QL FOR LETTER ONLY:** 2 pens per fill

NOTE: In the event that the preferred alternative is unavailable at the time of the request, exception can be made to approve the use of Symjepi for an appropriate length of time as designated by the reviewer.

If a formulary exception is approved, Symjepi will be paid for under the member's prescription drug benefit.

Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.

FORMULARY ALTERNATIVES:

epinephrine auto-injector (generic EpiPen)



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 564.0

**SECTION: Commercial Drug
SUBJECT: Symjepi**

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE
STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND
FEDERAL REGULATORY ENTITIES.**

**THIS POLICY WILL BE REVISED AS NECESSARY AND
REVIEWED NO LESS THAN ANNUALLY.**

Signed: _____

Title: Director, Pharmacy Services

Date: March 1, 2022

Devised: 7/23/19

Revised: 3/1/20 – annual review, added GHP Kids

Revised: 3/1/21 – annual review, updated logo, added MediSpan approval level, updated QL statement

Revised: 3/1/22 – annual review, updated referenced policies & covered LOBs



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 565.0

**SECTION: Commercial Drug
SUBJECT: Diacomit**

Applicable line of business:

Commercial	X	Medicaid	
Medicare		ACA	X
GHP Kids	X	Self-Insured	X

POLICY:

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for Diacomit for GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 487.0 Quantity Limit Exceptions

REQUIRED DEFINITIONS:

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ADDITIONAL DEFINITIONS:

1. **Formulary** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. **Non-formulary products** – those medications that are not included in the Formulary.
3. **Healthcare provider** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
4. **NCQA** – National Committee for Quality Assurance.
5. **Medically Necessary or Medical Necessity** – covered services rendered by a provider that the Health Plan determines are:



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 565.0

**SECTION: Commercial Drug
SUBJECT: Diacomit**

- A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
- B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
- C. In accordance with current standards of medical practice;
- D. Not primarily for the convenience of the Member, or the Member's Provider; and
- E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

PROCEDURE:

New members to the plan already established on therapy may be eligible for continuity of care coverage as long as there is medical record documentation that the safety and effectiveness of use for the prescribed indication is supported by Food and Drug Administration (FDA) approval or adequate medical and scientific evidence in the medical literature.

An exception for coverage of Diacomit may be made for members who meet the following criteria:

- Medical record documentation that Diacomit is prescribed by a neurologist **AND**
- Medical record documentation of age greater than or equal to 2 years **AND**
- Medical record documentation of a diagnosis of Dravet syndrome **AND**
- Medical record documentation that Diacomit is to be used in combination with clobazam

MEDISPAN AUTHORIZATION LEVEL: GPI-10

If a formulary exception is approved, Diacomit will be paid for under the member's prescription drug benefit.

Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.

FORMULARY ALTERNATIVES:

clobazam, divalproex, divalproex ER, valproic acid, levetiracetam, levetiracetam ER
topiramate



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 565.0

**SECTION: Commercial Drug
SUBJECT: Diacomit**

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE
STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND
FEDERAL REGULATORY ENTITIES.**

**THIS POLICY WILL BE REVISED AS NECESSARY AND
REVIEWED NO LESS THAN ANNUALLY.**

Signed: _____

Title: Director, Pharmacy Services

Date: March 1, 2022

Devised: 7/23/19
Revised: 3/1/20 – annual review, added GHP Kids
Revised: 3/1/21 – annual review, updated logo, added MediSpan approval level
Revised: 3/1/22 – annual review, updated referenced policies & covered LOBs



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 566.0

**SECTION: Commercial Drug
SUBJECT: Piqray**

Applicable line of business:

Commercial	X	Medicaid	
Medicare		ACA	X
GHP Kids	X	Self-Insured	X

POLICY:

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for Piqray for GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 487.0 Quantity Limit Exceptions

REQUIRED DEFINITIONS:

1. **Attachment** – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. **Exhibit** – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. **Devised** – the date the policy was implemented.
4. **Revised** – the date of every revision to the policy, including typographical and grammatical changes.
5. **Reviewed** – the date documenting the annual review if the policy has no revisions necessary.

ADDITIONAL DEFINITIONS:

1. **Formulary** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. **Non-formulary products** – those medications that are not included in the Formulary.
3. **Healthcare provider** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
4. **NCQA** – National Committee for Quality Assurance.
5. **Medically Necessary or Medical Necessity** – covered services rendered by a provider that the Health Plan determines are:



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 566.0

**SECTION: Commercial Drug
SUBJECT: Piqray**

- A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
- B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
- C. In accordance with current standards of medical practice;
- D. Not primarily for the convenience of the Member, or the Member's Provider; and
- E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

PROCEDURE:

New members to the plan already established on therapy may be eligible for continuity of care coverage as long as there is medical record documentation that the safety and effectiveness of use for the prescribed indication is supported by Food and Drug Administration (FDA) approval or adequate medical and scientific evidence in the medical literature.

An exception for coverage of Piqray may be made for members who meet the following criteria:

- Medical record documentation that Piqray is prescribed by an oncologist **AND**
- Medical record documentation of age greater than or equal to 18 years **AND**
- Medical record documentation that the patient is a male or a postmenopausal female **AND**
- Medical record documentation of a diagnosis of advanced or metastatic breast cancer that is hormone receptor-positive, HER2-negative (HR+/HER2-) **AND**
- Medical record documentation of a PIK3CA mutation determined using a Food and Drug Administration (FDA) approved test **AND**
- Medical record documentation of therapeutic failure on, intolerance to, or contraindication to prior endocrine therapy **AND**
- Medical record documentation that Piqray is being prescribed in combination with fulvestrant

NOTES: The FDA-approved test is the *therascreen*® PIK3CA RGQ PCR Kit.

Examples of endocrine therapy include: exemestane, letrozole, anastrozole, tamoxifen, and toremifene.



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 566.0

**SECTION: Commercial Drug
SUBJECT: Piqray**

MEDISPAN AUTHORIZATION LEVEL: GPI-12, number of claims authorized = 1, enter for the remainder of the calendar year

QUANTITY LIMIT: *No QLs need to be entered within the authorization unless the requested quantity exceeds the QL.*

- **QL FOR LETTER ONLY:**
 - 300 mg or 250 mg daily dose: 2 tablets per day, 28 day supply per fill
 - 200 mg daily dose: 1 tablet per day, 28 day supply per fill

RE-AUTHORIZATION CRITERIA: Piqray is configured as a prior authorization for new starts only. Piqray will no longer be covered if it is identified that the member is not receiving appropriate follow-up care from the prescribing specialist or if the member has greater than or equal to a 90 day break in therapy.

- Medical record documentation that the member is receiving appropriate follow-up care from the prescribing specialist

If a formulary exception is approved, Piqray will be paid for under the member's prescription drug benefit.

Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.

FORMULARY ALTERNATIVES:

anastrozole, letrozole, exemestane, tamoxifen, raloxifene, sirolimus, everolimus (generic Afinitor)*, Kisqali*, Kisqali-Femara*, Ibrance*, Verzenio*

*prior authorization required

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE
STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND
FEDERAL REGULATORY ENTITIES.**

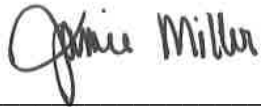
**THIS POLICY WILL BE REVISED AS NECESSARY AND
REVIEWED NO LESS THAN ANNUALLY.**

Geisinger

**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 566.0

**SECTION: Commercial Drug
SUBJECT: Piqray**



Signed: _____

Title: Director, Pharmacy Services

Date: March 1, 2022

Devised: 7/23/19

Revised: 3/1/20 – annual review, added GHP Kids

Revised: 3/1/21 – annual review, updated logo, added MediSpan approval level, updated QL statement

Revised: 11/30/21 – added one-time PA to approval crit., removed auth duration & added re-auth crit.

Revised: 3/1/22 – annual review, updated referenced policies & covered LOBs, updated FA



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 567.0

**SECTION: Commercial Drug
SUBJECT: Inveltys, Loteprednol
Suspension, Lotemax Gel, &
Lotemax SM**

Applicable line of business:

Commercial	X	Medicaid	
Medicare		ACA	X
GHP Kids	X	Self-Insured	X

POLICY:

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.00T Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for Inveltys, loteprednol suspension, Lotemax gel, and Lotemax SM for GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 487.0 Quantity Limit Exceptions

REQUIRED DEFINITIONS:

1. **Attachment** – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. **Exhibit** – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. **Devised** – the date the policy was implemented.
4. **Revised** – the date of every revision to the policy, including typographical and grammatical changes.
5. **Reviewed** – the date documenting the annual review if the policy has no revisions necessary.

ADDITIONAL DEFINITIONS:

1. **Formulary** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. **Non-formulary products** – those medications that are not included in the Formulary.
3. **Healthcare provider** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
4. **NCQA** – National Committee for Quality Assurance.

5. **Medically Necessary or Medical Necessity** – covered services rendered by a provider that the Health Plan determines are:
- A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
 - B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
 - C. In accordance with current standards of medical practice;
 - D. Not primarily for the convenience of the Member, or the Member's Provider; and
 - E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

PROCEDURE:

An exception for coverage of Inveltys, loteprednol, Lotemax Gel, or Lotemax SM may be made for members who meet the following criteria:

For Inveltys, Lotemax Gel, and Lotemax SM

- Medical record documentation of use for post-operative inflammation and pain following ocular surgery **AND**
- Medical record documentation of therapeutic failure on, intolerance to, or contraindication to three (3) formulary alternatives

For loteprednol suspension

- Medical record documentation for treatment of steroid-responsive inflammatory conditions of the palpebral and bulbar conjunctiva, cornea, and anterior segment of the globe **OR**
- Medical record documentation of use for post-operative inflammation and pain following ocular surgery **AND**
- Medical record documentation of therapeutic failure on, intolerance to, or contraindication to three (3) formulary alternatives

MEDISPAN AUTHORIZATION LEVEL: GPI-14

If a formulary exception is approved, Inveltys, loteprednol, Lotemax Gel, or Lotemax SM will be paid for under the member's prescription drug benefit.



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 567.0

**SECTION: Commercial Drug
SUBJECT: Inveltys, Loteprednol
Suspension, Lotemax Gel, &
Lotemax SM**

Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.

FORMULARY ALTERNATIVES:

dexamethasone sodium phosphate 0.1%, fluorometholone drops 0.1%, prednisolone acetate (pf), prednisolone acetate 1%, prednisolone sodium phosphate drops 1%, bromfenac 0.09%, ketorolac drops 0.4% and 0.5%, diclofenac sodium 0.1%, Maxidex, FML S.O.P.

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE
STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND
FEDERAL REGULATORY ENTITIES.**

**THIS POLICY WILL BE REVISED AS NECESSARY AND
REVIEWED NO LESS THAN ANNUALLY.**

Signed: _____

Title: Director, Pharmacy Services

Date: March 1, 2022

Devised: 7/23/19
Revised: 8/1/19 – added missing comma
Revised: 9/20/19 – added inflammatory conditions indication for loteprednol suspension
Revised: 3/1/20 – annual review, added GHP Kids
Revised: 3/1/21 – annual review, updated logo, added MediSpan approval level
Revised: 3/1/22 – annual review, updated referenced policies & covered LOBs



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 568.0

**SECTION: Commercial Drug
SUBJECT: Motegrity**

Applicable line of business:

Commercial	X	Medicaid	
Medicare		ACA	X
GHP Kids	X	Self-Insured	X

POLICY:

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for Motegrity for GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 487.0 Quantity Limit Exceptions

REQUIRED DEFINITIONS:

1. **Attachment** – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. **Exhibit** – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. **Devised** – the date the policy was implemented.
4. **Revised** – the date of every revision to the policy, including typographical and grammatical changes.
5. **Reviewed** – the date documenting the annual review if the policy has no revisions necessary.

ADDITIONAL DEFINITIONS:

1. **Formulary** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. **Non-formulary products** – those medications that are not included in the Formulary.
3. **Healthcare provider** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
4. **NCQA** – National Committee for Quality Assurance.
5. **Medically Necessary or Medical Necessity** – covered services rendered by a provider that the Health Plan determines are:



POLICY NUMBER: 568.0

**POLICY AND PROCEDURE
PHARMACY
MANUAL**

**SECTION: Commercial Drug
SUBJECT: Motegrity**

- A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
- B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
- C. In accordance with current standards of medical practice;
- D. Not primarily for the convenience of the Member, or the Member's Provider; and
- E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

PROCEDURE:

An exception for coverage of Motegrity may be made for members who meet the following criteria:

- Medical record documentation of age greater than or equal to 18 years **AND**
- Medical record documentation of a diagnosis of chronic idiopathic constipation **AND**
- Medical record documentation of therapeutic failure on, intolerance to, or contraindication to lubiprostone **AND** Linzess

MEDISPAN AUTHORIZATION LEVEL: GPI-12

QUANTITY LIMIT: *No QLs need to be entered within the authorization unless the requested quantity exceeds the QL.*

- **QL FOR LETTER ONLY:** 1 tablet per day

If a formulary exception is approved, Motegrity will be paid for under the member's prescription drug benefit.

Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.

FORMULARY ALTERNATIVES:

lubiprostone, Linzess



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 568.0

**SECTION: Commercial Drug
SUBJECT: Motegrity**

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE
STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND
FEDERAL REGULATORY ENTITIES.**

**THIS POLICY WILL BE REVISED AS NECESSARY AND
REVIEWED NO LESS THAN ANNUALLY.**

Signed: _____

Title: Director, Pharmacy Services

Date: March 1, 2022

Devised: 7/23/19

Revised: 3/1/20 – annual review, added GHP Kids

Revised: 3/1/21 – annual review, updated logo, added MediSpan approval level, updated Amitiza to generic

Revised: 3/1/22 – annual review, updated referenced policies & covered LOBs



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 569.0

**SECTION: Commercial Drug
SUBJECT: Fosfomycin**

Applicable line of business:

Commercial	X	Medicaid	
Medicare		ACA	X
GHP Kids	X	Self-Insured	X

POLICY:

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for fosfomycin for GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 487.0 Quantity Limit Exceptions

REQUIRED DEFINITIONS:

1. **Attachment** – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. **Exhibit** – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. **Devised** – the date the policy was implemented.
4. **Revised** – the date of every revision to the policy, including typographical and grammatical changes.
5. **Reviewed** – the date documenting the annual review if the policy has no revisions necessary.

ADDITIONAL DEFINITIONS:

1. **Formulary** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. **Non-formulary products** – those medications that are not included in the Formulary.
3. **Healthcare provider** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
4. **NCQA** – National Committee for Quality Assurance.
5. **Medically Necessary or Medical Necessity** – covered services rendered by a provider that the Health Plan determines are:

- A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
- B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
- C. In accordance with current standards of medical practice;
- D. Not primarily for the convenience of the Member, or the Member's Provider; and
- E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

PROCEDURE:

An exception for coverage of fosfomycin may be made for members who meet the following criteria:

Uncomplicated Cystitis

- Medical record documentation of use for treatment of uncomplicated cystitis **AND**
- Medical record documentation of therapeutic failure on, intolerance to, contraindication to, or bacterial resistance to nitrofurantoin **AND** sulfamethoxazole-trimethoprim

MEDISPAN AUTHORIZATION LEVEL: GPI-12

QUANTITY LIMIT: *QL must be entered within the authorization.*

- QL FOR LETTER & AUTHORIZATION: 1 dose

AUTHORIZATION DURATION: one-time approval, RX count 1

Uncomplicated Cystitis caused by ESBL or Multidrug Resistant Bacteria

- Medical record documentation of use for treatment of uncomplicated cystitis **AND**
- Medical record documentation of ESBL-producing bacteria or multidrug resistant bacteria **AND**
- Medical record documentation of susceptibility to fosfomycin **AND**
- Medical record documentation of culture and sensitivity showing the patient's infection is not susceptible to alternative oral antibiotic treatments **OR** a documented history of previous intolerance to or contraindication to other antibiotics shown to be susceptible on the culture and sensitivity

MEDISPAN AUTHORIZATION LEVEL: GPI-12



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 569.0

**SECTION: Commercial Drug
SUBJECT: Fosfomycin**

QUANTITY LIMIT: *QL must be entered within the authorization.*

- **QL FOR LETTER & AUTHORIZATION:** 3 doses

AUTHORIZATION DURATION: 9 days, RX count 1

NOTE: There is little to no evidence supporting use of fosfomycin as prophylaxis.

If a formulary exception is approved, fosfomycin will be paid for under the member's prescription drug benefit.

Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.

FORMULARY ALTERNATIVES:

nitrofurantoin, sulfamethoxazole-trimethoprim

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE
STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND
FEDERAL REGULATORY ENTITIES.**

**THIS POLICY WILL BE REVISED AS NECESSARY AND
REVIEWED NO LESS THAN ANNUALLY.**

Signed: _____

Title: Director, Pharmacy Services

Date: March 1, 2022

Devised: 7/23/19

Revised: 3/1/20 – annual review, added GHP Kids

Revised: 3/1/21 – annual review, updated logo, added MediSpan approval level, updated QL statement, updated Monurol to generic

Revised: 3/1/22 – annual review, updated referenced policies & covered LOBs



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 570.0

**SECTION: Commercial Drug
SUBJECT: Follistim AQ**

Applicable line of business:

Commercial	X	Medicaid	
Medicare		ACA	X
GHP Kids	X	Self-Insured	X

POLICY:

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for Follistim AQ for GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 487.0 Quantity Limit Exceptions

REQUIRED DEFINITIONS:

1. **Attachment** – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. **Exhibit** – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. **Devised** – the date the policy was implemented.
4. **Revised** – the date of every revision to the policy, including typographical and grammatical changes.
5. **Reviewed** – the date documenting the annual review if the policy has no revisions necessary.

ADDITIONAL DEFINITIONS:

1. **Formulary** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. **Non-formulary products** – those medications that are not included in the Formulary.
3. **Healthcare provider** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
4. **NCQA** – National Committee for Quality Assurance.
5. **Medically Necessary or Medical Necessity** – covered services rendered by a provider that the Health Plan determines are:



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 570.0

**SECTION: Commercial Drug
SUBJECT: Follistim AQ**

- A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
- B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
- C. In accordance with current standards of medical practice;
- D. Not primarily for the convenience of the Member, or the Member's Provider; and
- E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

PROCEDURE:

An exception for coverage of Follistim AQ may be made for members who meet the following criteria:

For Females:

- Medical record documentation that Follistim AQ is prescribed by or in consultation with a reproductive specialist or infertility specialist **AND**
- Medical record documentation of age greater than or equal to 18 years **AND**
- Medical record documentation of one of the following:
 - Poor/diminished ovarian reserve **OR**
 - Tubal factor infertility **OR**
 - Follistim AQ is being used with donor eggs **OR**
 - In Vitro Fertilization **AND**
- Medical record documentation of therapeutic failure, contraindication, or intolerance to Gonal-f

OR

- Medical record documentation that Follistim AQ is prescribed by or in consultation with a reproductive specialist or infertility specialist **AND**
- Medical record documentation of age greater than or equal to 18 years **AND**
- Medical record documentation that infertility is not due to primary ovarian failure **AND**
- Medical record documentation that Follistim AQ is being using concomitantly with an hCG product **AND**
- Medical record documentation of therapeutic failure, contraindication, or intolerance to Gonal-f **AND**
- For patients without a diagnosis of hyperprolactinemic anovulation:
 - Medical record documentation of therapeutic failure, contraindication, or intolerance to clomiphene and/or letrozole for a total of 3 cycles **OR**

- For patients with a diagnosis of hyperprolactinemic anovulation, one of the following:
 - Uncorrected prolactin levels, greater than 25 ng/mL, after 6 months of therapy on bromocriptine or cabergoline **OR**
 - Corrected prolactin levels, less than or equal to 25 ng/mL, on bromocriptine or cabergoline with therapeutic failure, contraindication, or intolerance to 3 cycles of clomiphene and/or letrozole

For Males:

- Medical record documentation that Follistim AQ is prescribed by or in consultation with a reproductive specialist or infertility specialist **AND**
- Medical record documentation of male factor infertility **AND**
- Medical record documentation of therapeutic failure, contraindication, or intolerance to Gonal-f

MEDISPAN AUTHORIZATION LEVEL: GPI-12

If an exception is made, Follistim AQ will be paid for under the member's prescription drug benefit.

Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.

FORMULARY ALTERNATIVES:

Gonal F

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE
STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND
FEDERAL REGULATORY ENTITIES.**

**THIS POLICY WILL BE REVISED AS NECESSARY AND
REVIEWED NO LESS THAN ANNUALLY.**

Signed:  _____

Title: Director, Pharmacy Services



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 570.0

**SECTION: Commercial Drug
SUBJECT: Follistim AQ**

Date: March 1, 2022

Devised: 9/20/19

Revised: 3/1/20 – annual review, added GHP Kids

Revised: 3/1/21 – annual review, updated logo, added MediSpan approval level

Revised: 3/1/22 – annual review, updated referenced policies & covered LOBs



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 572.0

**SECTION: Commercial Drug
SUBJECT: Human Chorionic
Gonadotropin (hCG)**

Applicable line of business:

Commercial	X	Medicaid	
Medicare		ACA	X
GHP Kids	X	Self-Insured	X

POLICY:

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for human chorionic gonadotropin (hCG) for GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 487.0 Quantity Limit Exceptions

REQUIRED DEFINITIONS:

1. **Attachment** – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. **Exhibit** – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. **Devised** – the date the policy was implemented.
4. **Revised** – the date of every revision to the policy, including typographical and grammatical changes.
5. **Reviewed** – the date documenting the annual review if the policy has no revisions necessary.

ADDITIONAL DEFINITIONS:

1. **Formulary** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. **Non-formulary products** – those medications that are not included in the Formulary.
3. **Healthcare provider** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
4. **NCQA** – National Committee for Quality Assurance.
5. **Medically Necessary or Medical Necessity** – covered services rendered by a provider that the Health Plan determines are:



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 572.0

**SECTION: Commercial Drug
SUBJECT: Human Chorionic
Gonadotropin (hCG)**

- A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
- B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
- C. In accordance with current standards of medical practice;
- D. Not primarily for the convenience of the Member, or the Member's Provider; and
- E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

PROCEDURE:

An exception for coverage of human chorionic gonadotropin (hCG) may be made for members who meet the following criteria:

- Medical record documentation that human chorionic gonadotropin (hCG) is prescribed by or in consultation with a reproductive specialist or infertility specialist **AND**
- Medical record documentation of age greater than or equal to 18 years **AND**
- Medical record documentation of use for ovulation induction in females **AND**
- Medical record documentation of therapeutic failure, contraindication, or intolerance to Pregnyl

OR

- Medical record documentation of use for a Food and Drug Administration (FDA) approved indication (hypogonadotropic hypogonadism in males or prepubertal cryptorchidism) **AND**
- Medical record documentation of therapeutic failure, contraindication, or intolerance to Pregnyl

MEDISPAN AUTHORIZATION LEVEL: GPI-12

If an exception is made, human chorionic gonadotropin (hCG) will be paid for under the member's prescription drug benefit.

Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 572.0

**SECTION: Commercial Drug
SUBJECT: Human Chorionic
Gonadotropin (hCG)**

FORMULARY ALTERNATIVES:

Pregnyl

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE
STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND
FEDERAL REGULATORY ENTITIES.**

**THIS POLICY WILL BE REVISED AS NECESSARY AND
REVIEWED NO LESS THAN ANNUALLY.**

Signed: _____

Title: Director, Pharmacy Services

Date: March 1, 2022

Devised: 9/23/19
Revised: 3/1/20 – annual review, added GHP Kids
Revised: 3/1/21 – annual review, updated logo, added MediSpan approval level
Revised: 3/1/22 – annual review, updated referenced policies & covered LOBs



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 573.0

**SECTION: Commercial Drug
SUBJECT: Novarel**

Applicable line of business:

Commercial	X	Medicaid	
Medicare		ACA	X
GHP Kids	X	Self-Insured	X

POLICY:

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for Novarel for GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 487.0 Quantity Limit Exceptions

REQUIRED DEFINITIONS:

1. **Attachment** – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. **Exhibit** – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. **Devised** – the date the policy was implemented.
4. **Revised** – the date of every revision to the policy, including typographical and grammatical changes.
5. **Reviewed** – the date documenting the annual review if the policy has no revisions necessary.

ADDITIONAL DEFINITIONS:

1. **Formulary** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. **Non-formulary products** – those medications that are not included in the Formulary.
3. **Healthcare provider** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
4. **NCQA** – National Committee for Quality Assurance.
5. **Medically Necessary or Medical Necessity** – covered services rendered by a provider that the Health Plan determines are:



POLICY NUMBER: 573.0

**POLICY AND PROCEDURE
PHARMACY
MANUAL**

**SECTION: Commercial Drug
SUBJECT: Novarel**

- A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
- B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
- C. In accordance with current standards of medical practice;
- D. Not primarily for the convenience of the Member, or the Member's Provider; and
- E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

PROCEDURE:

An exception for coverage of Novarel may be made for members who meet the following criteria:

- Medical record documentation that Novarel is prescribed by or in consultation with a reproductive specialist or infertility specialist **AND**
- Medical record documentation of age greater than or equal to 18 years **AND**
- Medical record documentation of use for ovulation induction in females **AND**
- Medical record documentation of therapeutic failure, contraindication, or intolerance to Pregnyl

OR

- Medical record documentation of use for a Food and Drug Administration (FDA) approved indication (hypogonadotropic hypogonadism in males or prepubertal cryptorchidism) **AND**
- Medical record documentation of therapeutic failure, contraindication, or intolerance to Pregnyl

MEDISPAN AUTHORIZATION LEVEL: NDC-9 (must enter 555661501 & 555661502)

If an exception is made, Novarel will be paid for under the member's prescription drug benefit.

Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.



POLICY NUMBER: 573.0

**POLICY AND PROCEDURE
PHARMACY
MANUAL**

**SECTION: Commercial Drug
SUBJECT: Novarel**

FORMULARY ALTERNATIVES:

Pregnyl

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE
STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND
FEDERAL REGULATORY ENTITIES.**

**THIS POLICY WILL BE REVISED AS NECESSARY AND
REVIEWED NO LESS THAN ANNUALLY.**

Signed: _____

Title: Director, Pharmacy Services

Date: March 1, 2022

Devised: 9/23/19

Revised: 3/1/20 – annual review, added GHP Kids

Revised: 3/1/21 – annual review, updated logo, added MediSpan approval level

Revised: 3/1/22 – annual review, updated referenced policies & covered LOBs



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 574.0

**SECTION: Commercial Drug
SUBJECT: Crinone**

Applicable line of business:

Commercial	X	Medicaid	
Medicare		ACA	X
GHP Kids	X	Self-Insured	X

POLICY:

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for Crinone for GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 487.0 Quantity Limit Exceptions

REQUIRED DEFINITIONS:

1. **Attachment** – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. **Exhibit** – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. **Devised** – the date the policy was implemented.
4. **Revised** – the date of every revision to the policy, including typographical and grammatical changes.
5. **Reviewed** – the date documenting the annual review if the policy has no revisions necessary.

ADDITIONAL DEFINITIONS:

1. **Formulary** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. **Non-formulary products** – those medications that are not included in the Formulary.
3. **Healthcare provider** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
4. **NCQA** – National Committee for Quality Assurance.
5. **Medically Necessary or Medical Necessity** – covered services rendered by a provider that the Health Plan determines are:



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 574.0

**SECTION: Commercial Drug
SUBJECT: Crinone**

- A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
- B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
- C. In accordance with current standards of medical practice;
- D. Not primarily for the convenience of the Member, or the Member's Provider; and
- E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

PROCEDURE:

An exception for coverage of Crinone may be made for members who meet the following criteria:

- Medical record documentation of use for secondary amenorrhea

OR

- Medical record documentation of use as part of assisted reproductive technology (ART) **AND**
- Medical record documentation of use of Crinone 8% gel **AND**
- Medical record documentation of therapeutic failure on, intolerance to, or contraindication to Endometrin

MEDISPAN AUTHORIZATION LEVEL: GPI-12

If an exception is made, Crinone will be paid for under the member's prescription drug benefit.

Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.

FORMULARY ALTERNATIVES:

Endometrin



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 574.0

**SECTION: Commercial Drug
SUBJECT: Crinone**

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE
STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND
FEDERAL REGULATORY ENTITIES.**

**THIS POLICY WILL BE REVISED AS NECESSARY AND
REVIEWED NO LESS THAN ANNUALLY.**

Signed: _____

Title: Director, Pharmacy Services

Date: March 1, 2022

Devised: 9/23/19
Revised: 3/1/20 – annual review, added GHP Kids
Revised: 3/1/21 – annual review, updated logo, added MediSpan approval level
Revised: 3/1/22 – annual review, updated referenced policies & covered LOBs



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 575.0

**SECTION: Commercial Drug
SUBJECT: Durezol**

Applicable line of business:

Commercial	X	Medicaid	
Medicare		ACA	X
GHP Kids	X	Self-Insured	X

POLICY:

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for Durezol for GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 487.0 Quantity Limit Exceptions

REQUIRED DEFINITIONS:

1. **Attachment** – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. **Exhibit** – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. **Devised** – the date the policy was implemented.
4. **Revised** – the date of every revision to the policy, including typographical and grammatical changes.
5. **Reviewed** – the date documenting the annual review if the policy has no revisions necessary.

ADDITIONAL DEFINITIONS:

1. **Formulary** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. **Non-formulary products** – those medications that are not included in the Formulary.
3. **Healthcare provider** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
4. **NCQA** – National Committee for Quality Assurance.
5. **Medically Necessary or Medical Necessity** – covered services rendered by a provider that the Health Plan determines are:



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 575.0

**SECTION: Commercial Drug
SUBJECT: Durezol**

- A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
- B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
- C. In accordance with current standards of medical practice;
- D. Not primarily for the convenience of the Member, or the Member's Provider; and
- E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

PROCEDURE:

An exception for coverage of Durezol may be made for members who meet the following criteria:

- Medical record documentation of a diagnosis of uveitis **AND**
- Medical record documentation of a therapeutic failure on, intolerance to, or contraindication to prednisolone acetate 1%

OR

- Medical record documentation of use for post-operative inflammation and pain following ocular surgery **AND**
- Medical record documentation of a therapeutic failure on, intolerance to, or contraindication to three formulary alternatives

MEDISPAN AUTHORIZATION LEVEL: GPI-12

If a formulary exception is approved, Durezol will be paid for under the member's prescription drug benefit.

Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.

FORMULARY ALTERNATIVES:

dexamethasone sodium phosphate 0.1%, fluorometholone drops 0.1%, prednisolone acetate (pf), prednisolone acetate 1%, prednisolone sodium phosphate drops 1%,



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 575.0

**SECTION: Commercial Drug
SUBJECT: Durezol**

bromfenac 0.09%, ketorolac drops 0.4% and 0.5%, diclofenac sodium 0.1%, Maxidex,
FML S.O.P.

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE
STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND
FEDERAL REGULATORY ENTITIES.**

**THIS POLICY WILL BE REVISED AS NECESSARY AND
REVIEWED NO LESS THAN ANNUALLY.**

Signed: _____

Title: Director, Pharmacy Services

Date: March 1, 2022

Devised: 9/25/19
Revised: 3/1/20 – annual review, added GHP Kids
Revised: 3/1/21 – annual review, updated logo, added MediSpan approval level
Revised: 3/1/22 – annual review, updated referenced policies & covered LOBs



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 576.0

**SECTION: Commercial Drug
SUBJECT: Alex**

Applicable line of business:

Commercial	X	Medicaid	
Medicare		ACA	X
GHP Kids	X	Self-Insured	X

POLICY:

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for Alex for GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 487.0 Quantity Limit Exceptions

REQUIRED DEFINITIONS:

1. **Attachment** – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. **Exhibit** – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. **Devised** – the date the policy was implemented.
4. **Revised** – the date of every revision to the policy, including typographical and grammatical changes.
5. **Reviewed** – the date documenting the annual review if the policy has no revisions necessary.

ADDITIONAL DEFINITIONS:

1. **Formulary** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. **Non-formulary products** – those medications that are not included in the Formulary.
3. **Healthcare provider** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
4. **NCQA** – National Committee for Quality Assurance.
5. **Medically Necessary or Medical Necessity** – covered services rendered by a provider that the Health Plan determines are:



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 576.0

**SECTION: Commercial Drug
SUBJECT: Alrex**

- A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
- B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
- C. In accordance with current standards of medical practice;
- D. Not primarily for the convenience of the Member, or the Member's Provider; and
- E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

PROCEDURE:

An exception for coverage of Alrex may be made for members who meet the following criteria:

- Medical record documentation of diagnosis of allergic conjunctivitis **AND**
- Medical record documentation of therapeutic failure on, intolerance to, or contraindication to one (1) of the following formulary alternatives: azelastine ophthalmic drops, epinastine, ophthalmic drops, **OR** olopatadine ophthalmic drops **AND**
- Medical record documentation of therapeutic failure on, intolerance to, or contraindication to two (2) formulary steroid **OR** non-steroidal anti-inflammatory drug (NSAID) eye drop alternatives

MEDISPAN AUTHORIZATION LEVEL: GPI-14

If a formulary exception is approved, Alrex will be paid for under the member's prescription drug benefit.

Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.

FORMULARY ALTERNATIVES:

dexamethasone sodium phosphate 0.1%, fluorometholone drops 0.1%, prednisolone acetate (pf), prednisolone acetate 1%, prednisolone sodium phosphate drops 1%, ketorolac drops 0.5%, Maxidex, FML S.O.P., azelastine drops 0.05%, epinastine drops 0.05%, olopatadine drops 0.1% and 0.2%



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 576.0

**SECTION: Commercial Drug
SUBJECT: Alrex**

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE
STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND
FEDERAL REGULATORY ENTITIES.**

**THIS POLICY WILL BE REVISED AS NECESSARY AND
REVIEWED NO LESS THAN ANNUALLY.**

Signed: _____

Title: Director, Pharmacy Services

Date: March 1, 2022

Devised: 9/25/19

Revised: 3/1/20 – annual review, added GHP Kids

Revised: 3/1/21 – annual review, updated logo, added MediSpan approval level

Revised: 3/1/22 – annual review, updated referenced policies & covered LOBs



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 577.0

**SECTION: Commercial Drug
SUBJECT: Pred Mild**

Applicable line of business:

Commercial	X	Medicaid	
Medicare		ACA	X
GHP Kids	X	Self-Insured	X

POLICY:

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for Pred Mild for GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 487.0 Quantity Limit Exceptions

REQUIRED DEFINITIONS:

1. **Attachment** – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. **Exhibit** – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. **Devised** – the date the policy was implemented.
4. **Revised** – the date of every revision to the policy, including typographical and grammatical changes.
5. **Reviewed** – the date documenting the annual review if the policy has no revisions necessary.

ADDITIONAL DEFINITIONS:

1. **Formulary** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. **Non-formulary products** – those medications that are not included in the Formulary.
3. **Healthcare provider** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
4. **NCQA** – National Committee for Quality Assurance.
5. **Medically Necessary or Medical Necessity** – covered services rendered by a provider that the Health Plan determines are:

- A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
- B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
- C. In accordance with current standards of medical practice;
- D. Not primarily for the convenience of the Member, or the Member's Provider; and
- E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

PROCEDURE:

An exception for coverage of Pred Mild may be made for members who meet the following criteria:

- Medical record documentation of diagnosis of a steroid responsive inflammatory condition of the palpebral and bulbar conjunctiva, cornea, and anterior segment of the globe **AND**
- Medical record documentation of therapeutic failure, contraindication, or intolerance to three (3) formulary alternatives

OR

- Medical record documentation of a diagnosis of corneal injury from chemical, radiation, or thermal burns, or penetration of foreign bodies **AND**
- Medical record documentation of therapeutic failure, contraindication, or intolerance to prednisolone acetate 1% **OR** prednisolone acetate 1% (P-F) **AND** dexamethasone sodium phosphate 0.1%

MEDISPAN AUTHORIZATION LEVEL: GPI-14

If a formulary exception is approved, Pred Mild will be paid for under the member's prescription drug benefit.

Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.



POLICY NUMBER: 577.0

**POLICY AND PROCEDURE
PHARMACY
MANUAL**

**SECTION: Commercial Drug
SUBJECT: Pred Mild**

FORMULARY ALTERNATIVES:

Steroid responsive inflammatory condition: dexamethasone sodium phosphate 0.1%, fluorometholone drops 0.1%, prednisolone acetate 1% (P-F), prednisolone acetate 1%, prednisolone sodium phosphate drops 1%, Maxidex, FML S.O.P.

Corneal injury: prednisolone acetate 1% (P-F), dexamethasone sodium phosphate 0.1%

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE
STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND
FEDERAL REGULATORY ENTITIES.**

**THIS POLICY WILL BE REVISED AS NECESSARY AND
REVIEWED NO LESS THAN ANNUALLY.**

Signed: _____

Title: Director, Pharmacy Services

Date: March 1, 2022

Devised: 9/25/19

Revised: 3/1/20 – annual review, added GHP Kids

Revised: 3/1/21 – annual review, updated logo, added MediSpan approval level

Revised: 3/1/22 – annual review, updated referenced policies & covered LOBs



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 578.0

**SECTION: Commercial Drug
SUBJECT: Acuvail, BromSite, Ilevro,
Nevanac, & Prolensa**

Applicable line of business:

Commercial	X	Medicaid	
Medicare		ACA	X
GHP Kids	X	Self-Insured	X

POLICY:

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for Acuvail, BromSite, Ilevro, Nevanac, and Prolensa for GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 487.0 Quantity Limit Exceptions

REQUIRED DEFINITIONS:

1. **Attachment** – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. **Exhibit** – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. **Devised** – the date the policy was implemented.
4. **Revised** – the date of every revision to the policy, including typographical and grammatical changes.
5. **Reviewed** – the date documenting the annual review if the policy has no revisions necessary.

ADDITIONAL DEFINITIONS:

1. **Formulary** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. **Non-formulary products** – those medications that are not included in the Formulary.
3. **Healthcare provider** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
4. **NCQA** – National Committee for Quality Assurance.
5. **Medically Necessary or Medical Necessity** – covered services rendered by a provider that the Health Plan determines are:



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 578.0

**SECTION: Commercial Drug
SUBJECT: Acuvail, BromSite, Ilevro,
Nevanac, & Prolensa**

- A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
- B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
- C. In accordance with current standards of medical practice;
- D. Not primarily for the convenience of the Member, or the Member's Provider; and
- E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

PROCEDURE:

An exception for coverage of Acuvail, BromSite, Ilevro, Nevanac, and Prolensa may be made for members who meet the following criteria:

- Medical record documentation of use for postoperative inflammation and reduction of ocular pain in patients who have undergone cataract surgery **AND**
- Medical record documentation of therapeutic failure on, intolerance to, or contraindication to three (3) formulary alternatives

MEDISPAN AUTHORIZATION LEVEL: GPI-14

If a formulary exception is approved, Acuvail, BromSite, Ilevro, Nevanac, or Prolensa will be paid for under the member's prescription drug benefit.

Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.

FORMULARY ALTERNATIVES:

dexamethasone sodium phosphate 0.1%, fluorometholone drops 0.1%, prednisolone acetate (pf), prednisolone acetate 1%, prednisolone sodium phosphate drops 1%, bromfenac 0.09%, ketorolac drops 0.4% and 0.5%, diclofenac sodium 0.1%, Maxidex, FML S.O.P.

Geisinger

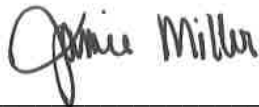
**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 578.0

**SECTION: Commercial Drug
SUBJECT: Acuvail, BromSite, Ilevro,
Nevanac, & Prolensa**

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE
STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND
FEDERAL REGULATORY ENTITIES.**

**THIS POLICY WILL BE REVISED AS NECESSARY AND
REVIEWED NO LESS THAN ANNUALLY.**



Signed: _____

Title: Director, Pharmacy Services

Date: March 1, 2022

Devised: 9/25/19
Revised: 3/1/20 – annual review, added GHP Kids
Revised: 3/1/21 – annual review, updated logo, added MediSpan approval level
Revised: 3/1/22 – annual review, updated referenced policies & covered LOBs



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 579.0

**SECTION: Commercial Drug
SUBJECT: Mavenclad**

Applicable line of business:

Commercial	X	Medicaid	
Medicare		ACA	X
GHP Kids	X	Self-Insured	X

POLICY:

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for Mavenclad for GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 487.0 Quantity Limit Exceptions

REQUIRED DEFINITIONS:

1. **Attachment** – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. **Exhibit** – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. **Devised** – the date the policy was implemented.
4. **Revised** – the date of every revision to the policy, including typographical and grammatical changes.
5. **Reviewed** – the date documenting the annual review if the policy has no revisions necessary.

ADDITIONAL DEFINITIONS:

1. **Formulary** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. **Non-formulary products** – those medications that are not included in the Formulary.
3. **Healthcare provider** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
4. **NCQA** – National Committee for Quality Assurance.
5. **Medically Necessary or Medical Necessity** – covered services rendered by a provider that the Health Plan determines are:

- A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
- B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
- C. In accordance with current standards of medical practice;
- D. Not primarily for the convenience of the Member, or the Member's Provider; and
- E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

PROCEDURE:

New members to the plan already established on therapy may be eligible for continuity of care coverage as long as there is medical record documentation that the safety and effectiveness of use for the prescribed indication is supported by Food and Drug Administration (FDA) approval or adequate medical and scientific evidence in the medical literature.

An exception for coverage of Mavenclad may be made for members who meet the following criteria:

- Medical record documentation that Mavenclad is prescribed by a neurologist **AND**
- Medical record documentation of age greater than or equal to 18 years **AND**
- Medical record documentation of a diagnosis of relapsing form of multiple sclerosis including relapsing-remitting disease and active secondary progressive disease **AND**
Note: Mavenclad is not indicated for the clinically isolated syndrome subtype of multiple sclerosis.
- Medical record documentation that Mavenclad will be used as monotherapy **AND**
- Medical record documentation that the prescribed dose is appropriate for member's weight **AND**
- Medical record documentation that member has not been treated with more than three (3) previous treatment cycles of Mavenclad for relapsing forms of multiple sclerosis **AND**
- Medical record documentation of therapeutic failure on, intolerance to, or contraindication to two (2) formulary alternatives for the treatment of multiple sclerosis



POLICY NUMBER: 579.0

**POLICY AND PROCEDURE
PHARMACY
MANUAL**

**SECTION: Commercial Drug
SUBJECT: Mavenclad**

NOTE: Cumulative use of Mavenclad for more than two years (4 cycles) of treatment during a member's lifetime has not been evaluated.

	Weight Range (kg)	First Cycle	Second Cycle
Dose of Mavenclad per cycle by member weight in each treatment course.	40* to less than 50	40 mg (4 tablets)	40 mg (4 tablets)
	50 to less than 60	50 mg (5 tablets)	50 mg (5 tablets)
	60 to less than 70	60 mg (6 tablets)	60 mg (6 tablets)
	70 to less than 80	70 mg (7 tablets)	70 mg (7 tablets)
	80 to less than 90	80 mg (8 tablets)	70 mg (7 tablets)
	90 to less than 100	90 mg (9 tablets)	80 mg (8 tablets)
	100 to less than 110	100 mg (10 tablets)	90 mg (9 tablets)
	110 and above	100 mg (10 tablets)	100 mg (10 tablets)

MEDISPAN AUTHORIZATION LEVEL: GPI-12

QUANTITY LIMIT: *No QLs need to be entered within the authorization unless the requested quantity exceeds the QL.*

- QL FOR LETTER ONLY:

Dosage	Quantity Limit
40 mg	4 tablets per 27 days
50 mg	5 tablets per 28 days
60 mg	6 tablets per 28 days
70 mg	7 tablets per 28 days
80 mg	8 tablets per 28 days
90 mg	9 tablets per 28 days
100 mg	10 tablets per 28 days

AUTHORIZATION DURATION: The initial authorization will be for 48 weeks with an RX Count of 2. One subsequent authorization will be for 48 weeks with an RX Count of 2 and will require the following:

- Medical record documentation that member has not received more than three previous cycles of Mavenclad treatment for relapsing forms of multiple sclerosis **AND**
- Medical record documentation that member has not experienced unacceptable toxicity or worsening of disease

FORMULARY ALTERNATIVES:

glatiramer acetate, Gilenya, dimethyl fumarate, Betaseron, Plegridy, Extavia, Aubagio 14 mg, Avonex, Rebif, Mayzent

Geisinger

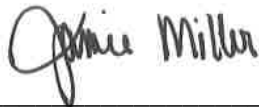
**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 579.0

**SECTION: Commercial Drug
SUBJECT: Mavenclad**

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE
STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND
FEDERAL REGULATORY ENTITIES.**

**THIS POLICY WILL BE REVISED AS NECESSARY AND
REVIEWED NO LESS THAN ANNUALLY.**



Signed: _____

Title: Director, Pharmacy Services

Date: March 1, 2022

Devised: 9/25/19

Revised: 3/1/20 – annual review, added GHP Kids

Revised: 3/1/21 – annual review, updated logo, added MediSpan approval level, updated QL statement & FA

Revised: 3/1/22 – annual review, updated referenced policies & covered LOBs



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 580.0

**SECTION: Commercial Drug
SUBJECT: Skyrizi**

Applicable line of business:

Commercial	X	Medicaid	
Medicare		ACA	X
GHP Kids	X	Self-Insured	X

POLICY:

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for Skyrizi for GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 487.0 Quantity Limit Exceptions

REQUIRED DEFINITIONS:

1. **Attachment** – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. **Exhibit** – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. **Devised** – the date the policy was implemented.
4. **Revised** – the date of every revision to the policy, including typographical and grammatical changes.
5. **Reviewed** – the date documenting the annual review if the policy has no revisions necessary.

ADDITIONAL DEFINITIONS:

1. **Formulary** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. **Non-formulary products** – those medications that are not included in the Formulary.
3. **Healthcare provider** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
4. **NCQA** – National Committee for Quality Assurance.
5. **Medically Necessary or Medical Necessity** – covered services rendered by a provider that the Health Plan determines are:



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 580.0

**SECTION: Commercial Drug
SUBJECT: Skyrizi**

- A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
- B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
- C. In accordance with current standards of medical practice;
- D. Not primarily for the convenience of the Member, or the Member's Provider; and
- E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

PROCEDURE:

New members to the plan already established on therapy may be eligible for continuity of care coverage as long as there is medical record documentation that the safety and effectiveness of use for the prescribed indication is supported by Food and Drug Administration (FDA) approval or adequate medical and scientific evidence in the medical literature.

A formulary exception for coverage of Skyrizi may be made for members who meet the following criteria:

For treatment of plaque psoriasis

- Medical record documentation of age greater than or equal to 18 years **AND**
- Medical record documentation that Skyrizi is prescribed by a dermatologist **AND**
- Medical record documentation of a diagnosis of moderate to severe plaque psoriasis with greater than or equal to 5% body surface area involved **OR** disease involving crucial areas of the body such as hands, feet, face, and/or genitals **AND**
- Medical record documentation of therapeutic failure on, intolerance to, or contraindication to Cosentyx* **AND** Humira* **AND**
- Medical record documentation that Skyrizi is not being used concurrently with a tumor necrosis factor (TNF) blocker or other biologic agent

MEDISPAN AUTHORIZATION LEVEL: GPI-12

QUANTITY LIMIT:

- **Prefilled Syringe Kit 75 mg/0.83 mL, Skyrizi 150 mg at weeks 0, 4, and then every 12 weeks thereafter**
 - In PA Hub: Add PA, PE, OQL, DS, OUP, max number of claims authorized 1, max quantity dispensed 1, min day supply 28, max day supply 28, with a duration of one month.



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 580.0

**SECTION: Commercial Drug
SUBJECT: Skyrizi**

- QL FOR LETTER: Loading dose: 1 kit per 28 days; Maintenance dose: 1 kit per 84 days
- **Prefilled 150 mg/mL Syringe or Auto-Injector, Skyrizi 150 mg at weeks 0, 4, and then every 12 weeks thereafter**
 - In PA Hub: Add PA, PE, OQL, DS, OUP, max number of claims authorized 1, max quantity dispensed 1, min day supply 28, max day supply 28, with a duration of one month.
 - QL FOR LETTER: Loading dose: 1 mL per 28 days; Maintenance dose: 1 mL per 84 days

RE-AUTHORIZATION CRITERIA: Skyrizi is configured as a prior authorization for new starts only. Skyrizi will no longer be covered if it is identified that the member is not receiving appropriate follow-up care from the prescribing specialist or if the member has greater than or equal to a 90 day break in therapy.

- Medical record documentation that the member is receiving appropriate follow-up care from the prescribing specialist

For treatment of psoriatic arthritis

- Medical record documentation of age greater than or equal to 18 years **AND**
- Medical record documentation that Skyrizi is prescribed by a rheumatologist or dermatologist **AND**
- Medical record documentation of active psoriatic arthritis (PsA) which must include the following:
 - Documentation of either active psoriatic lesions or a documented history of psoriasis **AND**
- Medical record documentation of therapeutic failure on, intolerance to, or contraindication to Cosentyx* **AND** Humira* **AND**
- Medical record documentation that Skyrizi is not being used concurrently with a tumor necrosis factor (TNF) blocker or other biologic agent

MEDISPAN AUTHORIZATION LEVEL: GPI-12

QUANTITY LIMIT:

- **Prefilled Syringe Kit 75 mg/0.83 mL, Skyrizi 150 mg at weeks 0, 4, and then every 12 weeks thereafter**
 - In PA Hub: Add PA, PE, OQL, DS, OUP, max number of claims authorized 1, max quantity dispensed 1, min day supply 28, max day supply 28, with a duration of one month.
 - QL FOR LETTER: Loading dose: 1 kit per 28 days; Maintenance dose: 1 kit per 84 days
- **Prefilled 150 mg/mL Syringe or Auto-Injector, Skyrizi 150 mg at weeks 0, 4, and then every 12 weeks thereafter**
 - In PA Hub: Add PA, PE, OQL, DS, OUP, max number of claims authorized 1, max quantity dispensed 1, min day supply 28, max day supply 28, with a duration of one month.
 - QL FOR LETTER: Loading dose: 1 mL per 28 days; Maintenance dose: 1 mL per 84 days

RE-AUTHORIZATION CRITERIA: Skyrizi is configured as a prior authorization for new starts only. Skyrizi will no longer be covered if it is identified that the member is not receiving appropriate follow-up care from the prescribing specialist or if the member has greater than or equal to a 90 day break in therapy.

- Medical record documentation that the member is receiving appropriate follow-up care from the prescribing specialist



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 580.0

**SECTION: Commercial Drug
SUBJECT: Skyrizi**

If a formulary exception is approved Skyrizi will be paid for under the member's prescription drug benefit.

Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.

FORMULARY ALTERNATIVES:

Cosentyx*, Humira*

*prior authorization required

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE
STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND
FEDERAL REGULATORY ENTITIES.**

**THIS POLICY WILL BE REVISED AS NECESSARY AND
REVIEWED NO LESS THAN ANNUALLY.**

Signed: _____

Title: Director, Pharmacy Services

Date: June 7, 2022

- Devised: 9/25/19
- Revised: 11/5/19 – corrected typo, adjusted QL
- Revised: 3/1/20 – annual review, added GHP Kids, updated QL statement
- Revised: 3/1/21 – annual review, updated logo, updated QL statement, added MediSpan approval level
- Revised: 7/1/21 – add QL for 150 mg syringe/autoinjector
- Revised: 12/2/21 – added one-time PA to approval crit., removed auth duration & added re-auth crit., updated QL auth entry to account for PA NSO
- Revised: 1/5/22 – added OUP override to authorization
- Revised: 3/1/22 – annual review, updated referenced policies & covered LOBs, updated how QL is entered
- Revised: 6/7/22 – added PsA indication



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 581.0

**SECTION: Commercial Drug
SUBJECT: Rocklatan**

Applicable line of business:

Commercial	X	Medicaid	
Medicare		ACA	X
GHP Kids	X	Self-Insured	X

POLICY:

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for Rocklatan for GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 487.0 Quantity Limit Exceptions

REQUIRED DEFINITIONS:

1. **Attachment** – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. **Exhibit** – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
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5. **Reviewed** – the date documenting the annual review if the policy has no revisions necessary.

ADDITIONAL DEFINITIONS:

1. **Formulary** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. **Non-formulary products** – those medications that are not included in the Formulary.
3. **Healthcare provider** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
4. **NCQA** – National Committee for Quality Assurance.
5. **Medically Necessary or Medical Necessity** – covered services rendered by a provider that the Health Plan determines are:



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 581.0

**SECTION: Commercial Drug
SUBJECT: Rocklatan**

- A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
- B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
- C. In accordance with current standards of medical practice;
- D. Not primarily for the convenience of the Member, or the Member's Provider; and
- E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

PROCEDURE:

An exception for coverage of Rocklatan may be made for members who meet the following criteria:

- Medical record documentation of therapeutic failure on, intolerance to, or contraindication to three (3) formulary alternatives, one of which must be a prostaglandin analog

MEDISPAN AUTHORIZATION LEVEL: GPI-12

QUANTITY LIMIT: *No QLs need to be entered within the authorization unless the requested quantity exceeds the QL.*

- QL FOR LETTER ONLY: 0.17 mL per day

NOTE: There are certain ocular inflammatory conditions including iritis and uveitis which do not warrant the use of Prostaglandin eye drops as first line therapy.

If a formulary exception is approved, Rocklatan will be paid for under the member's prescription drug benefit.

Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.

FORMULARY ALTERNATIVES:

brimonidine, latanoprost, timolol, Zioptan, travoprost, Alphagan P, Azopt, Vyzulta*, Lumigan*, Rhopressa*, Simbrinza, Combigan

*step therapy required



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 581.0

**SECTION: Commercial Drug
SUBJECT: Rocklatan**

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE
STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND
FEDERAL REGULATORY ENTITIES.**

**THIS POLICY WILL BE REVISED AS NECESSARY AND
REVIEWED NO LESS THAN ANNUALLY.**

Signed: _____

Title: Director, Pharmacy Services

Date: March 1, 2022

Devised: 9/25/19

Revised: 3/1/20 – annual review, added GHP Kids

Revised: 3/1/21 – annual review, updated logo, added MediSpan approval level, updated QL statement & FA

Revised: 3/1/22 – annual review, updated referenced policies & covered LOBs



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 582.0

**SECTION: Commercial Drug
SUBJECT: Vyndaqel and Vyndamax**

Applicable line of business:

Commercial	X	Medicaid	
Medicare		ACA	X
GHP Kids	X	Self-Insured	X

POLICY:

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for Vyndaqel and Vyndamax for GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 487.0 Quantity Limit Exceptions

REQUIRED DEFINITIONS:

1. **Attachment** – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
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5. **Reviewed** – the date documenting the annual review if the policy has no revisions necessary.

ADDITIONAL DEFINITIONS:

1. **Formulary** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. **Non-formulary products** – those medications that are not included in the Formulary.
3. **Healthcare provider** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
4. **NCQA** – National Committee for Quality Assurance.
5. **Medically Necessary or Medical Necessity** – covered services rendered by a provider that the Health Plan determines are:

- A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
- B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
- C. In accordance with current standards of medical practice;
- D. Not primarily for the convenience of the Member, or the Member's Provider; and
- E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

PROCEDURE:

An exception for coverage of Vyndaqel or Vyndamax may be made for members who meet the following criteria:

- Medical record documentation that Vyndaqel or Vyndamax is prescribed by or in consultation with a cardiologist **AND**
- Medical record documentation of age greater than or equal to 18 years **AND**
- Medical record documentation of a diagnosis of cardiomyopathy resulting from wild type transthyretin-mediated amyloidosis **OR** hereditary transthyretin-mediated amyloidosis as confirmed by ONE of the following:
 - Bone scan (scintigraphy) strongly positive for myocardial uptake of 99mTcPYP/DPD (*Note: Strongly positive defined as heart to contralateral lung [H/CL] ratio of at least 1.5 or Grade 2 or greater localization to the heart using the Perugini Grade 1-3 scoring system*) **OR**
 - Biopsy of tissue of the affected organ to confirm amyloid presence **AND** chemical typing to confirm presence of transthyretin (TTR) protein

AND

- Medical record documentation that the patient has New York Heart Association (NYHA) Class I, II, or III heart failure **AND**
- Medical record documentation that member has been evaluated and treated by a contracted Center of Excellence in amyloidosis management

NOTE: Center of Excellence (COE) requirements do not apply to strategic partner TPA plans (i.e., Northern Light Health).

MEDISPAN AUTHORIZATION LEVEL: GPI-12

Geisinger

**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 582.0

**SECTION: Commercial Drug
SUBJECT: Vyndaqel and Vyndamax**

QUANTITY LIMIT: *No QLs need to be entered within the authorization unless the requested quantity exceeds the QL.*

- **QL FOR LETTER ONLY:**
 - Vyndaqel – 4 tablets per 30, 30 day supply per fill
 - Vyndamax – 1 tablet per day, 30 day supply per fill

AUTHORIZATION DURATION: Initial approval will be for 12 months. Subsequent approvals will be for an additional 12 months, requiring prescriber attestation that the patient continues to benefit from tafamidis therapy. The medication will no longer be covered if the member experiences toxicity or progresses to NYHA class IV heart failure.

If a formulary exception is approved, Vyndaqel or Vyndamax will be paid for under the member's prescription drug benefit.

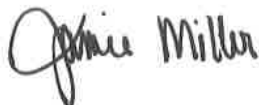
Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.

FORMULARY ALTERNATIVES:

none

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE
STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND
FEDERAL REGULATORY ENTITIES.**

**THIS POLICY WILL BE REVISED AS NECESSARY AND
REVIEWED NO LESS THAN ANNUALLY.**



Signed: _____

Title: Director, Pharmacy Services

Date: March 1, 2022

Devised: 9/25/19

Revised: 3/1/20 – annual review, added GHP Kids

Revised: 3/1/21 – annual review, updated logo, added MediSpan approval level, updated QL statement

HPRX02

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Dev. 9/25/19

Rev. 3/1/22



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 582.0

**SECTION: Commercial Drug
SUBJECT: Vyndaqel and Vyndamax**

Revised: 1/5/22 – added COE criterion and note

Revised: 3/1/22 – annual review, updated referenced policies & covered LOBs



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 583.0

**SECTION: Commercial Drug
SUBJECT: Duobrii**

Applicable line of business:

Commercial	X	Medicaid	
Medicare		ACA	X
GHP Kids	X	Self-Insured	X

POLICY:

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for Duobrii for GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 487.0 Quantity Limit Exceptions

REQUIRED DEFINITIONS:

1. **Attachment** – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. **Exhibit** – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. **Devised** – the date the policy was implemented.
4. **Revised** – the date of every revision to the policy, including typographical and grammatical changes.
5. **Reviewed** – the date documenting the annual review if the policy has no revisions necessary.

ADDITIONAL DEFINITIONS:

1. **Formulary** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. **Non-formulary products** – those medications that are not included in the Formulary.
3. **Healthcare provider** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
4. **NCQA** – National Committee for Quality Assurance.
5. **Medically Necessary or Medical Necessity** – covered services rendered by a provider that the Health Plan determines are:



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 583.0

**SECTION: Commercial Drug
SUBJECT: Duobrii**

- A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
- B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
- C. In accordance with current standards of medical practice;
- D. Not primarily for the convenience of the Member, or the Member's Provider; and
- E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

PROCEDURE:

An exception for coverage of Duobrii may be made for members who meet the following criteria:

- Medical record documentation that Duobrii is prescribed by or in consultation with a dermatologist **AND**
- Medical record documentation of age greater than or equal to 18 years **AND**
- Medical record documentation of a diagnosis of plaque psoriasis **AND**
- Medical record documentation of therapeutic failure on, intolerance to, or contraindication to tazarotene used in combination with three (3) different topical corticosteroids

MEDISPAN AUTHORIZATION LEVEL: GPI-12

If a formulary exception is approved, Duobrii will be paid for under the member's prescription drug benefit.

Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.

FORMULARY ALTERNATIVES:

tazarotene

Low-potency topical corticosteroids: alclometasone dipropionate 0.5% cream and ointment (Aclovate); fluocinolone acetonide 0.01% soln. (Synalar); hydrocortisone 2.5% cream, ointment, and lotion (Hytone)

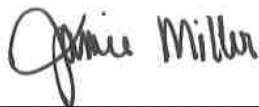
Medium-potency topical corticosteroids: betamethasone valerate 0.1% cream (Valisone); fluocinolone acetonide 0.025% cream and ointment (Synalar); fluticasone propionate 0.05% cream, ointment, and lotion (Cutivate); triamcinolone 0.1% cream, ointment and lotion (Kenalog); triamcinolone acetonide 0.025% cream, ointment and lotion (Kenalog); triamcinolone acetonide 0.147 mg/g aerosol (Kenalog Spray)

High-potency topical corticosteroids: augmented betamethasone dipropionate 0.05% cream (Diprolene AF); betamethasone valerate 0.1% ointment (Valisone); triamcinolone 0.5% cream (Kenalog); fluocinonide 0.05% cream, ointment and gel (Lidex)

Very high-potency topical corticosteroids: augmented betamethasone dipropionate 0.05% ointment, gel and lotion (Diprolene); clobetasol 0.05% cream, ointment, and scalp lotion (Temovate) diflorasone diacetate 0.05% cream and ointment (ApexiCon/Psorcon)

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE
STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND
FEDERAL REGULATORY ENTITIES.**

**THIS POLICY WILL BE REVISED AS NECESSARY AND
REVIEWED NO LESS THAN ANNUALLY.**



Signed: _____

Title: Director, Pharmacy Services

Date: March 1, 2022

Devised: 9/25/19

Revised: 3/1/20 – annual review, added GHP Kids

Revised: 3/1/21 – annual review, updated logo, added MediSpan approval level

Revised: 3/1/22 – annual review, updated referenced policies & covered LOBs



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 584.0

**SECTION: Commercial Drug
SUBJECT: Xpovio**

Applicable line of business:

Commercial	X	Medicaid	
Medicare		ACA	X
GHP Kids	X	Self-Insured	X

POLICY:

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for Xpovio for GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 487.0 Quantity Limit Exceptions

REQUIRED DEFINITIONS:

1. **Attachment** – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. **Exhibit** – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. **Devised** – the date the policy was implemented.
4. **Revised** – the date of every revision to the policy, including typographical and grammatical changes.
5. **Reviewed** – the date documenting the annual review if the policy has no revisions necessary.

ADDITIONAL DEFINITIONS:

1. **Formulary** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. **Non-formulary products** – those medications that are not included in the Formulary.
3. **Healthcare provider** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
4. **NCQA** – National Committee for Quality Assurance.
5. **Medically Necessary or Medical Necessity** – covered services rendered by a provider that the Health Plan determines are:



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 584.0

**SECTION: Commercial Drug
SUBJECT: Xpovio**

- A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
- B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
- C. In accordance with current standards of medical practice;
- D. Not primarily for the convenience of the Member, or the Member's Provider; and
- E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

PROCEDURE:

New members to the plan already established on therapy may be eligible for continuity of care coverage as long as there is medical record documentation that the safety and effectiveness of use for the prescribed indication is supported by Food and Drug Administration (FDA) approval or adequate medical and scientific evidence in the medical literature.

An exception for coverage of Xpovio may be made for members who meet the following criteria:

Multiple Myeloma

- Medical record documentation that Xpovio is prescribed by a hematologist or oncologist **AND**
 - Medical record documentation of age greater than or equal to 18 years **AND**
 - Medical record documentation of one of the following:
 - Medical record documentation of a diagnosis of relapsed or refractory multiple myeloma and the member has received at least four prior complete regimens which include at least two proteasome inhibitors, at least two immunomodulatory agents, and an anti-CD38 monoclonal antibody **AND** Medical record documentation that Xpovio will be used in combination with dexamethasone
- OR**
- Medical record documentation of a diagnosis of multiple myeloma and the member has received at least one prior therapy **AND** Medical record documentation that Xpovio will be used in combination with bortezomib **AND** dexamethasone



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 584.0

**SECTION: Commercial Drug
SUBJECT: Xpovio**

NOTE: Currently approved agents for the treatment of multiple myeloma

Class	Single-agent (+/- steroids)	Combination therapy
Immunomodulatory agents (IMiD)	Revlimid (lenalidomide) Pomalyst (pomalidomide)	--
Proteasome inhibitors (PI)	Velcade (bortezomib) Kyprolis (carfilzomib)	Ninlaro (ixazomib) (with lenalidomide)
anti-CD38	Darzalex (daratumumab)	--
Anti-SLAM F7	--	Empliciti (elotuzumab) (with IMiD)
Histone deacetylase inhibitor (HDAC)	--	Farydak (panobinostat) (with bortezomib)

MEDISPAN AUTHORIZATION LEVEL: GPI-12, number of claims authorized = 1, enter for the remainder of the calendar year

QUANTITY LIMIT: *No QLs need to be entered within the authorization unless the requested quantity exceeds the QL.*

- **QL FOR LETTER ONLY:**

40 mg once weekly	8 tablets per 28 days
60 mg once weekly	12 tablets per 28 days
80 mg once weekly	16 tablets per 28 days
100 mg once weekly	20 tablets per 28 days
60 mg twice weekly	24 tablets per 28 days
80 mg twice daily	32 tablets per 28 days

RE-AUTHORIZATION CRITERIA: Xpovio is configured as a prior authorization for new starts only. Xpovio will no longer be covered if it is identified that the member is not receiving appropriate follow-up care from the prescribing specialist or if the member has greater than or equal to a 90 day break in therapy.

- Medical record documentation that the member is receiving appropriate follow-up care from the prescribing specialist

If a formulary exception is approved, Xpovio will be paid for under the member's prescription drug benefit.

Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 584.0

**SECTION: Commercial Drug
SUBJECT: Xpovio**

FORMULARY ALTERNATIVES:

Revlimid*, Pomalyst*, Ninlaro*, Farydak*

*prior authorization required

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE
STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND
FEDERAL REGULATORY ENTITIES.**

**THIS POLICY WILL BE REVISED AS NECESSARY AND
REVIEWED NO LESS THAN ANNUALLY.**

Signed: _____

Title: Director, Pharmacy Services

Date: March 1, 2022

Devised: 9/25/19
Revised: 3/1/20 – annual review, added GHP Kids
Revised: 10/12/20 – added B-cell lymphoma indication, updated QL
Revised: 3/1/21 – annual review, updated logo, added MediSpan approval level, updated QL statement
Revised: 3/26/21 – updated multiple myeloma to include combo with bortezomib/dexamethasone
Revised: 12/2/21 – added one-time PA to approval crit., removed auth duration & added re-auth crit.
Revised: 3/1/22 – annual review, updated referenced policies & covered LOBs



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 585.0

**SECTION: Commercial Drug
SUBJECT: Nubeqa**

Applicable line of business:

Commercial	X	Medicaid	
Medicare		ACA	X
GHP Kids	X	Self-Insured	X

POLICY:

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for Nubeqa for GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 487.0 Quantity Limit Exceptions

REQUIRED DEFINITIONS:

1. **Attachment** – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. **Exhibit** – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. **Devised** – the date the policy was implemented.
4. **Revised** – the date of every revision to the policy, including typographical and grammatical changes.
5. **Reviewed** – the date documenting the annual review if the policy has no revisions necessary.

ADDITIONAL DEFINITIONS:

1. **Formulary** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. **Non-formulary products** – those medications that are not included in the Formulary.
3. **Healthcare provider** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
4. **NCQA** – National Committee for Quality Assurance.
5. **Medically Necessary or Medical Necessity** – covered services rendered by a provider that the Health Plan determines are:



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 585.0

**SECTION: Commercial Drug
SUBJECT: Nubeqa**

- A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
- B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
- C. In accordance with current standards of medical practice;
- D. Not primarily for the convenience of the Member, or the Member's Provider; and
- E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

PROCEDURE:

New members to the plan already established on therapy may be eligible for continuity of care coverage as long as there is medical record documentation that the safety and effectiveness of use for the prescribed indication is supported by Food and Drug Administration (FDA) approval or adequate medical and scientific evidence in the medical literature.

An exception for coverage of Nubeqa may be made for members who meet the following criteria:

- Medical record documentation that Nubeqa is prescribed by an oncologist or urologist **AND**
- Medical record documentation of age greater than or equal to 18 years **AND**
- Medical record documentation of a diagnosis of non-metastatic, castration-resistant prostate cancer **AND**
- Medical record documentation that members is receiving GnRH analog(s) concurrently **OR** that member has had an bilateral orchiectomy

MEDISPAN AUTHORIZATION LEVEL: GPI-12, number of claims authorized = 1, enter for the remainder of the calendar year

QUANTITY LIMIT: *No QLs need to be entered within the authorization unless the requested quantity exceeds the QL.*

- **QL FOR LETTER ONLY:** 4 tablets per day, 30 day supply per fill



POLICY NUMBER: 585.0

**POLICY AND PROCEDURE
PHARMACY
MANUAL**

**SECTION: Commercial Drug
SUBJECT: Nubeqa**

RE-AUTHORIZATION CRITERIA: Nubeqa is configured as a prior authorization for new starts only. Nubeqa will no longer be covered if it is identified that the member is not receiving appropriate follow-up care from the prescribing specialist or if the member has greater than or equal to a 90 day break in therapy.

- Medical record documentation that the member is receiving appropriate follow-up care from the prescribing specialist

If a formulary exception is approved, Nubeqa will be paid for under the member's prescription drug benefit.

Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.

FORMULARY ALTERNATIVES:

Erleada*, Xtandi*

*prior authorization required

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE
STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND
FEDERAL REGULATORY ENTITIES.**

**THIS POLICY WILL BE REVISED AS NECESSARY AND
REVIEWED NO LESS THAN ANNUALLY.**

Signed: _____

Title: Director, Pharmacy Services

Date: March 1, 2022

Devised: 9/27/19
Revised: 3/1/20 – annual review, added GHP Kids
Revised: 3/1/21 – annual review, updated logo, added MediSpan approval level, updated QL statement
Revised: 11/30/21 – added one-time PA to approval crit., removed auth duration & added re-auth crit.
Revised: 3/1/22 – annual review, updated referenced policies & covered LOBs



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 586.0

**SECTION: Commercial Drug
SUBJECT: Turalio**

Applicable line of business:

Commercial	X	Medicaid	
Medicare		ACA	X
GHP Kids	X	Self-Insured	X

POLICY:

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for Turalio for GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 487.0 Quantity Limit Exceptions

REQUIRED DEFINITIONS:

1. **Attachment** – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. **Exhibit** – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. **Devised** – the date the policy was implemented.
4. **Revised** – the date of every revision to the policy, including typographical and grammatical changes.
5. **Reviewed** – the date documenting the annual review if the policy has no revisions necessary.

ADDITIONAL DEFINITIONS:

1. **Formulary** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. **Non-formulary products** – those medications that are not included in the Formulary.
3. **Healthcare provider** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
4. **NCQA** – National Committee for Quality Assurance.
5. **Medically Necessary or Medical Necessity** – covered services rendered by a provider that the Health Plan determines are:



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 586.0

**SECTION: Commercial Drug
SUBJECT: Turalio**

- A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
- B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
- C. In accordance with current standards of medical practice;
- D. Not primarily for the convenience of the Member, or the Member's Provider; and
- E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

PROCEDURE:

New members to the plan already established on therapy may be eligible for continuity of care coverage as long as there is medical record documentation that the safety and effectiveness of use for the prescribed indication is supported by Food and Drug Administration (FDA) approval or adequate medical and scientific evidence in the medical literature.

An exception for coverage of Turalio may be made for members who meet the following criteria:

- Medical record documentation that Turalio is prescribed by an oncologist **AND**
- Medical record documentation of age greater than or equal to 18 years **AND**
- Medical record documentation of a diagnosis of tenosynovial giant cell tumor that meets both of the following criteria:
 - Associated with functional limitations or severe morbidity **AND**
 - Not amenable to improvement with surgery

MEDISPAN AUTHORIZATION LEVEL: GPI-12, number of claims authorized = 1, enter for the remainder of the calendar year

QUANTITY LIMIT: *No QLs need to be entered within the authorization unless the requested quantity exceeds the QL.*

- **QL FOR LETTER ONLY:** 4 capsules per day, 30 day supply per fill



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 586.0

**SECTION: Commercial Drug
SUBJECT: Turalio**

RE-AUTHORIZATION CRITERIA: Turalio is configured as a prior authorization for new starts only. Turalio will no longer be covered if it is identified that the member is not receiving appropriate follow-up care from the prescribing specialist or if the member has greater than or equal to a 90 day break in therapy.

- Medical record documentation that the member is receiving appropriate follow-up care from the prescribing specialist

If a formulary exception is approved, Turalio will be paid for under the member's prescription drug benefit.

Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.

FORMULARY ALTERNATIVES:

none

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE
STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND
FEDERAL REGULATORY ENTITIES.**

**THIS POLICY WILL BE REVISED AS NECESSARY AND
REVIEWED NO LESS THAN ANNUALLY.**

Signed: _____

Title: Director, Pharmacy Services

Date: March 1, 2022

Devised: 9/27/19
Revised: 3/1/20 – annual review, added GHP Kids
Revised: 3/1/21 – annual review, updated logo, added MediSpan approval level, updated QL statement
Revised: 12/1/21 – added one-time PA to approval crit., removed auth duration & added re-auth crit.
Revised: 3/1/22 – annual review, updated referenced policies & covered LOBs



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 587.0

**SECTION: Commercial Drug
SUBJECT: Sunosi**

Applicable line of business:

Commercial	X	Medicaid	
Medicare		ACA	X
GHP Kids	X	Self-Insured	X

POLICY:

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for Sunosi for GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 487.0 Quantity Limit Exceptions

REQUIRED DEFINITIONS:

1. **Attachment** – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. **Exhibit** – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. **Devised** – the date the policy was implemented.
4. **Revised** – the date of every revision to the policy, including typographical and grammatical changes.
5. **Reviewed** – the date documenting the annual review if the policy has no revisions necessary.

ADDITIONAL DEFINITIONS:

1. **Formulary** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. **Non-formulary products** – those medications that are not included in the Formulary.
3. **Healthcare provider** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
4. **NCQA** – National Committee for Quality Assurance.
5. **Medically Necessary or Medical Necessity** – covered services rendered by a provider that the Health Plan determines are:



POLICY NUMBER: 587.0

**POLICY AND PROCEDURE
PHARMACY
MANUAL**

**SECTION: Commercial Drug
SUBJECT: Sunosi**

- A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
- B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
- C. In accordance with current standards of medical practice;
- D. Not primarily for the convenience of the Member, or the Member's Provider; and
- E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

PROCEDURE:

An exception for coverage of Sunosi may be made for members who meet the following criteria:

Narcolepsy

- Medical record documentation of a diagnosis of excessive daytime sleepiness associated with narcolepsy **AND**
- Medical record documentation of age greater than or equal to 18 years **AND**
- Medical record documentation of therapeutic failure on, intolerance to, or contraindication to: modafinil* or armodafinil* **AND** methylphenidate immediate release or amphetamine/dextroamphetamine immediate release

Obstructive Sleep Apnea

- Medical record documentation of a diagnosis of excessive daytime sleepiness associated with obstructive sleep apnea **AND**
- Medical record documentation of age greater than or equal to 18 years **AND**
- Medical record documentation that the member's underlying airway obstruction has been treated (e.g., with a continuous positive airway pressure (CPAP)) for at least one month prior to the initiation of Sunosi **AND**
- Medical record documentation that the member will continue to use this treatment modality (e.g., CPAP) while received Sunosi **AND**
- Medical record documentation of therapeutic failure on, intolerance to, or contraindication to: modafinil* **OR** armodafinil*

MEDISPAN AUTHORIZATION LEVEL: GPI-12

QUANTITY LIMIT: *No QLs need to be entered within the authorization unless the requested quantity exceeds the QL.*

- QL FOR LETTER ONLY: 1 tablet per day



POLICY NUMBER: 587.0

**POLICY AND PROCEDURE
PHARMACY
MANUAL**

**SECTION: Commercial Drug
SUBJECT: Sunosi**

If a formulary exception is approved, Sunosi will be paid for under the member's prescription drug benefit.

Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.

FORMULARY ALTERNATIVES:

For Narcolepsy: dextroamphetamine/amphetamine, dextroamphetamine, methylphenidate, armodafinil*, modafinil*, Xyrem*, Xywav*

For Obstructive Sleep Apnea: armodafinil*, modafinil*

*prior authorization required

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE
STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND
FEDERAL REGULATORY ENTITIES.**

**THIS POLICY WILL BE REVISED AS NECESSARY AND
REVIEWED NO LESS THAN ANNUALLY.**

Signed: _____

Title: Director, Pharmacy Services

Date: March 1, 2022

Devised: 11/20/19

Revised: 3/1/20 – annual review, added GHP Kids

Revised: 3/1/21 – annual review, updated logo, added MediSpan approval level, updated QL statement

Revised: 3/1/22 – annual review, updated referenced policies & covered LOBs, updated FA



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 588.0

**SECTION: Commercial Drug
SUBJECT: Rozlytrek**

Applicable line of business:

Commercial	X	Medicaid	
Medicare		ACA	X
GHP Kids	X	Self-Insured	X

POLICY:

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for Rozlytrek for GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 487.0 Quantity Limit Exceptions

REQUIRED DEFINITIONS:

1. **Attachment** – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. **Exhibit** – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. **Devised** – the date the policy was implemented.
4. **Revised** – the date of every revision to the policy, including typographical and grammatical changes.
5. **Reviewed** – the date documenting the annual review if the policy has no revisions necessary.

ADDITIONAL DEFINITIONS:

1. **Formulary** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. **Non-formulary products** – those medications that are not included in the Formulary.
3. **Healthcare provider** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
4. **NCQA** – National Committee for Quality Assurance.
5. **Medically Necessary or Medical Necessity** – covered services rendered by a provider that the Health Plan determines are:

- A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
- B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
- C. In accordance with current standards of medical practice;
- D. Not primarily for the convenience of the Member, or the Member's Provider; and
- E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

PROCEDURE:

New members to the plan already established on therapy may be eligible for continuity of care coverage as long as there is medical record documentation that the safety and effectiveness of use for the prescribed indication is supported by Food and Drug Administration (FDA) approval or adequate medical and scientific evidence in the medical literature.

An exception for coverage of Rozlytrek may be made for members who meet the following criteria:

NTRK-Fusion Positive Solid Tumors

- Medical record documentation that Rozlytrek is prescribed by an oncologist or hematologist **AND**
- Medical record documentation of age greater than or equal to 12 years **AND**
- Medical record documentation of unresectable or metastatic solid tumors with a neurotrophic receptor tyrosine kinase (NTRK) gene fusion without a known acquired resistance mutation **AND**
- One of the following:
 - Medical record documentation that the member must have progressed following treatment **OR**
 - Medical record documentation that no satisfactory alternative treatments are available

ROS1-Positive Non-Small Cell Lung Cancer

- Medical record documentation that Rozlytrek is prescribed by an oncologist **AND**
- Medical record documentation of age greater than or equal to 18 years **AND**
- Medical record documentation of a diagnosis of metastatic non-small cell lung cancer (NSCLC) whose tumors are *ROS1*-positive



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 588.0

**SECTION: Commercial Drug
SUBJECT: Rozlytrek**

MEDISPAN AUTHORIZATION LEVEL: GPI-12, number of claims authorized = 1, enter for the remainder of the calendar year

QUANTITY LIMIT: *No QLs need to be entered within the authorization unless the requested quantity exceeds the QL.*

- **QL FOR LETTER ONLY:**
 - 100 mg capsules: 1 capsule per day, 30 day supply per fill
 - 200 mg capsules: 3 capsules per day, 30 day supply per fill

RE-AUTHORIZATION CRITERIA: Rozlytrek is configured as a prior authorization for new starts only. Rozlytrek will no longer be covered if it is identified that the member is not receiving appropriate follow-up care from the prescribing specialist or if the member has greater than or equal to a 90 day break in therapy.

- Medical record documentation that the member is receiving appropriate follow-up care from the prescribing specialist

If a formulary exception is approved, Rozlytrek will be paid for under the member's prescription drug benefit.

Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.

FORMULARY ALTERNATIVES:

none

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE
STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND
FEDERAL REGULATORY ENTITIES.**

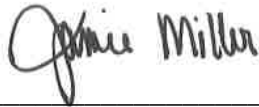
**THIS POLICY WILL BE REVISED AS NECESSARY AND
REVIEWED NO LESS THAN ANNUALLY.**

Geisinger

**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 588.0

**SECTION: Commercial Drug
SUBJECT: Rozlytrek**



Signed: _____

Title: Director, Pharmacy Services

Date: March 1, 2022

Devised: 11/20/19

Revised: 3/1/20 – annual review, added GHP Kids

Revised: 3/1/21 – annual review, updated logo, added MediSpan approval level, updated QL Statement

Revised: 12/1/21 – added one-time PA to approval crit., removed auth duration & added re-auth crit.

Revised: 3/1/22 – annual review, updated referenced policies & covered LOBs



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 589.0

**SECTION: Commercial Drug
SUBJECT: Inrebic**

Applicable line of business:

Commercial	X	Medicaid	
Medicare		ACA	X
GHP Kids	X	Self-Insured	X

POLICY:

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for Inrebic for GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 487.0 Quantity Limit Exceptions

REQUIRED DEFINITIONS:

1. **Attachment** – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. **Exhibit** – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. **Devised** – the date the policy was implemented.
4. **Revised** – the date of every revision to the policy, including typographical and grammatical changes.
5. **Reviewed** – the date documenting the annual review if the policy has no revisions necessary.

ADDITIONAL DEFINITIONS:

1. **Formulary** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. **Non-formulary products** – those medications that are not included in the Formulary.
3. **Healthcare provider** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
4. **NCQA** – National Committee for Quality Assurance.
5. **Medically Necessary or Medical Necessity** – covered services rendered by a provider that the Health Plan determines are:



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 589.0

**SECTION: Commercial Drug
SUBJECT: Inrebic**

- A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
- B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
- C. In accordance with current standards of medical practice;
- D. Not primarily for the convenience of the Member, or the Member's Provider; and
- E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

PROCEDURE:

New members to the plan already established on therapy may be eligible for continuity of care coverage as long as there is medical record documentation that the safety and effectiveness of use for the prescribed indication is supported by Food and Drug Administration (FDA) approval or adequate medical and scientific evidence in the medical literature.

An exception for coverage of Inrebic may be made for members who meet the following criteria:

- Medical record documentation that Inrebic is prescribed by a hematologist or oncologist **AND**
- Medical record documentation of age greater than or equal to 18 years **AND**
- Medical record documentation of a diagnosis of intermediate-2 (INT-2) or high-risk myelofibrosis, including primary myelofibrosis, post-polycythemia vera myelofibrosis or post-essential thrombocythemia myelofibrosis **AND**
- Medical record documentation of platelet count greater than or equal to $50 \times 10^9/L$ **AND**
- Medical record documentation of splenomegaly as measured by computed tomography (CT), magnetic resonance imaging (MRI), or ultrasound **AND**
- Medical record documentation of baseline total symptom score as measured by the modified Myelofibrosis Symptom Assessment Form (MFSAF) **AND**
- Medical record documentation that Inrebic will not be used concurrently with Jakafi **AND**
- Medical record documentation that the member is ineligible for allogeneic hematopoietic cell transplantation

MEDISPAN AUTHORIZATION LEVEL: GPI-12



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 589.0

**SECTION: Commercial Drug
SUBJECT: Inrebic**

QUANTITY LIMIT: *No QLs need to be entered within the authorization unless the requested quantity exceeds the QL.*

- QL FOR LETTER ONLY: 4 capsules per day, 30 day supply per fill

AUTHORIZATION DURATION: Each treatment period will be defined as six (6) months. Re-review with occur every six (6) months. Inrebic will no longer be covered if medical record documentation does not show:

- Medical record documentation of platelet count greater than or equal to $50 \times 10^9/L$
AND
- The member has achieved a reduction from pretreatment baseline of at least 35% in spleen volume as measured by computed tomography (CT), magnetic resonance imaging (MRI), or ultrasound **OR**
- The member has achieved a 50% or greater reduction in the Total Symptom Score from baseline as measured by the modified Myelofibrosis Symptom Assessment Form (MFSAF)

NOTE: Intermediate or High-Risk Myelofibrosis is defined by having at least 2 of the following factors:

- Age > 65 years
- WBC > $25 \times 10^9/L$
- Hemoglobin < 10 g/dL
- Blood Blasts $\geq 1\%$
- Presence of Constitutional Symptoms (weight loss, fever, excessive sweats, etc.)
- Transfusion dependency
- Platelets less than $100 \times 10^9/L$
- Unfavorable karyotype

If a formulary exception is approved, Inrebic will be paid for under the member's prescription drug benefit.

Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.

FORMULARY ALTERNATIVES:

Jakafi*

*prior authorization required



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 589.0

**SECTION: Commercial Drug
SUBJECT: Inrebic**

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE
STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND
FEDERAL REGULATORY ENTITIES.**

**THIS POLICY WILL BE REVISED AS NECESSARY AND
REVIEWED NO LESS THAN ANNUALLY.**

Signed: _____

Title: Director, Pharmacy Services

Date: March 1, 2022

Devised: 11/20/19

Revised: 3/1/20 – annual review, added GHP Kids

Revised: 3/1/21 – annual review, updated logo, added MediSpan approval level, updated QL statement

Revised: 3/1/22 – annual review, updated referenced policies & covered LOBs



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 590.0

**SECTION: Commercial Drug
SUBJECT: Nuzyra**

Applicable line of business:

Commercial	X	Medicaid	
Medicare		ACA	X
GHP Kids	X	Self-Insured	X

POLICY:

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for Nuzyra for GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 487.0 Quantity Limit Exceptions

REQUIRED DEFINITIONS:

1. **Attachment** – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. **Exhibit** – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. **Devised** – the date the policy was implemented.
4. **Revised** – the date of every revision to the policy, including typographical and grammatical changes.
5. **Reviewed** – the date documenting the annual review if the policy has no revisions necessary.

ADDITIONAL DEFINITIONS:

1. **Formulary** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. **Non-formulary products** – those medications that are not included in the Formulary.
3. **Healthcare provider** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
4. **NCQA** – National Committee for Quality Assurance.
5. **Medically Necessary or Medical Necessity** – covered services rendered by a provider that the Health Plan determines are:

- A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
- B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
- C. In accordance with current standards of medical practice;
- D. Not primarily for the convenience of the Member, or the Member's Provider; and
- E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

PROCEDURE:

An exception for coverage of Nuzyra may be made for members who meet the following criteria:

- Medical record documentation that Nuzyra is prescribed by or in consultation with infectious disease **AND**
- Medical record documentation of age greater than or equal to 18 years **AND**
- Medical record documentation of one of the following:
 - Diagnosis of Community-acquired bacterial pneumonia caused by *Streptococcus pneumoniae*, *Staphylococcus aureus* (methicillin-susceptible isolates), *Haemophilus influenzae*, *Haemophilus parainfluenzae*, *Klebsiella pneumoniae*, *Legionella pneumophila*, *Mycoplasma pneumoniae*, and *Chlamydophila pneumoniae* **OR**
 - Diagnosis of an acute bacterial skin and skin structure infection (including cellulitis/erysipelas, wound infection, and major cutaneous abscess) caused by *Staphylococcus aureus* (methicillin-susceptible and -resistant isolates), *Staphylococcus lugdunensis*, *Streptococcus pyogenes*, *Streptococcus anginosus* grp. (includes *S. anginosus*, *S. intermedius*, and *S. constellatus*), *Enterococcus faecalis*, *Enterobacter cloacae*, and *Klebsiella pneumoniae* **AND**
- Medical record documentation of a culture and sensitivity showing the member's infection is not susceptible to alternative antibiotic treatment **OR** documented history of previous intolerance to or contraindication to three (3) alternative antibiotics shown to be susceptible on the culture and sensitivity **OR**
- Medical record documentation that treatment with Nuzyra was initiated during an inpatient stay

MEDISPAN AUTHORIZATION LEVEL: GPI-12

QUANTITY LIMIT: *No QLs need to be entered within the authorization unless the requested quantity exceeds the QL.*

- QL FOR LETTER ONLY: 30 tablets per 14 days

AUTHORIZATION DURATION: 14 days

If a formulary exception is approved, Nuzyra will be paid for under the member's prescription drug benefit.

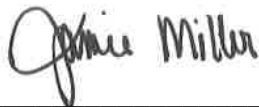
Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.

FORMULARY ALTERNATIVES:

amoxicillin, azithromycin, cephalexin, clarithromycin, doxycycline, erythromycin, levofloxacin, linezolid, moxifloxacin, penicillin, vancomycin capsules, Firvanq

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE
STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND
FEDERAL REGULATORY ENTITIES.**

**THIS POLICY WILL BE REVISED AS NECESSARY AND
REVIEWED NO LESS THAN ANNUALLY.**



Signed: _____

Title: Director, Pharmacy Services

Date: March 1, 2022

Devised: 11/20/19

Revised: 3/1/20 – annual review, added GHP Kids

Revised: 3/1/21 – annual review, updated logo, added MediSpan approval level, updated QL statement

Revised: 3/1/22 – annual review, updated referenced policies & covered LOBs



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 591.0

**SECTION: Commercial Drug
SUBJECT: Nayzilam**

Applicable line of business:

Commercial	X	Medicaid	
Medicare		ACA	X
GHP Kids	X	Self-Insured	X

POLICY:

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for Nayzilam for GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 487.0 Quantity Limit Exceptions

REQUIRED DEFINITIONS:

1. **Attachment** – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. **Exhibit** – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. **Devised** – the date the policy was implemented.
4. **Revised** – the date of every revision to the policy, including typographical and grammatical changes.
5. **Reviewed** – the date documenting the annual review if the policy has no revisions necessary.

ADDITIONAL DEFINITIONS:

1. **Formulary** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. **Non-formulary products** – those medications that are not included in the Formulary.
3. **Healthcare provider** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
4. **NCQA** – National Committee for Quality Assurance.
5. **Medically Necessary or Medical Necessity** – covered services rendered by a provider that the Health Plan determines are:



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 591.0

**SECTION: Commercial Drug
SUBJECT: Nayzilam**

- A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
- B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
- C. In accordance with current standards of medical practice;
- D. Not primarily for the convenience of the Member, or the Member's Provider; and
- E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

PROCEDURE:

An exception for coverage of Nayzilam may be made for members who meet the following criteria:

- Medical record documentation of age greater than or equal to 12 years
OR
- Medical record documentation that the safety and effectiveness of use for the prescribed indication is supported by Food and Drug Administration (FDA) approval or adequate medical and scientific evidence in the medical literature **AND**
- For members at least 2 years of age: medical record documentation of why diazepam rectal gel cannot be used

MEDISPAN AUTHORIZATION LEVEL: GPI-12

QUANTITY LIMIT: *No QLs need to be entered within the authorization unless the requested quantity exceeds the QL.*

- **QL FOR LETTER ONLY:** 10 nasal spray units per 30 days

If a formulary exception is approved, Nayzilam will be paid for under the member's prescription drug benefit.

Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.

FORMULARY ALTERNATIVES:

diazepam rectal gel



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 591.0

**SECTION: Commercial Drug
SUBJECT: Nayzilam**

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE
STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND
FEDERAL REGULATORY ENTITIES.**

**THIS POLICY WILL BE REVISED AS NECESSARY AND
REVIEWED NO LESS THAN ANNUALLY.**

Signed: _____

Title: Director, Pharmacy Services

Date: March 1, 2022

Devised: 11/20/19
Revised: 3/1/20 – annual review, added GHP Kids
Revised: 3/1/21 – annual review, updated logo, added MediSpan approval level, updated QL statement
Revised: 3/1/22 – annual review, updated referenced policies & covered LOBs



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 592.0

**SECTION: Commercial Drug
SUBJECT: Nucala for Self-
Administration**

Applicable line of business:

Commercial	X	Medicaid	
Medicare		ACA	X
GHP Kids	X	Self-Insured	X

POLICY:

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for Nucala for self-administration for GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 487.0 Quantity Limit Exceptions

REQUIRED DEFINITIONS:

1. **Attachment** – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. **Exhibit** – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
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4. **Revised** – the date of every revision to the policy, including typographical and grammatical changes.
5. **Reviewed** – the date documenting the annual review if the policy has no revisions necessary.

ADDITIONAL DEFINITIONS:

1. **Formulary** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. **Non-formulary products** – those medications that are not included in the Formulary.
3. **Healthcare provider** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
4. **NCQA** – National Committee for Quality Assurance.
5. **Medically Necessary or Medical Necessity** – covered services rendered by a provider that the Health Plan determines are:



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 592.0

**SECTION: Commercial Drug
SUBJECT: Nucala for Self-
Administration**

- A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
- B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
- C. In accordance with current standards of medical practice;
- D. Not primarily for the convenience of the Member, or the Member's Provider; and
- E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

PROCEDURE:

An exception for coverage of Nucala for self-administration may be made for members who meet the following criteria:

Severe Eosinophilic Asthma

- Medical record documentation that Nucala is prescribed by an allergist or pulmonologist **AND**
- Medical record documentation of age greater than or equal to 12 years **AND**
- Medical record documentation of a diagnosis of severe eosinophilic asthma **AND** that Nucala is being used as add-on maintenance treatment **AND**
- Medical record documentation of a blood eosinophil count of either greater than 300 cells/mcL during the 12-month period before screening and/or greater than 150 cells/mcL within 3 months of the start of therapy **AND**
- Medical record documentation of:
 - Intolerance to or not well controlled or very poorly controlled symptoms* despite at least a 3- month trial of: high-dose inhaled corticosteroids and/or oral systemic corticosteroids plus a long-acting beta agonist **OR**
 - Two or more exacerbations in the previous 12 months requiring additional medical treatment (oral corticosteroids, emergency department or urgent care visits, or hospitalization) despite current therapy with high-dose inhaled corticosteroids plus a long-acting beta agonist **AND**
- Medical record documentation that member is adherent to current therapeutic regimen and must demonstrate appropriate inhaler technique **AND**
- Medical record documentation that known environmental triggers within the member's control have been eliminated **AND**
- Medical record documentation that Nucala will not be used in combination with another biologic medication indicated for asthma treatment (e.g., Xolair, Fasenna, Dupixent, Cinqair, or Tezspire)



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 592.0

**SECTION: Commercial Drug
SUBJECT: Nucala for Self-
Administration**

***Measures of disease severity**

Measure	Not Well Controlled	Very Poorly Controlled
Symptoms	> 2 days per week	Throughout the day
Nighttime awakenings	1-3x/week	> 4x/week
Interference with normal activity	Some limitation	Extremely limited
SABA use for symptom control (not to prevent exercise-induced bronchospasm)	> 2 days/week	Several times per day
FEV1 (% predicted) or peak flow (% personal best)	60-80%	< 60%
Asthma Control Test (ACT) Score	16-19	< 15

MEDISPAN AUTHORIZATION LEVEL: GPI-10

QUANTITY LIMIT: *QL must be entered within the authorization.*

- **QL FOR LETTER & AUTHORIZATION:** 1 prefilled syringe or 1 autoinjector (100 mg) per 28 days

AUTHORIZATION DURATION: Initial approval will be for 12 months or less if the reviewing provider feels it is medically appropriate. Subsequent approvals will be for an additional 12 months or less if the reviewing provider feels it is medically appropriate and will require medical record documentation of continued disease improvement or lack of disease progression. The medication will no longer be covered if patient experiences toxicity or worsening of disease.

Eosinophilic Granulomatosis (EGPA)

- Medical record documentation that Nucala is prescribed by an allergist/immunologist, pulmonologist, and/or rheumatologist **AND**
- Medical record documentation of age greater than or equal to 18 years **AND**
- Medical record documentation of eosinophilic granulomatosis (EGPA) confirmed by biopsy evidence of vasculitis **AND** at least four (4) of the following criteria:
 - Asthma (a history of wheezing or the finding of diffuse high-pitched wheezes on expiration)
 - Eosinophilia (blood eosinophil level of $\geq 10\%$ or ≥ 1500 cells/microL on differential white blood cell count)
 - Mononeuropathy (including multiplex) or polyneuropathy
 - Migratory or transient pulmonary opacities detected radiographically
 - Paranasal sinus abnormality
 - Biopsy containing a blood vessel showing the accumulation of eosinophils in extravascular areas

AND

- Medical record documentation of a therapeutic failure on, contraindication to, or intolerance to systemic glucocorticoid therapy **AND** at least one immunosuppressant therapy (cyclophosphamide, azathioprine, methotrexate)

MEDISPAN AUTHORIZATION LEVEL: GPI-10

QUANTITY LIMIT: QL must be entered within the authorization.

- **QL FOR LETTER & AUTHORIZATION:** 3 prefilled syringes or 3 autoinjectors (300 mg) per 28 days

AUTHORIZATION DURATION: Initial approval will be for 12 months or less if the reviewing provider feels it is medically appropriate. Subsequent approvals will be for an additional 12 months or less if the reviewing provider feels it is medically appropriate and will require medical record documentation of continued disease improvement or lack of disease progression. The medication will no longer be covered if patient experiences toxicity or worsening of disease.



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 592.0

**SECTION: Commercial Drug
SUBJECT: Nucala for Self-
Administration**

Hypereosinophilic Syndrome (HES)

- Medical record documentation of age greater than or equal to 12 years **AND**
- Medical record documentation of a diagnosis of hypereosinophilic syndrome (HES) for greater than or equal to 6 months **AND**
- Medical record documentation that member has been evaluated for and does NOT have an identifiable non-hematologic secondary cause* or FIP1 like 1-platelet derived growth factor receptor (FIP1L1-PDGFR α) kinase-positive hypereosinophilic syndrome (HES) **AND**
- Medical record documentation of a blood eosinophil count of 1,000 cells/mcL or higher **AND**
- Medical record documentation of at least two hypereosinophilic syndrome (HES) flares within the previous 12 months with a worsening of clinical symptoms of HES or increasing blood eosinophil level requiring an escalation in therapy **AND**
- Medical record documentation that member is on stable hypereosinophilic syndrome (HES) therapy including, but not limited to oral corticosteroids, immunosuppressives, or cytotoxic therapy

MEDISPAN AUTHORIZATION LEVEL: GPI-10

QUANTITY LIMIT: *QL must be entered within the authorization.*

- **QL FOR LETTER & AUTHORIZATION:** 3 prefilled syringes or 3 autoinjectors (300 mg) per 28 days

AUTHORIZATION DURATION: Initial approval will be for 12 months or less if the reviewing provider feels it is medically appropriate. Subsequent approvals will be for an additional 12 months or less if the reviewing provider feels it is medically appropriate and will require medical record documentation of continued disease improvement or lack of disease progression. The medication will no longer be covered if patient experiences toxicity or worsening of disease.



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 592.0

**SECTION: Commercial Drug
SUBJECT: Nucala for Self-
Administration**

Chronic Rhinosinusitis with Nasal Polyps (CRSwNP)

- Medical record documentation that Nucala is prescribed by or in consultation with an allergist, pulmonologist, immunologist or otolaryngologist (ENT provider) **AND**
- Medical record documentation of age greater than or equal to 18 years **AND**
- Medical record documentation of a diagnosis of chronic rhinosinusitis with nasal polyps (CRSwNP) **AND**
- Medical record documentation that Nucala will be used as add-on maintenance treatment **AND**
- Medical record documentation of a therapeutic failure on, intolerance to, or contraindication to three (3) intranasal corticosteroids

MEDISPAN AUTHORIZATION LEVEL: GPI-10

QUANTITY LIMIT: *QL must be entered within the authorization.*

- **QL FOR LETTER & AUTHORIZATION:** 1 prefilled syringe or 1 autoinjector (100 mg) per 28 days

AUTHORIZATION DURATION: Initial approval will be for 12 months or less if the reviewing provider feels it is medically appropriate. Subsequent approvals will be for an additional 12 months or less if the reviewing provider feels it is medically appropriate and will require medical record documentation of continued disease improvement or lack of disease progression. The medication will no longer be covered if patient experiences toxicity or worsening of disease.



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 592.0

**SECTION: Commercial Drug
SUBJECT: Nucala for Self-
Administration**

FORMULARY ALTERNATIVES:

Severe Eosinophilic Asthma: dexamethasone, methylprednisolone, prednisone, fluticasone/salmeterol, Breo Ellipta, Dulera, Serevent Diskus, Arnuity Ellipta, Asmanex, Flovent, Pulmicort Flexhaler, QVAR RediHaler

EGPA: dexamethasone, methylprednisolone, prednisone, cyclophosphamide, azathioprine, methotrexate

CRSwNP: fluticasone propionate, triamcinolone acetonide, mometasone furoate

If a formulary exception is approved, Nucala for self-administration will be paid for under the member's prescription drug benefit.

Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE
STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND
FEDERAL REGULATORY ENTITIES.**

**THIS POLICY WILL BE REVISED AS NECESSARY AND
REVIEWED NO LESS THAN ANNUALLY.**

Signed: _____

Title: Director, Pharmacy Services

Date: June 7, 2022

Devised: 11/20/19
Revised: 3/1/20 – annual review, added GHP Kids
Revised: 3/1/21 – annual review, updated logo, added MediSpan approval level, updated QL statement
Revised: 3/26/21 – added HES indication
Revised: 1/5/22 – added CRSwNP indication
Revised: 3/1/22 – annual review, updated referenced policies & covered LOBs
Revised: 4/6/22 – added prescribers for CRSwNP
Revised: 6/7/22 – updated concurrent biologic criterion in asthma indication



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 593.0

**SECTION: Commercial Drug
SUBJECT: Fasenra for Self-
Administration**

Applicable line of business:

Commercial	X	Medicaid	
Medicare		ACA	X
GHP Kids	X	Self-Insured	X

POLICY:

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for Fasenra for self-administration for GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 487.0 Quantity Limit Exceptions

REQUIRED DEFINITIONS:

1. **Attachment** – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. **Exhibit** – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. **Devised** – the date the policy was implemented.
4. **Revised** – the date of every revision to the policy, including typographical and grammatical changes.
5. **Reviewed** – the date documenting the annual review if the policy has no revisions necessary.

ADDITIONAL DEFINITIONS:

1. **Formulary** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. **Non-formulary products** – those medications that are not included in the Formulary.
3. **Healthcare provider** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
4. **NCQA** – National Committee for Quality Assurance.
5. **Medically Necessary or Medical Necessity** – covered services rendered by a provider that the Health Plan determines are:



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 593.0

**SECTION: Commercial Drug
SUBJECT: Fasenra for Self-
Administration**

- A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
- B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
- C. In accordance with current standards of medical practice;
- D. Not primarily for the convenience of the Member, or the Member's Provider; and
- E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

PROCEDURE:

An exception for coverage of Fasenra for self-administration may be made for members who meet the following criteria:

- Medical record documentation that Fasenra is prescribed by an allergist/immunologist or pulmonologist **AND**
- Medical record documentation of age greater than or equal to 12 years **AND**
- Medical record documentation of a diagnosis of severe eosinophilic asthma **AND** that Fasenra is being used as add-on maintenance treatment **AND**
- Medical record documentation of a blood eosinophil count greater than 150 cells/mcL (0.15 x 10E3/uL) within the past 3 months **AND**
- Medical record documentation of:
 - Intolerance to or not well controlled or very poorly controlled symptoms* despite at least a 3-month trial of: high-dose inhaled corticosteroids and/or oral systemic corticosteroids plus a long-acting beta agonist **OR**
 - Two or more exacerbations in the previous 12 months requiring additional medical treatment (oral corticosteroids, emergency department or urgent care visits, or hospitalization) despite current therapy with high-dose inhaled corticosteroids plus a long-acting beta agonist **AND**
- Medical record documentation that member is adherent to current therapeutic regimen and must demonstrate appropriate inhaler technique **AND**
- Medical record documentation that known environmental triggers within the member's control have been eliminated **AND**
- Medical record documentation that Fasenra will not be used in combination with another biologic medication indicated for asthma treatment (e.g., Xolair, Dupixent, Nucala, Cinqair, or Tezspire)



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 593.0

**SECTION: Commercial Drug
SUBJECT: Fasentra for Self-
Administration**

***Measures of disease severity**

Measure	Not Well Controlled	Very Poorly Controlled
Symptoms	> 2 days per week	Throughout the day
Nighttime awakenings	1-3x/week	> 4x/week
Interference with normal activity	Some limitation	Extremely limited
SABA use for symptom control (not to prevent exercise-induced bronchospasm)	> 2 days/week	Several times per day
FEV1 (% predicted) or peak flow (% personal best)	60-80%	< 60%
Asthma Control Test (ACT) Score	16-19	< 15

MEDISPAN AUTHORIZATION LEVEL: GPI-10

QUANTITY LIMIT:

- **Initial Approval** – *Two authorizations must be entered.*
 - Fasentra 30 mg every 4 weeks for the first 3 doses, then once every 8 weeks
 1. In PA Hub: Add PA only.
 2. In Darwin: Add OQL, DS, max number of claims authorized 3, max quantity dispensed 1, min day supply 28, max day supply 28, with a duration of 3 months.
 - QL FOR LETTER: Loading dose: 1 mL per 28 days; Maintenance dose: 1 mL per 56 days
- **Renewal** – *No QLs need to be entered within the authorization unless the requested quantity exceeds the QL.*
 - QL FOR LETTER ONLY: 1 mL per 56 days

AUTHORIZATION DURATION: Initial approval will be for 12 months or less if the reviewing provider feels it is medically appropriate. Subsequent approvals will be for an additional 12 months or less if the reviewing provider feels it is medically appropriate and will require medical record documentation of the following:

- Documentation that patient is not experiencing toxicity or worsening of disease **AND**
- Medical record documentation of at least one of the following:
 - Medical record documentation of continued disease improvement or lack of disease progression as evidenced by a reduction in asthma exacerbations (e.g. reduced use of rescue medications, reduced urgent care visits, reduced hospitalizations) **OR**



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 593.0

**SECTION: Commercial Drug
SUBJECT: Fasenra for Self-
Administration**

- Medical record documentation of decreased oral corticosteroid use (if on maintenance treatment prior to Fasenra initiation)

If a formulary exception is approved, Fasenra for self-administration will be paid for under the member's prescription drug benefit.

Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.

FORMULARY ALTERNATIVES:

dexamethasone, methylprednisolone, prednisone, fluticasone/salmeterol, Breo Ellipta, Dulera, Serevent Diskus, Arnuity Ellipta, Asmanex, Flovent, Pulmicort Flexhaler, QVAR RediHaler

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE
STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND
FEDERAL REGULATORY ENTITIES.**

**THIS POLICY WILL BE REVISED AS NECESSARY AND
REVIEWED NO LESS THAN ANNUALLY.**

Signed: _____

Title: Director, Pharmacy Services

Date: June 7, 2022

Devised: 11/20/19
Revised: 3/1/20 – annual review, added GHP Kids
Revised: 3/1/21 – annual review, updated logo, added MediSpan approval level, updated QL statement
Revised: 3/1/22 – annual review, updated referenced policies & covered LOBs, updated how QL is entered
Revised: 6/7/22 – updated concurrent biologic criterion in asthma indication



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 595.0

**SECTION: Commercial Drug
SUBJECT: Bijuva**

Applicable line of business:

Commercial	X	Medicaid	
Medicare		ACA	X
GHP Kids	X	Self-Insured	X

POLICY:

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for Bijuva for GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 487.0 Quantity Limit Exceptions

REQUIRED DEFINITIONS:

1. **Attachment** – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. **Exhibit** – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. **Devised** – the date the policy was implemented.
4. **Revised** – the date of every revision to the policy, including typographical and grammatical changes.
5. **Reviewed** – the date documenting the annual review if the policy has no revisions necessary.

ADDITIONAL DEFINITIONS:

1. **Formulary** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. **Non-formulary products** – those medications that are not included in the Formulary.
3. **Healthcare provider** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
4. **NCQA** – National Committee for Quality Assurance.
5. **Medically Necessary or Medical Necessity** – covered services rendered by a provider that the Health Plan determines are:



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 595.0

**SECTION: Commercial Drug
SUBJECT: Bijuva**

- A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
- B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
- C. In accordance with current standards of medical practice;
- D. Not primarily for the convenience of the Member, or the Member's Provider; and
- E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

PROCEDURE:

An exception for coverage of Bijuva may be made for members who meet the following criteria:

- Medical record documentation of use for treatment of moderate to severe vasomotor symptoms due to menopause AND
- Medical record documentation of an intact uterus AND
- Medical record documentation of therapeutic failure on, intolerance to, or contraindication to estradiol used in combination with progesterone

MEDISPAN AUTHORIZATION LEVEL: GPI-12

QUANTITY LIMIT: *No QLs need to be entered within the authorization unless the requested quantity exceeds the QL.*

- QL FOR LETTER ONLY: 1 tablet per day

If an exception is made, Bijuva will be paid for under the member's prescription drug benefit.

Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.

FORMULARY ALTERNATIVES:

estradiol (tablets, patches, cream), estradiol/norethindrone, Fyavolv, Lopreeza, medroxyprogesterone, Mimvey Lo, northethindrone/ethinyl estradiol, progesterone, Combipatch, Premarin, Prempro, Premphase

Geisinger

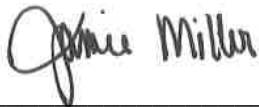
**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 595.0

**SECTION: Commercial Drug
SUBJECT: Bijuva**

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE
STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND
FEDERAL REGULATORY ENTITIES.**

**THIS POLICY WILL BE REVISED AS NECESSARY AND
REVIEWED NO LESS THAN ANNUALLY.**



Signed: _____

Title: Director, Pharmacy Services

Date: March 1, 2022

Devised: 1/16/20

Revised: 3/1/20 – annual review, added GHP Kids

Revised: 3/1/21 – annual review, updated logo, added MediSpan approval level, updated QL statement

Revised: 3/1/22 – annual review, updated referenced policies & covered LOBs



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 596.0

**SECTION: Commercial Drug
SUBJECT: Cequa**

Applicable line of business:

Commercial	X	Medicaid	
Medicare		ACA	X
GHP Kids	X	Self-Insured	X

POLICY:

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for Cequa for GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 487.0 Quantity Limit Exceptions

REQUIRED DEFINITIONS:

1. **Attachment** – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. **Exhibit** – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. **Devised** – the date the policy was implemented.
4. **Revised** – the date of every revision to the policy, including typographical and grammatical changes.
5. **Reviewed** – the date documenting the annual review if the policy has no revisions necessary.

ADDITIONAL DEFINITIONS:

1. **Formulary** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. **Non-formulary products** – those medications that are not included in the Formulary.
3. **Healthcare provider** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
4. **NCQA** – National Committee for Quality Assurance.
5. **Medically Necessary or Medical Necessity** – covered services rendered by a provider that the Health Plan determines are:



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 596.0

**SECTION: Commercial Drug
SUBJECT: Cequa**

- A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
- B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
- C. In accordance with current standards of medical practice;
- D. Not primarily for the convenience of the Member, or the Member's Provider; and
- E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

PROCEDURE:

An exception for coverage of Cequa may be made for members who meet the following criteria:

- Medical record documentation of a diagnosis of keratoconjunctivitis sicca (dry eye).
- Medical record documentation of a therapeutic failure on, intolerance to, or contraindication to Xiidra (lifitegrast) **AND** Restasis (cyclosporine)

MEDISPAN AUTHORIZATION LEVEL: GPI-12

QUANTITY LIMIT: *No QLs need to be entered within the authorization unless the requested quantity exceeds the QL.*

- **QL FOR LETTER ONLY:** 2 vials per day

If a formulary exception is approved, Cequa will be paid for under the member's prescription drug benefit.

Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.

FORMULARY ALTERNATIVES:

Cyclosporine ophthalmic emulsion (generic Restasis), Restasis MultiDose, Xiidra

Geisinger

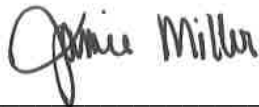
**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 596.0

**SECTION: Commercial Drug
SUBJECT: Cequa**

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE
STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND
FEDERAL REGULATORY ENTITIES.**

**THIS POLICY WILL BE REVISED AS NECESSARY AND
REVIEWED NO LESS THAN ANNUALLY.**



Signed: _____

Title: Director, Pharmacy Services

Date: March 1, 2022

Devised: 1/17/20

Revised: 3/1/20 – annual review, added GHP Kids

Revised: 3/1/21 – annual review, updated logo, added MediSpan approval level, updated QL statement

Revised: 3/1/22 – annual review, updated referenced policies & covered LOBs, updated FA



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 597.0

**SECTION: Commercial Drug
SUBJECT: Drizalma**

Applicable line of business:

Commercial	X	Medicaid	
Medicare		ACA	X
GHP Kids	X	Self-Insured	X

POLICY:

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for Drizalma for GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 487.0 Quantity Limit Exceptions

REQUIRED DEFINITIONS:

1. **Attachment** – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. **Exhibit** – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. **Devised** – the date the policy was implemented.
4. **Revised** – the date of every revision to the policy, including typographical and grammatical changes.
5. **Reviewed** – the date documenting the annual review if the policy has no revisions necessary.

ADDITIONAL DEFINITIONS:

1. **Formulary** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. **Non-formulary products** – those medications that are not included in the Formulary.
3. **Healthcare provider** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
4. **NCQA** – National Committee for Quality Assurance.
5. **Medically Necessary or Medical Necessity** – covered services rendered by a provider that the Health Plan determines are:



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 597.0

**SECTION: Commercial Drug
SUBJECT: Drizalma**

- A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
- B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
- C. In accordance with current standards of medical practice;
- D. Not primarily for the convenience of the Member, or the Member's Provider; and
- E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

PROCEDURE:

New members to the plan already established on therapy may be eligible for continuity of care coverage as long as there is medical record documentation that the safety and effectiveness of use for the prescribed indication is supported by Food and Drug Administration (FDA) approval or adequate medical and scientific evidence in the medical literature.

An exception for coverage of Drizalma may be made for members who meet the following criteria:

- Medical record documentation of one of the following:
 - Medical record documentation major depressive disorder, diabetic peripheral neuropathic pain, chronic musculoskeletal pain, or fibromyalgia in member age greater than or equal to 18 years **OR**
 - Medical record documentation of generalized anxiety disorder in members age greater than or equal to 7 years

AND

- Medical record documentation of difficulty swallowing **OR**
- Medical record documentation of administration through a nasogastric tube **OR**
- Medical record documentation of therapeutic failure on, intolerance to, or contraindication to three (3) formulary alternatives, one of which must be duloxetine capsules

MEDISPAN AUTHORIZATION LEVEL: GPI-12

QUANTITY LIMIT: *No QLs need to be entered within the authorization unless the requested quantity exceeds the QL.*

- **QL FOR LETTER ONLY:** 2 capsules per day



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 597.0

**SECTION: Commercial Drug
SUBJECT: Drizalma**

If an exception is made, Drizalma will be paid for under the member's prescription drug benefit.

Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.

FORMULARY ALTERNATIVES:

Major depressive disorder: duloxetine capsules, amitriptyline, bupropion, citalopram, desvenlafaxine, doxepin, escitalopram, fluoxetine, mirtazapine, nortriptyline, phenelzine, sertraline, trazodone, venlafaxine, desvenlafaxine

Diabetic peripheral neuropathic pain: duloxetine capsules, pregabalin solution

Chronic musculoskeletal pain: duloxetine capsules

Fibromyalgia: duloxetine capsules, pregabalin solution, Savella

Generalized Anxiety Disorder: duloxetine capsules, escitalopram, paroxetine, venlafaxine

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE
STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND
FEDERAL REGULATORY ENTITIES.**

**THIS POLICY WILL BE REVISED AS NECESSARY AND
REVIEWED NO LESS THAN ANNUALLY.**

Signed: _____

Title: Director, Pharmacy Services

Date: March 1, 2022

Devised: 1/17/20

Revised: 3/1/20 – annual review, added GHP Kids

Revised: 3/1/21 – annual review, updated logo, added MediSpan approval level, updated QL statement

Revised: 11/1/21 – added fibromyalgia indication, updated FA

Revised: 3/1/22 – annual review, updated referenced policies & covered LOBs, updated FA



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 598.0

**SECTION: Commercial Drug
SUBJECT: Ezallor**

Applicable line of business:

Commercial	X	Medicaid	
Medicare		ACA	X
GHP Kids	X	Self-Insured	X

POLICY:

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for Ezallor for GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 487.0 Quantity Limit Exceptions

REQUIRED DEFINITIONS:

1. **Attachment** – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. **Exhibit** – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. **Devised** – the date the policy was implemented.
4. **Revised** – the date of every revision to the policy, including typographical and grammatical changes.
5. **Reviewed** – the date documenting the annual review if the policy has no revisions necessary.

ADDITIONAL DEFINITIONS:

1. **Formulary** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. **Non-formulary products** – those medications that are not included in the Formulary.
3. **Healthcare provider** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
4. **NCQA** – National Committee for Quality Assurance.
5. **Medically Necessary or Medical Necessity** – covered services rendered by a provider that the Health Plan determines are:



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 598.0

**SECTION: Commercial Drug
SUBJECT: Ezallor**

- A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
- B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
- C. In accordance with current standards of medical practice;
- D. Not primarily for the convenience of the Member, or the Member's Provider; and
- E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

PROCEDURE:

An exception for coverage of Ezallor may be made for members who meet the following criteria:

- Medical record documentation of difficulty swallowing **OR**
- Medical record documentation of administration through a nasogastric tube **OR**
- Medical record documentation of therapeutic failure on, intolerance to, or contraindication to three (3) formulary alternatives, one of which must be rosuvastatin

MEDISPAN AUTHORIZATION LEVEL: GPI-12

QUANTITY LIMIT: *No QLs need to be entered within the authorization unless the requested quantity exceeds the QL.*

- **QL FOR LETTER ONLY:** 1 capsule per day

If a formulary exception is approved Ezallor will be paid for under the member's prescription drug benefit.

Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.

FORMULARY ALTERNATIVES:

atorvastatin, lovastatin, pravastatin, simvastatin, rosuvastatin



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 598.0

**SECTION: Commercial Drug
SUBJECT: Ezallor**

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE
STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND
FEDERAL REGULATORY ENTITIES.**

**THIS POLICY WILL BE REVISED AS NECESSARY AND
REVIEWED NO LESS THAN ANNUALLY.**

Signed: _____

Title: Director, Pharmacy Services

Date: March 1, 2022

Devised: 1/17/20

Revised: 3/1/20 – annual review, added GHP Kids

Revised: 3/1/21 – annual review, updated logo, added MediSpan approval level, updated QL statement

Revised: 3/1/22 – annual review, updated referenced policies & covered LOBs



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 599.0

**SECTION: Commercial Drug
SUBJECT: Kapsargo**

Applicable line of business:

Commercial	X	Medicaid	
Medicare		ACA	X
GHP Kids	X	Self-Insured	X

POLICY:

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for Kapsargo for GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 487.0 Quantity Limit Exceptions

REQUIRED DEFINITIONS:

1. **Attachment** – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. **Exhibit** – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. **Devised** – the date the policy was implemented.
4. **Revised** – the date of every revision to the policy, including typographical and grammatical changes.
5. **Reviewed** – the date documenting the annual review if the policy has no revisions necessary.

ADDITIONAL DEFINITIONS:

1. **Formulary** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. **Non-formulary products** – those medications that are not included in the Formulary.
3. **Healthcare provider** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
4. **NCQA** – National Committee for Quality Assurance.
5. **Medically Necessary or Medical Necessity** – covered services rendered by a provider that the Health Plan determines are:



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 599.0

**SECTION: Commercial Drug
SUBJECT: Kaspargo**

- A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
- B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
- C. In accordance with current standards of medical practice;
- D. Not primarily for the convenience of the Member, or the Member's Provider; and
- E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

PROCEDURE:

An exception for coverage of Kaspargo may be made for members who meet the following criteria:

- Medical record documentation of difficulty swallowing **OR**
- Medical record documentation of use through nasogastric tube **OR**
- Medical record documentation of a therapeutic failure on, intolerance to, or contraindication to three (3) generic formulary beta-blocking agents, one of which must be metoprolol succinate

MEDISPAN AUTHORIZATION LEVEL: GPI-12

QUANTITY LIMIT: *No QLs need to be entered within the authorization unless the requested quantity exceeds the QL.*

- **QL FOR LETTER ONLY:**
 - 25 mg, 50 mg, and 100 mg capsule: 1 capsule per day
 - 200 mg capsule: 2 capsules per day

If a formulary exception is approved Kaspargo will be paid for under the member's prescription drug benefit.

Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 599.0

**SECTION: Commercial Drug
SUBJECT: Kaspargo**

FORMULARY ALTERNATIVES:

acebutolol, atenolol-chlorthalidone, betaxolol, bisoprolol, bisoprolol-hydrochlorothiazide, carvedilol, labetalol, metoprolol succinate, metoprolol-hydrochlorothiazide, nadolol, nadolol-bendroflumethiazide, pindolol, propranolol, propranolol-hydrochlorothiazide, sotalol, timolol

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE
STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND
FEDERAL REGULATORY ENTITIES.**

**THIS POLICY WILL BE REVISED AS NECESSARY AND
REVIEWED NO LESS THAN ANNUALLY.**

Signed: _____

Title: Director, Pharmacy Services

Date: March 1, 2022

Devised: 1/17/20

Revised: 3/1/20 – annual review, added GHP Kids

Revised: 3/1/21 – annual review, updated logo, added MediSpan approval level, updated QL statement

Revised: 3/1/22 – annual review, updated referenced policies & covered LOBs



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 600.0

**SECTION: Commercial Drug
SUBJECT: Qmiiz ODT**

Applicable line of business:

Commercial	X	Medicaid	
Medicare		ACA	X
GHP Kids	X	Self-Insured	X

POLICY:

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for Qmiiz ODT for GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 487.0 Quantity Limit Exceptions

REQUIRED DEFINITIONS:

1. **Attachment** – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. **Exhibit** – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. **Devised** – the date the policy was implemented.
4. **Revised** – the date of every revision to the policy, including typographical and grammatical changes.
5. **Reviewed** – the date documenting the annual review if the policy has no revisions necessary.

ADDITIONAL DEFINITIONS:

1. **Formulary** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. **Non-formulary products** – those medications that are not included in the Formulary.
3. **Healthcare provider** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
4. **NCQA** – National Committee for Quality Assurance.
5. **Medically Necessary or Medical Necessity** – covered services rendered by a provider that the Health Plan determines are:



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 600.0

**SECTION: Commercial Drug
SUBJECT: Qmiiz ODT**

- A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
- B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
- C. In accordance with current standards of medical practice;
- D. Not primarily for the convenience of the Member, or the Member's Provider; and
- E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

PROCEDURE:

An exception for coverage of Qmiiz ODT may be made for members who meet the following criteria:

- Medical record documentation of one of the following:
 - Medical record documentation of a diagnosis of osteoarthritis or rheumatoid arthritis **OR**
 - Medical record documentation of diagnosis juvenile rheumatoid arthritis in member age greater than or equal to 2 years and weighing at least 60 kg

AND

- Medical record documentation of difficulty swallowing **OR**
- Medical record documentation of a therapeutic failure on, intolerance to, or contraindication to three (3) formulary medications, one of which must be meloxicam

MEDISPAN AUTHORIZATION LEVEL: GPI-12

QUANTITY LIMIT: *No QLs need to be entered within the authorization unless the requested quantity exceeds the QL.*

- **QL FOR LETTER ONLY:** 1 tablet per day

If an exception is made, Qmiiz ODT will be paid for under the member's prescription drug benefit.

Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.



POLICY NUMBER: 600.0

**POLICY AND PROCEDURE
PHARMACY
MANUAL**

**SECTION: Commercial Drug
SUBJECT: Qmiiz ODT**

FORMULARY ALTERNATIVES:

celecoxib, choline salicylate/magnesium salicylate, diclofenac, diclofenac-misoprostol, diflunisal, etodolac, fenoprofen, flurbiprofen, ibuprofen, indomethacin, ketoprofen, meclufenamate sodium, meloxicam, nabumetone, naproxen, oxaprozin, piroxicam, salsalate, sulindac, tolmetin

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE
STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND
FEDERAL REGULATORY ENTITIES.**

**THIS POLICY WILL BE REVISED AS NECESSARY AND
REVIEWED NO LESS THAN ANNUALLY.**

Signed: _____

Title: Director, Pharmacy Services

Date: March 1, 2022

Devised: 1/17/20

Revised: 3/1/20 – annual review, added GHP Kids

Revised: 3/1/21 – annual review, updated logo, added MediSpan approval level, updated QL statement

Revised: 3/1/22 – annual review, updated referenced policies & covered LOBs



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 601.0

**SECTION: Commercial Drug
SUBJECT: Siklos**

Applicable line of business:

Commercial	X	Medicaid	
Medicare		ACA	X
GHP Kids	X	Self-Insured	X

POLICY:

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for Siklos for GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 487.0 Quantity Limit Exceptions

REQUIRED DEFINITIONS:

1. **Attachment** – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. **Exhibit** – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. **Devised** – the date the policy was implemented.
4. **Revised** – the date of every revision to the policy, including typographical and grammatical changes.
5. **Reviewed** – the date documenting the annual review if the policy has no revisions necessary.

ADDITIONAL DEFINITIONS:

1. **Formulary** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. **Non-formulary products** – those medications that are not included in the Formulary.
3. **Healthcare provider** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
4. **NCQA** – National Committee for Quality Assurance.
5. **Medically Necessary or Medical Necessity** – covered services rendered by a provider that the Health Plan determines are:



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 601.0

**SECTION: Commercial Drug
SUBJECT: Siklos**

- A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
- B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
- C. In accordance with current standards of medical practice;
- D. Not primarily for the convenience of the Member, or the Member's Provider; and
- E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

PROCEDURE:

A formulary exception for coverage of Siklos may be made for members who meet the following criteria:

- Medical record documentation that Siklos is prescribed by or in consultation with a hematologist **AND**
- Medical record documentation of the age greater than or equal to 2 years **AND**
- Medical record documentation of a diagnosis of sickle cell anemia **AND**
- Medical record documentation of intolerance to, or contraindication to, or therapeutic failure on a minimum 3 month trial of generic hydroxyurea.

NOTE: Siklos can be dispersed in a small quantity of water in a teaspoon and administered immediately.

- Hydroxyurea is available as 500 mg capsules.
- Droxia (hydroxyurea) is available as 200 mg, 300 mg, 400 mg capsules.
- Siklos is available in 100 mg and 1,000 mg tablets. The 100 mg tablets can be split into 2 parts (50 mg each). The 1,000 mg tablets can be split into 4 parts (250 mg each).

MEDISPAN AUTHORIZATION LEVEL: GPI-12

If a formulary exception is approved Siklos will be paid for under the member's prescription drug benefit.

Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 601.0

**SECTION: Commercial Drug
SUBJECT: Siklos**

FORMULARY ALTERNATIVES:

hydroxyurea

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE
STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND
FEDERAL REGULATORY ENTITIES.**

**THIS POLICY WILL BE REVISED AS NECESSARY AND
REVIEWED NO LESS THAN ANNUALLY.**

Signed: _____

Title: Director, Pharmacy Services

Date: March 1, 2022

Devised: 1/17/20

Revised: 3/1/20 – annual review, added GHP Kids

Revised: 3/1/21 – annual review, updated logo, added MediSpan approval level

Revised: 3/1/22 – annual review, updated referenced policies & covered LOBs



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 602.0

**SECTION: Commercial Drug
SUBJECT: Xelpros**

Applicable line of business:

Commercial	X	Medicaid	
Medicare		ACA	X
GHP Kids	X	Self-Insured	X

POLICY:

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for Xelpros for GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 487.0 Quantity Limit Exceptions

REQUIRED DEFINITIONS:

1. **Attachment** – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. **Exhibit** – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. **Devised** – the date the policy was implemented.
4. **Revised** – the date of every revision to the policy, including typographical and grammatical changes.
5. **Reviewed** – the date documenting the annual review if the policy has no revisions necessary.

ADDITIONAL DEFINITIONS:

1. **Formulary** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. **Non-formulary products** – those medications that are not included in the Formulary.
3. **Healthcare provider** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
4. **NCQA** – National Committee for Quality Assurance.
5. **Medically Necessary or Medical Necessity** – covered services rendered by a provider that the Health Plan determines are:



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 602.0

**SECTION: Commercial Drug
SUBJECT: Xelpros**

- A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
- B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
- C. In accordance with current standards of medical practice;
- D. Not primarily for the convenience of the Member, or the Member's Provider; and
- E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

PROCEDURE:

An exception for coverage of Xelpros may be made for members who meet the following criteria:

- Electronic step therapy of on-line prescription drug claims history showing 15 days use of latanoprost (generic Xalatan) within the previous 180 days. If this electronic step is met, the claim will automatically adjudicate **OR**
- If the electronic step therapy criteria are not met, prescribing provider should request an exception for coverage indicating therapeutic failure on, intolerance to, or contraindication to latanoprost

MEDISPAN AUTHORIZATION LEVEL: GPI-12

If an exception is made, Xelpros will be paid for under the member's prescription drug benefit.

Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.

FORMULARY ALTERNATIVES:

latanoprost (generic Xalatan), travoprost



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 602.0

**SECTION: Commercial Drug
SUBJECT: Xelpros**

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE
STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND
FEDERAL REGULATORY ENTITIES.**

**THIS POLICY WILL BE REVISED AS NECESSARY AND
REVIEWED NO LESS THAN ANNUALLY.**

Signed: _____

Title: Director, Pharmacy Services

Date: March 1, 2022

Devised: 1/17/20

Revised: 3/1/20 – annual review, added GHP Kids

Revised: 3/1/21 – annual review, updated logo, added MediSpan approval level, updated FA

Revised: 3/1/22 – annual review, updated referenced policies & covered LOBs



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 603.0

**SECTION: Commercial Drug
SUBJECT: Zioptan**

Applicable line of business:

Commercial	X	Medicaid	
Medicare		ACA	X
GHP Kids	X	Self-Insured	X

POLICY:

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for Zioptan for GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 487.0 Quantity Limit Exceptions

REQUIRED DEFINITIONS:

1. **Attachment** – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. **Exhibit** – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. **Devised** – the date the policy was implemented.
4. **Revised** – the date of every revision to the policy, including typographical and grammatical changes.
5. **Reviewed** – the date documenting the annual review if the policy has no revisions necessary.

ADDITIONAL DEFINITIONS:

1. **Formulary** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. **Non-formulary products** – those medications that are not included in the Formulary.
3. **Healthcare provider** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
4. **NCQA** – National Committee for Quality Assurance.
5. **Medically Necessary or Medical Necessity** – covered services rendered by a provider that the Health Plan determines are:



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 603.0

**SECTION: Commercial Drug
SUBJECT: Zioptan**

- A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
- B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
- C. In accordance with current standards of medical practice;
- D. Not primarily for the convenience of the Member, or the Member's Provider; and
- E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

PROCEDURE:

An exception for coverage of Zioptan may be made for members who meet the following criteria:

- Medical record documentation of a therapeutic failure on, intolerance to, or contraindication to latanoprost or Xelpros **AND** travoprost

MEDISPAN AUTHORIZATION LEVEL: GPI-12

If an exception is made, Zioptan will be paid for under the member's prescription drug benefit.

Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.

FORMULARY ALTERNATIVES:

latanoprost (generic Xalatan), travoprost, Xelpros*

*step therapy required

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE
STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND
FEDERAL REGULATORY ENTITIES.**

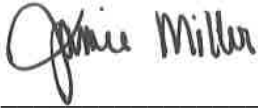
**THIS POLICY WILL BE REVISED AS NECESSARY AND
REVIEWED NO LESS THAN ANNUALLY.**

Geisinger

**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 603.0

**SECTION: Commercial Drug
SUBJECT: Zioptan**



Signed: _____

Title: Director, Pharmacy Services

Date: March 1, 2022

Devised: 1/17/20

Revised: 3/1/20 – annual review, added GHP Kids

Revised: 3/1/20 – annual review, added GHP Kids

Revised: 3/1/21 – annual review, updated logo, added MediSpan approval level, updated Travatan to generic, added ST indicator to Xelpros

Revised: 3/1/22 – annual review, updated referenced policies & covered LOBs



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 604.0

**SECTION: Commercial Drug
SUBJECT: Sympazan**

Applicable line of business:

Commercial	X	Medicaid	
Medicare		ACA	X
GHP Kids	X	Self-Insured	X

POLICY:

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for Sympazan for GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 487.0 Quantity Limit Exceptions

REQUIRED DEFINITIONS:

1. **Attachment** – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. **Exhibit** – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. **Devised** – the date the policy was implemented.
4. **Revised** – the date of every revision to the policy, including typographical and grammatical changes.
5. **Reviewed** – the date documenting the annual review if the policy has no revisions necessary.

ADDITIONAL DEFINITIONS:

1. **Formulary** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. **Non-formulary products** – those medications that are not included in the Formulary.
3. **Healthcare provider** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
4. **NCQA** – National Committee for Quality Assurance.
5. **Medically Necessary or Medical Necessity** – covered services rendered by a provider that the Health Plan determines are:

- A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
- B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
- C. In accordance with current standards of medical practice;
- D. Not primarily for the convenience of the Member, or the Member's Provider; and
- E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

PROCEDURE:

New members to the plan already established on therapy may be eligible for continuity of care coverage as long as there is medical record documentation that the safety and effectiveness of use for the prescribed indication is supported by Food and Drug Administration (FDA) approval or adequate medical and scientific evidence in the medical literature.

An exception for coverage of Sympazan may be made for members who meet the following criteria:

- Medical record documentation of a diagnosis of Lennox-Gastaut syndrome **AND**
- Medical record documentation that Sympazan is being prescribed by or in consultation with a neurologist **AND**
- Medical record documentation of age greater than or equal to 2 years **AND**
- Medical record documentation of a therapeutic failure on, intolerance to, or contraindication to two formulary alternatives, one of which must be clobazam tablets or clobazam oral suspension

MEDISPAN AUTHORIZATION LEVEL: GPI-12

QUANTITY LIMIT: *No QLs need to be entered within the authorization unless the requested quantity exceeds the QL.*

- **QL FOR LETTER ONLY:** 2 films per day



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 604.0

**SECTION: Commercial Drug
SUBJECT: Sympazan**

If an exception is made, Sympazan will be paid for under the member's prescription drug benefit.

Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.

FORMULARY ALTERNATIVES:

clobazam tablets, clobazam suspension, lamotrigine, topiramate, felbamate

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE
STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND
FEDERAL REGULATORY ENTITIES.**

**THIS POLICY WILL BE REVISED AS NECESSARY AND
REVIEWED NO LESS THAN ANNUALLY.**

Signed: _____

Title: Director, Pharmacy Services

Date: March 1, 2022

Devised: 1/17/20

Revised: 3/1/20 – annual review, added GHP Kids

Revised: 3/1/21 – annual review, updated logo, added MediSpan approval level, updated QL statement

Revised: 3/1/22 – annual review, updated referenced policies & covered LOBs



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 605.0

**SECTION: Commercial Drug
SUBJECT: Rinvoq**

Applicable line of business:

Commercial	X	Medicaid	
Medicare		ACA	X
GHP Kids	X	Self-Insured	X

POLICY:

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for Rinvoq for GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 487.0 Quantity Limit Exceptions

REQUIRED DEFINITIONS:

1. **Attachment** – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. **Exhibit** – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. **Devised** – the date the policy was implemented.
4. **Revised** – the date of every revision to the policy, including typographical and grammatical changes.
5. **Reviewed** – the date documenting the annual review if the policy has no revisions necessary.

ADDITIONAL DEFINITIONS:

1. **Formulary** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. **Non-formulary products** – those medications that are not included in the Formulary.
3. **Healthcare provider** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
4. **NCQA** – National Committee for Quality Assurance.
5. **Medically Necessary or Medical Necessity** – covered services rendered by a provider that the Health Plan determines are:



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 605.0

**SECTION: Commercial Drug
SUBJECT: Rinvoq**

- A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
- B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
- C. In accordance with current standards of medical practice;
- D. Not primarily for the convenience of the Member, or the Member's Provider; and
- E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

6. **DMARD** – *disease modifying anti-rheumatic drug*

PROCEDURE:

New members to the plan already established on therapy may be eligible for continuity of care coverage as long as there is medical record documentation that the safety and effectiveness of use for the prescribed indication is supported by Food and Drug Administration (FDA) approval or adequate medical and scientific evidence in the medical literature.

For treatment of rheumatoid arthritis

An exception for coverage of Rinvoq may be made for members who meet the following criteria:

- Medical record documentation that Rinvoq is prescribed by a rheumatologist **AND**
- Medical record documentation of age greater than or equal to 18 years **AND**
- Medical record documentation of a diagnosis of moderate to severe rheumatoid arthritis (made in accordance with the American College of Rheumatology Criteria for the Classification and Diagnosis of Rheumatoid Arthritis) **AND**
- Medical record documentation that Rinvoq is not being used concurrently with a TNF blocker or other biologic agent **AND**
- Medical record documentation of therapeutic failure on, intolerance to, or contraindication to methotrexate

MEDISPAN AUTHORIZATION LEVEL: GPI-14, number of claims authorized = 1, enter for the remainder of the calendar year

QUANTITY LIMIT: *No QLs need to be entered within the authorization unless the requested quantity exceeds the QL.*

1. QL FOR LETTER ONLY: 1 tablet per day, 30 day supply per fill



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 605.0

**SECTION: Commercial Drug
SUBJECT: Rinvoq**

RE-AUTHORIZATION CRITERIA: Rinvoq is configured as a prior authorization for new starts only. Rinvoq will no longer be covered if it is identified that the member is not receiving appropriate follow-up care from the prescribing specialist or if the member has greater than or equal to a 90 day break in therapy.

- Medical record documentation that the member is receiving appropriate follow-up care from the prescribing specialist

FORMULARY ALTERNATIVES:

azathioprine, cyclosporine, hydroxychloroquine, methotrexate, sulfasalazine, leflunomide, Depen, Ridaura



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 605.0

**SECTION: Commercial Drug
SUBJECT: Rinvoq**

For treatment of psoriatic arthritis (PsA)

An exception for coverage of Rinvoq may be made for members who meet the following criteria:

- Medical record documentation of a diagnosis of psoriatic arthritis **AND**
- Medical record documentation that Rinvoq is prescribed by a rheumatologist or dermatologist **AND**
- Medical record documentation of age greater than or equal to 18 years **AND**
- Medical record documentation of either active psoriatic arthritis which must include the following:
 - Documentation of either active psoriatic lesions or a documented history of psoriasis **AND**
- Medical record documentation of therapeutic failure on, intolerance to, or contraindication to at least 3 months of therapy with Cosentyx* **AND** Humira* **AND**
- Medical record documentation that Rinvoq is not being used concurrently with a TNF blocker or other biologic agent

MEDISPAN AUTHORIZATION LEVEL: GPI-14, number of claims authorized = 1, enter for the remainder of the calendar year

QUANTITY LIMIT: *No QLs need to be entered within the authorization unless the requested quantity exceeds the QL.*

2. QL FOR LETTER ONLY: 1 tablet per day, 30 day supply per fill

RE-AUTHORIZATION CRITERIA: Rinvoq is configured as a prior authorization for new starts only. Rinvoq will no longer be covered if it is identified that the member is not receiving appropriate follow-up care from the prescribing specialist or if the member has greater than or equal to a 90 day break in therapy.

- Medical record documentation that the member is receiving appropriate follow-up care from the prescribing specialist

FORMULARY ALTERNATIVES:

Cosentyx*, Humira*

*prior authorization required



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 605.0

**SECTION: Commercial Drug
SUBJECT: Rinvoq**

For treatment of ankylosis spondylitis (AS)

An exception for coverage of Rinvoq may be made for members who meet the following criteria:

- Medical record documentation of a diagnosis of ankylosing spondylitis **AND**
- Medical record documentation that Rinvoq is prescribed by a rheumatologist **AND**
- Medical record documentation of age greater than or equal to 18 years **AND**
- Medical record documentation of therapeutic failure on, intolerance to, or contraindication to at least 3 months of therapy with Cosentyx* **AND** Humira* **AND**
- Medical record documentation that Rinvoq is not being used concurrently with a TNF blocker or other biologic agent

MEDISPAN AUTHORIZATION LEVEL: GPI-14, number of claims authorized = 1, enter for the remainder of the calendar year

QUANTITY LIMIT: *No QLs need to be entered within the authorization unless the requested quantity exceeds the QL.*

3. QL FOR LETTER ONLY: 1 tablet per day, 30 day supply per fill

RE-AUTHORIZATION CRITERIA: Rinvoq is configured as a prior authorization for new starts only. Rinvoq will no longer be covered if it is identified that the member is not receiving appropriate follow-up care from the prescribing specialist or if the member has greater than or equal to a 90 day break in therapy.

- Medical record documentation that the member is receiving appropriate follow-up care from the prescribing specialist

FORMULARY ALTERNATIVES:

Cosentyx*, Humira*

*prior authorization required



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 605.0

**SECTION: Commercial Drug
SUBJECT: Rinvoq**

For treatment of atopic dermatitis (AD)

An exception for coverage of Rinvoq may be made for members who meet the following criteria:

- Medical record documentation of a diagnosis of moderate to severe atopic dermatitis **AND**
- Medical record documentation that Rinvoq is prescribed by an allergist, dermatologist, or immunologist **AND**
- Medical record documentation of age greater than or equal to 12 years **AND**
- Medical record documentation of one of the following:
 - Therapeutic failure on an adequate trial of at least one medium (or higher) potency topical corticosteroid **OR**
 - For members with an intolerance or contraindication to topical corticosteroids or for members in whom topical corticosteroids are inadvisable (use on sensitive areas, age between 2 and 15 years): Therapeutic failure on, intolerance to, or contraindication to a topical calcineurin inhibitor **AND**
- Medical record documentation of contraindication to, intolerance to, or therapeutic failure on an adequate trial of phototherapy (UVA/UVB treatment) **AND**
- Medical record documentation of contraindication to, intolerance to, or therapeutic failure to Dupixent

MEDISPAN AUTHORIZATION LEVEL: GPI-12, number of claims authorized = 1, enter for the remainder of the calendar year

QUANTITY LIMIT: *No QLs need to be entered within the authorization unless the requested quantity exceeds the QL.*

4. QL FOR LETTER ONLY: 1 tablet per day, 30 day supply per fill

RE-AUTHORIZATION CRITERIA: Rinvoq is configured as a prior authorization for new starts only. Rinvoq will no longer be covered if it is identified that the member is not receiving appropriate follow-up care from the prescribing specialist or if the member has greater than or equal to a 90 day break in therapy.

- Medical record documentation that the member is receiving appropriate follow-up care from the prescribing specialist



POLICY NUMBER: 605.0

**POLICY AND PROCEDURE
PHARMACY
MANUAL**

**SECTION: Commercial Drug
SUBJECT: Rinvoq**

FORMULARY ALTERNATIVES:

Dupixent*

Calcineurin Inhibitors: tacrolimus ointment, pimecrolimus cream*

Low-potency topical corticosteroids: alclometasone dipropionate 0.5% cream and ointment (Aclovate); fluocinolone acetonide 0.01% soln. (Synalar); hydrocortisone 2.5% cream, ointment, and lotion (Hytone)

Medium-potency topical corticosteroids: betamethasone valerate 0.1% cream (Valisone); fluocinolone acetonide 0.025% cream and ointment (Synalar); fluticasone propionate 0.05% cream, ointment, and lotion (Cutivate); triamcinolone 0.1% cream, ointment and lotion (Kenalog); triamcinolone acetonide 0.025% cream, ointment and lotion (Kenalog); triamcinolone acetonide 0.147 mg/g aerosol (Kenalog Spray)

High-potency topical corticosteroids: augmented betamethasone dipropionate 0.05% cream (Diprolene AF); betamethasone valerate 0.1% ointment (Valisone); triamcinolone 0.5% cream (Kenalog); fluocinonide 0.05% cream, ointment and gel (Lidex)

Very high-potency topical corticosteroids: augmented betamethasone dipropionate 0.05% ointment, gel and lotion (Diprolene); clobetasol 0.05% cream, ointment, and scalp lotion (Temovate) diflorasone diacetate 0.05% cream and ointment (ApexiCon/Psorcon)

*prior authorization required



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 605.0

**SECTION: Commercial Drug
SUBJECT: Rinvoq**

For treatment of ulcerative colitis (UC)

An exception for coverage of Rinvoq may be made for members who meet the following criteria:

- Medical record documentation of a diagnosis of moderate to severe ulcerative colitis **AND**
- Medical record documentation that Rinvoq is prescribed by a gastroenterologist **AND**
- Medical record documentation of age greater than or equal to 18 years **AND**
- Medical record documentation of therapeutic failure on, intolerance to, or contraindication to at least 3 months of therapy with Humira* **AND**
- Medical record documentation that Rinvoq is not being used concurrently with a TNF blocker or other biologic agent

MEDISPAN AUTHORIZATION LEVEL: GPI-12

QUANTITY LIMIT: 45 mg once daily for 8 weeks

1. In PA Hub: Add PA, OQL, number of claims authorized 1, max quantity dispensed 56 with a duration of 8 weeks
 - QL FOR LETTER: Loading dose: 56 tablets per 180 days; Maintenance dose: 1 tablet per day, 30 day supply per fill

RE-AUTHORIZATION CRITERIA: Rinvoq is configured as a prior authorization for new starts only. Rinvoq will no longer be covered if it is identified that the member is not receiving appropriate follow-up care from the prescribing specialist or if the member has greater than or equal to a 90 day break in therapy.

- Medical record documentation that the member is receiving appropriate follow-up care from the prescribing specialist

FORMULARY ALTERNATIVES:

Humira*

*prior authorization required

If an exception is made, Rinvoq will be paid for under the member's prescription drug benefit.

Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 605.0

**SECTION: Commercial Drug
SUBJECT: Rinvoq**

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE
STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND
FEDERAL REGULATORY ENTITIES.**

**THIS POLICY WILL BE REVISED AS NECESSARY AND
REVIEWED NO LESS THAN ANNUALLY.**

Signed: _____

Title: Director, Pharmacy Services

Date: June 7, 2022

Devised: 1/27/20
Revised: 3/1/20 – annual review, added GHP Kids
Revised: 3/1/21 – annual review, updated logo, added MediSpan approval level, updated QL statement
Revised: 12/2/21 – added one-time PA to approval crit., removed auth duration & added re-auth crit.
Revised: 3/1/22 – annual review, updated referenced policies & covered LOBs
Revised: 6/7/22 – updated RA to GPI-14, added PsA, AS, AD, & UC indications



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 606.0

**SECTION: Commercial Drug
SUBJECT: Trikafta**

Applicable line of business:

Commercial	X	Medicaid	
Medicare		ACA	X
GHP Kids	X	Self-Insured	X

POLICY:

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for Trikafta for GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 487.0 Quantity Limit Exceptions

REQUIRED DEFINITIONS:

1. **Attachment** – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. **Exhibit** – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. **Devised** – the date the policy was implemented.
4. **Revised** – the date of every revision to the policy, including typographical and grammatical changes.
5. **Reviewed** – the date documenting the annual review if the policy has no revisions necessary.

ADDITIONAL DEFINITIONS:

1. **Formulary** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. **Non-formulary products** – those medications that are not included in the Formulary.
3. **Healthcare provider** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
4. **NCQA** – National Committee for Quality Assurance.
5. **Medically Necessary or Medical Necessity** – covered services rendered by a provider that the Health Plan determines are:



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 606.0

**SECTION: Commercial Drug
SUBJECT: Trikafta**

- A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
- B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
- C. In accordance with current standards of medical practice;
- D. Not primarily for the convenience of the Member, or the Member's Provider; and
- E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

PROCEDURE:

A formulary exception for coverage of Trikafta may be made for members who meet the following criteria:

- Medical record documentation of age greater than or equal to 6 years **AND**
- Medical record documentation of a diagnosis of cystic fibrosis **AND**
- Medical record documentation that the medication is prescribed by, or in consultation with, a pulmonologist or a physician who specializes in the treatment of cystic fibrosis **AND**
- Medical record documentation of one of the following, as detected by a Food and Drug Administration (FDA) cleared cystic fibrosis mutation test:
 - Medical record documentation that the patient has at least one F508del mutation in the cystic fibrosis transmembrane conductance regulator (CFTR) gene **OR**
 - Medical record documentation that the patient has a mutation in the cystic fibrosis transmembrane conductance regulator (CFTR) gene that is responsive based on in vitro data per product labeling

MEDISPAN AUTHORIZATION LEVEL: GPI-12

QUANTITY LIMIT: *No QLs need to be entered within the authorization unless the requested quantity exceeds the QL.*

- **QL FOR LETTER ONLY:** 3 tablets per day, 28 day supply per fill

AUTHORIZATION DURATION: Initial approval will be for four (4) months and subsequent approvals will be for twelve (12) months. Additional authorizations will require medical record documentation of improvement or stabilization in the signs and symptoms of cystic fibrosis. The medication will no longer be covered if the member experiences worsening of disease.



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 606.0

**SECTION: Commercial Drug
SUBJECT: Trikafta**

NOTE: List of CFTR mutations that is responsive to Trikafta

3141del9	E822K	G1069R	L967S	R117L	S912L
546insCTA	F191V	G1244E	L997F	R117P	S945L
A46D	F311del	G1249R	L1077P	R170H	S977F
A120T	F311L	G1349D	L1324P	R258G	S1159F
A234D	F508C	H139R	L1335P	R334L	S1159P
A349V	F508C;S1251N [†]	H199Y	L1480P	R334Q	S1251N
A455E	F508del*	H939R	M152V	R347H	S1255P
A554E	F575Y	H1054D	M265R	R347L	T338I
A1006E	F1016S	H1085P	M952I	R347P	T1036N
A1067T	F1052V	H1085R	M952T	R352Q	T1053I
D110E	F1074L	H1375P	M1101K	R352W	V201M
D110H	F1099L	I148T	P5L	R553Q	V232D
D192G	G27R	I175V	P67L	R668C	V456A
D443Y	G85E	I336K	P205S	R751L	V456F
D443Y;G576A;R668C [†]	G126D	I502T	P574H	R792G	V562I
D579G	G178E	I601F	Q98R	R933G	V754M
D614G	G178R	I618T	Q237E	R1066H	V1153E
D836Y	G194R	I807M	Q237H	R1070Q	V1240G
D924N	G194V	I980K	Q359R	R1070W	V1293G
D979V	G314E	I1027T	Q1291R	R1162L	W361R
D1152H	G463V	I1139V	R31L	R1283M	W1098C
D1270N	G480C	I1269N	R74Q	R1283S	W1282R
E56K	G551D	I1366N	R74W	S13F	Y109N
E60K	G551S	K1060T	R74W;D1270N [†]	S341P	Y161D
E92K	G576A	L15P	R74W;V201M [†]	S364P	Y161S
E116K	G576A;R668C [†]	L165S	R74W;V201M;D1270N [†]	S492F	Y563N
E193K	G622D	L206W	R75Q	S549N	Y1014C
E403D	G628R	L320V	R117C	S549R	Y1032C
E474K	G970D	L346P	R117G	S589N	
E588V	G1061R	L453S	R117H	S737F	

* F508del is a responsive CFTR mutation based on both clinical and *in vitro* data [see Clinical Studies (14)].
[†] Complex/compound mutations where a single allele of the CFTR gene has multiple mutations; these exist independent of the presence of mutations on the other allele.

If a formulary exception is approved Trikafta will be paid for under the member's prescription drug benefit.

Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.

FORMULARY ALTERNATIVES:

none



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 606.0

**SECTION: Commercial Drug
SUBJECT: Trikafta**

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE
STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND
FEDERAL REGULATORY ENTITIES.**

**THIS POLICY WILL BE REVISED AS NECESSARY AND
REVIEWED NO LESS THAN ANNUALLY.**

Signed: _____

Title: Director, Pharmacy Services

Date: March 1, 2022

Devised: 1/28/20
Revised: 3/1/20 – annual review, added GHP Kids
Revised: 3/1/21 – annual review, updated logo, added MediSpan approval level, updated QL statement
Revised: 11/24/21 – added CFTR mutations based on *in vitro* data, added chart to note
Revised: 3/1/22 – annual review, updated referenced policies & covered LOBs



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 607.0

**SECTION: Commercial Drug
SUBJECT: Xenleta**

Applicable line of business:

Commercial	X	Medicaid	
Medicare		ACA	X
GHP Kids	X	Self-Insured	X

POLICY:

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for Xenleta for GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 487.0 Quantity Limit Exceptions

REQUIRED DEFINITIONS:

1. **Attachment** – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. **Exhibit** – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. **Devised** – the date the policy was implemented.
4. **Revised** – the date of every revision to the policy, including typographical and grammatical changes.
5. **Reviewed** – the date documenting the annual review if the policy has no revisions necessary.

ADDITIONAL DEFINITIONS:

1. **Formulary** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. **Non-formulary products** – those medications that are not included in the Formulary.
3. **Healthcare provider** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
4. **NCQA** – National Committee for Quality Assurance.
5. **Medically Necessary or Medical Necessity** – covered services rendered by a provider that the Health Plan determines are:



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 607.0

**SECTION: Commercial Drug
SUBJECT: Xenleta**

- A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
- B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
- C. In accordance with current standards of medical practice;
- D. Not primarily for the convenience of the Member, or the Member's Provider; and
- E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

PROCEDURE:

An exception for coverage of Xenleta may be made for members who meet the following criteria:

- Medical record documentation that Xenleta is prescribed by or in consultation with infectious disease **AND**
- Medical record documentation of a diagnosis of community-acquired bacterial pneumonia (CABP) caused by the following susceptible microorganisms: *Streptococcus pneumoniae*, *Staphylococcus aureus* (methicillin-susceptible isolates), *Haemophilus influenzae*, *Legionella pneumophila*, *Mycoplasma pneumoniae*, and *Chlamydomphila pneumoniae* **AND**
- Medical record documentation of age greater than or equal to 18 years **AND**
- Medical record documentation of a culture and sensitivity showing the patient's infection is not susceptible to alternative antibiotic treatments **OR** a documented history of previous intolerance to or contraindication to three (3) alternative antibiotics shown to be susceptible on the culture and sensitivity **OR**
- Medical record documentation that treatment with Xenleta was initiated within an inpatient setting

MEDISPAN AUTHORIZATION LEVEL: GPI-12

QUANTITY LIMIT: *No QLs need to be entered within the authorization unless the requested quantity exceeds the QL.*

- QL FOR LETTER ONLY: 10 tablets per 5 days

AUTHORIZATION DURATION: 5 days



POLICY NUMBER: 607.0

**POLICY AND PROCEDURE
PHARMACY
MANUAL**

**SECTION: Commercial Drug
SUBJECT: Xenleta**

If a formulary exception is approved, Xenleta will be paid for under the member's prescription drug benefit.

Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.

FORMULARY ALTERNATIVES:

amoxicillin, azithromycin, clarithromycin, doxycycline, erythromycin, levofloxacin, moxifloxacin, penicillin

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE
STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND
FEDERAL REGULATORY ENTITIES.**

**THIS POLICY WILL BE REVISED AS NECESSARY AND
REVIEWED NO LESS THAN ANNUALLY.**

Signed: _____

Title: Director, Pharmacy Services

Date: March 1, 2022

Devised: 1/28/20

Revised: 3/1/20 – annual review, added GHP Kids

Revised: 3/1/21 – annual review, updated logo, added MediSpan approval level, updated QL statement

Revised: 3/1/22 – annual review, updated referenced policies & covered LOBs



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 608.0

**SECTION: Commercial Drug
SUBJECT: Brukinsa**

Applicable line of business:

Commercial	X	Medicaid	
Medicare		ACA	X
GHP Kids	X	Self-Insured	X

POLICY:

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for Brukinsa for GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 487.0 Quantity Limit Exceptions

REQUIRED DEFINITIONS:

1. **Attachment** – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. **Exhibit** – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. **Devised** – the date the policy was implemented.
4. **Revised** – the date of every revision to the policy, including typographical and grammatical changes.
5. **Reviewed** – the date documenting the annual review if the policy has no revisions necessary.

ADDITIONAL DEFINITIONS:

1. **Formulary** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. **Non-formulary products** – those medications that are not included in the Formulary.
3. **Healthcare provider** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
4. **NCQA** – National Committee for Quality Assurance.
5. **Medically Necessary or Medical Necessity** – covered services rendered by a provider that the Health Plan determines are:

- A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
- B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
- C. In accordance with current standards of medical practice;
- D. Not primarily for the convenience of the Member, or the Member's Provider; and
- E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

PROCEDURE:

New members to the plan already established on therapy may be eligible for continuity of care coverage as long as there is medical record documentation that the safety and effectiveness of use for the prescribed indication is supported by Food and Drug Administration (FDA) approval or adequate medical and scientific evidence in the medical literature.

An exception for coverage of Brukinsa may be made for members who meet the following criteria:

- Medical record documentation of age greater than or equal to 18 years **AND**
- Medical record documentation that Brukinsa is prescribed by a hematologist or oncologist
- Medical record documentation of a diagnosis of mantle cell lymphoma
- Medical record documentation of therapeutic failure on or intolerance to one prior therapy

MEDISPAN AUTHORIZATION LEVEL: GPI-12

QUANTITY LIMIT: *No QLs need to be entered within the authorization unless the requested quantity exceeds the QL.*

- **QL FOR LETTER ONLY:** 4 capsules per day, 30 day supply per fill

AUTHORIZATION DURATION: Each treatment period will be defined as 12 months. Subsequent approval after 12 months will require documentation of continued disease improvement or lack of disease progression.



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 608.0

**SECTION: Commercial Drug
SUBJECT: Brukinsa**

If a formulary exception is approved, Brukinsa will be paid for under the member's prescription drug benefit.

Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.

FORMULARY ALTERNATIVES:

Imbruvica*, Revlimid*, Calquence*

*prior authorization required

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE
STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND
FEDERAL REGULATORY ENTITIES.**

**THIS POLICY WILL BE REVISED AS NECESSARY AND
REVIEWED NO LESS THAN ANNUALLY.**

Signed: _____

Title: Director, Pharmacy Services

Date: March 1, 2022

Devised: 1/28/20
Revised: 3/1/20 – annual review, added GHP Kids
Revised: 3/1/21 – annual review, updated logo, added MediSpan approval level, updated QL statement
Revised: 3/1/22 – annual review, updated referenced policies & covered LOBs



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 609.0

**SECTION: Commercial Drug
SUBJECT: Enstilar**

Applicable line of business:

Commercial	X	Medicaid	
Medicare		ACA	X
GHP Kids	X	Self-Insured	X

POLICY:

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for Enstilar for GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 487.0 Quantity Limit Exceptions

REQUIRED DEFINITIONS:

1. **Attachment** – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. **Exhibit** – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. **Devised** – the date the policy was implemented.
4. **Revised** – the date of every revision to the policy, including typographical and grammatical changes.
5. **Reviewed** – the date documenting the annual review if the policy has no revisions necessary.

ADDITIONAL DEFINITIONS:

1. **Formulary** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. **Non-formulary products** – those medications that are not included in the Formulary.
3. **Healthcare provider** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
4. **NCQA** – National Committee for Quality Assurance.
5. **Medically Necessary or Medical Necessity** – covered services rendered by a provider that the Health Plan determines are:



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 609.0

**SECTION: Commercial Drug
SUBJECT: Enstilar**

- A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
- B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
- C. In accordance with current standards of medical practice;
- D. Not primarily for the convenience of the Member, or the Member's Provider; and
- E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

PROCEDURE:

An exception for coverage of Enstilar may be made for members who meet the following criteria:

- Medical record documentation of age greater than or equal to 12 years **AND**
- Medical record documentation of a diagnosis of plaque psoriasis **AND**
- Medical record documentation of therapeutic failure, intolerance to, or contraindication to a combination of a topical vitamin D analog and a topical corticosteroid

MEDISPAN AUTHORIZATION LEVEL: GPI-12

If a formulary exception is approved, Enstilar will be paid for under the member's prescription drug benefit.

Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.

FORMULARY ALTERNATIVES:

Vitamin D Analogs: calcipotriene 0.005% cream/ointment*, calcitriol 3 mcg/g ointment*

Low-potency topical corticosteroids: aclometasone dipropionate 0.5% cream and ointment (Aclovate); fluocinolone acetonide 0.01% soln. (Synalar); hydrocortisone 2.5% cream, ointment, and lotion (Hytone)

Medium-potency topical corticosteroids: betamethasone valerate 0.1% cream (Valisone); fluocinolone acetonide 0.025% cream and ointment (Synalar); fluticasone propionate 0.05% cream and lotion (Cutivate); triamcinolone 0.1% cream, ointment and lotion (Kenalog); triamcinolone acetonide 0.025% cream, ointment and lotion (Kenalog); triamcinolone acetonide 0.147 mg/g aerosol (Kenalog Spray)

Geisinger

**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 609.0

**SECTION: Commercial Drug
SUBJECT: Enstilar**

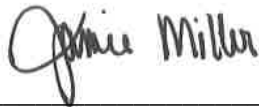
High-potency topical corticosteroids: augmented betamethasone dipropionate 0.05% cream (Diprolene AF) (13 years and older) ; betamethasone valerate 0.1% ointment (Valisone); triamcinolone 0.5% cream (Kenalog); fluocinonide 0.05% cream and ointment (Lidex)

Very high-potency topical corticosteroids: augmented betamethasone dipropionate 0.05% ointment (13 years and older), gel and lotion (Diprolene); clobetasol 0.05% cream, ointment, and scalp lotion (Temovate)

*off-label for under 18 years of age

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE
STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND
FEDERAL REGULATORY ENTITIES.**

**THIS POLICY WILL BE REVISED AS NECESSARY AND
REVIEWED NO LESS THAN ANNUALLY.**



Signed: _____

Title: Director, Pharmacy Services

Date: March 1, 2022

Devised: 9/25/19

Revised: 3/1/20 – annual review, added GHP Kids

Revised: 3/1/21 – annual review, updated logo, added MediSpan approval level

Revised: 3/1/22 – annual review, updated referenced policies & covered LOBs



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 610.0

**SECTION: Commercial Drug
SUBJECT: Vascepa**

Applicable line of business:

Commercial	X	Medicaid	
Medicare		ACA	X
GHP Kids	X	Self-Insured	X

POLICY:

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for Vascepa for GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 487.0 Quantity Limit Exceptions

REQUIRED DEFINITIONS:

1. **Attachment** – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. **Exhibit** – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. **Devised** – the date the policy was implemented.
4. **Revised** – the date of every revision to the policy, including typographical and grammatical changes.
5. **Reviewed** – the date documenting the annual review if the policy has no revisions necessary.

ADDITIONAL DEFINITIONS:

1. **Formulary** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. **Non-formulary products** – those medications that are not included in the Formulary.
3. **Healthcare provider** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
4. **NCQA** – National Committee for Quality Assurance.
5. **Medically Necessary or Medical Necessity** – covered services rendered by a provider that the Health Plan determines are:



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 610.0

**SECTION: Commercial Drug
SUBJECT: Vascepa**

- A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
- B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
- C. In accordance with current standards of medical practice;
- D. Not primarily for the convenience of the Member, or the Member's Provider; and
- E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

PROCEDURE:

An exception for coverage of Vascepa may be made for members who meet the following criteria:

- Medical record documentation of a diagnosis of severe hypertriglyceridemia (triglycerides greater than or equal to 500 mg/dL) **AND**
- Medical record documentation of a therapeutic failure on, intolerance to, or contraindication to omega-3 acid ethyl esters (generic Lovaza)

OR

- Medical record documentation of established cardiovascular disease (documented history of coronary heart disease, cerebrovascular or carotid disease, or peripheral arterial disease) **OR** documentation of a diagnosis of diabetes mellitus and at least **TWO** cardiovascular additional risk factors* **AND**
- Medical record documentation of use in combination with, or an intolerance to, or contraindication to moderate- or high-intensity statin therapy **AND**
- Medical record documentation of a baseline (pre-initiation of Vascepa) triglyceride level greater than or equal to 150 mg/dL

MEDISPAN AUTHORIZATION LEVEL: GPI-12

QUANTITY LIMIT: *No QLs need to be entered within the authorization unless the requested quantity exceeds the QL.*

- **QL FOR LETTER ONLY:**
 - Vascepa 0.5 grams: 8 capsules per day
 - Vascepa 1 gram: 4 capsules per day



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 610.0

**SECTION: Commercial Drug
SUBJECT: Vascepa**

***NOTE:** Cardiovascular Risk Factors

- Age (men ≥ 55 ; women ≥ 65 years of age);
- Cigarette smoker or stopped smoking within 3 months;
- Hypertension (BP ≥ 140 mmHg systolic OR ≥ 90 mmHg diastolic) or on antihypertensive medication;
- HDL-C ≤ 40 mg/dL for men or ≤ 50 mg/dL for women;
- High sensitivity C-Reactive Protein > 3.00 mg/L (0.3 mg/dL);
- CrCL > 30 and < 60 mL/min;
- Retinopathy;
- Micro- or macroalbuminuria;
- ABI < 0.9 without symptoms of intermittent claudication

If a formulary exception is approved Vascepa will be paid for under the member's prescription drug benefit.

Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.

FORMULARY ALTERNATIVES:

atorvastatin, lovastatin, pravastatin, simvastatin, rosuvastatin, omega-3 acid ethyl esters

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE
STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND
FEDERAL REGULATORY ENTITIES.**

**THIS POLICY WILL BE REVISED AS NECESSARY AND
REVIEWED NO LESS THAN ANNUALLY.**

Signed: _____

Title: Director, Pharmacy Services

Date: March 1, 2022

Devised: 1/29/20

Revised: 3/1/20 – annual review, added GHP Kids

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Dev. 1/29/20

Rev. 3/1/22



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 610.0

**SECTION: Commercial Drug
SUBJECT: Vascepa**

Revised: 3/1/21 – annual review, updated logo, added MediSpan approval level, updated QL statement
Revised: 3/1/22 – annual review, updated referenced policies & covered LOBs



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 611.0

**SECTION: Commercial Drug
SUBJECT: Ayvakit**

Applicable line of business:

Commercial	X	Medicaid	
Medicare		ACA	X
GHP Kids	X	Self-Insured	X

POLICY:

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for Ayvakit for GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 487.0 Quantity Limit Exceptions

REQUIRED DEFINITIONS:

1. **Attachment** – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. **Exhibit** – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. **Devised** – the date the policy was implemented.
4. **Revised** – the date of every revision to the policy, including typographical and grammatical changes.
5. **Reviewed** – the date documenting the annual review if the policy has no revisions necessary.

ADDITIONAL DEFINITIONS:

1. **Formulary** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. **Non-formulary products** – those medications that are not included in the Formulary.
3. **Healthcare provider** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
4. **NCQA** – National Committee for Quality Assurance.
5. **Medically Necessary or Medical Necessity** – covered services rendered by a provider that the Health Plan determines are:

- A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
- B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
- C. In accordance with current standards of medical practice;
- D. Not primarily for the convenience of the Member, or the Member's Provider; and
- E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

PROCEDURE:

New members to the plan already established on therapy may be eligible for continuity of care coverage as long as there is medical record documentation that the safety and effectiveness of use for the prescribed indication is supported by Food and Drug Administration (FDA) approval or adequate medical and scientific evidence in the medical literature.

An exception for coverage of Ayvakit may be made for members who meet the following criteria:

Gastrointestinal Stromal Tumor (GIST)

- Medical record documentation of age greater than or equal to 18 years **AND**
- Medical record documentation that Ayvakit is prescribed by a hematologist or oncologist **AND**
- Medical record documentation of unresectable or metastatic gastrointestinal stromal tumor (GIST) **AND**
- Medical record documentation of a platelet-derived growth factor receptor alpha (PDGFRA) exon 18 mutation

Advanced Systemic Mastocytosis (AdvSM)

- Medical record documentation that Ayvakit is prescribed by a hematologist or oncologist **AND**
- Medical record documentation of age greater than or equal to 18 years **AND**
- Medical record documentation of a platelet count greater than or equal to $50 \times 10^9/L$ **AND**
- Medical record documentation of a diagnosis of aggressive systemic mastocytosis (ASM), systemic mastocytosis with an associated hematological neoplasm (SM-AHN), or mast cell leukemia (MCL)

MEDISPAN AUTHORIZATION LEVEL: GPI-12, number of claims authorized = 1, enter for the remainder of the calendar year

QUANTITY LIMIT: *No QLs need to be entered within the authorization unless the requested quantity exceeds the QL.*

- QL FOR LETTER ONLY: 1 tablet per day, 30 day supply per fill

RE-AUTHORIZATION CRITERIA: Ayvakit is configured as a prior authorization for new starts only. Ayvakit will no longer be covered if it is identified that the member is not receiving appropriate follow-up care from the prescribing specialist or if the member has greater than or equal to a 90 day break in therapy.

- Medical record documentation that the member is receiving appropriate follow-up care from the prescribing specialist

If a formulary exception is approved, Ayvakit will be paid for under the member's prescription drug benefit.

Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.

FORMULARY ALTERNATIVES:

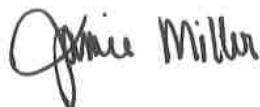
GIST: imatinib*, Sprycel*, Stivarga*, sunitinib*

*prior authorization required

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE
STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND
FEDERAL REGULATORY ENTITIES.**

**THIS POLICY WILL BE REVISED AS NECESSARY AND
REVIEWED NO LESS THAN ANNUALLY.**

Signed: _____



Title: Director, Pharmacy Services



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 611.0

**SECTION: Commercial Drug
SUBJECT: Ayvakit**

Date: March 1, 2022

Devised: 4/9/20
Revised: 3/1/21 – annual review, updated logo, added MediSpan approval level, updated QL statement
Revised: 9/1/21 – added AdvSM indication
Revised: 11/24/21 – added one-time PA to approval crit., removed auth duration & added re-auth crit.
Revised: 3/1/22 – annual review, updated referenced policies & covered LOBs, updated FA



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 612.0

**SECTION: Commercial Drug
SUBJECT: Wakix**

Applicable line of business:

Commercial	X	Medicaid	
Medicare		ACA	X
GHP Kids	X	Self-Insured	X

POLICY:

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for Wakix for GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 487.0 Quantity Limit Exceptions

REQUIRED DEFINITIONS:

1. **Attachment** – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. **Exhibit** – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. **Devised** – the date the policy was implemented.
4. **Revised** – the date of every revision to the policy, including typographical and grammatical changes.
5. **Reviewed** – the date documenting the annual review if the policy has no revisions necessary.

ADDITIONAL DEFINITIONS:

1. **Formulary** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. **Non-formulary products** – those medications that are not included in the Formulary.
3. **Healthcare provider** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
4. **NCQA** – National Committee for Quality Assurance.
5. **Medically Necessary or Medical Necessity** – covered services rendered by a provider that the Health Plan determines are:



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 612.0

**SECTION: Commercial Drug
SUBJECT: Wakix**

- A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
- B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
- C. In accordance with current standards of medical practice;
- D. Not primarily for the convenience of the Member, or the Member's Provider; and
- E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

PROCEDURE:

An exception for coverage of Wakix may be made for members who meet the following criteria:

- Medical record documentation of age greater than or equal to 18 years **AND**
- Medical record documentation of one of the following:
 - Diagnosis of narcolepsy with cataplexy **OR**
 - Diagnosis of excessive daytime sleepiness associated with narcolepsy **AND**
- Medical record documentation of therapeutic failure on, intolerance to, or contraindication to modafinil* or armodafinil **AND** methylphenidate immediate release or amphetamine/dextroamphetamine immediate release

MEDISPAN AUTHORIZATION LEVEL: GPI-12

QUANTITY LIMIT: *No QLs need to be entered within the authorization unless the requested quantity exceeds the QL.*

- QL FOR LETTER ONLY: 2 tablets per day

AUTHORIZATION DURATION:

Initial approval will be for 12 months or less if the reviewing provider feels it is medically appropriate. For continued coverage, the following is required:

- Medical record documentation of reduction in symptoms of excessive daytime sleepiness **OR**
- Medical record documentation of reduction in frequency of cataplexy attacks

After the initial 12 month approval, subsequent approvals will be for a duration of 12 months. Reevaluation will be every 12 months requiring the following:

- Medical record documentation of continued or sustained reduction in symptoms of excessive daytime sleepiness **OR**



**POLICY AND PROCEDURE
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MANUAL**

POLICY NUMBER: 612.0

**SECTION: Commercial Drug
SUBJECT: Wakix**

- Medical record documentation of continued or sustained reduction in frequency of cataplexy attacks

If a formulary exception is approved Wakix will be paid for under the member's prescription drug benefit.

Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.

FORMULARY ALTERNATIVES:

armodafinil*, modafinil*, dextroamphetamine/amphetamine immediate release
methylphenidate immediate release

*prior authorization required

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE
STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND
FEDERAL REGULATORY ENTITIES.**

**THIS POLICY WILL BE REVISED AS NECESSARY AND
REVIEWED NO LESS THAN ANNUALLY.**

Signed: _____

Title: Director, Pharmacy Services

Date: March 1, 2022

Devised: 4/9/20
Revised: 11/18/20 – added authorization duration
Revised: 3/1/21 – annual review, updated logo, added MediSpan approval level, updated QL statement
Revised: 3/26/21 – added narcolepsy with cataplexy indication
Revised: 3/1/22 – annual review, updated referenced policies & covered LOBs



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 613.0

**SECTION: Commercial Drug
SUBJECT: Tazverik**

Applicable line of business:

Commercial	X	Medicaid	
Medicare		ACA	X
GHP Kids	X	Self-Insured	X

POLICY:

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for Tazverik for GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 487.0 Quantity Limit Exceptions

REQUIRED DEFINITIONS:

1. **Attachment** – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. **Exhibit** – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. **Devised** – the date the policy was implemented.
4. **Revised** – the date of every revision to the policy, including typographical and grammatical changes.
5. **Reviewed** – the date documenting the annual review if the policy has no revisions necessary.

ADDITIONAL DEFINITIONS:

1. **Formulary** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. **Non-formulary products** – those medications that are not included in the Formulary.
3. **Healthcare provider** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
4. **NCQA** – National Committee for Quality Assurance.
5. **Medically Necessary or Medical Necessity** – covered services rendered by a provider that the Health Plan determines are:

- A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
- B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
- C. In accordance with current standards of medical practice;
- D. Not primarily for the convenience of the Member, or the Member's Provider; and
- E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

PROCEDURE:

New members to the plan already established on therapy may be eligible for continuity of care coverage as long as there is medical record documentation that the safety and effectiveness of use for the prescribed indication is supported by Food and Drug Administration (FDA) approval or adequate medical and scientific evidence in the medical literature.

An exception for coverage of Tazverik may be made for members who meet the following criteria:

Advanced Epithelioid Sarcoma

- Medical record documentation of age greater than or equal to 16 years **AND**
- Medical record documentation that Tazverik is prescribed by or in consultation with a hematologist or oncologist **AND**
- Medical record documentation of metastatic or locally advanced epithelioid sarcoma **AND**
- Medical record documentation that member is not eligible for complete resection

Relapsed or Refractory Follicular Lymphoma

- Medical record documentation of age greater than or equal to 18 years **AND**
- Medical record documentation that Tazverik is prescribed by or in consultation with a hematologist or oncologist **AND**
- Medical record documentation of relapsed or refractory follicular lymphoma **AND**
- Medical record documentation of one of the following:
 - Documentation of an EXH2 mutation as detected by a Food and Drug Administration (FDA) approved test **AND** documentation that member has received at least two (2) prior systemic therapies **OR**
 - Documentation of no satisfactory alternative treatment options



POLICY NUMBER: 613.0

**POLICY AND PROCEDURE
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**SECTION: Commercial Drug
SUBJECT: Tazverik**

***NOTE:** The FDA-approved test for the detection of EZH2 mutation in relapsed or refractory lymphoma is the cobas EZH2 Mutation Test. The cobas® EZH2 Mutation Test is a real-time allele-specific PCR test for qualitative detection of single nucleotide mutations for Y646N, Y646F or Y646X (Y646H, Y646S, or Y646C), A682G, and A692V of the EZH2 gene.

MEDISPAN AUTHORIZATION LEVEL: GPI-12, number of claims authorized = 1, enter for the remainder of the calendar year

QUANTITY LIMIT: *No QLs need to be entered within the authorization unless the requested quantity exceeds the QL.*

- **QL FOR LETTER ONLY:** 8 tablets per day, 30 day supply per fill

RE-AUTHORIZATION CRITERIA: Tazverik is configured as a prior authorization for new starts only. Tazverik will no longer be covered if it is identified that the member is not receiving appropriate follow-up care from the prescribing specialist or if the member has greater than or equal to a 90 day break in therapy.

- Medical record documentation that the member is receiving appropriate follow-up care from the prescribing specialist

If a formulary exception is approved, Tazverik will be paid for under the member's prescription drug benefit.

Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.

FORMULARY ALTERNATIVES:

none

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE
STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND
FEDERAL REGULATORY ENTITIES.**

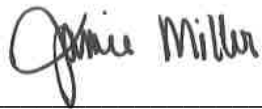
**THIS POLICY WILL BE REVISED AS NECESSARY AND
REVIEWED NO LESS THAN ANNUALLY.**

Geisinger

**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 613.0

**SECTION: Commercial Drug
SUBJECT: Tazverik**



Signed: _____

Title: Director, Pharmacy Services

Date: March 1, 2022

Devised: 4/21/20

Revised: 10/12/20 – added follicular lymphoma indication and note

Revised: 3/1/21 – annual review, updated logo, added MediSpan approval level, updated QL statement

Revised: 12/1/21 – added one-time PA to approval crit., removed auth duration & added re-auth crit.

Revised: 3/1/22 – annual review, updated referenced policies & covered LOBs



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 614.0

**SECTION: Commercial Drug
SUBJECT: Nourianz**

Applicable line of business:

Commercial	X	Medicaid	
Medicare		ACA	X
GHP Kids	X	Self-Insured	X

POLICY:

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for Nourianz for GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 487.0 Quantity Limit Exceptions

REQUIRED DEFINITIONS:

1. **Attachment** – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. **Exhibit** – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. **Devised** – the date the policy was implemented.
4. **Revised** – the date of every revision to the policy, including typographical and grammatical changes.
5. **Reviewed** – the date documenting the annual review if the policy has no revisions necessary.

ADDITIONAL DEFINITIONS:

1. **Formulary** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. **Non-formulary products** – those medications that are not included in the Formulary.
3. **Healthcare provider** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
4. **NCQA** – National Committee for Quality Assurance.
5. **Medically Necessary or Medical Necessity** – covered services rendered by a provider that the Health Plan determines are:



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 614.0

**SECTION: Commercial Drug
SUBJECT: Nourianz**

- A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
- B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
- C. In accordance with current standards of medical practice;
- D. Not primarily for the convenience of the Member, or the Member's Provider; and
- E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

PROCEDURE:

An exception for coverage of Nourianz may be made for members who meet the following criteria:

- Medical record documentation of age greater than or equal to 18 years **AND**
- Medical record documentation that Nourianz is prescribed by or in consultation with a neurologist **AND**
- Medical record documentation of Parkinson's disease with "OFF" episodes or motor fluctuations **AND**
- Medical record documentation that Nourianz will be used as adjunctive treatment to carbidopa/levodopa **AND**
- Medical record documentation of therapeutic failure on, intolerance to, or contraindication to three (3) formulary alternatives

MEDISPAN AUTHORIZATION LEVEL: GPI-12

QUANTITY LIMIT: *No QLs need to be entered within the authorization unless the requested quantity exceeds the QL.*

- **QL FOR LETTER ONLY:** 1 tablet per day

If a formulary exception is approved, Nourianz will be paid for under the member's prescription drug benefit.

Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.

Geisinger

**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 614.0

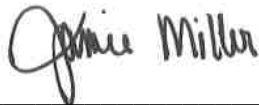
**SECTION: Commercial Drug
SUBJECT: Nourianz**

FORMULARY ALTERNATIVES:

carbidopa/levodopa/entacapone, entacapone, pramipexole, rasagiline, ropinirole, selegiline

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE
STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND
FEDERAL REGULATORY ENTITIES.**

**THIS POLICY WILL BE REVISED AS NECESSARY AND
REVIEWED NO LESS THAN ANNUALLY.**



Signed: _____

Title: Director, Pharmacy Services

Date: March 1, 2022

Devised: 4/21/20

Revised: 3/1/21 – annual review, updated logo, added MediSpan approval level, updated QL statement

Revised: 3/1/22 – annual review, updated referenced policies & covered LOBs



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 615.0

**SECTION: Commercial Drug
SUBJECT: Tolcapone**

Applicable line of business:

Commercial	X	Medicaid	
Medicare		ACA	X
GHP Kids	X	Self-Insured	X

POLICY:

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for tolcapone for GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 487.0 Quantity Limit Exceptions

REQUIRED DEFINITIONS:

1. **Attachment** – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. **Exhibit** – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. **Devised** – the date the policy was implemented.
4. **Revised** – the date of every revision to the policy, including typographical and grammatical changes.
5. **Reviewed** – the date documenting the annual review if the policy has no revisions necessary.

ADDITIONAL DEFINITIONS:

1. **Formulary** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. **Non-formulary products** – those medications that are not included in the Formulary.
3. **Healthcare provider** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
4. **NCQA** – National Committee for Quality Assurance.
5. **Medically Necessary or Medical Necessity** – covered services rendered by a provider that the Health Plan determines are:



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 615.0

**SECTION: Commercial Drug
SUBJECT: Tolcapone**

- A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
- B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
- C. In accordance with current standards of medical practice;
- D. Not primarily for the convenience of the Member, or the Member's Provider; and
- E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

PROCEDURE:

An exception for coverage of tolcapone may be made for members who meet the following criteria:

- Electronic step therapy of on-line prescription drug claims history showing 15 days use of Ongentys **AND** entacapone or carbidopa/levodopa/entacapone within the previous 180 days. If this electronic step is met, the claim will automatically adjudicate **OR**
- If the electronic step therapy criteria are not met, prescribing provider should request an exception for coverage indicating therapeutic failure on, intolerance to, or contraindication to Ongentys **AND** entacapone or carbidopa/levodopa/entacapone

MEDISPAN AUTHORIZATION LEVEL: GPI-12, generic only

If a formulary exception is approved, tolcapone will be paid for under the member's prescription drug benefit.

Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.

FORMULARY ALTERNATIVES:

carbidopa/levodopa/entacapone, entacapone, pramipexole, pramipexole extended release*, rasagiline, ropinirole, selegiline, Apokyn*, Inbrija, Ongentys*

*prior authorization or step therapy required

Geisinger

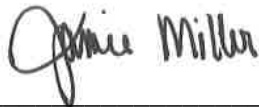
**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 615.0

**SECTION: Commercial Drug
SUBJECT: Tolcapone**

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE
STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND
FEDERAL REGULATORY ENTITIES.**

**THIS POLICY WILL BE REVISED AS NECESSARY AND
REVIEWED NO LESS THAN ANNUALLY.**



Signed: _____

Title: Director, Pharmacy Services

Date: March 1, 2022

Devised: 4/21/20
Revised: 1/22/21 – Added failure of Ongentys to ST, updated FA, added MediSpan approval level
Revised: 3/1/21 – annual review, updated logo
Revised: 3/1/22 – annual review, updated referenced policies & covered LOBs



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 616.0

**SECTION: Commercial Drug
SUBJECT: Pretomanid**

Applicable line of business:

Commercial	X	Medicaid	
Medicare		ACA	X
GHP Kids	X	Self-Insured	X

POLICY:

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for Pretomanid for GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 487.0 Quantity Limit Exceptions

REQUIRED DEFINITIONS:

1. **Attachment** – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. **Exhibit** – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. **Devised** – the date the policy was implemented.
4. **Revised** – the date of every revision to the policy, including typographical and grammatical changes.
5. **Reviewed** – the date documenting the annual review if the policy has no revisions necessary.

ADDITIONAL DEFINITIONS:

1. **Formulary** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. **Non-formulary products** – those medications that are not included in the Formulary.
3. **Healthcare provider** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
4. **NCQA** – National Committee for Quality Assurance.
5. **Medically Necessary or Medical Necessity** – covered services rendered by a provider that the Health Plan determines are:

- A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
- B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
- C. In accordance with current standards of medical practice;
- D. Not primarily for the convenience of the Member, or the Member's Provider; and
- E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

PROCEDURE:

An exception for coverage of Pretomanid may be made for members who meet the following criteria:

- Medical record documentation of age greater than or equal to 18 years **AND**
- Medical record documentation that Pretomanid is prescribed by a physician specializing in infectious disease **AND**
- Medical record documentation of pulmonary infection due to *Mycobacterium tuberculosis* **AND**
- Medical record documentation of one of the following:
 - Extensively drug resistant tuberculosis (XDR-TB) **OR**
 - Treatment-intolerant or nonresponsive multidrug-resistant tuberculosis (TI/NR MDR-TB) **AND**
- Medical record documentation that Pretomanid will be used in combination with Sirturo (bedaquiline) and linezolid

MEDISPAN AUTHORIZATION LEVEL: GPI-12

QUANTITY LIMIT: *No QLs need to be entered within the authorization unless the requested quantity exceeds the QL.*

- QL FOR LETTER ONLY: 1 tablet per day

AUTHORIZATION DURATION: 26 weeks

NOTE:

- TI/NR MDR-TB organisms are resistant to rifampin and isoniazid and possibly additional agents.
- XDR-TB organisms are resistant to isoniazid, rifampin, and fluoroquinolones as well as either aminoglycosides and/or capreomycin.



POLICY NUMBER: 616.0

**POLICY AND PROCEDURE
PHARMACY
MANUAL**

**SECTION: Commercial Drug
SUBJECT: Pretomanid**

If a formulary exception is approved, Pretomanid will be paid for under the member's prescription drug benefit.

Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.

FORMULARY ALTERNATIVES:

moxifloxacin, levofloxacin, linezolid tablets, linezolid suspension*, ethambutol, pyrazinamide, Sirturo*

*prior authorization required

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE
STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND
FEDERAL REGULATORY ENTITIES.**

**THIS POLICY WILL BE REVISED AS NECESSARY AND
REVIEWED NO LESS THAN ANNUALLY.**

Signed: _____

Title: Director, Pharmacy Services

Date: March 1, 2022

Devised: 4/21/20

Revised: 3/1/21 – annual review, updated logo, added MediSpan approval level, updated QL statement

Revised: 3/1/22 – annual review, updated referenced policies & covered LOBs



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 617.0

**SECTION: Commercial Drug
SUBJECT: Valtoco**

Applicable line of business:

Commercial	X	Medicaid	
Medicare		ACA	X
GHP Kids	X	Self-Insured	X

POLICY:

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for Valtoco for GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 487.0 Quantity Limit Exceptions

REQUIRED DEFINITIONS:

1. **Attachment** – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. **Exhibit** – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. **Devised** – the date the policy was implemented.
4. **Revised** – the date of every revision to the policy, including typographical and grammatical changes.
5. **Reviewed** – the date documenting the annual review if the policy has no revisions necessary.

ADDITIONAL DEFINITIONS:

1. **Formulary** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. **Non-formulary products** – those medications that are not included in the Formulary.
3. **Healthcare provider** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
4. **NCQA** – National Committee for Quality Assurance.
5. **Medically Necessary or Medical Necessity** – covered services rendered by a provider that the Health Plan determines are:



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 617.0

**SECTION: Commercial Drug
SUBJECT: Valtoco**

- A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
- B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
- C. In accordance with current standards of medical practice;
- D. Not primarily for the convenience of the Member, or the Member's Provider; and
- E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

PROCEDURE:

New members to the plan already established on therapy may be eligible for continuity of care coverage as long as there is medical record documentation that the safety and effectiveness of use for the prescribed indication is supported by Food and Drug Administration (FDA) approval or adequate medical and scientific evidence in the medical literature.

An exception for coverage of Valtoco may be made for members who meet the following criteria:

- Medical record documentation of age greater than or equal to 6 years **AND**
- Medical record documentation that the safety and effectiveness of use for the prescribed indication is supported by Food and Drug Administration (FDA) approval or adequate medical and scientific evidence in the medical literature **AND**
- For patients are least 2 years of age: medical record documentation of why diazepam rectal gel cannot be used

MEDISPAN AUTHORIZATION LEVEL: GPI-12 (must include 7210003000C4 & 721000300009)

QUANTITY LIMIT: *No QLs need to be entered within the authorization unless the requested quantity exceeds the QL.*

- **QL FOR LETTER ONLY:** 10 nasal spray units per 30 days

If a formulary exception is approved, Valtoco will be paid for under the member's prescription drug benefit.

Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 617.0

**SECTION: Commercial Drug
SUBJECT: Valtoco**

FORMULARY ALTERNATIVES:

diazepam rectal gel, Nayzilam[^], Diastat AcuDial

[^]quantity limits apply

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE
STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND
FEDERAL REGULATORY ENTITIES.**

**THIS POLICY WILL BE REVISED AS NECESSARY AND
REVIEWED NO LESS THAN ANNUALLY.**

Signed: _____

Title: Director, Pharmacy Services

Date: March 1, 2022

Devised: 4/21/20

Revised: 3/1/21 – annual review, updated logo, added MediSpan approval level, updated QL statement

Revised: 3/1/22 – annual review, updated referenced policies & covered LOBs



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 618.0

**SECTION: Commercial Drug
SUBJECT: Caplyta**

Applicable line of business:

Commercial	X	Medicaid	
Medicare		ACA	X
GHP Kids	X	Self-Insured	X

POLICY:

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for Caplyta for GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 487.0 Quantity Limit Exceptions

REQUIRED DEFINITIONS:

1. **Attachment** – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. **Exhibit** – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. **Devised** – the date the policy was implemented.
4. **Revised** – the date of every revision to the policy, including typographical and grammatical changes.
5. **Reviewed** – the date documenting the annual review if the policy has no revisions necessary.

ADDITIONAL DEFINITIONS:

1. **Formulary** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. **Non-formulary products** – those medications that are not included in the Formulary.
3. **Healthcare provider** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
4. **NCQA** – National Committee for Quality Assurance.
5. **Medically Necessary or Medical Necessity** – covered services rendered by a provider that the Health Plan determines are:



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 618.0

**SECTION: Commercial Drug
SUBJECT: Caplyta**

- A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
- B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
- C. In accordance with current standards of medical practice;
- D. Not primarily for the convenience of the Member, or the Member's Provider; and
- E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

PROCEDURE:

New members to the plan already established on therapy may be eligible for continuity of care coverage as long as there is medical record documentation that the safety and effectiveness of use for the prescribed indication is supported by Food and Drug Administration (FDA) approval or adequate medical and scientific evidence in the medical literature.

An exception for coverage of Caplyta may be made for members who meet the following criteria:

Schizophrenia

- Medical record documentation of age greater than or equal to 18 years **AND**
- Medical record documentation of a diagnosis of schizophrenia **AND**
- Medical record documentation of therapeutic failure on, intolerance to, or contraindication to three (3) formulary atypical antipsychotics **OR**
- Medical record documentation of therapeutic failure on, intolerance to, or contraindication to ziprasidone **AND** aripiprazole for members with metabolic syndrome

Bipolar Depression

- Medical record documentation of age greater than or equal to 18 years **AND**
- Medical record documentation of a diagnosis of depressive episodes associated with bipolar I or bipolar II disorder (bipolar depression) **AND**
- Medical record documentation of therapeutic failure on, intolerance to, or contraindication to quetiapine

MEDISPAN AUTHORIZATION LEVEL: GPI-12



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 618.0

**SECTION: Commercial Drug
SUBJECT: Caplyta**

QUANTITY LIMIT: *No QLs need to be entered within the authorization unless the requested quantity exceeds the QL.*

- **QL FOR LETTER ONLY:** 1 capsule per day

If a formulary exception is approved, Caplyta will be paid for under the member's prescription drug benefit.

Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.

FORMULARY ALTERNATIVES:

Schizophrenia: aripiprazole, olanzapine, quetiapine, risperidone, ziprasidone

Bipolar Depression: quetiapine

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE
STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND
FEDERAL REGULATORY ENTITIES.**

**THIS POLICY WILL BE REVISED AS NECESSARY AND
REVIEWED NO LESS THAN ANNUALLY.**

Signed: _____

Title: Director, Pharmacy Services

Date: March 1, 2022

Devised: 4/21/20

Revised: 3/1/21 – annual review, updated logo, added MediSpan approval level, updated QL statement

Revised: 3/1/22 – annual review, updated referenced policies & covered LOBs, added bipolar depression



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 619.0

**SECTION: Commercial Drug
SUBJECT: Abilify Mycite**

Applicable line of business:

Commercial	X	Medicaid	
Medicare		ACA	X
GHP Kids	X	Self-Insured	X

POLICY:

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for Abilify Mycite for GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 487.0 Quantity Limit Exceptions

REQUIRED DEFINITIONS:

1. **Attachment** – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. **Exhibit** – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
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4. **Revised** – the date of every revision to the policy, including typographical and grammatical changes.
5. **Reviewed** – the date documenting the annual review if the policy has no revisions necessary.

ADDITIONAL DEFINITIONS:

1. **Formulary** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. **Non-formulary products** – those medications that are not included in the Formulary.
3. **Healthcare provider** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
4. **NCQA** – National Committee for Quality Assurance.
5. **Medically Necessary or Medical Necessity** – covered services rendered by a provider that the Health Plan determines are:



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 619.0

**SECTION: Commercial Drug
SUBJECT: Abilify Mycite**

- A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
- B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
- C. In accordance with current standards of medical practice;
- D. Not primarily for the convenience of the Member, or the Member's Provider; and
- E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

PROCEDURE:

New members to the plan already established on therapy may be eligible for continuity of care coverage as long as there is medical record documentation that the safety and effectiveness of use for the prescribed indication is supported by Food and Drug Administration (FDA) approval or adequate medical and scientific evidence in the medical literature.

An exception for coverage of Abilify Mycite may be made for members who meet the following criteria:

- Medical record documentation of age greater than or equal to 18 years **AND**
- Medical record documentation of one of the following:
 - Diagnosis of schizophrenia **OR**
 - Diagnosis of use for acute treatment of manic and mixed episodes or maintenance treatment of Bipolar I disorder as monotherapy or as adjunct to lithium or valproate **OR**
 - Diagnosis of use as adjunctive treatment of major depressive disorder

AND

- Medical record documentation of a history of poor adherence to oral medications and documentation that education to improve adherence has been attempted **AND**
- Medical record documentation of access to a compatible smart phone **AND**
- Medical record documentation of one of the following:
 - For schizophrenia and bipolar I disorder:
 - Medical record documentation of reason why aripiprazole oral tablets **AND** Abilify Maintena cannot be used

OR

- For major depressive disorder (MDD)
 - Medical record documentation of reason why aripiprazole oral tablets cannot be used



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 619.0

**SECTION: Commercial Drug
SUBJECT: Abilify Mycite**

MEDISPAN AUTHORIZATION LEVEL: GPI-12

QUANTITY LIMIT: *No QLs need to be entered within the authorization unless the requested quantity exceeds the QL.*

- **QL FOR LETTER ONLY:** 1 tablet per day

AUTHORIZATION DURATION: Initial authorizations for Abilify Mycite will be approved for a period of 12 months. Reauthorizations will be for a period of 12 months each provided the following criteria are met:

- Claims history and attestation from the provider showing the patient is adherent to Abilify Mycite **OR** continued need to monitor drug ingestion **AND**
- Medical record documentation of one of the following:
 - For schizophrenia and bipolar I disorder:
 - Medical record documentation or reason why aripiprazole oral tablets **AND** Abilify Maintena cannot be used **OR**
 - For major depressive disorder (MDD):
 - Medical record documentation of reason why aripiprazole oral tablets cannot be used

If a formulary exception is approved, Abilify Mycite will be paid for under the member's prescription drug benefit.

Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.

FORMULARY ALTERNATIVES:

aripiprazole, clozapine, olanzapine, quetiapine, risperidone, ziprasidone

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE
STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND
FEDERAL REGULATORY ENTITIES.**

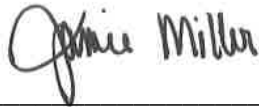
**THIS POLICY WILL BE REVISED AS NECESSARY AND
REVIEWED NO LESS THAN ANNUALLY.**

Geisinger

**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 619.0

**SECTION: Commercial Drug
SUBJECT: Abilify Mycite**



Signed: _____

Title: Director, Pharmacy Services

Date: March 1, 2022

Devised: 5/29/20

Revised: 7/29/20 – added alternative criteria to reauthorization

Revised: 3/1/21 – annual review, updated logo, added MediSpan approval level, updated QL statement

Revised: 3/1/22 – annual review, updated referenced policies & covered LOBs



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 620.0

**SECTION: Commercial Drug
SUBJECT: Consensi**

Applicable line of business:

Commercial	X	Medicaid	
Medicare		ACA	X
GHP Kids	X	Self-Insured	X

POLICY:

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for Consensi for GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 487.0 Quantity Limit Exceptions

REQUIRED DEFINITIONS:

1. **Attachment** – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. **Exhibit** – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. **Devised** – the date the policy was implemented.
4. **Revised** – the date of every revision to the policy, including typographical and grammatical changes.
5. **Reviewed** – the date documenting the annual review if the policy has no revisions necessary.

ADDITIONAL DEFINITIONS:

1. **Formulary** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. **Non-formulary products** – those medications that are not included in the Formulary.
3. **Healthcare provider** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
4. **NCQA** – National Committee for Quality Assurance.
5. **Medically Necessary or Medical Necessity** – covered services rendered by a provider that the Health Plan determines are:



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 620.0

**SECTION: Commercial Drug
SUBJECT: Consensi**

- A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
- B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
- C. In accordance with current standards of medical practice;
- D. Not primarily for the convenience of the Member, or the Member's Provider; and
- E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

PROCEDURE:

An exception for coverage of Consensi may be made for members who meet the following criteria:

- Medical record documentation of therapeutic failure or intolerance to an adequate trial of three (3) combinations of formulary NSAID **AND** calcium-channel blocker therapies, one of which must be amlodipine and celecoxib used in combination

MEDISPAN AUTHORIZATION LEVEL: GPI-12

QUANTITY LIMIT: *No QLs need to be entered within the authorization unless the requested quantity exceeds the QL.*

- **QL FOR LETTER ONLY:** 1 tablet per day

If a formulary exception is approved, Consensi will be paid for under the member's prescription drug benefit.

Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 620.0

**SECTION: Commercial Drug
SUBJECT: Consensi**

FORMULARY ALTERNATIVES:

Calcium-Channel Blockers: amlodipine, felodipine extended release, nifedipine extended release

NSAIDs: celecoxib, choline magnesium salicylate, diclofenac, diclofenac extended release, diflunisal, etodolac, etodolac extended release, fenoprofen, flurbiprofen, ibuprofen, indomethacin, indomethacin sustained release, ketoprofen, ketorolac, meclofenamate, meloxicam, nabumetone, naproxen, naproxen sodium, naproxen EC, oxaprozin, piroxicam, salsalate, sulindac, tolmetin

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE
STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND
FEDERAL REGULATORY ENTITIES.**

**THIS POLICY WILL BE REVISED AS NECESSARY AND
REVIEWED NO LESS THAN ANNUALLY.**

Signed: _____

Title: Director, Pharmacy Services

Date: March 1, 2022

Devised: 5/29/20

Revised: 3/1/21 – annual review, updated logo, added MediSpan approval level, updated QL statement

Revised: 3/1/22 – annual review, updated referenced policies & covered LOBs



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 621.0

**SECTION: Commercial Drug
SUBJECT: Koselugo**

Applicable line of business:

Commercial	X	Medicaid	
Medicare		ACA	X
GHP Kids	X	Self-Insured	X

POLICY:

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for Koselugo for GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 487.0 Quantity Limit Exceptions

REQUIRED DEFINITIONS:

1. **Attachment** – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
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4. **Revised** – the date of every revision to the policy, including typographical and grammatical changes.
5. **Reviewed** – the date documenting the annual review if the policy has no revisions necessary.

ADDITIONAL DEFINITIONS:

1. **Formulary** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. **Non-formulary products** – those medications that are not included in the Formulary.
3. **Healthcare provider** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
4. **NCQA** – National Committee for Quality Assurance.
5. **Medically Necessary or Medical Necessity** – covered services rendered by a provider that the Health Plan determines are:

- A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
- B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
- C. In accordance with current standards of medical practice;
- D. Not primarily for the convenience of the Member, or the Member's Provider; and
- E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

PROCEDURE:

New members to the plan already established on therapy may be eligible for continuity of care coverage as long as there is medical record documentation that the safety and effectiveness of use for the prescribed indication is supported by Food and Drug Administration (FDA) approval or adequate medical and scientific evidence in the medical literature.

An exception for coverage of Koselugo may be made for members who meet the following criteria:

- Medical record documentation that Koselugo is prescribed by or in consultation with at least one of the following:
 - Pediatric oncologist
 - Pediatric neurologist
 - Pediatric geneticist **AND**
- Medical record documentation of age greater than or equal to 2 years **AND**
- Medical record documentation of neurofibromatosis type 1 as defined by a positive *NF1* mutation **OR** two of the following:
 - Diagnosis of schizophrenia **OR**
 - Six or more brown oval/circular spots on the skin called café-au-lait macules (> 5 mm diameter in prepubertal individuals and > 15 mm in post-pubertal individuals)
 - Freckling in axillary or inguinal regions
 - Two or more neurofibromas of any type, or one plexiform neurofibroma
 - A tumor of the nerve to the eye called optic glioma
 - Two or more Lisch nodules (iris hamartomas)
 - A distinctive osseous lesion (sphenoid dysplasia or tibial pseudarthrosis)
 - A first degree relative with *NF1*

AND



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 621.0

**SECTION: Commercial Drug
SUBJECT: Koselugo**

- Medical record documentation of symptomatic, inoperable* plexiform neurofibromas (PN)

MEDISPAN AUTHORIZATION LEVEL: GPI-12, number of claims authorized = 1, enter for the remainder of the calendar year

QUANTITY LIMIT: *No QLs need to be entered within the authorization unless the requested quantity exceeds the QL.*

- **QL FOR LETTER ONLY:**
 - 10 mg capsules: 8 capsules per day, 30 day supply per fill
 - 25 mg capsules: 4 capsules per day, 30 day supply per fill

RE-AUTHORIZATION CRITERIA: Koselugo is configured as a prior authorization for new starts only. Koselugo will no longer be covered if it is identified that the member is not receiving appropriate follow-up care from the prescribing specialist or if the member has greater than or equal to a 90 day break in therapy.

- Medical record documentation that the member is receiving appropriate follow-up care from the prescribing specialist

***NOTE:** In clinical trials, inoperable PN was defined as a PN that could not be completely removed without risk for substantial morbidity due to encasement of, or close proximity to, vital structures, invasiveness, or high vascularity of the PN.

If a formulary exception is approved, Koselugo will be paid for under the member's prescription drug benefit.

Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.

FORMULARY ALTERNATIVES:

none

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE
STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND
FEDERAL REGULATORY ENTITIES.**

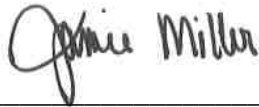
**THIS POLICY WILL BE REVISED AS NECESSARY AND
REVIEWED NO LESS THAN ANNUALLY.**

Geisinger

**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 621.0

**SECTION: Commercial Drug
SUBJECT: Koselugo**



Signed: _____

Title: Director, Pharmacy Services

Date: March 1, 2022

Devised: 5/29/20

Revised: 3/1/21 – annual review, updated logo, added MediSpan approval level, updated QL statement

Revised: 11/24/21 – added one-time PA to approval crit., removed auth duration & added re-auth crit.

Revised: 3/1/22 – annual review, updated referenced policies & covered LOBs



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 622.0

**SECTION: Commercial Drug
SUBJECT: Oxbryta**

Applicable line of business:

Commercial	X	Medicaid	
Medicare		ACA	X
GHP Kids	X	Self-Insured	X

POLICY:

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for Oxbryta for GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 487.0 Quantity Limit Exceptions

REQUIRED DEFINITIONS:

1. **Attachment** – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. **Exhibit** – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. **Devised** – the date the policy was implemented.
4. **Revised** – the date of every revision to the policy, including typographical and grammatical changes.
5. **Reviewed** – the date documenting the annual review if the policy has no revisions necessary.

ADDITIONAL DEFINITIONS:

1. **Formulary** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. **Non-formulary products** – those medications that are not included in the Formulary.
3. **Healthcare provider** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
4. **NCQA** – National Committee for Quality Assurance.
5. **Medically Necessary or Medical Necessity** – covered services rendered by a provider that the Health Plan determines are:

- A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
- B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
- C. In accordance with current standards of medical practice;
- D. Not primarily for the convenience of the Member, or the Member's Provider; and
- E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

PROCEDURE:

An exception for coverage of Oxbryta may be made for members who meet the following criteria:

- Medical record documentation that Oxbryta is prescribed by or in consultation with a hematologist **AND**
- Medical record documentation of age greater than or equal to 4 years **AND**
- Medical record documentation of a diagnosis of sickle cell disease **AND**
- Medical record documentation of baseline hemoglobin **AND**
- Medical record documentation of one of the following:
 - For members 5 years of age and older: medical record documentation of therapeutic failure on, intolerance to, or contraindication to a minimum three (3) month trial of generic hydroxyurea **AND** Endari
 - For members less than 5 years of age: medical record documentation of therapeutic failure on, intolerance to, or contraindication to a minimum three (3) month trial of generic hydroxyurea **AND**
- If the requested quantity exceeds three tablets per day or Oxbryta 500 mg or five tablets per day of Oxbryta 300 mg: Medical record documentation that the patient is using Oxbryta in combination with a strong or moderate CYP3A4 inducer, including but not limited to apalutamide, bosentan, carbamazepine, efavirenz, etravirine, enzalutamide, mitotane, phenobarbital, phenytoin, primidone, rifampin, St. John's Wort

MEDISPAN AUTHORIZATION LEVEL: GPI-12

QUANTITY LIMIT: *No QLs need to be entered within the authorization unless the requested quantity exceeds the QL.*

- **QL FOR LETTER ONLY:** 3 tablets per day, 30 day supply per fill

AUTHORIZATION DURATION: Each treatment period will be defined as 12 months. Re-review will occur every 12 months. The following criteria is recommended for reauthorization:

- Medical record documentation of an increase in hemoglobin from baseline or an improvement in complications of sickle cell disease (e.g., decrease in vaso-occlusive crisis related emergencies) **AND**
- If the requested quantity exceeds three tablets per day or Oxbryta 500 mg or five tablets per day of Oxbryta 300 mg: Medical record documentation that the patient is using Oxbryta in combination with a strong or moderate CYP3A4 inducer, including but not limited to apalutamide, bosentan, carbamazepine, efavirenz, etravirine, enzalutamide, mitotane, phenobarbital, phenytoin, primidone, rifampin, St. John's Wort

If a formulary exception is approved, Oxbryta will be paid for under the member's prescription drug benefit.

Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.

FORMULARY ALTERNATIVES:

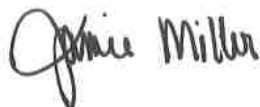
hydroxyurea, Endari*, Siklos*

*prior authorization required

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE
STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND
FEDERAL REGULATORY ENTITIES.**

**THIS POLICY WILL BE REVISED AS NECESSARY AND
REVIEWED NO LESS THAN ANNUALLY.**

Signed: _____



Title: Director, Pharmacy Services



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 622.0

**SECTION: Commercial Drug
SUBJECT: Oxbryta**

Date: June 7, 2022

Devised: 5/29/20

Revised: 3/1/21 – annual review, updated logo, added MediSpan approval level, updated QL statement

Revised: 3/1/22 – annual review, updated referenced policies & covered LOBs, corrected typo

Revised: 6/7/22 – updated age to 4 years, updated FA criterion to separate ages, updated QL criterion



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 623.0

**SECTION: Commercial Drug
SUBJECT: Oxervate**

Applicable line of business:

Commercial	X	Medicaid	
Medicare		ACA	X
GHP Kids	X	Self-Insured	X

POLICY:

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for Oxervate for GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 487.0 Quantity Limit Exceptions

REQUIRED DEFINITIONS:

1. **Attachment** – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. **Exhibit** – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. **Devised** – the date the policy was implemented.
4. **Revised** – the date of every revision to the policy, including typographical and grammatical changes.
5. **Reviewed** – the date documenting the annual review if the policy has no revisions necessary.

ADDITIONAL DEFINITIONS:

1. **Formulary** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. **Non-formulary products** – those medications that are not included in the Formulary.
3. **Healthcare provider** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
4. **NCQA** – National Committee for Quality Assurance.
5. **Medically Necessary or Medical Necessity** – covered services rendered by a provider that the Health Plan determines are:



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 623.0

**SECTION: Commercial Drug
SUBJECT: Oxervate**

- A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
- B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
- C. In accordance with current standards of medical practice;
- D. Not primarily for the convenience of the Member, or the Member's Provider; and
- E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

PROCEDURE:

An exception for coverage of Oxervate may be made for members who meet the following criteria:

- Medical record documentation that Oxervate is prescribed by an ophthalmologist **AND**
- Medical record documentation of age greater than or equal to 2 years **AND**
- Medical record documentation of a diagnosis of neurotrophic keratitis (MK) as confirmed by a decrease or loss in corneal sensitivity **AND** one of the following:
 - Superficial keratopathy
 - Persistent epithelial defects
 - Corneal ulcers

AND

- Medical record documentation of therapeutic failure on, intolerance to, or contraindication to at least one conventional non-surgical treatment for neurotrophic keratitis (NK) (e.g., preservative-free artificial tears, gels/ointments; discontinuation of preserved topical drops and medications that can decrease corneal sensitivity; therapeutic contact lenses) **AND**
- Medical record documentation of therapeutic failure on, intolerance to, or contraindication to Restasis **OR** Xiidra

MEDISPAN AUTHORIZATION LEVEL: GPI-12

QUANTITY LIMIT: *No QLs need to be entered within the authorization unless the requested quantity exceeds the QL.*

- QL FOR LETTER ONLY: 56 vials per 28 days

AUTHORIZATION DURATION: 8 weeks



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 623.0

**SECTION: Commercial Drug
SUBJECT: Oxervate**

For requests beyond the FDA-approved treatment duration (8 weeks), documentation of medical or scientific literature to support the use of this agent beyond the FDA-approved treatment duration is required.

If a formulary exception is approved, Oxervate will be paid for under the member's prescription drug benefit.

Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.

FORMULARY ALTERNATIVES:

cyclosporine ophthalmic suspension (generic Restasis), Restasis Multidose, Xiidra

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE
STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND
FEDERAL REGULATORY ENTITIES.**

**THIS POLICY WILL BE REVISED AS NECESSARY AND
REVIEWED NO LESS THAN ANNUALLY.**

Signed: _____

Title: Director, Pharmacy Services

Date: March 1, 2022

Devised: 5/29/20

Revised: 3/1/21 – annual review, updated logo, added MediSpan approval level, updated QL statement

Revised: 3/1/22 – annual review, updated referenced policies & covered LOBs, updated FA



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 624.0

**SECTION: Commercial Drug
SUBJECT: Secuado**

Applicable line of business:

Commercial	X	Medicaid	
Medicare		ACA	X
GHP Kids	X	Self-Insured	X

POLICY:

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for Secuado for GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 487.0 Quantity Limit Exceptions

REQUIRED DEFINITIONS:

1. **Attachment** – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. **Exhibit** – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. **Devised** – the date the policy was implemented.
4. **Revised** – the date of every revision to the policy, including typographical and grammatical changes.
5. **Reviewed** – the date documenting the annual review if the policy has no revisions necessary.

ADDITIONAL DEFINITIONS:

1. **Formulary** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. **Non-formulary products** – those medications that are not included in the Formulary.
3. **Healthcare provider** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
4. **NCQA** – National Committee for Quality Assurance.
5. **Medically Necessary or Medical Necessity** – covered services rendered by a provider that the Health Plan determines are:



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 624.0

**SECTION: Commercial Drug
SUBJECT: Secuado**

- A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
- B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
- C. In accordance with current standards of medical practice;
- D. Not primarily for the convenience of the Member, or the Member's Provider; and
- E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

PROCEDURE:

New members to the plan already established on therapy may be eligible for continuity of care coverage as long as there is medical record documentation that the safety and effectiveness of use for the prescribed indication is supported by Food and Drug Administration (FDA) approval or adequate medical and scientific evidence in the medical literature.

An exception for coverage of Secuado may be made for members who meet the following criteria:

- Medical record documentation of age greater than or equal to 18 years **AND**
- Medical record documentation of a diagnosis of schizophrenia **AND**
- Medical record documentation of therapeutic failure on, intolerance to, or contraindication to asenapine (Saphris) **AND** two additional formulary alternatives

MEDISPAN AUTHORIZATION LEVEL: GPI-12

QUANTITY LIMIT: *No QLs need to be entered within the authorization unless the requested quantity exceeds the QL.*

- QL FOR LETTER ONLY: 1 patch per day

If a formulary exception is approved, Secuado will be paid for under the member's prescription drug benefit.

Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 624.0

**SECTION: Commercial Drug
SUBJECT: Secuado**

FORMULARY ALTERNATIVES:

asenapine*, aripiprazole, clozapine, olanzapine, quetiapine, risperidone, ziprasidone

*prior authorization required

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE
STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND
FEDERAL REGULATORY ENTITIES.**

**THIS POLICY WILL BE REVISED AS NECESSARY AND
REVIEWED NO LESS THAN ANNUALLY.**

Signed: _____

Title: Director, Pharmacy Services

Date: March 1, 2022

Devised: 6/4/20

Revised: 3/1/21 – annual review, updated logo, added MediSpan approval level, updated QL statement & FA

Revised: 3/1/22 – annual review, updated referenced policies & covered LOBs



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 625.0

**SECTION: Commercial Drug
SUBJECT: Talicia**

Applicable line of business:

Commercial	X	Medicaid	
Medicare		ACA	X
GHP Kids	X	Self-Insured	X

POLICY:

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for Talicia for GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 487.0 Quantity Limit Exceptions

REQUIRED DEFINITIONS:

1. **Attachment** – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. **Exhibit** – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. **Devised** – the date the policy was implemented.
4. **Revised** – the date of every revision to the policy, including typographical and grammatical changes.
5. **Reviewed** – the date documenting the annual review if the policy has no revisions necessary.

ADDITIONAL DEFINITIONS:

1. **Formulary** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. **Non-formulary products** – those medications that are not included in the Formulary.
3. **Healthcare provider** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
4. **NCQA** – National Committee for Quality Assurance.
5. **Medically Necessary or Medical Necessity** – covered services rendered by a provider that the Health Plan determines are:



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 625.0

**SECTION: Commercial Drug
SUBJECT: Talicia**

- A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
- B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
- C. In accordance with current standards of medical practice;
- D. Not primarily for the convenience of the Member, or the Member's Provider; and
- E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

PROCEDURE:

An exception for coverage of Talicia may be made for members who meet the following criteria:

- Medical record documentation of confirmed *Helicobacter pylori* infection **AND**
- Medical record documentation of therapeutic failure on, intolerance to, or contraindication to at least one prior therapy for *H. pylori* infection **AND**
- Medical record documentation of therapeutic failure on, intolerance to, or contraindication to amoxicillin **AND** rifabutin **AND** a formulary proton pump inhibitor

MEDISPAN AUTHORIZATION LEVEL: GPI-12

QUANTITY LIMIT: *No QLs need to be entered within the authorization unless the requested quantity exceeds the QL.*

- QL FOR LETTER ONLY: 168 tablets per 14 days

If a formulary exception is approved, Talicia will be paid for under the member's prescription drug benefit.

Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.

FORMULARY ALTERNATIVES:

amoxicillin, rifabutin, esomeprazole, lansoprazole, omeprazole, pantoprazole, rabeprazole



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 625.0

**SECTION: Commercial Drug
SUBJECT: Talicia**

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE
STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND
FEDERAL REGULATORY ENTITIES.**

**THIS POLICY WILL BE REVISED AS NECESSARY AND
REVIEWED NO LESS THAN ANNUALLY.**

Signed: _____

Title: Director, Pharmacy Services

Date: March 1, 2022

Devised: 6/4/20

Revised: 3/1/21 – annual review, updated logo, added MediSpan approval level, updated QL statement

Revised: 3/1/22 – annual review, updated referenced policies & covered LOBs



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 626.0

**SECTION: Commercial Drug
SUBJECT: Ubrelvy**

Applicable line of business:

Commercial	X	Medicaid	
Medicare		ACA	X
GHP Kids	X	Self-Insured	X

POLICY:

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for Ubrelvy for GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 487.0 Quantity Limit Exceptions

REQUIRED DEFINITIONS:

1. **Attachment** – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. **Exhibit** – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. **Devised** – the date the policy was implemented.
4. **Revised** – the date of every revision to the policy, including typographical and grammatical changes.
5. **Reviewed** – the date documenting the annual review if the policy has no revisions necessary.

ADDITIONAL DEFINITIONS:

1. **Formulary** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. **Non-formulary products** – those medications that are not included in the Formulary.
3. **Healthcare provider** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
4. **NCQA** – National Committee for Quality Assurance.
5. **Medically Necessary or Medical Necessity** – covered services rendered by a provider that the Health Plan determines are:



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 626.0

**SECTION: Commercial Drug
SUBJECT: Ubrelvy**

- A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
- B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
- C. In accordance with current standards of medical practice;
- D. Not primarily for the convenience of the Member, or the Member's Provider; and
- E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

PROCEDURE:

An exception for coverage of Ubrelvy may be made for members who meet the following criteria:

- Medical record documentation of age greater than or equal to 18 years **AND**
- Medical record documentation that Ubrelvy will be used for the acute treatment of migraine with or without aura **AND**
- Medical record documentation of therapeutic failure on, intolerance to, or contraindication to two (2) formulary triptans **AND**
- Medical record documentation that Ubrelvy will not be used concomitantly with another calcitonin gene-related peptide (CGRP) receptor antagonist indicated for the acute treatment of migraine (e.g., Nurtec ODT)

MEDISPAN AUTHORIZATION LEVEL: GPI-12

QUANTITY LIMIT: *No QLs need to be entered within the authorization unless the requested quantity exceeds the QL.*

- **QL FOR LETTER ONLY:** 16 tablets per 30 days

If a formulary exception is approved, Ubrelvy will be paid for under the member's prescription drug benefit.

Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.



POLICY NUMBER: 626.0

**POLICY AND PROCEDURE
PHARMACY
MANUAL**

**SECTION: Commercial Drug
SUBJECT: Ubrelvy**

FORMULARY ALTERNATIVES:

dihydroergotamine nasal spray, diclofenac, ibuprofen, naproxen, butorphanol nasal spray, almotriptan[^], eletriptan[^], frovatriptan[^], naratriptan[^], rizatriptan[^], sumatriptan[^], zolmitriptan[^], sumatriptan/naproxen[^]

*prior authorization required, [^]quantity limits apply

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE
STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND
FEDERAL REGULATORY ENTITIES.**

**THIS POLICY WILL BE REVISED AS NECESSARY AND
REVIEWED NO LESS THAN ANNUALLY.**

Signed: _____

Title: Director, Pharmacy Services

Date: March 1, 2022

Devised: 6/4/20
Revised: 7/28/20 – added concomitant CGRP criterion
Revised: 3/1/21 – annual review, updated logo, added MediSpan approval level, updated QL statement
Revised: 11/19/21 – removed failure of NSAID, changed triptans from 3 to 2
Revised: 3/1/22 – annual review, updated referenced policies & covered LOBs



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 627.0

**SECTION: Commercial Drug
SUBJECT: Pemazyre**

Applicable line of business:

Commercial	X	Medicaid	
Medicare		ACA	X
GHP Kids	X	Self-Insured	X

POLICY:

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for Pemazyre for GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 487.0 Quantity Limit Exceptions

REQUIRED DEFINITIONS:

1. **Attachment** – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. **Exhibit** – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. **Devised** – the date the policy was implemented.
4. **Revised** – the date of every revision to the policy, including typographical and grammatical changes.
5. **Reviewed** – the date documenting the annual review if the policy has no revisions necessary.

ADDITIONAL DEFINITIONS:

1. **Formulary** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. **Non-formulary products** – those medications that are not included in the Formulary.
3. **Healthcare provider** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
4. **NCQA** – National Committee for Quality Assurance.
5. **Medically Necessary or Medical Necessity** – covered services rendered by a provider that the Health Plan determines are:

- A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
- B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
- C. In accordance with current standards of medical practice;
- D. Not primarily for the convenience of the Member, or the Member's Provider; and
- E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

PROCEDURE:

New members to the plan already established on therapy may be eligible for continuity of care coverage as long as there is medical record documentation that the safety and effectiveness of use for the prescribed indication is supported by Food and Drug Administration (FDA) approval or adequate medical and scientific evidence in the medical literature.

An exception for coverage of Pemazyre may be made for members who meet the following criteria:

- Medical record documentation that Pemazyre is prescribed by a hematologist or oncologist **AND**
- Medical record documentation of age greater than or equal to 18 years **AND**
- Medical record documentation of unresectable locally advanced or metastatic cholangiocarcinoma **AND**
- Medical record documentation of a fibroblast growth factor receptor 2 (FGFR2) fusions or other rearrangement as verified by a Food and Drug Administration (FDA) approved test **AND**
- Medical record documentation of one prior line of therapy

NOTE: The FDA approved test is the FoundationOne CDx.

MEDISPAN AUTHORIZATION LEVEL: GPI-12, number of claims authorized = 1, enter for the remainder of the calendar year

QUANTITY LIMIT: *No QLs need to be entered within the authorization unless the requested quantity exceeds the QL.*

- **QL FOR LETTER ONLY:** 14 tablets per 21 days



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 627.0

**SECTION: Commercial Drug
SUBJECT: Pemazyre**

RE-AUTHORIZATION CRITERIA: Pemazyre is configured as a prior authorization for new starts only. Pemazyre will no longer be covered if it is identified that the member is not receiving appropriate follow-up care from the prescribing specialist or if the member has greater than or equal to a 90 day break in therapy.

- Medical record documentation that the member is receiving appropriate follow-up care from the prescribing specialist

If a formulary exception is approved, Pemazyre will be paid for under the member's prescription drug benefit.

Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.

FORMULARY ALTERNATIVES:

none

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE
STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND
FEDERAL REGULATORY ENTITIES.**

**THIS POLICY WILL BE REVISED AS NECESSARY AND
REVIEWED NO LESS THAN ANNUALLY.**

Signed: _____

Title: Director, Pharmacy Services

Date: March 1, 2022

Devised: 7/28/20
Revised: 3/1/21 – annual review, updated logo, added MediSpan approval level, updated QL statement
Revised: 9/1/21 – corrected typo from P&T by adding unresectable to diagnosis criterion
Revised: 11/30/21 – added one-time PA to approval crit., removed auth duration & added re-auth crit.
Revised: 3/1/22 – annual review, updated referenced policies & covered LOBs



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 628.0

**SECTION: Commercial Drug
SUBJECT: Xcopri**

Applicable line of business:

Commercial	X	Medicaid	
Medicare		ACA	X
GHP Kids	X	Self-Insured	X

POLICY:

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for Xcopri for GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 487.0 Quantity Limit Exceptions

REQUIRED DEFINITIONS:

1. **Attachment** – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. **Exhibit** – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. **Devised** – the date the policy was implemented.
4. **Revised** – the date of every revision to the policy, including typographical and grammatical changes.
5. **Reviewed** – the date documenting the annual review if the policy has no revisions necessary.

ADDITIONAL DEFINITIONS:

1. **Formulary** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. **Non-formulary products** – those medications that are not included in the Formulary.
3. **Healthcare provider** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
4. **NCQA** – National Committee for Quality Assurance.
5. **Medically Necessary or Medical Necessity** – covered services rendered by a provider that the Health Plan determines are:



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 628.0

**SECTION: Commercial Drug
SUBJECT: Xcopri**

- A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
- B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
- C. In accordance with current standards of medical practice;
- D. Not primarily for the convenience of the Member, or the Member's Provider; and
- E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

PROCEDURE:

New members to the plan already established on therapy may be eligible for continuity of care coverage as long as there is medical record documentation that the safety and effectiveness of use for the prescribed indication is supported by Food and Drug Administration (FDA) approval or adequate medical and scientific evidence in the medical literature.

An exception for coverage of Xcopri may be made for members who meet the following criteria:

- Medical record documentation that Xcopri is prescribed by or in consultation with a neurologist **AND**
- Medical record documentation of age greater than or equal to 18 years **AND**
- Medical record documentation of a diagnosis of partial onset seizures **AND**
- Medical record documentation of therapeutic failure on, intolerance to, or contraindication to three (3) formulary alternatives

MEDISPAN AUTHORIZATION LEVEL: GPI-10

QUANTITY LIMIT: *No QLs need to be entered within the authorization unless the requested quantity exceeds the QL.*

- **QL FOR LETTER ONLY:**
 - 50 mg, 100 mg, 150 mg: 1 tablet per day
 - Maintenance Pack, 200 mg: 2 tablets per day
 - Titration Pack: 28 tablets per 180 days



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 628.0

**SECTION: Commercial Drug
SUBJECT: Xcopri**

If a formulary exception is approved, Xcopri will be paid for under the member's prescription drug benefit.

Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.

FORMULARY ALTERNATIVES:

carbamazepine, divalproex, felbamate, gabapentin, tiagabine, lamotrigine IR, lamotrigine ER, levetiracetam IR, levetiracetam ER, oxcarbazepine, phenobarbital, phenytoin, pregabalin, topiramate IR, topiramate ER*, zonisamide

*prior authorization required

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE
STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND
FEDERAL REGULATORY ENTITIES.**

**THIS POLICY WILL BE REVISED AS NECESSARY AND
REVIEWED NO LESS THAN ANNUALLY.**

Signed: _____

Title: Director, Pharmacy Services

Date: March 1, 2022

Devised: 7/28/20

Revised: 3/1/21 – annual review, updated logo, added MediSpan approval level, updated QL statement

Revised: 3/1/22 – annual review, updated referenced policies & covered LOBs, updated FA



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 629.0

**SECTION: Commercial Drug
SUBJECT: Nurtec ODT**

Applicable line of business:

Commercial	X	Medicaid	
Medicare		ACA	X
GHP Kids	X	Self-Insured	X

POLICY:

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for Nurtec ODT for GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 487.0 Quantity Limit Exceptions

REQUIRED DEFINITIONS:

1. **Attachment** – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. **Exhibit** – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. **Devised** – the date the policy was implemented.
4. **Revised** – the date of every revision to the policy, including typographical and grammatical changes.
5. **Reviewed** – the date documenting the annual review if the policy has no revisions necessary.

ADDITIONAL DEFINITIONS:

1. **Formulary** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. **Non-formulary products** – those medications that are not included in the Formulary.
3. **Healthcare provider** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
4. **NCQA** – National Committee for Quality Assurance.
5. **Medically Necessary or Medical Necessity** – covered services rendered by a provider that the Health Plan determines are:



POLICY NUMBER: 629.0

**POLICY AND PROCEDURE
PHARMACY
MANUAL**

**SECTION: Commercial Drug
SUBJECT: Nurtec ODT**

- A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
- B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
- C. In accordance with current standards of medical practice;
- D. Not primarily for the convenience of the Member, or the Member's Provider; and
- E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

PROCEDURE:

An exception for coverage of Nurtec ODT may be made for members who meet the following criteria:

Acute Migraine Treatment

- Medical record documentation of age greater than or equal to 18 years **AND**
- Medical record documentation that Nurtec ODT will be used for the acute treatment of migraine with or without aura **AND**
- Medical record documentation of therapeutic failure on, intolerance to, or contraindication to two (2) formulary triptans **AND**
- Medical record documentation that Nurtec ODT will not be used concomitantly with another calcitonin gene-related peptide (CGRP) receptor antagonist indicated for the acute treatment of migraine (e.g., Ubrelvy)

Preventive Migraine Treatment

- Medical record documentation that Nurtec ODT is prescribed by or in consultation with a neurologist or headache specialist **AND**
- Medical record documentation of age greater than or equal to 18 years **AND**
- Medical record documentation of a diagnosis of migraine with or without aura, based on the International Classification of Headache Disorders (ICHD)-III diagnostic criteria **AND**
- Medical record documentation of number of baseline migraine or headache days per month **AND**
- Medical record documentation of diagnosis of episodic migraine (no more than 14 headache days per month) **AND**
- Medical record documentation of therapeutic failure on, intolerance to, or contraindication to at least three (3) of the following:
 - One (1) beta blocker (metoprolol, propranolol, timolol, atenolol, nadolol)
 - Topiramate

- Divalproex/sodium valproate
- Amitriptyline
- Venlafaxine **AND**
- Medical record documentation of therapeutic failure on, intolerance to, or contraindication to Aimovig **AND** Emgality **AND**
- Medical record documentation that Nurtec ODT will not be used concomitantly with another calcitonin gene-related peptide (CGRP) receptor antagonist indicated for the preventive treatment of migraine (e.g., Aimovig, Ajovy, Emgality, Vyepti) **AND**
- Medical record documentation that Nurtec ODT will not be used in combination with botulinum toxin for preventive treatment **OR**
 - Medical record documentation of a therapeutic failure on a minimum 3 month trial of at least one CGRP antagonists without the concomitant use of Botox **AND**
 - Medical record documentation of therapeutic failure on a minimum 6 month trial of Botox without the concomitant use of a CGRP antagonist

AUTHORIZATION DURATION FOR PREVENTIVE TREATMENT: Initial approval will be for six (6) months and subsequent approvals will be for twelve (12) months. Requests for continuation of coverage will be approved for members who meet the following criteria:

- Medical record documentation of continued or sustained reduction in migraine or headache frequency or has experienced a decrease in severity or duration of migraine **AND**
- Medical record documentation that Nurtec ODT will not be used concomitantly with another calcitonin gene-related peptide (CGRP) receptor antagonist indicated for the preventive treatment of migraine (e.g., Aimovig, Ajovy, Emgality, Vyepti) **AND**
- Medical record documentation that Nurtec ODT will not be used in combination with botulinum toxin for preventive treatment **OR**
 - Medical record documentation of a therapeutic failure on a minimum 3 month trial of at least one CGRP antagonists without the concomitant use of Botox **AND**
 - Medical record documentation of therapeutic failure on a minimum 6 month trial of Botox without the concomitant use of a CGRP antagonist

MEDISPAN AUTHORIZATION LEVEL: GPI-12

QUANTITY LIMIT: *No QLs need to be entered within the authorization unless the requested quantity exceeds the QL.*

- **QL FOR LETTER ONLY:** 18 tablets per 30 days



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 629.0

**SECTION: Commercial Drug
SUBJECT: Nurtec ODT**

ICHD-III Diagnostic Criteria³

Migraine without Aura:	Migraine with Aura:
A) At least five (5) attacks fulfilling criteria B through D below:	A) At least two (2) attacks fulfilling criteria B through C below:
B) Headache lasting 4 to 72 hours (untreated or unsuccessfully treated)	B) One (1) or more of the following fully reversible aura symptoms: <ul style="list-style-type: none"> o Visual o Sensory o Speech and/or language o Motor o Brainstem o Retinal
C) Headache with at least two (2) of the following characteristics: <ul style="list-style-type: none"> o unilateral location o pulsating quality o moderate to severe pain intensity o aggravation by or causing avoidance of routine physical activity (e.g. walking or climbing stairs) 	C) At least three (3) of the following: <ul style="list-style-type: none"> o at least one (1) aura symptom spreads over 5 or more minutes o two (2) or more aura symptoms occur in succession o each individual aura symptom lasts 5 to 60 minutes¹ o at least one (1) aura symptom is unilateral² o at least one (1) aura symptom is positive³ o the aura is accompanied, or followed within 60 minutes, by a headache
D) At least one of the following during the headache: <ul style="list-style-type: none"> o nausea and/or vomiting o photophobia and phonophobia 	D) Not better accounted for by another ICHD-3 diagnosis
E) Not better accounted for by another ICHD-3 diagnosis	

If a formulary exception is approved, Nurtec ODT will be paid for under the member's prescription drug benefit.

Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.

FORMULARY ALTERNATIVES:

Acute Treatment: dihydroergotamine nasal spray, diclofenac, ibuprofen, naproxen, butorphanol nasal spray, almotriptan[^], eletriptan[^], frovatriptan[^], naratriptan[^], rizatriptan[^], sumatriptan[^], zolmitriptan[^], sumatriptan/naproxen[^]

Preventive Treatment: metoprolol, propranolol, timolol, atenolol, nadolol, topiramate, divalproex, sodium valproate, amitriptyline, venlafaxine

[^]prior authorization required, [^]quantity limits apply

Geisinger

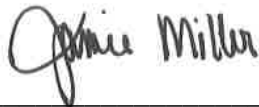
**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 629.0

**SECTION: Commercial Drug
SUBJECT: Nurtec ODT**

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE
STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND
FEDERAL REGULATORY ENTITIES.**

**THIS POLICY WILL BE REVISED AS NECESSARY AND
REVIEWED NO LESS THAN ANNUALLY.**



Signed: _____

Title: Director, Pharmacy Services

Date: March 1, 2022

Devised: 7/28/20

Revised: 3/1/21 – annual review, updated logo, added MediSpan approval level, updated QL statement

Revised: 11/19/21 – acute indication: removed failure of NSAID, changes from 3 to 2 triptans, added preventive indication, updated QL to 18 tablets, updated FA, added ICHD tablet

Revised: 3/1/22 – annual review, updated referenced policies & covered LOBs



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 630.0

**SECTION: Commercial Drug
SUBJECT: Palforzia**

Applicable line of business:

Commercial	X	Medicaid	
Medicare		ACA	X
GHP Kids	X	Self-Insured	X

POLICY:

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for Palforzia for GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 487.0 Quantity Limit Exceptions

REQUIRED DEFINITIONS:

1. **Attachment** – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. **Exhibit** – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. **Devised** – the date the policy was implemented.
4. **Revised** – the date of every revision to the policy, including typographical and grammatical changes.
5. **Reviewed** – the date documenting the annual review if the policy has no revisions necessary.

ADDITIONAL DEFINITIONS:

1. **Formulary** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. **Non-formulary products** – those medications that are not included in the Formulary.
3. **Healthcare provider** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
4. **NCQA** – National Committee for Quality Assurance.
5. **Medically Necessary or Medical Necessity** – covered services rendered by a provider that the Health Plan determines are:



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 630.0

**SECTION: Commercial Drug
SUBJECT: Palforzia**

- A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
- B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
- C. In accordance with current standards of medical practice;
- D. Not primarily for the convenience of the Member, or the Member's Provider; and
- E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

PROCEDURE:

An exception for coverage of Palforzia may be made for members who meet the following criteria:

- Medical record documentation that Palforzia is prescribed by an allergist, immunologist, or a physician qualified to prescribe allergy immunotherapy **AND**
- If the request is for initial dose escalation: Medical record documentation that member is greater than or equal to 4 years of age to less than 18 years of age **OR**
- If the request is for up-dosing or maintenance dose: Medical record documentation that member is greater than or equal to 4 years of age

AND

- Medical record documentation of confirmed diagnosis of peanut-allergy with history of allergic reaction from peanuts **AND** one of the following:
 - positive skin test **OR**
 - *in vitro* testing for peanut-specific IgE antibodies

AND

- Medical record documentation that Palforzia will be used in conjunction with peanut-avoidant diet **AND**
- Medical record documentation that the member has (or will receive) a prescription for an epinephrine auto-injector **AND**
- Medical record documentation that the member does not have severe, unstable, or uncontrolled asthma **AND**
- Medical record documentation that the member has no experienced severe or life-threatening anaphylaxis within 60 days of Palforzia initiation

MEDISPAN AUTHORIZATION LEVEL: GPI-10



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 630.0

**SECTION: Commercial Drug
SUBJECT: Palforzia**

QUANTITY LIMIT: *No QLs need to be entered within the authorization unless the requested quantity exceeds the QL.*

- **QL FOR LETTER ONLY:**

Packaging Presentation	Quantity Limits
Initial Dose Escalation	
0.5 mg to 6 mg capsules	13 capsules / 1 day
Up-Dosing	
3 mg (Level 1)	3 capsules / day, 30 day supply per fill
6 mg (Level 2)	6 capsules / day, 30 day supply per fill
12 mg (Level 3)	3 capsules / day, 30 day supply per fill
20 mg (Level 4)	1 capsule / day, 30 day supply per fill
40 mg (Level 5)	2 capsules / day, 30 day supply per fill
80 mg (Level 6)	4 capsules / day, 30 day supply per fill
120 mg (Level 7)	2 capsules / day, 30 day supply per fill
160 mg (Level 8)	4 capsules / day, 30 day supply per fill
200 mg (Level 9)	2 capsules / day, 30 day supply per fill
240 mg (Level 10)	4 capsules / day, 30 day supply per fill
300 mg (Level 11)	1 packet / day, 30 day supply per fill
Maintenance	
300 mg (Level 11)	1 packet / day, 30 day supply per fill

AUTHORIZATION DURATION: Initial authorizations for Palforzia will be approved for a period of 12 months. Subsequent authorizations will be for a period of 12 months and will require the following criteria:

- Claims history and attestation from the provider showing the patient is adherent to daily dosing of Palforzia **AND**.
- Medical record documentation that patient is not experiencing unacceptable toxicity **AND**
- Medical record documentation that patient does not have recurrent asthma exacerbations or persistent loss of asthma control **AND**
- Medical record documentation that patient does not have suspected eosinophilic esophagitis

If a formulary exception is approved, Palforzia will be paid for under the member's prescription drug benefit.

Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 630.0

**SECTION: Commercial Drug
SUBJECT: Palforzia**

FORMULARY ALTERNATIVES:

none

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE
STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND
FEDERAL REGULATORY ENTITIES.**

**THIS POLICY WILL BE REVISED AS NECESSARY AND
REVIEWED NO LESS THAN ANNUALLY.**

Signed: _____

Title: Director, Pharmacy Services

Date: March 1, 2022

Devised: 7/28/20

Revised: 10/13/20 – removed Pemazyre criteria

Revised: 3/1/21 – annual review, updated logo, added MediSpan approval level, updated QL statement

Revised: 3/1/22 – annual review, updated referenced policies & covered LOBs



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 631.0

**SECTION: Commercial Drug
SUBJECT: Qinlock**

Applicable line of business:

Commercial	X	Medicaid	
Medicare		ACA	X
GHP Kids	X	Self-Insured	X

POLICY:

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for Qinlock for GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 487.0 Quantity Limit Exceptions

REQUIRED DEFINITIONS:

1. **Attachment** – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. **Exhibit** – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. **Devised** – the date the policy was implemented.
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5. **Reviewed** – the date documenting the annual review if the policy has no revisions necessary.

ADDITIONAL DEFINITIONS:

1. **Formulary** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. **Non-formulary products** – those medications that are not included in the Formulary.
3. **Healthcare provider** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
4. **NCQA** – National Committee for Quality Assurance.
5. **Medically Necessary or Medical Necessity** – covered services rendered by a provider that the Health Plan determines are:



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 631.0

**SECTION: Commercial Drug
SUBJECT: Qinlock**

- A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
- B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
- C. In accordance with current standards of medical practice;
- D. Not primarily for the convenience of the Member, or the Member's Provider; and
- E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

PROCEDURE:

New members to the plan already established on therapy may be eligible for continuity of care coverage as long as there is medical record documentation that the safety and effectiveness of use for the prescribed indication is supported by Food and Drug Administration (FDA) approval or adequate medical and scientific evidence in the medical literature.

An exception for coverage of Qinlock may be made for members who meet the following criteria:

- Medical record documentation that Qinlock is prescribed by or in consultation with a hematologist or oncologist **AND**
- Medical record documentation of age greater than or equal to 18 years **AND**
- Medical record documentation of advanced gastrointestinal stromal tumor (GIST) **AND**
- Medical record documentation of prior treatment with three (3) or more kinase inhibitors, including imatinib

MEDISPAN AUTHORIZATION LEVEL: GPI-12, number of claims authorized = 1, enter for the remainder of the calendar year

QUANTITY LIMIT: *No QLs need to be entered within the authorization unless the requested quantity exceeds the QL.*

- **QL FOR LETTER ONLY:** 90 tablets per 30 days



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 631.0

**SECTION: Commercial Drug
SUBJECT: Qinlock**

RE-AUTHORIZATION CRITERIA: Qinlock is configured as a prior authorization for new starts only. Qinlock will no longer be covered if it is identified that the member is not receiving appropriate follow-up care from the prescribing specialist or if the member has greater than or equal to a 90 day break in therapy.

- Medical record documentation that the member is receiving appropriate follow-up care from the prescribing specialist

If a formulary exception is approved, Qinlock will be paid for under the member's prescription drug benefit.

Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.

FORMULARY ALTERNATIVES:

imatinib*, sunitinib*, Stivarga*, Ayvakit*

*prior authorization required

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE
STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND
FEDERAL REGULATORY ENTITIES.**

**THIS POLICY WILL BE REVISED AS NECESSARY AND
REVIEWED NO LESS THAN ANNUALLY.**

Signed: _____

Title: Director, Pharmacy Services

Date: March 1, 2022

Devised: 7/28/20
Revised: 3/1/21 – annual review, updated logo, added MediSpan approval level, updated QL statement
Revised: 12/1/21 – added one-time PA to approval crit., removed auth duration & added re-auth crit.
Revised: 3/1/22 – annual review, updated referenced policies & covered LOBs, updated FA



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 632.0

**SECTION: Commercial Drug
SUBJECT: Retevmo**

Applicable line of business:

Commercial	X	Medicaid	
Medicare		ACA	X
GHP Kids	X	Self-Insured	X

POLICY:

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for Retevmo for GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 487.0 Quantity Limit Exceptions

REQUIRED DEFINITIONS:

1. **Attachment** – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. **Exhibit** – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. **Devised** – the date the policy was implemented.
4. **Revised** – the date of every revision to the policy, including typographical and grammatical changes.
5. **Reviewed** – the date documenting the annual review if the policy has no revisions necessary.

ADDITIONAL DEFINITIONS:

1. **Formulary** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. **Non-formulary products** – those medications that are not included in the Formulary.
3. **Healthcare provider** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
4. **NCQA** – National Committee for Quality Assurance.
5. **Medically Necessary or Medical Necessity** – covered services rendered by a provider that the Health Plan determines are:



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 632.0

**SECTION: Commercial Drug
SUBJECT: Retevmo**

- A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
- B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
- C. In accordance with current standards of medical practice;
- D. Not primarily for the convenience of the Member, or the Member's Provider; and
- E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

PROCEDURE:

New members to the plan already established on therapy may be eligible for continuity of care coverage as long as there is medical record documentation that the safety and effectiveness of use for the prescribed indication is supported by Food and Drug Administration (FDA) approval or adequate medical and scientific evidence in the medical literature.

An exception for coverage of Retevmo may be made for members who meet the following criteria:

Non-Small Cell Lung Cancer

- Medical record documentation that Retevmo is prescribed by a hematologist or oncologist **AND**
- Medical record documentation of age greater than or equal to 18 years **AND**
- Medical record documentation of *RET*-fusion positive non-small cell lung cancer (NSCLC)

Thyroid Cancer

- Medical record documentation that Retevmo is prescribed by a hematologist or oncologist **AND**
- Medical record documentation of age greater than or equal to 12 years **AND**
- Medical record documentation of advanced metastatic *RET*-mutant medullary thyroid cancer (MTC) **AND** medical record documentation that systemic therapy is required

OR

- Medical record documentation of advanced or metastatic *RET* fusion-positive thyroid cancer **AND** medical record documentation of both of the following:
 - Documentation that systemic therapy is required **AND**
 - Documentation that member is radioactive-iodine refractory when radioactive iodine is appropriate



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 632.0

**SECTION: Commercial Drug
SUBJECT: Retevmo**

MEDISPAN AUTHORIZATION LEVEL: GPI-12, number of claims authorized = 1, enter for the remainder of the calendar year

QUANTITY LIMIT: *No QLs need to be entered within the authorization unless the requested quantity exceeds the QL.*

- **QL FOR LETTER ONLY:**
 - 40 mg capsules: 2 capsules per day, 30 day supply per fill
 - 80 mg capsules: 4 capsules per day, 30 day supply per fill

RE-AUTHORIZATION CRITERIA: Retevmo is configured as a prior authorization for new starts only. Retevmo will no longer be covered if it is identified that the member is not receiving appropriate follow-up care from the prescribing specialist or if the member has greater than or equal to a 90 day break in therapy.

- Medical record documentation that the member is receiving appropriate follow-up care from the prescribing specialist

If a formulary exception is approved, Retevmo will be paid for under the member's prescription drug benefit.

Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.

FORMULARY ALTERNATIVES:

none

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE
STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND
FEDERAL REGULATORY ENTITIES.**

**THIS POLICY WILL BE REVISED AS NECESSARY AND
REVIEWED NO LESS THAN ANNUALLY.**

Signed:  _____

Title: Director, Pharmacy Services



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 632.0

**SECTION: Commercial Drug
SUBJECT: Retevmo**

Date: March 1, 2022

Devised: 7/28/20

Revised: 3/1/21 – annual review, updated logo, added MediSpan approval level, updated QL statement

Revised: 12/1/21 – added one-time PA to approval crit., removed auth duration & added re-auth crit.

Revised: 3/1/22 – annual review, updated referenced policies & covered LOBs



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 633.0

**SECTION: Commercial Drug
SUBJECT: Reyvow**

Applicable line of business:

Commercial	X	Medicaid	
Medicare		ACA	X
GHP Kids	X	Self-Insured	X

POLICY:

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for Reyvow for GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 487.0 Quantity Limit Exceptions

REQUIRED DEFINITIONS:

1. **Attachment** – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. **Exhibit** – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. **Devised** – the date the policy was implemented.
4. **Revised** – the date of every revision to the policy, including typographical and grammatical changes.
5. **Reviewed** – the date documenting the annual review if the policy has no revisions necessary.

ADDITIONAL DEFINITIONS:

1. **Formulary** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. **Non-formulary products** – those medications that are not included in the Formulary.
3. **Healthcare provider** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
4. **NCQA** – National Committee for Quality Assurance.
5. **Medically Necessary or Medical Necessity** – covered services rendered by a provider that the Health Plan determines are:



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 633.0

**SECTION: Commercial Drug
SUBJECT: Reyvow**

- A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
- B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
- C. In accordance with current standards of medical practice;
- D. Not primarily for the convenience of the Member, or the Member's Provider; and
- E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

PROCEDURE:

An exception for coverage of Reyvow may be made for members who meet the following criteria:

- Medical record documentation of age greater than or equal to 18 years **AND**
- Medical record documentation that Reyvow will be used for the acute treatment of migraine with or without aura **AND**
- Medical record documentation of therapeutic failure on, intolerance to, or contraindication to nonsteroidal anti-inflammatory drug (NSAID) therapy **AND**
- Medical record documentation of therapeutic failure on, intolerance to, or contraindication to three (3) formulary triptans **AND**
- Medical record documentation of therapeutic failure on, intolerance to, or contraindication to Ubrelvy **AND** Nurtec ODT for acute treatment

MEDISPAN AUTHORIZATION LEVEL: GPI-12

QUANTITY LIMIT: *No QLs need to be entered within the authorization unless the requested quantity exceeds the QL.*

- **QL FOR LETTER ONLY:**
 - 50 mg: 4 tablets per 30 days
 - 100 mg: 8 tablets per 30 days

If a formulary exception is approved, Reyvow will be paid for under the member's prescription drug benefit.

Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 633.0

**SECTION: Commercial Drug
SUBJECT: Reyvow**

FORMULARY ALTERNATIVES:

dihydroergotamine nasal spray, diclofenac, ibuprofen, naproxen, butorphanol nasal spray, almotriptan[^], eletriptan[^], frovatriptan[^], naratriptan[^], rizatriptan[^], sumatriptan[^], zolmitriptan[^], sumatriptan/naproxen[^]

*prior authorization required, [^]quantity limits apply

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE
STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND
FEDERAL REGULATORY ENTITIES.**

**THIS POLICY WILL BE REVISED AS NECESSARY AND
REVIEWED NO LESS THAN ANNUALLY.**

Signed: _____

Title: Director, Pharmacy Services

Date: March 1, 2022

Devised: 7/28/20

Revised: 3/1/21 – annual review, updated logo, added MediSpan approval level, updated QL statement

Revised: 11/19/21 – added failure of Ubrelvy and Nurtec

Revised: 3/1/22 – annual review, updated referenced policies & covered LOBs



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 634.0

**SECTION: Commercial Drug
SUBJECT: Tabrecta**

Applicable line of business:

Commercial	X	Medicaid	
Medicare		ACA	X
GHP Kids	X	Self-Insured	X

POLICY:

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for Tabrecta for GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 487.0 Quantity Limit Exceptions

REQUIRED DEFINITIONS:

1. **Attachment** – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. **Exhibit** – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. **Devised** – the date the policy was implemented.
4. **Revised** – the date of every revision to the policy, including typographical and grammatical changes.
5. **Reviewed** – the date documenting the annual review if the policy has no revisions necessary.

ADDITIONAL DEFINITIONS:

1. **Formulary** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. **Non-formulary products** – those medications that are not included in the Formulary.
3. **Healthcare provider** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
4. **NCQA** – National Committee for Quality Assurance.
5. **Medically Necessary or Medical Necessity** – covered services rendered by a provider that the Health Plan determines are:



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 634.0

**SECTION: Commercial Drug
SUBJECT: Tabrecta**

- A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
- B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
- C. In accordance with current standards of medical practice;
- D. Not primarily for the convenience of the Member, or the Member's Provider; and
- E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

PROCEDURE:

New members to the plan already established on therapy may be eligible for continuity of care coverage as long as there is medical record documentation that the safety and effectiveness of use for the prescribed indication is supported by Food and Drug Administration (FDA) approval or adequate medical and scientific evidence in the medical literature.

An exception for coverage of Tabrecta may be made for members who meet the following criteria:

- Medical record documentation that Tabrecta is prescribed by a hematologist or oncologist **AND**
- Medical record documentation of age greater than or equal to 18 years **AND**
- Medical record documentation of a diagnosis of metastatic non-small cell lung cancer (NSCLC) whose tumors have a mutation that leads to mesenchymal-epithelial transition (MET) exon 14 skipping

MEDISPAN AUTHORIZATION LEVEL: GPI-12, number of claims authorized = 1, enter for the remainder of the calendar year

QUANTITY LIMIT: *No QLs need to be entered within the authorization unless the requested quantity exceeds the QL.*

- **QL FOR LETTER ONLY:** 4 tablets per day, 30 day supply per fill



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 634.0

**SECTION: Commercial Drug
SUBJECT: Tabrecta**

RE-AUTHORIZATION CRITERIA: Tabrecta is configured as a prior authorization for new starts only. Tabrecta will no longer be covered if it is identified that the member is not receiving appropriate follow-up care from the prescribing specialist or if the member has greater than or equal to a 90 day break in therapy.

- Medical record documentation that the member is receiving appropriate follow-up care from the prescribing specialist

If a formulary exception is approved, Tabrecta will be paid for under the member's prescription drug benefit.

Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.

FORMULARY ALTERNATIVES:

none

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE
STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND
FEDERAL REGULATORY ENTITIES.**

**THIS POLICY WILL BE REVISED AS NECESSARY AND
REVIEWED NO LESS THAN ANNUALLY.**

Signed: _____

Title: Director, Pharmacy Services

Date: March 1, 2022

Devised: 7/28/20
Revised: 3/1/21 – annual review, updated logo, added MediSpan approval level, updated QL statement
Revised: 12/1/21 – added one-time PA to approval crit., removed auth duration & added re-auth crit.
Revised: 3/1/22 – annual review, updated referenced policies & covered LOBs



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 635.0

**SECTION: Commercial Drug
SUBJECT: Tukysa**

Applicable line of business:

Commercial	X	Medicaid	
Medicare		ACA	X
GHP Kids	X	Self-Insured	X

POLICY:

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for Tukysa for GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 487.0 Quantity Limit Exceptions

REQUIRED DEFINITIONS:

1. **Attachment** – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. **Exhibit** – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. **Devised** – the date the policy was implemented.
4. **Revised** – the date of every revision to the policy, including typographical and grammatical changes.
5. **Reviewed** – the date documenting the annual review if the policy has no revisions necessary.

ADDITIONAL DEFINITIONS:

1. **Formulary** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. **Non-formulary products** – those medications that are not included in the Formulary.
3. **Healthcare provider** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
4. **NCQA** – National Committee for Quality Assurance.
5. **Medically Necessary or Medical Necessity** – covered services rendered by a provider that the Health Plan determines are:



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 635.0

**SECTION: Commercial Drug
SUBJECT: Tukysa**

- A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
- B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
- C. In accordance with current standards of medical practice;
- D. Not primarily for the convenience of the Member, or the Member's Provider; and
- E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

PROCEDURE:

New members to the plan already established on therapy may be eligible for continuity of care coverage as long as there is medical record documentation that the safety and effectiveness of use for the prescribed indication is supported by Food and Drug Administration (FDA) approval or adequate medical and scientific evidence in the medical literature.

An exception for coverage of Tukysa may be made for members who meet the following criteria:

- Medical record documentation that Tukysa is prescribed by a hematologist or oncologist **AND**
- Medical record documentation of age greater than or equal to 18 years **AND**
- Medical record documentation of advanced unresectable or metastatic HER2-positive breast cancer, including patients with brain metastases **AND**
- Medical record documentation that Tukysa will be given in combination with trastuzumab and capecitabine **AND**
- Medical record documentation of prior treatment with at least one anti-HER2 based regimen in the metastatic setting

MEDISPAN AUTHORIZATION LEVEL: GPI-12, number of claims authorized = 1, enter for the remainder of the calendar year

QUANTITY LIMIT: *No QLs need to be entered within the authorization unless the requested quantity exceeds the QL.*

- **QL FOR LETTER ONLY:** 4 tablets per day, 30 day supply per fill



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 635.0

**SECTION: Commercial Drug
SUBJECT: Tukysa**

RE-AUTHORIZATION CRITERIA: Tukysa is configured as a prior authorization for new starts only. Tukysa will no longer be covered if it is identified that the member is not receiving appropriate follow-up care from the prescribing specialist or if the member has greater than or equal to a 90 day break in therapy.

- Medical record documentation that the member is receiving appropriate follow-up care from the prescribing specialist

If a formulary exception is approved, Tukysa will be paid for under the member's prescription drug benefit.

Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.

FORMULARY ALTERNATIVES:

none

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE
STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND
FEDERAL REGULATORY ENTITIES.**

**THIS POLICY WILL BE REVISED AS NECESSARY AND
REVIEWED NO LESS THAN ANNUALLY.**

Signed: _____

Title: Director, Pharmacy Services

Date: March 1, 2022

Devised: 7/28/20
Revised: 3/1/21 – annual review, updated logo, added MediSpan approval level, updated QL statement
Revised: 12/1/21 – added one-time PA to approval crit., removed auth duration & added re-auth crit.
Revised: 3/1/22 – annual review, updated referenced policies & covered LOBs



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 636.0

**SECTION: Commercial Drug
SUBJECT: Dayvigo**

Applicable line of business:

Commercial	X	Medicaid	
Medicare		ACA	X
GHP Kids	X	Self-Insured	X

POLICY:

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for Dayvigo for GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 487.0 Quantity Limit Exceptions

REQUIRED DEFINITIONS:

1. **Attachment** – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. **Exhibit** – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. **Devised** – the date the policy was implemented.
4. **Revised** – the date of every revision to the policy, including typographical and grammatical changes.
5. **Reviewed** – the date documenting the annual review if the policy has no revisions necessary.

ADDITIONAL DEFINITIONS:

1. **Formulary** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. **Non-formulary products** – those medications that are not included in the Formulary.
3. **Healthcare provider** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
4. **NCQA** – National Committee for Quality Assurance.
5. **Medically Necessary or Medical Necessity** – covered services rendered by a provider that the Health Plan determines are:

- A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
- B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
- C. In accordance with current standards of medical practice;
- D. Not primarily for the convenience of the Member, or the Member's Provider; and
- E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

PROCEDURE:

An exception for coverage of Dayvigo may be made for members who meet the following criteria:

- Medical record documentation of age greater than or equal to 18 years **AND**
- Medical record documentation of a diagnosis of insomnia **AND**
- Medical record documentation of therapeutic failure on, intolerance to, or contraindication to three (3) formulary alternatives

MEDISPAN AUTHORIZATION LEVEL: GPI-12

QUANTITY LIMIT: *No QLs need to be entered within the authorization unless the requested quantity exceeds the QL.*

- QL FOR LETTER ONLY: 1 tablet per day

If a formulary exception is approved, Dayvigo will be paid for under the member's prescription drug benefit.

Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.

FORMULARY ALTERNATIVES:

zolpidem immediate release, zolpidem extended release, eszopiclone, zaleplon, quazepam, estazolam, flurazepam, triazolam, temazepam, zolpidem sublingual*, ramelteon*

*prior authorization or step therapy required

Geisinger

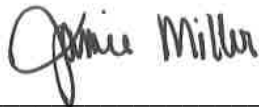
**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 636.0

**SECTION: Commercial Drug
SUBJECT: Dayvigo**

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE
STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND
FEDERAL REGULATORY ENTITIES.**

**THIS POLICY WILL BE REVISED AS NECESSARY AND
REVIEWED NO LESS THAN ANNUALLY.**



Signed: _____

Title: Director, Pharmacy Services

Date: March 1, 2022

Devised: 10/5/20

Revised: 3/1/21 – annual review, updated logo, added MediSpan approval level, updated QL statement,
corrected typo

Revised: 3/1/22 – annual review, updated referenced policies & covered LOBs



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 637.0

**SECTION: Commercial Drug
SUBJECT: Fintepla**

Applicable line of business:

Commercial	X	Medicaid	
Medicare		ACA	X
GHP Kids	X	Self-Insured	X

POLICY:

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for Fintepla for GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 487.0 Quantity Limit Exceptions

REQUIRED DEFINITIONS:

1. **Attachment** – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. **Exhibit** – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. **Devised** – the date the policy was implemented.
4. **Revised** – the date of every revision to the policy, including typographical and grammatical changes.
5. **Reviewed** – the date documenting the annual review if the policy has no revisions necessary.

ADDITIONAL DEFINITIONS:

1. **Formulary** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. **Non-formulary products** – those medications that are not included in the Formulary.
3. **Healthcare provider** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
4. **NCQA** – National Committee for Quality Assurance.
5. **Medically Necessary or Medical Necessity** – covered services rendered by a provider that the Health Plan determines are:



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 637.0

**SECTION: Commercial Drug
SUBJECT: Fintepla**

- A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
- B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
- C. In accordance with current standards of medical practice;
- D. Not primarily for the convenience of the Member, or the Member's Provider; and
- E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

PROCEDURE:

New members to the plan already established on therapy may be eligible for continuity of care coverage as long as there is medical record documentation that the safety and effectiveness of use for the prescribed indication is supported by Food and Drug Administration (FDA) approval or adequate medical and scientific evidence in the medical literature.

An exception for coverage of Fintepla may be made for members who meet the following criteria:

- Medical record documentation that Fintepla is prescribed by a neurologist **AND**
- Medical record documentation of age greater than or equal to 2 years **AND**
- Medical record documentation of a diagnosis of one of the following:
 - Dravet syndrome **OR**
 - Lennox-Gastaut syndrome **AND**
- Medical record documentation of therapeutic failure on, intolerance to, or contraindication to two (2) formulary alternatives appropriate for diagnosis

MEDISPAN AUTHORIZATION LEVEL: GPI-12

QUANTITY LIMIT: *No QLs need to be entered within the authorization unless the requested quantity exceeds the QL.*

- **QL FOR LETTER ONLY:** 12 mL per day

If a formulary exception is approved, Fintepla will be paid for under the member's prescription drug benefit.



POLICY NUMBER: 637.0

**POLICY AND PROCEDURE
PHARMACY
MANUAL**

**SECTION: Commercial Drug
SUBJECT: Fintepla**

Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.

FORMULARY ALTERNATIVES:

Dravet syndrome:

For patients > 2 years of age: clobazam, Diacomit*, Epidiolex*, topiramate IR, topiramate ER (generic Qudexy XR)*

Additional formulary alternatives for patients over certain ages: levetiracetam IR (4+), divalproex (10+), valproic acid (10+), levetiracetam ER (12+)

Lennox-Gastaut syndrome:

For patients > 2 years of age: clobazam, clonazepam, Epidiolex*, felbamate, lamotrigine IR, rufinamide*, Sympazan*, topiramate IR, topiramate ER (generic Qudexy XR)*

Additional formulary alternatives for patients over certain ages: lamotrigine ER (13+),

*prior authorization required

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE
STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND
FEDERAL REGULATORY ENTITIES.**

**THIS POLICY WILL BE REVISED AS NECESSARY AND
REVIEWED NO LESS THAN ANNUALLY.**

Signed: _____

Title: Director, Pharmacy Services

Date: June 7, 2022

Devised: 10/5/20
Revised: 3/1/21 – annual review, updated logo, added MediSpan approval level, updated QL statement
Revised: 3/1/22 – annual review, updated referenced policies & covered LOBs, updated FA
Revised: 6/7/22 – added Lennox-Gastaut, updated FA



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 638.0

**SECTION: Commercial Drug
SUBJECT: Isturisa**

Applicable line of business:

Commercial	X	Medicaid	
Medicare		ACA	X
GHP Kids	X	Self-Insured	X

POLICY:

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for Isturisa for GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 487.0 Quantity Limit Exceptions

REQUIRED DEFINITIONS:

1. **Attachment** – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. **Exhibit** – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. **Devised** – the date the policy was implemented.
4. **Revised** – the date of every revision to the policy, including typographical and grammatical changes.
5. **Reviewed** – the date documenting the annual review if the policy has no revisions necessary.

ADDITIONAL DEFINITIONS:

1. **Formulary** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. **Non-formulary products** – those medications that are not included in the Formulary.
3. **Healthcare provider** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
4. **NCQA** – National Committee for Quality Assurance.
5. **Medically Necessary or Medical Necessity** – covered services rendered by a provider that the Health Plan determines are:



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 638.0

**SECTION: Commercial Drug
SUBJECT: Isturisa**

- A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
- B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
- C. In accordance with current standards of medical practice;
- D. Not primarily for the convenience of the Member, or the Member's Provider; and
- E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

PROCEDURE:

An exception for coverage of Isturisa may be made for members who meet the following criteria:

- Medical record documentation that Isturisa is prescribed by an endocrinologist **AND**
- Medical record documentation of age greater than or equal to 18 years **AND**
- Medical record documentation of a diagnosis of Cushing's disease **AND**
- Medical record documentation that pituitary surgery is not an option or has not been curative **AND**
- Medical record documentation of therapeutic failure on, intolerance to, or contraindication to two (2) of the following: ketoconazole, metopirone, Signifor, Signifor LAR

MEDISPAN AUTHORIZATION LEVEL: GPI-12

QUANTITY LIMIT: *No QLs need to be entered within the authorization unless the requested quantity exceeds the QL.*

- **QL FOR LETTER ONLY:**
 - 1 mg tablets: 8 tablets per day, 30 day supply per fill
 - 5 mg tablets: 2 tablets per day, 30 day supply per fill
 - 10 mg tablets: 6 tablets per day, 30 day supply per fill

AUTHORIZATION DURATION: Initial approval will be for 12 months. Subsequent approvals will be for an additional 12 months or less if the reviewing provider feels it is medically appropriate. Reauthorization requires medical record documentation of improvement in urinary free cortisol levels compared to baseline.



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 638.0

**SECTION: Commercial Drug
SUBJECT: Isturisa**

If a formulary exception is approved, Isturisa will be paid for under the member's prescription drug benefit.

Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.

FORMULARY ALTERNATIVES:

ketoconazole, cabergoline, Lysodren, Signifor*, Korlym*

*prior authorization required

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE
STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND
FEDERAL REGULATORY ENTITIES.**

**THIS POLICY WILL BE REVISED AS NECESSARY AND
REVIEWED NO LESS THAN ANNUALLY.**

Signed: _____

Title: Director, Pharmacy Services

Date: March 1, 2022

Devised: 10/5/20

Revised: 3/1/21 – annual review, updated logo, added MediSpan approval level, updated QL statement

Revised: 3/1/22 – annual review, updated referenced policies & covered LOBs



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 639.0

**SECTION: Commercial Drug
SUBJECT: Kristalose Packets**

Applicable line of business:

Commercial	X	Medicaid	
Medicare		ACA	X
GHP Kids	X	Self-Insured	X

POLICY:

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for Kristalose packets for GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 487.0 Quantity Limit Exceptions

REQUIRED DEFINITIONS:

1. **Attachment** – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. **Exhibit** – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. **Devised** – the date the policy was implemented.
4. **Revised** – the date of every revision to the policy, including typographical and grammatical changes.
5. **Reviewed** – the date documenting the annual review if the policy has no revisions necessary.

ADDITIONAL DEFINITIONS:

1. **Formulary** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. **Non-formulary products** – those medications that are not included in the Formulary.
3. **Healthcare provider** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
4. **NCQA** – National Committee for Quality Assurance.
5. **Medically Necessary or Medical Necessity** – covered services rendered by a provider that the Health Plan determines are:



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 639.0

**SECTION: Commercial Drug
SUBJECT: Kristalose Packets**

- A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
- B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
- C. In accordance with current standards of medical practice;
- D. Not primarily for the convenience of the Member, or the Member's Provider; and
- E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

PROCEDURE:

An exception for coverage of Kristalose packets may be made for members who meet the following criteria:

- Medical record documentation of therapeutic failure on, intolerance to, or contraindication to lactulose liquid

MEDISPAN AUTHORIZATION LEVEL: GPI-12

If a formulary exception is approved, Kristalose packets will be paid for under the member's prescription drug benefit.

Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.

FORMULARY ALTERNATIVES:

lactulose liquid

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE
STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND
FEDERAL REGULATORY ENTITIES.**

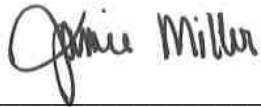
**THIS POLICY WILL BE REVISED AS NECESSARY AND
REVIEWED NO LESS THAN ANNUALLY.**

Geisinger

**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 639.0

**SECTION: Commercial Drug
SUBJECT: Kristalose Packets**



Signed: _____

Title: Director, Pharmacy Services

Date: March 1, 2022

Devised: 10/12/20

Revised: 3/1/21 – annual review, updated logo, added MediSpan approval level

Revised: 3/1/22 – annual review, updated referenced policies & covered LOBs



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 640.0

**SECTION: Commercial Drug
SUBJECT: Nexletol**

Applicable line of business:

Commercial	X	Medicaid	
Medicare		ACA	X
GHP Kids	X	Self-Insured	X

POLICY:

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for Nexletol for GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 487.0 Quantity Limit Exceptions

REQUIRED DEFINITIONS:

1. **Attachment** – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. **Exhibit** – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
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4. **Revised** – the date of every revision to the policy, including typographical and grammatical changes.
5. **Reviewed** – the date documenting the annual review if the policy has no revisions necessary.

ADDITIONAL DEFINITIONS:

1. **Formulary** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. **Non-formulary products** – those medications that are not included in the Formulary.
3. **Healthcare provider** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
4. **NCQA** – National Committee for Quality Assurance.
5. **Medically Necessary or Medical Necessity** – covered services rendered by a provider that the Health Plan determines are:

- A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
- B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
- C. In accordance with current standards of medical practice;
- D. Not primarily for the convenience of the Member, or the Member's Provider; and
- E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

PROCEDURE:

An exception for coverage of Nexletol may be made for members who meet the following criteria:

- Medical record documentation of a diagnosis of:
 - Clinical atherosclerotic cardiovascular disease (ASCVD), including acute coronary syndromes (a history of myocardial infarction or unstable angina), coronary or other arterial revascularization, stroke, transient ischemic attack, or peripheral arterial disease presumed to be of atherosclerotic origin **OR**
 - Heterozygous familial hypercholesterolemia (HeFH) **AND** either:
 - Genetic testing to confirm a mutation in the low-density lipoprotein (LDL) receptor, PCSK9, or ApoB gene **OR**
 - Medical record documentation of definite heterozygous familial hypercholesterolemia (HeFH) (score greater than 8) on the diagnostic criteria scoring system (Table 1) as defined by the Dutch Lipid Clinic Network diagnostic criteria **AND**
- Medical record documentation that Nexletol is prescribed by a cardiologist or lipidologist **AND**
- Medical record documentation of age greater than or equal to 18 years **AND**
- Medical record documentation of a baseline low-density lipoprotein (LDL) drawn within 3 months of the start of Nexletol therapy with one of the following:
 - Low-density lipoprotein (LDL) greater than 100 if the patient has a diagnosis of heterozygous familial hypercholesterolemia (HeFH) and is using Nexletol for primary prevention **OR**
 - Low-density lipoprotein (LDL) greater than 70 if the patient has a diagnosis of atherosclerotic cardiovascular disease (ASCVD) or either heterozygous familial hypercholesterolemia (HeFH) and is using Nexletol for secondary prevention **AND**



POLICY NUMBER: 640.0

**POLICY AND PROCEDURE
PHARMACY
MANUAL**

**SECTION: Commercial Drug
SUBJECT: Nexletol**

- Medical record documentation that patient is currently on and is adherent to (taking at least 90% of prescribed doses over the past three months) maximally tolerated dose of atorvastatin or rosuvastatin or has documented therapeutic failure on, intolerance to, or contraindication to atorvastatin and rosuvastatin **AND**
- Medical record documentation that non-pharmacologic therapies are in place including cholesterol lowering diet, exercise, and weight management strategies **AND**
- Medical record documentation of a therapeutic failure on, intolerance to, or contraindication to ezetimibe

MEDISPAN AUTHORIZATION LEVEL: GPI-12

QUANTITY LIMIT: *No QLs need to be entered within the authorization unless the requested quantity exceeds the QL.*

- QL FOR LETTER ONLY: 1 tablet per day

If a formulary exception is approved, Nexletol will be paid for under the member's prescription drug benefit.

Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.

FORMULARY ALTERNATIVES:

atorvastatin, rosuvastatin, ezetimibe, cholestyramine, colestipol, fenofibrate, fluvastatin, gemfibrozil, lovastatin, pravastatin, simvastatin

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE
STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND
FEDERAL REGULATORY ENTITIES.**

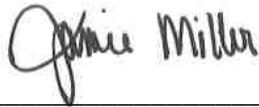
**THIS POLICY WILL BE REVISED AS NECESSARY AND
REVIEWED NO LESS THAN ANNUALLY.**

Geisinger

**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 640.0

**SECTION: Commercial Drug
SUBJECT: Nexletol**



Signed: _____

Title: Director, Pharmacy Services

Date: April 6, 2022

Devised: 11/17/20

Revised: 3/1/21 – annual review, updated logo, added MediSpan approval level, updated QL statement

Revised: 3/1/22 – annual review, updated referenced policies & covered LOBs

Revised: 4/6/22 – updated ESC/EAS to Dutch Lipid



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 641.0

**SECTION: Commercial Drug
SUBJECT: Nexlizet**

Applicable line of business:

Commercial	X	Medicaid	
Medicare		ACA	X
GHP Kids	X	Self-Insured	X

POLICY:

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for Nexlizet for GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 487.0 Quantity Limit Exceptions

REQUIRED DEFINITIONS:

1. **Attachment** – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. **Exhibit** – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. **Devised** – the date the policy was implemented.
4. **Revised** – the date of every revision to the policy, including typographical and grammatical changes.
5. **Reviewed** – the date documenting the annual review if the policy has no revisions necessary.

ADDITIONAL DEFINITIONS:

1. **Formulary** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. **Non-formulary products** – those medications that are not included in the Formulary.
3. **Healthcare provider** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
4. **NCQA** – National Committee for Quality Assurance.
5. **Medically Necessary or Medical Necessity** – covered services rendered by a provider that the Health Plan determines are:

- A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
- B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
- C. In accordance with current standards of medical practice;
- D. Not primarily for the convenience of the Member, or the Member's Provider; and
- E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

PROCEDURE:

An exception for coverage of Nexlizet may be made for members who meet the following criteria:

- Medical record documentation of a diagnosis of:
 - Clinical atherosclerotic cardiovascular disease (ASCVD), including acute coronary syndromes (a history of myocardial infarction or unstable angina), coronary or other arterial revascularization, stroke, transient ischemic attack, or peripheral arterial disease presumed to be of atherosclerotic origin **OR**
 - Heterozygous familial hypercholesterolemia (HeFH) **AND** either:
 - Genetic testing to confirm a mutation in the low-density lipoprotein (LDL) receptor, PCSK9, or ApoB gene **OR**
 - Medical record documentation of definite heterozygous familial hypercholesterolemia (HeFH) (score greater than 8) on the diagnostic criteria scoring system (Table 1) as defined by the Dutch Lipid Clinic Network diagnostic criteria **AND**
- Medical record documentation that Nexlizet is prescribed by a cardiologist or lipidologist **AND**
- Medical record documentation of age greater than or equal to 18 years **AND**
- Medical record documentation of a baseline low-density lipoprotein (LDL) drawn within 3 months of the start of Nexlizet therapy with one of the following:
 - Low-density lipoprotein (LDL) greater than 100 if the patient has a diagnosis of heterozygous familial hypercholesterolemia (HeFH) and is using Nexlizet for primary prevention **OR**
 - Low-density lipoprotein (LDL) greater than 70 if the patient has a diagnosis of atherosclerotic cardiovascular disease (ASCVD) or either heterozygous familial hypercholesterolemia (HeFH) and is using Nexlizet for secondary prevention **AND**



POLICY NUMBER: 641.0

**POLICY AND PROCEDURE
PHARMACY
MANUAL**

**SECTION: Commercial Drug
SUBJECT: Nexlizet**

- Medical record documentation that patient is currently on and is adherent to (taking at least 90% of prescribed doses over the past three months) maximally tolerated dose of atorvastatin or rosuvastatin or has documented therapeutic failure on, intolerance to, or contraindication to atorvastatin and rosuvastatin **AND**
- Medical record documentation that non-pharmacologic therapies are in place including cholesterol lowering diet, exercise, and weight management strategies **AND**
- Medical record documentation of a therapeutic failure on, intolerance to, or contraindication to ezetimibe alone

MEDISPAN AUTHORIZATION LEVEL: GPI-12

QUANTITY LIMIT: *No QLs need to be entered within the authorization unless the requested quantity exceeds the QL.*

- QL FOR LETTER ONLY: 1 tablet per day

If a formulary exception is approved, Nexlizet will be paid for under the member's prescription drug benefit.

Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.

FORMULARY ALTERNATIVES:

atorvastatin, rosuvastatin, ezetimibe, cholestyramine, colestipol, fenofibrate, fluvastatin, gemfibrozil, lovastatin, pravastatin, simvastatin

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE
STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND
FEDERAL REGULATORY ENTITIES.**

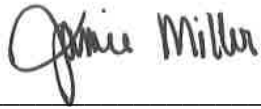
**THIS POLICY WILL BE REVISED AS NECESSARY AND
REVIEWED NO LESS THAN ANNUALLY.**

Geisinger

**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 641.0

**SECTION: Commercial Drug
SUBJECT: Nexlizet**



Signed: _____

Title: Director, Pharmacy Services

Date: April 6, 2022

Devised: 11/17/20

Revised: 3/1/21 – annual review, updated logo, added MediSpan approval level, updated QL statement

Revised: 3/1/22 – annual review, updated referenced policies & covered LOBs

Revised: 4/6/22 – updated ESC/EAS to Dutch Lipid



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 642.0

**SECTION: Commercial Drug
SUBJECT: Santyl**

Applicable line of business:

Commercial	X	Medicaid	
Medicare		ACA	X
GHP Kids	X	Self-Insured	X

POLICY:

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for Santyl for GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 487.0 Quantity Limit Exceptions

REQUIRED DEFINITIONS:

1. **Attachment** – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. **Exhibit** – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. **Devised** – the date the policy was implemented.
4. **Revised** – the date of every revision to the policy, including typographical and grammatical changes.
5. **Reviewed** – the date documenting the annual review if the policy has no revisions necessary.

ADDITIONAL DEFINITIONS:

1. **Formulary** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. **Non-formulary products** – those medications that are not included in the Formulary.
3. **Healthcare provider** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
4. **NCQA** – National Committee for Quality Assurance.
5. **Medically Necessary or Medical Necessity** – covered services rendered by a provider that the Health Plan determines are:



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 642.0

**SECTION: Commercial Drug
SUBJECT: Santyl**

- A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
- B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
- C. In accordance with current standards of medical practice;
- D. Not primarily for the convenience of the Member, or the Member's Provider; and
- E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

PROCEDURE:

An exception for coverage of Santyl may be made for members who meet the following criteria:

- Medical record documentation that the member has been evaluated by a burn, a wound care specialist, or other specialist with experience in the management of severe wounds **AND**
- Medical record documentation of the wound length and width **AND**
- Medical record documentation of anticipated duration of therapy **AND**
- Medical record documentation that the prescribed dose is medically necessary based on the size and intended duration of therapy*

***NOTE:** Please calculate the dose on the manufacturer's website to confirm it is within a medically appropriate range - <https://santyl.com/hcp/dosing>

MEDISPAN AUTHORIZATION LEVEL: GPI-12

AUTHORIZATION DURATION: Initial approval will be for 3 months. Subsequent approval will be for 3 months. Reauthorization will require:

- Medical record documentation that the member has been evaluated by a burn, a wound care specialist, or other specialist with experience in the management of severe wounds **AND**
- Medical record documentation of the wound length and width **AND**
- Medical record documentation of anticipated duration of therapy **AND**
- Medical record documentation that the prescribed dose is medically necessary based on the size and intended duration of therapy*



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 642.0

**SECTION: Commercial Drug
SUBJECT: Santyl**

If a formulary exception is approved, Santyl will be paid for under the member's prescription drug benefit.

Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.

FORMULARY ALTERNATIVES:

none

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE
STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND
FEDERAL REGULATORY ENTITIES.**

**THIS POLICY WILL BE REVISED AS NECESSARY AND
REVIEWED NO LESS THAN ANNUALLY.**

Signed: _____

Title: Director, Pharmacy Services

Date: March 1, 2022

Devised: 11/18/20
Revised: 3/1/21 – annual review, updated logo, added MediSpan approval level
Revised: 8/24/21 – updated reauthorization criteria
Revised: 3/1/22 – annual review, updated referenced policies & covered LOBs



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 643.0

**SECTION: Commercial Drug
SUBJECT: Inqovi**

Applicable line of business:

Commercial	X	Medicaid	
Medicare		ACA	X
GHP Kids	X	Self-Insured	X

POLICY:

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for Inqovi for GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 487.0 Quantity Limit Exceptions

REQUIRED DEFINITIONS:

1. **Attachment** – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. **Exhibit** – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. **Devised** – the date the policy was implemented.
4. **Revised** – the date of every revision to the policy, including typographical and grammatical changes.
5. **Reviewed** – the date documenting the annual review if the policy has no revisions necessary.

ADDITIONAL DEFINITIONS:

1. **Formulary** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. **Non-formulary products** – those medications that are not included in the Formulary.
3. **Healthcare provider** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
4. **NCQA** – National Committee for Quality Assurance.
5. **Medically Necessary or Medical Necessity** – covered services rendered by a provider that the Health Plan determines are:



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 643.0

**SECTION: Commercial Drug
SUBJECT: Inqovi**

- A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
- B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
- C. In accordance with current standards of medical practice;
- D. Not primarily for the convenience of the Member, or the Member's Provider; and
- E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

PROCEDURE:

New members to the plan already established on therapy may be eligible for continuity of care coverage as long as there is medical record documentation that the safety and effectiveness of use for the prescribed indication is supported by Food and Drug Administration (FDA) approval or adequate medical and scientific evidence in the medical literature.

An exception for coverage of Inqovi may be made for members who meet the following criteria:

- Medical record documentation that Inqovi is prescribed by or in consultation with an oncologist or hematologist **AND**
- Medical record documentation of age greater than or equal to 18 years **AND**
- Medical record documentation of a diagnosis of myelodysplastic syndromes (MDS), including previously treated and untreated, de novo and secondary MDS with the following French-American-British subtypes (refractory anemia, refractory anemia with ringed sideroblasts, refractory anemia with excess blasts, and chronic myelomonocytic leukemia [CMML]) and intermediate-1, intermediate-2, and high-risk International Prognostic Scoring System groups

MEDISPAN AUTHORIZATION LEVEL: GPI-12, number of claims authorized = 1, enter for the remainder of the calendar year

QUANTITY LIMIT: *No QLs need to be entered within the authorization unless the requested quantity exceeds the QL.*

- **QL FOR LETTER ONLY:** 5 tablets per 28 days



POLICY NUMBER: 643.0

**POLICY AND PROCEDURE
PHARMACY
MANUAL**

**SECTION: Commercial Drug
SUBJECT: Inqovi**

RE-AUTHORIZATION CRITERIA: Inqovi is configured as a prior authorization for new starts only. Inqovi will no longer be covered if it is identified that the member is not receiving appropriate follow-up care from the prescribing specialist or if the member has greater than or equal to a 90 day break in therapy.

- Medical record documentation that the member is receiving appropriate follow-up care from the prescribing specialist

If a formulary exception is approved, Inqovi will be paid for under the member's prescription drug benefit.

Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.

FORMULARY ALTERNATIVES:

none

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE
STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND
FEDERAL REGULATORY ENTITIES.**

**THIS POLICY WILL BE REVISED AS NECESSARY AND
REVIEWED NO LESS THAN ANNUALLY.**

Signed: _____

Title: Director, Pharmacy Services

Date: March 1, 2022

Devised: 11/17/20
Revised: 3/1/21 – annual review, updated logo, added MediSpan approval level, updated QL statement
Revised: 11/24/21 – added one-time PA to approval crit., removed auth duration & added re-auth crit.
Revised: 3/1/22 – annual review, updated referenced policies & covered LOBs



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 644.0

**SECTION: Commercial Drug
SUBJECT: Dojolvi**

Applicable line of business:

Commercial	X	Medicaid	
Medicare		ACA	X
GHP Kids	X	Self-Insured	X

POLICY:

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for Dojolvi for GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 487.0 Quantity Limit Exceptions

REQUIRED DEFINITIONS:

1. **Attachment** – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. **Exhibit** – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. **Devised** – the date the policy was implemented.
4. **Revised** – the date of every revision to the policy, including typographical and grammatical changes.
5. **Reviewed** – the date documenting the annual review if the policy has no revisions necessary.

ADDITIONAL DEFINITIONS:

1. **Formulary** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. **Non-formulary products** – those medications that are not included in the Formulary.
3. **Healthcare provider** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
4. **NCQA** – National Committee for Quality Assurance.
5. **Medically Necessary or Medical Necessity** – covered services rendered by a provider that the Health Plan determines are:



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 644.0

**SECTION: Commercial Drug
SUBJECT: Dojolvi**

- A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
- B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
- C. In accordance with current standards of medical practice;
- D. Not primarily for the convenience of the Member, or the Member's Provider; and
- E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

PROCEDURE:

An exception for coverage of Dojolvi may be made for members who meet the following criteria:

- Medical record documentation that Dojolvi is prescribed by or in consultation with a metabolic specialist or a physician who specialized in the management of long-chain fatty acid oxidation disorders **AND**
- Medical record documentation of a diagnosis of long-chain fatty acid oxidation disorders (LC-FAOD) confirmed by at least two of the following:
 - Disease specific elevation of acylcarnitines on a newborn blood spot or in plasma
 - Low enzyme activity in cultured fibroblasts
 - One or more known pathogenic mutations in a gene associated with a long-chain fatty acid oxidation disorder (e.g. *CPT2*, *ACADVL*, *HADHA*, or *HADHB*)**AND**
- Medical record documentation that the member is currently managed on a treatment regimen which may include a low-fat, high carbohydrate diet; avoidance or fasting; and/or medium-chain triglyceride (MCT) oil

MEDISPAN AUTHORIZATION LEVEL: GPI-12

AUTHORIZATION DURATION: Initial approval will be for 12 months or less if the reviewing provider feels it is medically appropriate. Subsequent approvals will be for an additional 12 months or less if the reviewing provider feels it is medically appropriate and will require medical record documentation of continued disease improvement* or lack of disease progression. The medication will no longer be covered if the member experiences unacceptable toxicity or worsening of disease.



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 644.0

**SECTION: Commercial Drug
SUBJECT: Dojolvi**

***NOTE:** Signs of improvement for a patient with LC-FAOD can include any of the following, but are not limited to: gross motor development/motor function for infants and young children, exercise tolerance and endurance for older children and adults, and a decrease in the frequency of major medical episodes of hypoglycemia, rhabdomyolysis, and exacerbation of cardiomyopathy.

If a formulary exception is approved, Dojolvi will be paid for under the member's prescription drug benefit.

Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.

FORMULARY ALTERNATIVES:

none

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE
STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND
FEDERAL REGULATORY ENTITIES.**

**THIS POLICY WILL BE REVISED AS NECESSARY AND
REVIEWED NO LESS THAN ANNUALLY.**

Signed: _____

Title: Director, Pharmacy Services

Date: March 1, 2022

Devised: 11/18/20

Revised: 3/1/21 – annual review, updated logo, added MediSpan approval level

Revised: 3/1/22 – annual review, updated referenced policies & covered LOBs



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 645.0

**SECTION: Commercial Drug
SUBJECT: Gavreto**

Applicable line of business:

Commercial	X	Medicaid	
Medicare		ACA	X
GHP Kids	X	Self-Insured	X

POLICY:

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for Gavreto for GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 487.0 Quantity Limit Exceptions

REQUIRED DEFINITIONS:

1. **Attachment** – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. **Exhibit** – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. **Devised** – the date the policy was implemented.
4. **Revised** – the date of every revision to the policy, including typographical and grammatical changes.
5. **Reviewed** – the date documenting the annual review if the policy has no revisions necessary.

ADDITIONAL DEFINITIONS:

1. **Formulary** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. **Non-formulary products** – those medications that are not included in the Formulary.
3. **Healthcare provider** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
4. **NCQA** – National Committee for Quality Assurance.
5. **Medically Necessary or Medical Necessity** – covered services rendered by a provider that the Health Plan determines are:

- A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
- B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
- C. In accordance with current standards of medical practice;
- D. Not primarily for the convenience of the Member, or the Member's Provider; and
- E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

PROCEDURE:

New members to the plan already established on therapy may be eligible for continuity of care coverage as long as there is medical record documentation that the safety and effectiveness of use for the prescribed indication is supported by Food and Drug Administration (FDA) approval or adequate medical and scientific evidence in the medical literature.

An exception for coverage of Gavreto may be made for members who meet the following criteria:

Non-Small Cell Lung Cancer

- Medical record documentation that Gavreto is prescribed by an oncologist or hematologist **AND**
- Medical record documentation of age greater than or equal to 18 years **AND**
- Medical record documentation of a diagnosis of metastatic non-small cell lung cancer (NSCLC) **AND**
- Medical record documentation of a rearranged during transfection (RET) – fusion positive tumor as detected by a Food and Drug Administration (FDA) approved test*

Thyroid Cancer

- Medical record documentation that Gavreto is prescribed by an oncologist or hematologist **AND**
- Medical record documentation of age greater than or equal to 12 years **AND**
- Medical record documentation of one of the following:
 - Medical record documentation of advanced or metastatic RET-mutant medullary thyroid cancer (MTC) **AND** documentation that systemic therapy is required **OR**
 - Medical record documentation of advanced or metastatic RET fusion-positive thyroid cancer **AND** medical record documentation of both of the following:



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 645.0

**SECTION: Commercial Drug
SUBJECT: Gavreto**

- Documentation that systemic therapy is required **AND**
- Documentation that patient is radioactive-iodine refractory when radioactive iodine is appropriate

***NOTE:** The FDA approved companion diagnostic test for Gavreto to determine the presence of a RET gene fusion is the Oncomine Dx Target Test.

MEDISPAN AUTHORIZATION LEVEL: GPI-12, number of claims authorized = 1, enter for the remainder of the calendar year

QUANTITY LIMIT: *No QLs need to be entered within the authorization unless the requested quantity exceeds the QL.*

- QL FOR LETTER ONLY: 4 capsules per day, 30 day supply per fill

RE-AUTHORIZATION CRITERIA: Gavreto is configured as a prior authorization for new starts only. Gavreto will no longer be covered if it is identified that the member is not receiving appropriate follow-up care from the prescribing specialist or if the member has greater than or equal to a 90 day break in therapy.

- Medical record documentation that the member is receiving appropriate follow-up care from the prescribing specialist

If a formulary exception is approved, Gavreto will be paid for under the member's prescription drug benefit.

Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.

FORMULARY ALTERNATIVES:

Caprelsa*, Cometriq*, Retevmo*

*prior authorization required

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STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND
FEDERAL REGULATORY ENTITIES.**

**THIS POLICY WILL BE REVISED AS NECESSARY AND
REVIEWED NO LESS THAN ANNUALLY.**



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 645.0

**SECTION: Commercial Drug
SUBJECT: Gavreto**

Signed: _____

Title: Director, Pharmacy Services

Date: March 1, 2022

Devised: 11/18/20
Revised: 3/1/21 – annual review, updated logo, added MediSpan approval level, updated QL statement
Revised: 3/26/21 – added thyroid cancer indication
Revised: 11/24/21 – added one-time PA to approval crit., removed auth duration & added re-auth crit.
Revised: 3/1/22 – annual review, updated referenced policies & covered LOBs



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 646.0

**SECTION: Commercial Drug
SUBJECT: Onureg**

Applicable line of business:

Commercial	X	Medicaid	
Medicare		ACA	X
GHP Kids	X	Self-Insured	X

POLICY:

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for Onureg for GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 487.0 Quantity Limit Exceptions

REQUIRED DEFINITIONS:

1. **Attachment** – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. **Exhibit** – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. **Devised** – the date the policy was implemented.
4. **Revised** – the date of every revision to the policy, including typographical and grammatical changes.
5. **Reviewed** – the date documenting the annual review if the policy has no revisions necessary.

ADDITIONAL DEFINITIONS:

1. **Formulary** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. **Non-formulary products** – those medications that are not included in the Formulary.
3. **Healthcare provider** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
4. **NCQA** – National Committee for Quality Assurance.
5. **Medically Necessary or Medical Necessity** – covered services rendered by a provider that the Health Plan determines are:



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 646.0

**SECTION: Commercial Drug
SUBJECT: Onureg**

- A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
- B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
- C. In accordance with current standards of medical practice;
- D. Not primarily for the convenience of the Member, or the Member's Provider; and
- E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

PROCEDURE:

New members to the plan already established on therapy may be eligible for continuity of care coverage as long as there is medical record documentation that the safety and effectiveness of use for the prescribed indication is supported by Food and Drug Administration (FDA) approval or adequate medical and scientific evidence in the medical literature.

An exception for coverage of Onureg may be made for members who meet the following criteria:

- Medical record documentation that Onureg is prescribed by an oncologist or hematologist **AND**
- Medical record documentation of age greater than or equal to 18 years **AND**
- Medical record documentation of a diagnosis of acute myeloid leukemia **AND**
- Medical record documentation the member achieved first complete remission (CR) or complete remission with incomplete blood count recovery (Cri) following intensive induction chemotherapy **AND**
- Medical record documentation that member is not able to complete intensive curative therapy

MEDISPAN AUTHORIZATION LEVEL: GPI-12, number of claims authorized = 1, enter for the remainder of the calendar year

QUANTITY LIMIT: *No QLs need to be entered within the authorization unless the requested quantity exceeds the QL.*

- **QL FOR LETTER ONLY:** 14 tablets per 28 days



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 646.0

**SECTION: Commercial Drug
SUBJECT: Onureg**

RE-AUTHORIZATION CRITERIA: Onureg is configured as a prior authorization for new starts only. Onureg will no longer be covered if it is identified that the member is not receiving appropriate follow-up care from the prescribing specialist or if the member has greater than or equal to a 90 day break in therapy.

- Medical record documentation that the member is receiving appropriate follow-up care from the prescribing specialist

If a formulary exception is approved, Onureg will be paid for under the member's prescription drug benefit.

Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.

FORMULARY ALTERNATIVES:

none

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE
STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND
FEDERAL REGULATORY ENTITIES.**

**THIS POLICY WILL BE REVISED AS NECESSARY AND
REVIEWED NO LESS THAN ANNUALLY.**

Signed: _____

Title: Director, Pharmacy Services

Date: March 1, 2022

Devised: 11/18/20
Revised: 1/21/21 – corrected Gavreto typo
Revised: 3/1/21 – annual review, updated logo, added MediSpan approval level, updated QL statement
Revised: 11/30/21 – added one-time PA to approval crit., removed auth duration & added re-auth crit.
Revised: 3/1/22 – annual review, updated referenced policies & covered LOBs



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 647.0

**SECTION: Commercial Drug
SUBJECT: Evrysdi**

Applicable line of business:

Commercial	X	Medicaid	
Medicare		ACA	X
GHP Kids	X	Self-Insured	X

POLICY:

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for Evrysdi for GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 487.0 Quantity Limit Exceptions

REQUIRED DEFINITIONS:

1. **Attachment** – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. **Exhibit** – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. **Devised** – the date the policy was implemented.
4. **Revised** – the date of every revision to the policy, including typographical and grammatical changes.
5. **Reviewed** – the date documenting the annual review if the policy has no revisions necessary.

ADDITIONAL DEFINITIONS:

1. **Formulary** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. **Non-formulary products** – those medications that are not included in the Formulary.
3. **Healthcare provider** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
4. **NCQA** – National Committee for Quality Assurance.
5. **Medically Necessary or Medical Necessity** – covered services rendered by a provider that the Health Plan determines are:

- A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
- B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
- C. In accordance with current standards of medical practice;
- D. Not primarily for the convenience of the Member, or the Member's Provider; and
- E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

PROCEDURE:

An exception for coverage of Evrysdi may be made for members who meet the following criteria:

- Medical record documentation that Evrysdi is prescribed by a neurologist or pediatric neurologist **AND**
- Medical record documentation of age greater than or equal to 2 months **AND**
- Medical record documentation of one of the following:
 - A confirmed diagnosis of 5q Spinal Muscular Atrophy (SMA) by genetic testing with results showing one of the following:
 - Homozygous exon 7 gene deletion **OR**
 - Homozygous exon 7 conversion mutation **OR**
 - Compound heterozygous exon 7 mutation **OR**
 - Medical record documentation of diagnostic testing confirming zero (0) SMN1 copies

AND

- Medical record documentation that the patient has not received prior treatment with gene therapy (e.g., Zolgensma)* **AND**
- Medical record documentation that patient will not receive routine concomitant SMN modifying therapy (e.g., Spinraza)

***NOTE:** Requests for members that show decline in clinical status following treatment with Zolgensma will be reviewed on a case by case basis.

MEDISPAN AUTHORIZATION LEVEL: GPI-12

QUANTITY LIMIT: *No QLs need to be entered within the authorization unless the requested quantity exceeds the QL.*

- **QL FOR LETTER ONLY:** 240 mL per 36 days

AUTHORIZATION DURATION: Evrysdi will be approved for an initial authorization duration of 12 months. Subsequent authorizations will be determined medically necessary and should be approved for an authorization duration of 12 months when the following criteria are met:

- Medical record documentation that member is compliant with the prescribed risdiplam regimen **AND**
- Medical record documentation that the patient has not received prior treatment with gene therapy (e.g., Zolgensma)* **AND**
- Medical record documentation that patient will not receive routine concomitant SMN modifying therapy (e.g., Spinraza)

***NOTE:** Requests for members that show decline in clinical status following treatment with Zolgensma will be reviewed on a case by case basis.

If a formulary exception is approved, Evrysdi will be paid for under the member's prescription drug benefit.

Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.

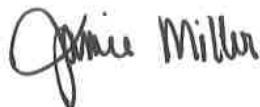
FORMULARY ALTERNATIVES:

none

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE
STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND
FEDERAL REGULATORY ENTITIES.**

**THIS POLICY WILL BE REVISED AS NECESSARY AND
REVIEWED NO LESS THAN ANNUALLY.**

Signed: _____



Title: Director, Pharmacy Services

Date: March 1, 2022



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 647.0

**SECTION: Commercial Drug
SUBJECT: Evrysdi**

Devised: 1/21/21
Revised: 3/1/21 – annual review, updated logo
Revised: 3/1/22 – annual review, updated referenced policies & covered LOBs



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 648.0

**SECTION: Commercial Drug
SUBJECT: Bafiertam**

Applicable line of business:

Commercial	X	Medicaid	
Medicare		ACA	X
GHP Kids	X	Self-Insured	X

POLICY:

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for Bafiertam for GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 487.0 Quantity Limit Exceptions

REQUIRED DEFINITIONS:

1. **Attachment** – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. **Exhibit** – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. **Devised** – the date the policy was implemented.
4. **Revised** – the date of every revision to the policy, including typographical and grammatical changes.
5. **Reviewed** – the date documenting the annual review if the policy has no revisions necessary.

ADDITIONAL DEFINITIONS:

1. **Formulary** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. **Non-formulary products** – those medications that are not included in the Formulary.
3. **Healthcare provider** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
4. **NCQA** – National Committee for Quality Assurance.
5. **Medically Necessary or Medical Necessity** – covered services rendered by a provider that the Health Plan determines are:



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 648.0

**SECTION: Commercial Drug
SUBJECT: Bafiertam**

- A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
- B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
- C. In accordance with current standards of medical practice;
- D. Not primarily for the convenience of the Member, or the Member's Provider; and
- E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

PROCEDURE:

New members to the plan already established on therapy may be eligible for continuity of care coverage as long as there is medical record documentation that the safety and effectiveness of use for the prescribed indication is supported by Food and Drug Administration (FDA) approval or adequate medical and scientific evidence in the medical literature.

An exception for coverage of Bafiertam may be made for members who meet the following criteria:

- Electronic step therapy of on-line prescription drug claims history showing 15 days use of dimethyl fumarate within the previous 180 days. If this electronic step is met, the claim will automatically adjudicate **OR**
- If the electronic step therapy criteria are not met, prescribing provider should request an exception for coverage indicating therapeutic failure on, intolerance to, or contraindication to dimethyl fumarate

MEDISPAN AUTHORIZATION LEVEL: GPI-12

QUANTITY LIMIT: *No QLs need to be entered within the authorization unless the requested quantity exceeds the QL.*

- **QL FOR LETTER ONLY:** 4 capsules per day, 30-day supply per fill

If a formulary exception is approved, Bafiertam will be paid for under the member's prescription drug benefit.

Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 648.0

**SECTION: Commercial Drug
SUBJECT: Bafiertam**

FORMULARY ALTERNATIVES:
dimethyl fumarate

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE
STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND
FEDERAL REGULATORY ENTITIES.**

**THIS POLICY WILL BE REVISED AS NECESSARY AND
REVIEWED NO LESS THAN ANNUALLY.**

Signed: _____

Title: Director, Pharmacy Services

Date: March 1, 2022

Devised: 1/22/21

Revised: 3/1/21 – annual review, updated logo

Revised: 3/1/22 – annual review, updated referenced policies & covered LOBs



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 649.0

**SECTION: Commercial Drug
SUBJECT: Vumerity**

Applicable line of business:

Commercial	X	Medicaid	
Medicare		ACA	X
GHP Kids	X	Self-Insured	X

POLICY:

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for Vumerity for GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 487.0 Quantity Limit Exceptions

REQUIRED DEFINITIONS:

1. **Attachment** – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. **Exhibit** – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. **Devised** – the date the policy was implemented.
4. **Revised** – the date of every revision to the policy, including typographical and grammatical changes.
5. **Reviewed** – the date documenting the annual review if the policy has no revisions necessary.

ADDITIONAL DEFINITIONS:

1. **Formulary** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. **Non-formulary products** – those medications that are not included in the Formulary.
3. **Healthcare provider** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
4. **NCQA** – National Committee for Quality Assurance.
5. **Medically Necessary or Medical Necessity** – covered services rendered by a provider that the Health Plan determines are:



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 649.0

**SECTION: Commercial Drug
SUBJECT: Vumerity**

- A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
- B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
- C. In accordance with current standards of medical practice;
- D. Not primarily for the convenience of the Member, or the Member's Provider; and
- E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

PROCEDURE:

New members to the plan already established on therapy may be eligible for continuity of care coverage as long as there is medical record documentation that the safety and effectiveness of use for the prescribed indication is supported by Food and Drug Administration (FDA) approval or adequate medical and scientific evidence in the medical literature.

An exception for coverage of Vumerity may be made for members who meet the following criteria:

- Electronic step therapy of on-line prescription drug claims history showing 15 days use of dimethyl fumarate within the previous 180 days. If this electronic step is met, the claim will automatically adjudicate **OR**
- If the electronic step therapy criteria are not met, prescribing provider should request an exception for coverage indicating therapeutic failure on, intolerance to, or contraindication to dimethyl fumarate

MEDISPAN AUTHORIZATION LEVEL: GPI-12

QUANTITY LIMIT: *No QLs need to be entered within the authorization unless the requested quantity exceeds the QL.*

- **QL FOR LETTER ONLY:** 4 capsules per day, 30-day supply per fill

If a formulary exception is approved, Vumerity will be paid for under the member's prescription drug benefit.

Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 649.0

**SECTION: Commercial Drug
SUBJECT: Vumerity**

FORMULARY ALTERNATIVES:
dimethyl fumarate

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE
STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND
FEDERAL REGULATORY ENTITIES.**

**THIS POLICY WILL BE REVISED AS NECESSARY AND
REVIEWED NO LESS THAN ANNUALLY.**

Signed: _____

Title: Director, Pharmacy Services

Date: March 1, 2022

Devised: 1/22/21

Revised: 3/1/21 – annual review, updated logo

Revised: 3/1/22 – annual review, updated referenced policies & covered LOBs



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 650.0

**SECTION: Commercial Drug
SUBJECT: Enspryng**

Applicable line of business:

Commercial	X	Medicaid	
Medicare		ACA	X
GHP Kids	X	Self-Insured	X

POLICY:

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for Enspryng for GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 487.0 Quantity Limit Exceptions

REQUIRED DEFINITIONS:

1. **Attachment** – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. **Exhibit** – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. **Devised** – the date the policy was implemented.
4. **Revised** – the date of every revision to the policy, including typographical and grammatical changes.
5. **Reviewed** – the date documenting the annual review if the policy has no revisions necessary.

ADDITIONAL DEFINITIONS:

1. **Formulary** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. **Non-formulary products** – those medications that are not included in the Formulary.
3. **Healthcare provider** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
4. **NCQA** – National Committee for Quality Assurance.
5. **Medically Necessary or Medical Necessity** – covered services rendered by a provider that the Health Plan determines are:



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 650.0

**SECTION: Commercial Drug
SUBJECT: Enspryng**

- A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
- B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
- C. In accordance with current standards of medical practice;
- D. Not primarily for the convenience of the Member, or the Member's Provider; and
- E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

PROCEDURE:

An exception for coverage of Enspryng may be made for members who meet the following criteria:

- Medical record documentation that Enspryng is prescribed by or in consultation with a neurologist **AND**
- Medical record documentation of age greater than or equal to 18 years **AND**
- Medical record documentation of diagnosis of Neuromyelitis Optica Spectrum Disorder (NMOSD) **AND**
- Medical record documentation that member is anti-aquaporin-4 (AQP4) antibody positive **AND**
- Medical record documentation of failure on, intolerance to, or contraindication to rituximab or rituximab biosimilar

MEDISPAN AUTHORIZATION LEVEL: GPI-12

QUANTITY LIMIT:

- **Initial Approval** – *Two authorizations must be entered.*
 - 120 once every 2 weeks for 3 doses, then 120 every 4 weeks
 1. In PA Hub: Add PA only.
 2. In Darwin: Add OQL, DS, max number of claims authorized 1, max quantity dispensed 3, min day supply 28, max day supply 28, with a duration of two weeks.
 - **QL FOR LETTER:** Loading dose: 3 mL per 28 days;
Maintenance dose: 1 mL per 28 days
- **Renewal** – *No QLs need to be entered within the authorization unless the requested quantity exceeds the QL.*
 - **QL FOR LETTER:** 1 mL per 28 days



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 650.0

**SECTION: Commercial Drug
SUBJECT: Enspryng**

AUTHORIZATION DURATION: Initial approval will be for 12 months or less if the reviewing provider feels it is medically appropriate. Subsequent approvals will be for an additional 12 months or less if the reviewing provider feels it is medically appropriate and will require medical record documentation of continued disease improvement or lack of disease progression. The medication will no longer be covered if patient experiences toxicity or worsening of disease.

If a formulary exception is approved, Enspryng will be paid for under the member's prescription drug benefit.

Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.

FORMULARY ALTERNATIVES:

none

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE
STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND
FEDERAL REGULATORY ENTITIES.**

**THIS POLICY WILL BE REVISED AS NECESSARY AND
REVIEWED NO LESS THAN ANNUALLY.**

Signed: _____

Title: Director, Pharmacy Services

Date: March 1, 2022

Devised: 1/22/21

Revised: 3/1/21 – annual review, updated logo, updated QL statement

Revised: 3/1/22 – annual review, updated referenced policies & covered LOBs, updated how QL is entered



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 651.0

**SECTION: Commercial Drug
SUBJECT: Apokyn**

Applicable line of business:

Commercial	X	Medicaid	
Medicare		ACA	X
GHP Kids	X	Self-Insured	X

POLICY:

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for Apokyn for GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 487.0 Quantity Limit Exceptions

REQUIRED DEFINITIONS:

1. **Attachment** – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. **Exhibit** – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. **Devised** – the date the policy was implemented.
4. **Revised** – the date of every revision to the policy, including typographical and grammatical changes.
5. **Reviewed** – the date documenting the annual review if the policy has no revisions necessary.

ADDITIONAL DEFINITIONS:

1. **Formulary** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. **Non-formulary products** – those medications that are not included in the Formulary.
3. **Healthcare provider** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
4. **NCQA** – National Committee for Quality Assurance.
5. **Medically Necessary or Medical Necessity** – covered services rendered by a provider that the Health Plan determines are:



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 651.0

**SECTION: Commercial Drug
SUBJECT: Apokyn**

- A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
- B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
- C. In accordance with current standards of medical practice;
- D. Not primarily for the convenience of the Member, or the Member's Provider; and
- E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

PROCEDURE:

An exception for coverage of Apokyn may be made for members who meet the following criteria:

- Electronic step therapy of on-line prescription drug claims history showing 15 days use of Kynmobi within the previous 180 days. If this electronic step is met, the claim with automatically adjudicate **OR**
- If the electronic step therapy criteria are not met, prescribing provider should request an exception for coverage indicating therapeutic failure on, intolerance to, or contraindication to Kynmobi

MEDISPAN AUTHORIZATION LEVEL: GPI-12

If a formulary exception is approved, Apokyn will be paid for under the member's prescription drug benefit.

Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.

FORMULARY ALTERNATIVES:

Kynmobi, carbidopa/levodopa/entacapone, entacapone, pramipexole, pramipexole extended release*, rasagiline, ropinirole, selegiline, tolcapone*, Inbrija

*prior authorization or step therapy required

Geisinger

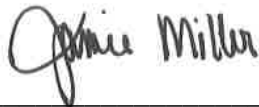
**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 651.0

**SECTION: Commercial Drug
SUBJECT: Apokyn**

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE
STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND
FEDERAL REGULATORY ENTITIES.**

**THIS POLICY WILL BE REVISED AS NECESSARY AND
REVIEWED NO LESS THAN ANNUALLY.**



Signed: _____

Title: Director, Pharmacy Services

Date: March 1, 2022

Devised: 1/22/21

Revised: 3/1/21 – annual review, updated logo

Revised: 3/1/22 – annual review, updated referenced policies & covered LOBs



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 652.0

**SECTION: Commercial Drug
SUBJECT: Ongentys**

Applicable line of business:

Commercial	X	Medicaid	
Medicare		ACA	X
GHP Kids	X	Self-Insured	X

POLICY:

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for Ongentys for GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 487.0 Quantity Limit Exceptions

REQUIRED DEFINITIONS:

1. **Attachment** – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. **Exhibit** – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. **Devised** – the date the policy was implemented.
4. **Revised** – the date of every revision to the policy, including typographical and grammatical changes.
5. **Reviewed** – the date documenting the annual review if the policy has no revisions necessary.

ADDITIONAL DEFINITIONS:

1. **Formulary** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. **Non-formulary products** – those medications that are not included in the Formulary.
3. **Healthcare provider** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
4. **NCQA** – National Committee for Quality Assurance.
5. **Medically Necessary or Medical Necessity** – covered services rendered by a provider that the Health Plan determines are:

- A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
- B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
- C. In accordance with current standards of medical practice;
- D. Not primarily for the convenience of the Member, or the Member's Provider; and
- E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

PROCEDURE:

An exception for coverage of Ongentys may be made for members who meet the following criteria:

- Electronic step therapy of on-line prescription drug claims history showing 15 days use of entacapone, carbidopa/levodopa/entacapone, or tolcapone within the previous 180 days. If this electronic step is met, the claim will automatically adjudicate **OR**
- If the electronic step therapy criteria are not met, prescribing provider should request an exception for coverage indicating therapeutic failure on, intolerance to, or contraindication to entacapone, carbidopa/levodopa/entacapone, or tolcapone

MEDISPAN AUTHORIZATION LEVEL: GPI-12

QUANTITY LIMIT: *No QLs need to be entered within the authorization unless the requested quantity exceeds the QL.*

- **QL FOR LETTER ONLY:** 1 tablet per day

If a formulary exception is approved, Ongentys will be paid for under the member's prescription drug benefit.

Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.

FORMULARY ALTERNATIVES:

carbidopa/levodopa/entacapone, entacapone, pramipexole, pramipexole extended release*, rasagiline, ropinirole, selegiline, tolcapone*, Apokyn*, Inbrija, Kynmobi

*prior authorization or step therapy required

Geisinger

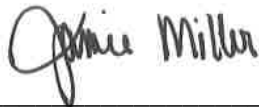
**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 652.0

**SECTION: Commercial Drug
SUBJECT: Ongentys**

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE
STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND
FEDERAL REGULATORY ENTITIES.**

**THIS POLICY WILL BE REVISED AS NECESSARY AND
REVIEWED NO LESS THAN ANNUALLY.**



Signed: _____

Title: Director, Pharmacy Services

Date: March 1, 2022

Devised: 1/22/21

Revised: 3/1/21 – annual review, updated logo

Revised: 3/1/22 – annual review, updated referenced policies & covered LOBs



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 653.0

**SECTION: Commercial Drug
SUBJECT: Lampit**

Applicable line of business:

Commercial	X	Medicaid	
Medicare		ACA	X
GHP Kids	X	Self-Insured	X

POLICY:

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for Lampit for GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 487.0 Quantity Limit Exceptions

REQUIRED DEFINITIONS:

1. **Attachment** – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. **Exhibit** – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. **Devised** – the date the policy was implemented.
4. **Revised** – the date of every revision to the policy, including typographical and grammatical changes.
5. **Reviewed** – the date documenting the annual review if the policy has no revisions necessary.

ADDITIONAL DEFINITIONS:

1. **Formulary** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. **Non-formulary products** – those medications that are not included in the Formulary.
3. **Healthcare provider** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
4. **NCQA** – National Committee for Quality Assurance.
5. **Medically Necessary or Medical Necessity** – covered services rendered by a provider that the Health Plan determines are:

- A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
- B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
- C. In accordance with current standards of medical practice;
- D. Not primarily for the convenience of the Member, or the Member's Provider; and
- E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

PROCEDURE:

An exception for coverage of Lampit may be made for members who meet the following criteria:

- Medical record documentation that Lampit is prescribed by an infectious disease specialist **AND**
- Medical record documentation of age less than or equal to 18 years **AND**
- Medical record documentation of weight greater than or equal to 2.5 kg **AND**
- Medical record documentation of a diagnosis of Chagas disease confirmed by one (1) of the following diagnostic tests:
 - Detection of circulating *T. cruzi* trypomastigotes on microscopy **OR**
 - Detection of *T. cruzi* DNA by polymerase chain reaction assay **OR**
 - Two positive diagnostic serologic tests* using different techniques (ex. enzyme-linked immunoassay (ELISA), indirect fluorescent antibody (IFA)) and antigens (ex. whole-parasite lysate, recombinant antigens) showing IgG antibodies to *T. cruzi*

MEDISPAN AUTHORIZATION LEVEL: GPI-12

QUANTITY LIMIT: *No QLs need to be entered within the authorization unless the requested quantity exceeds the QL.*

- **QL FOR LETTER ONLY:**
 - 30 mg tablets: 9 tablets per day, 30 day-supply per fill
 - 120 mg tablets: 7.5 tablets per day, 30-day supply per fill

AUTHORIZATION DURATION: 60 days, RX count 2



POLICY NUMBER: 653.0

**POLICY AND PROCEDURE
PHARMACY
MANUAL**

**SECTION: Commercial Drug
SUBJECT: Lampit**

If a formulary exception is approved, Lampit will be paid for under the member's prescription drug benefit.

Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.

FORMULARY ALTERNATIVES:

none

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE
STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND
FEDERAL REGULATORY ENTITIES.**

**THIS POLICY WILL BE REVISED AS NECESSARY AND
REVIEWED NO LESS THAN ANNUALLY.**

Signed: _____

Title: Director, Pharmacy Services

Date: March 1, 2022

Devised: 3/26/21

Revised: 3/1/22 – annual review, updated referenced policies & covered LOBs



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 654.0

**SECTION: Commercial Drug
SUBJECT: Orgovyx**

Applicable line of business:

Commercial	X	Medicaid	
Medicare		ACA	X
GHP Kids	X	Self-Insured	X

POLICY:

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for Orgovyx for GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 487.0 Quantity Limit Exceptions

REQUIRED DEFINITIONS:

1. **Attachment** – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. **Exhibit** – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. **Devised** – the date the policy was implemented.
4. **Revised** – the date of every revision to the policy, including typographical and grammatical changes.
5. **Reviewed** – the date documenting the annual review if the policy has no revisions necessary.

ADDITIONAL DEFINITIONS:

1. **Formulary** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. **Non-formulary products** – those medications that are not included in the Formulary.
3. **Healthcare provider** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
4. **NCQA** – National Committee for Quality Assurance.
5. **Medically Necessary or Medical Necessity** – covered services rendered by a provider that the Health Plan determines are:



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 654.0

**SECTION: Commercial Drug
SUBJECT: Orgovyx**

- A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
- B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
- C. In accordance with current standards of medical practice;
- D. Not primarily for the convenience of the Member, or the Member's Provider; and
- E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

PROCEDURE:

New members to the plan already established on therapy may be eligible for continuity of care coverage as long as there is medical record documentation that the safety and effectiveness of use for the prescribed indication is supported by Food and Drug Administration (FDA) approval or adequate medical and scientific evidence in the medical literature.

An exception for coverage of Orgovyx may be made for members who meet the following criteria:

- Medical record documentation that Orgovyx is prescribed by a hematologist, oncologist, or urologist **AND**
- Medical record documentation of a diagnosis of advanced prostate cancer

MEDISPAN AUTHORIZATION LEVEL: GPI-12

QUANTITY LIMIT: *No QLs need to be entered within the authorization unless the requested quantity exceeds the QL.*

- QL FOR LETTER ONLY: 64 tablets per 30 days

If a formulary exception is approved, Orgovyx will be paid for under the member's prescription drug benefit.

Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.

FORMULARY ALTERNATIVES:

none



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 654.0

**SECTION: Commercial Drug
SUBJECT: Orgovyx**

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE
STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND
FEDERAL REGULATORY ENTITIES.**

**THIS POLICY WILL BE REVISED AS NECESSARY AND
REVIEWED NO LESS THAN ANNUALLY.**

Signed: _____

Title: Director, Pharmacy Services

Date: March 1, 2022

Devised: 3/26/21

Revised: 6/4/21 – removed reference to lung cancer

Revised: 3/1/22 – annual review, updated referenced policies & covered LOBs



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 655.0

**SECTION: Commercial Drug
SUBJECT: Xywav**

Applicable line of business:

Commercial	X	Medicaid	
Medicare		ACA	X
GHP Kids	X	Self-Insured	X

POLICY:

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for Xywav for GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 487.0 Quantity Limit Exceptions

REQUIRED DEFINITIONS:

1. **Attachment** – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. **Exhibit** – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. **Devised** – the date the policy was implemented.
4. **Revised** – the date of every revision to the policy, including typographical and grammatical changes.
5. **Reviewed** – the date documenting the annual review if the policy has no revisions necessary.

ADDITIONAL DEFINITIONS:

1. **Formulary** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. **Non-formulary products** – those medications that are not included in the Formulary.
3. **Healthcare provider** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
4. **NCQA** – National Committee for Quality Assurance.
5. **Medically Necessary or Medical Necessity** – covered services rendered by a provider that the Health Plan determines are:



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 655.0

**SECTION: Commercial Drug
SUBJECT: Xywav**

- A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
- B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
- C. In accordance with current standards of medical practice;
- D. Not primarily for the convenience of the Member, or the Member's Provider; and
- E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

PROCEDURE:

An exception for coverage of Xywav may be made for members who meet the following criteria:

Cataplexy or Excessive Daytime Sleepiness with Narcolepsy

- Medical record documentation of excessive daytime sleepiness in a patient with narcolepsy or cataplexy with narcolepsy **AND**
- Medical record documentation of therapeutic failure on modafinil **AND** methylphenidate immediate release or amphetamine/dextroamphetamine immediate release **AND**
- Medical record documentation of one of the following:
 - Medical record documentation of therapeutic failure on, intolerance to, or contraindication to Xyrem **OR**
 - Medical record documentation the patient requires a low sodium diet due to a concomitant diagnosis of heart failure, hypertension, or renal impairment

Idiopathic Hypersomnia

- Medical record documentation of a diagnosis of idiopathic hypersomnia **AND**
- Medical record documentation of an age greater than or equal to 18 **AND**
- Medical record documentation that member was evaluated and treated for other etiologies of excessive daytime sleepiness **AND**
- Medical record documentation of therapeutic failure on, intolerance to, or contraindication to modafinil

MEDISPAN AUTHORIZATION LEVEL: GPI-12

QUANTITY LIMIT: *No QLs need to be entered within the authorization unless the requested quantity exceeds the QL.*

- **QL FOR LETTER ONLY: 18 mL per day, 30 day supply per fill**



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 655.0

**SECTION: Commercial Drug
SUBJECT: Xywav**

AUTHORIZATION DURATION:

Initial approval will be for 12 months or less if the reviewing provider feels it is medically appropriate. For continued coverage, the following is required:

- Medical record documentation of reduction in frequency of cataplexy attacks **OR**
- Medical record documentation of reduction in symptoms of excessive daytime sleepiness

After the initial 12 month approval, subsequent approvals will be for a duration of 12 months. Reevaluation will be every 12 months requiring the following:

- Medical record documentation of continued or sustained reduction in frequency of cataplexy attacks **OR**
- Medical record documentation of continued or sustained reduction in symptoms of excessive daytime sleepiness

If an exception is made, Xywav will be paid for under the member's prescription drug benefit.

Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.

FORMULARY ALTERNATIVES:

Narcolepsy: armodafinil*, modafinil*, dextroamphetamine, dextroamphetamine/amphetamine immediate release, methylphenidate immediate release, Xyrem*

Idiopathic Hypersomnia: modafinil*

*prior authorization required

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE
STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND
FEDERAL REGULATORY ENTITIES.**

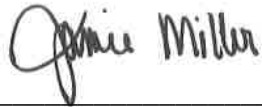
**THIS POLICY WILL BE REVISED AS NECESSARY AND
REVIEWED NO LESS THAN ANNUALLY.**

Geisinger

**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 655.0

**SECTION: Commercial Drug
SUBJECT: Xywav**



Signed: _____

Title: Director, Pharmacy Services

Date: March 1, 2022

Devised: 3/26/21

Revised: 1/21/22 – updated indication criteria for narcolepsy, added hypersomnia indication, updated FA

Revised: 3/1/22 – annual review, updated referenced policies & covered LOBs



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 656.0

**SECTION: Commercial Drug
SUBJECT: Conjupri**

Applicable line of business:

Commercial	X	Medicaid	
Medicare		ACA	X
GHP Kids	X	Self-Insured	X

POLICY:

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for Conjupri for GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 487.0 Quantity Limit Exceptions

REQUIRED DEFINITIONS:

1. **Attachment** – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. **Exhibit** – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. **Devised** – the date the policy was implemented.
4. **Revised** – the date of every revision to the policy, including typographical and grammatical changes.
5. **Reviewed** – the date documenting the annual review if the policy has no revisions necessary.

ADDITIONAL DEFINITIONS:

1. **Formulary** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. **Non-formulary products** – those medications that are not included in the Formulary.
3. **Healthcare provider** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
4. **NCQA** – National Committee for Quality Assurance.
5. **Medically Necessary or Medical Necessity** – covered services rendered by a provider that the Health Plan determines are:



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 656.0

**SECTION: Commercial Drug
SUBJECT: Conjupri**

- A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
- B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
- C. In accordance with current standards of medical practice;
- D. Not primarily for the convenience of the Member, or the Member's Provider; and
- E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

PROCEDURE:

An exception for coverage of Conjupri may be made for members who meet the following criteria:

- Medical record documentation of therapeutic failure on, intolerance to, or contraindication to three (3) generic formulary calcium channel blockers, one of which must be amlodipine

MEDISPAN AUTHORIZATION LEVEL: GPI-12

QUANTITY LIMIT: *No QLs need to be entered within the authorization unless the requested quantity exceeds the QL.*

- **QL FOR LETTER ONLY:** 1 tablet per day

If an exception is made, Conjupri will be paid for under the member's prescription drug benefit.

Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.

FORMULARY ALTERNATIVES:

amlodipine, amlodipine/benazepril, Cartia XT, diltiazem, diltiazem extended release, felodipine extended release, nifedipine, Taztia XT, Tiadylt extended release, nifedipine extended release, verapamil, verapamil extended release



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 656.0

**SECTION: Commercial Drug
SUBJECT: Conjupri**

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE
STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND
FEDERAL REGULATORY ENTITIES.**

**THIS POLICY WILL BE REVISED AS NECESSARY AND
REVIEWED NO LESS THAN ANNUALLY.**

Signed: _____

Title: Director, Pharmacy Services

Date: March 1, 2022

Devised: 6/4/21

Revised: 3/1/22 – annual review, updated referenced policies & covered LOBs



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 657.0

**SECTION: Commercial Drug
SUBJECT: Katerzia**

Applicable line of business:

Commercial	X	Medicaid	
Medicare		ACA	X
GHP Kids	X	Self-Insured	X

POLICY:

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for Katerzia for GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 487.0 Quantity Limit Exceptions

REQUIRED DEFINITIONS:

1. **Attachment** – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. **Exhibit** – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. **Devised** – the date the policy was implemented.
4. **Revised** – the date of every revision to the policy, including typographical and grammatical changes.
5. **Reviewed** – the date documenting the annual review if the policy has no revisions necessary.

ADDITIONAL DEFINITIONS:

1. **Formulary** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. **Non-formulary products** – those medications that are not included in the Formulary.
3. **Healthcare provider** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
4. **NCQA** – National Committee for Quality Assurance.
5. **Medically Necessary or Medical Necessity** – covered services rendered by a provider that the Health Plan determines are:



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 657.0

**SECTION: Commercial Drug
SUBJECT: Katerzia**

- A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
- B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
- C. In accordance with current standards of medical practice;
- D. Not primarily for the convenience of the Member, or the Member's Provider; and
- E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

PROCEDURE:

An exception for coverage of Katerzia may be made for members who meet the following criteria:

- Medical record documentation of difficulty swallowing **OR**
- Medical record documentation of therapeutic failure on, intolerance to, or contraindication to three (3) generic formulary calcium channel blockers, one of which must be amlodipine

MEDISPAN AUTHORIZATION LEVEL: GPI-12

QUANTITY LIMIT: *No QLs need to be entered within the authorization unless the requested quantity exceeds the QL.*

- QL FOR LETTER ONLY: 10 mL per day

If an exception is made, Katerzia will be paid for under the member's prescription drug benefit.

Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.

FORMULARY ALTERNATIVES:

amlodipine, amlodipine/benazepril, Cartia XT, diltiazem, diltiazem extended release, felodipine extended release, nifedipine, Taztia XT, Tiadylt extended release, nifedipine extended release, verapamil, verapamil extended release

Geisinger

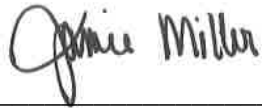
**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 657.0

**SECTION: Commercial Drug
SUBJECT: Katerzia**

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE
STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND
FEDERAL REGULATORY ENTITIES.**

**THIS POLICY WILL BE REVISED AS NECESSARY AND
REVIEWED NO LESS THAN ANNUALLY.**



Signed: _____

Title: Director, Pharmacy Services

Date: March 1, 2022

Devised: 6/4/21

Revised: 3/1/22 – annual review, updated referenced policies & covered LOBs



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 658.0

**SECTION: Commercial Drug
SUBJECT: Tepmetko**

Applicable line of business:

Commercial	X	Medicaid	
Medicare		ACA	X
GHP Kids	X	Self-Insured	X

POLICY:

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for Tepmetko for GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 487.0 Quantity Limit Exceptions

REQUIRED DEFINITIONS:

1. **Attachment** – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. **Exhibit** – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. **Devised** – the date the policy was implemented.
4. **Revised** – the date of every revision to the policy, including typographical and grammatical changes.
5. **Reviewed** – the date documenting the annual review if the policy has no revisions necessary.

ADDITIONAL DEFINITIONS:

1. **Formulary** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. **Non-formulary products** – those medications that are not included in the Formulary.
3. **Healthcare provider** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
4. **NCQA** – National Committee for Quality Assurance.
5. **Medically Necessary or Medical Necessity** – covered services rendered by a provider that the Health Plan determines are:



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 658.0

**SECTION: Commercial Drug
SUBJECT: Tepmetko**

- A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
- B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
- C. In accordance with current standards of medical practice;
- D. Not primarily for the convenience of the Member, or the Member's Provider; and
- E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

PROCEDURE:

New members to the plan already established on therapy may be eligible for continuity of care coverage as long as there is medical record documentation that the safety and effectiveness of use for the prescribed indication is supported by Food and Drug Administration (FDA) approval or adequate medical and scientific evidence in the medical literature.

An exception for coverage of Tepmetko may be made for members who meet the following criteria:

- Medical record documentation that Tepmetko is prescribed by or in consultation with an oncologist or hematologist **AND**
- Medical record documentation of age greater than or equal to 18 years **AND**
- Medical record documentation of a diagnosis of metastatic non-small cell lung cancer (NSCLC) harboring mesenchymal-epithelial transition (MET) exon 14 skipping alterations

MEDISPAN AUTHORIZATION LEVEL: GPI-12, number of claims authorized = 1, enter for the remainder of the calendar year

QUANTITY LIMIT: *No QLs need to be entered within the authorization unless the requested quantity exceeds the QL.*

- **QL FOR LETTER ONLY:** 2 tablets per day, 30 day supply per fill



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 658.0

**SECTION: Commercial Drug
SUBJECT: Tepmetko**

RE-AUTHORIZATION CRITERIA: Tepmetko is configured as a prior authorization for new starts only. Tepmetko will no longer be covered if it is identified that the member is not receiving appropriate follow-up care from the prescribing specialist or if the member has greater than or equal to a 90 day break in therapy.

- Medical record documentation that the member is receiving appropriate follow-up care from the prescribing specialist

If a formulary exception is approved, Tepmetko will be paid for under the member's prescription drug benefit.

Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.

FORMULARY ALTERNATIVES:

Tabrecta*

*prior authorization required

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE
STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND
FEDERAL REGULATORY ENTITIES.**

**THIS POLICY WILL BE REVISED AS NECESSARY AND
REVIEWED NO LESS THAN ANNUALLY.**

Signed: _____

Title: Director, Pharmacy Services

Date: March 1, 2022

Devised: 6/4/21

Revised: 12/1/21 – added one-time PA to approval crit., removed auth duration & added re-auth crit.

Revised: 3/1/22 – annual review, updated referenced policies & covered LOBs



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 659.0

**SECTION: Commercial Drug
SUBJECT: Ukoniq**

Applicable line of business:

Commercial	X	Medicaid	
Medicare		ACA	X
GHP Kids	X	Self-Insured	X

POLICY:

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for Ukoniq for GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 487.0 Quantity Limit Exceptions

REQUIRED DEFINITIONS:

1. **Attachment** – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. **Exhibit** – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. **Devised** – the date the policy was implemented.
4. **Revised** – the date of every revision to the policy, including typographical and grammatical changes.
5. **Reviewed** – the date documenting the annual review if the policy has no revisions necessary.

ADDITIONAL DEFINITIONS:

1. **Formulary** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. **Non-formulary products** – those medications that are not included in the Formulary.
3. **Healthcare provider** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
4. **NCQA** – National Committee for Quality Assurance.
5. **Medically Necessary or Medical Necessity** – covered services rendered by a provider that the Health Plan determines are:



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 659.0

**SECTION: Commercial Drug
SUBJECT: Ukoniq**

- A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
- B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
- C. In accordance with current standards of medical practice;
- D. Not primarily for the convenience of the Member, or the Member's Provider; and
- E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

PROCEDURE:

New members to the plan already established on therapy may be eligible for continuity of care coverage as long as there is medical record documentation that the safety and effectiveness of use for the prescribed indication is supported by Food and Drug Administration (FDA) approval or adequate medical and scientific evidence in the medical literature.

An exception for coverage of Ukoniq may be made for members who meet the following criteria:

Marginal Zone Lymphoma

- Medical record documentation that Ukoniq is prescribed by a hematologist or oncologist **AND**
- Medical record documentation of age greater than or equal to 18 years **AND**
- Medical record documentation of a diagnosis of marginal zone lymphoma **AND**
- Medical record documentation of relapsed or refractory disease after at least one prior anti-CD20-based regimen

Follicular Lymphoma

- Medical record documentation that Ukoniq is prescribed by a hematologist or oncologist **AND**
- Medical record documentation of age greater than or equal to 18 years **AND**
- Medical record documentation of diagnosis of follicular lymphoma **AND**
- Medical record documentation of relapsed or refractory disease after at least three prior lines of systemic therapy

MEDISPAN AUTHORIZATION LEVEL: GPI-12, number of claims authorized = 1, enter for the remainder of the calendar year

Geisinger

**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 659.0

**SECTION: Commercial Drug
SUBJECT: Ukoniq**

QUANTITY LIMIT: *No QLs need to be entered within the authorization unless the requested quantity exceeds the QL.*

- QL FOR LETTER ONLY: 4 tablets per day, 30 day supply per fill

RE-AUTHORIZATION CRITERIA: Ukoniq is configured as a prior authorization for new starts only. Ukoniq will no longer be covered if it is identified that the member is not receiving appropriate follow-up care from the prescribing specialist or if the member has greater than or equal to a 90 day break in therapy.

- Medical record documentation that the member is receiving appropriate follow-up care from the prescribing specialist

If a formulary exception is approved, Ukoniq will be paid for under the member's prescription drug benefit.

Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.

FORMULARY ALTERNATIVES:

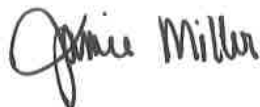
Copiktra*, Imbruvica*, Tazverik*, Zydelig*

*prior authorization required

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE
STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND
FEDERAL REGULATORY ENTITIES.**

**THIS POLICY WILL BE REVISED AS NECESSARY AND
REVIEWED NO LESS THAN ANNUALLY.**

Signed: _____



Title: Director, Pharmacy Services

Date: March 1, 2022

Devised: 6/4/21

HPRX02

\\geisinger.edu\dfs\0004\0142\142006\COMMERCIAL\Commercial 2022-2023\Policy 659.0 Ukoniq.docx

Dev. 6/4/21

Rev. 3/1/22



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 659.0

**SECTION: Commercial Drug
SUBJECT: Ukoniq**

Revised: 12/1/21 – added one-time PA to approval crit., removed auth duration & added re-auth crit.
Revised: 3/1/22 – annual review, updated referenced policies & covered LOBs



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 660.0

**SECTION: Commercial Drug
SUBJECT: Orladeyo**

Applicable line of business:

Commercial	X	Medicaid	
Medicare		ACA	X
GHP Kids	X	Self-Insured	X

POLICY:

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for Orladeyo for GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 487.0 Quantity Limit Exceptions

REQUIRED DEFINITIONS:

1. **Attachment** – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. **Exhibit** – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. **Devised** – the date the policy was implemented.
4. **Revised** – the date of every revision to the policy, including typographical and grammatical changes.
5. **Reviewed** – the date documenting the annual review if the policy has no revisions necessary.

ADDITIONAL DEFINITIONS:

1. **Formulary** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. **Non-formulary products** – those medications that are not included in the Formulary.
3. **Healthcare provider** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
4. **NCQA** – National Committee for Quality Assurance.
5. **Medically Necessary or Medical Necessity** – covered services rendered by a provider that the Health Plan determines are:



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 660.0

**SECTION: Commercial Drug
SUBJECT: Orladeyo**

- A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
- B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
- C. In accordance with current standards of medical practice;
- D. Not primarily for the convenience of the Member, or the Member's Provider; and
- E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

PROCEDURE:

An exception for coverage of Orladeyo may be made for members who meet the following criteria:

- Medical record documentation of age greater than or equal to 12 years **AND**
- Medical record documentation that Orladeyo is prescribed by an allergist, immunologist, hematologist, or dermatologist **AND**
- Medical record documentation of a diagnosis of hereditary angioedema (HAE) established and supported by documentation of:
 - Recurrent, self-limiting, non-inflammatory subcutaneous angioedema without urticaria which lasts more than 12 hours **OR**
 - Laryngeal edema **OR**
 - Recurrent, self-remitting abdominal pain which lasts more than 6 hours, without clear organic etiology **AND**
- Medical record documentation of specific abnormalities in complement proteins, in the setting of a suggestive clinical history or episodic angioedema without urticaria; supported by:
 - Medical record documentation of two (2) or more sets of complement studies, separated by one month or more, showing consistent results of:
 - Low C4 levels **AND**
 - Less than 50% of the lower limit of normal C1-INH antigenic protein levels **OR**
 - Less than 50% of the lower limit of normal C1-INH functions levels **AND**
- Medical record documentation of history of more than one (1) severe event per month **OR** a history of laryngeal attacks **AND**
- Medical record documentation that Orladeyo is being used as prophylactic therapy for hereditary angioedema (HAE) attacks **AND**



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 660.0

**SECTION: Commercial Drug
SUBJECT: Orladeyo**

- Medical record documentation that Orladeyo is not being used in combination with another prophylactic human C1 esterase inhibitor (Cinryze or Haegarda) or lanadelumab (Takhzyro) therapy for hereditary angioedema **AND**
- Medical record documentation of therapeutic failure on, intolerance to, or contraindication to danazol

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MEDISPAN AUTHORIZATION LEVEL: GPI-12

QUANTITY LIMIT: *No QLs need to be entered within the authorization unless the requested quantity exceeds the QL.*

- **QL FOR LETTER ONLY:** 1 capsule per day, 28 day supply per fill

AUTHORIZATION DURATION: Initial approval will be for 6 months or less if the reviewing provider feels it is medically appropriate. Subsequent approvals will be for an additional 12 months or less if the reviewing provider feels it is medically appropriate and will required medical record documentation of continued disease improvement or lack of disease progression. Orladeyo will no longer be covered if the member experiences unacceptable toxicity or worsening of disease.

If a formulary exception is approved, Orladeyo will be paid for under the member's prescription drug benefit.

Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.

FORMULARY ALTERNATIVES:

Haegarda*, Takhzyro*

*prior authorization required

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE
STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND
FEDERAL REGULATORY ENTITIES.**

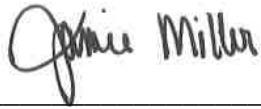
**THIS POLICY WILL BE REVISED AS NECESSARY AND
REVIEWED NO LESS THAN ANNUALLY.**

Geisinger

**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 660.0

**SECTION: Commercial Drug
SUBJECT: Orladeyo**



Signed: _____

Title: Director, Pharmacy Services

Date: March 1, 2022

Devised: 6/4/21

Revised: 3/1/22 – annual review, updated referenced policies & covered LOBs



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 661.0

**SECTION: Commercial Drug
SUBJECT: Xolair for Self-
Administration**

Applicable line of business:

Commercial	X	Medicaid	
Medicare		ACA	X
GHP Kids	X	Self-Insured	X

POLICY:

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for Xolair for self-administration for GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 487.0 Quantity Limit Exceptions

REQUIRED DEFINITIONS:

1. **Attachment** – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. **Exhibit** – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. **Devised** – the date the policy was implemented.
4. **Revised** – the date of every revision to the policy, including typographical and grammatical changes.
5. **Reviewed** – the date documenting the annual review if the policy has no revisions necessary.

ADDITIONAL DEFINITIONS:

1. **Formulary** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. **Non-formulary products** – those medications that are not included in the Formulary.
3. **Healthcare provider** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
4. **NCQA** – National Committee for Quality Assurance.
5. **Medically Necessary or Medical Necessity** – covered services rendered by a provider that the Health Plan determines are:



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 661.0

**SECTION: Commercial Drug
SUBJECT: Xolair for Self-
Administration**

- A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
- B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
- C. In accordance with current standards of medical practice;
- D. Not primarily for the convenience of the Member, or the Member's Provider; and
- E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

PROCEDURE:

An exception for coverage of Xolair for self-administration may be made for members who meet the following criteria:

Asthma

- Medical record documentation that Xolair is prescribed by an allergist or pulmonologist **AND**
- Medical record documentation of age greater than or equal to 6 years **AND**
- Medical record documentation that member is compliant with current therapeutic regimen **AND**
- Medical record documentation of diagnosis of moderate to severe persistent asthma* with evidence of reversible airway disease [i.e., greater than 12% improvement in forced expiratory volume in one second (FEV1) with at least 200 ml increase or at least a 20% or greater improvement in peak expiratory flow (PEF) after administration of albuterol] **AND**
- Medical record documentation of inadequate control or intolerance, despite a 3 month trial of: medium –high dose inhaled corticosteroids or systemic corticosteroids **AND** long-acting beta agonists or leukotriene receptor antagonists **AND**
- Medical record documentation of the following:
 - For members age 12 and older, an IgE level of greater than 30 IU/ml and less than 700 IU/ml **OR**
 - For members age 6 through 11, an IgE level of greater than 30 IU/ml and less than 1300 IU/ml **AND**
- Medical record documentation of evidence of a specific allergic reactivity to a perennial aeroallergen by positive skin or blood test for a specific IgE **AND**
- Medical record documentation that known environmental triggers within the member's control have been eliminated **AND**



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 661.0

**SECTION: Commercial Drug
SUBJECT: Xolair for Self-
Administration**

- Medical record documentation that Xolair will not be used in combination with another biologic medication indicated for asthma treatment (e.g., Dupixent, Fasenna, Nucala, Cinqair, or Tezspire)

***NOTES**

Moderate persistent asthma is defined by the National Heart, Lung and Blood institute (NHLBI) as:

1. Daily symptoms
2. Daily use of inhaled short-acting beta agonist
3. Exacerbations affect activity
4. Exacerbations at least twice a week, which may last days
5. Nighttime symptoms more frequently than one time per week
6. Lung function of FEV1 greater than 60% but less than 80%

Severe persistent asthma is defined by the NHLBI as:

1. Continual symptoms
2. Limited physical activity
3. Frequent exacerbations
4. Frequent nighttime symptoms
5. Lung function of FEV1 less than or equal to 60% predicted

**The 12% improvement target value is calculated using the following methodology:

The target value = baseline FEV1 x 1.12
The actual clinical calculation is: post-treatment FEV1 – baseline FEV1 = % improvement baseline FEV1

MEDISPAN AUTHORIZATION LEVEL: GPI-12

QUANTITY LIMIT: *No QLs need to be entered within the authorization unless the requested quantity exceeds the QL.*

- **QL FOR LETTER ONLY:**
 - 75 mg/0.5mL prefilled syringe: 5 mL per 28 days
 - 150 mg/1mL prefilled syringe: 4 mL per 28 days

AUTHORIZATION DURATION: Initial approval will be for 12 months. Reauthorization will require documentation of improvement in the signs and symptoms of disease and will be for a duration of 12 months.



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 661.0

**SECTION: Commercial Drug
SUBJECT: Xolair for Self-
Administration**

Chronic Idiopathic Urticaria:

- Medical record documentation that Xolair is prescribed by an allergist, immunologist, or dermatologist **AND**
- Medical record documentation of age greater than or equal to 12 years of age **AND**
- Medical record documentation of a diagnosis of moderate-to-severe chronic idiopathic urticaria **AND**
- Medical record documentation of at least 6 week history of symptoms (e.g., hives associated with itching, angioedema) **AND**
- Medical record documentation of a therapeutic failure on Xolair 150 mg dose, when Xolair 300 mg dose is requested **AND**
- Medical record documentation of contraindication to, therapeutic failure on, or intolerance to a four week trial of ALL of the following treatment alternatives:
 - At least two different high dose antihistamines
 - Maximum dose antihistamine(s) used in combination with a leukotriene receptor antagonist (e.g., montelukast)
 - High dose antihistamine used in combination with H2 receptor antagonist (e.g., ranitidine)
 - Dose advancement of potent antihistamine (e.g., hydroxyzine or doxepin)

MEDISPAN AUTHORIZATION LEVEL: GPI-12

QUANTITY LIMIT: *QL must be entered within the authorization.*

1. In PA Hub: Add PA, OQL, and max quantity dispensed 2.
 - QL FOR LETTER: 2 mL per 28 days

AUTHORIZATION DURATION: Initial approval will be for 12 months. Reauthorization will require documentation of improvement in the signs and symptoms of disease and will be for a duration of 12 months.



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 661.0

**SECTION: Commercial Drug
SUBJECT: Xolair for Self-
Administration**

Nasal Polyps

- Medical record documentation that Xolair is prescribed by or in consultation with an allergist, pulmonologist, immunologist or otolaryngologist (ENT provider) **AND**
- Medical record documentation of age greater than or equal to 18 years **AND**
- Medical record documentation of a diagnosis of nasal polyps **AND**
- Medical record documentation that Xolair will be used as add-on maintenance treatment **AND**
- Medical record documentation of therapeutic failure on, intolerance to, or contraindication to three (3) intranasal corticosteroids

MEDISPAN AUTHORIZATION LEVEL: GPI-12

QUANTITY LIMIT: *QL must be entered within the authorization.*

1. In PA Hub: Add PA, OQL, and max quantity dispensed 8.
 - QL FOR LETTER: 8 mL per 28 days

AUTHORIZATION DURATION: Initial approval will be for 12 months. Reauthorization will require documentation of improvement in the signs and symptoms of disease and will be for a duration of 12 months.

If a formulary exception is approved, Xolair for self-administration will be paid for under the member's prescription drug benefit.

Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.

FORMULARY ALTERNATIVES:

Asthma: dexamethasone, methylprednisolone, prednisone, fluticasone/salmeterol, Breo Ellipta, Dulera, Serevent Diskus, Arnuity Ellipta, Asmanex, Flovent, Pulmicort Flexhaler, QVAR RediHaler, montelukast

Chronic Idiopathic Urticaria: hydroxyzine, doxepin, montelukast, ranitidine, cimetidine, famotidine

Nasal Polyps: fluticasone propionate, triamcinolone acetonide, mometasone furoate, Beconase AQ*, Qnasl*, Omnaris*, Zetonna*

*prior authorization required



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 661.0

**SECTION: Commercial Drug
SUBJECT: Xolair for Self-
Administration**

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE
STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND
FEDERAL REGULATORY ENTITIES.**

**THIS POLICY WILL BE REVISED AS NECESSARY AND
REVIEWED NO LESS THAN ANNUALLY.**

Signed: _____

Title: Director, Pharmacy Services

Date: June 7, 2022

Devised: 6/7/21
Revised: 1/21/22 – updated how quantity limits are entered
Revised: 3/1/22 – annual review, updated referenced policies & covered LOBs
Revised: 4/6/22 – added prescribers for nasal polyps
Revised: 6/7/22 – updated concurrent biologic criterion in asthma indication



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 662.0

**SECTION: Commercial Drug
SUBJECT: Fluoxetine for PMDD
(generic Sarafem)**

Applicable line of business:

Commercial	X	Medicaid	
Medicare		ACA	X
GHP Kids	X	Self-Insured	X

POLICY:

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for fluoxetine for PMDD (generic Sarafem) for GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 487.0 Quantity Limit Exceptions

REQUIRED DEFINITIONS:

1. **Attachment** – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. **Exhibit** – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. **Devised** – the date the policy was implemented.
4. **Revised** – the date of every revision to the policy, including typographical and grammatical changes.
5. **Reviewed** – the date documenting the annual review if the policy has no revisions necessary.

ADDITIONAL DEFINITIONS:

1. **Formulary** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. **Non-formulary products** – those medications that are not included in the Formulary.
3. **Healthcare provider** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
4. **NCQA** – National Committee for Quality Assurance.
5. **Medically Necessary or Medical Necessity** – covered services rendered by a provider that the Health Plan determines are:



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 662.0

**SECTION: Commercial Drug
SUBJECT: Fluoxetine for PMDD
(generic Sarafem)**

- A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
 - B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
 - C. In accordance with current standards of medical practice;
 - D. Not primarily for the convenience of the Member, or the Member's Provider; and
 - E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.
6. **PMDD** – Premenstrual dysphoric disorder

PROCEDURE:

An exception for coverage of fluoxetine for PMDD (generic Sarafem) may be made for members who meet the following criteria:

- Medical record documentation of use for premenstrual dysphoric disorder **AND**
- Medical record documentation of therapeutic failure on, intolerance to, or contraindication to sertraline

MEDISPAN AUTHORIZATION LEVEL: GPI-12, generic only

If a formulary exception is approved, fluoxetine for PMDD (generic Sarafem) will be paid for under the member's prescription drug benefit.

Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.

FORMULARY ALTERNATIVES:

paroxetine controlled release, sertraline

Geisinger

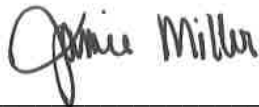
**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 662.0

**SECTION: Commercial Drug
SUBJECT: Fluoxetine for PMDD
(generic Sarafem)**

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE
STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND
FEDERAL REGULATORY ENTITIES.**

**THIS POLICY WILL BE REVISED AS NECESSARY AND
REVIEWED NO LESS THAN ANNUALLY.**



Signed: _____

Title: Director, Pharmacy Services

Date: March 1, 2022

Devised: 6/8/21

Revised: 3/1/22 – annual review, updated referenced policies & covered LOBs



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 663.0

**SECTION: Commercial Drug
SUBJECT: Fotivda**

Applicable line of business:

Commercial	X	Medicaid	
Medicare		ACA	X
GHP Kids	X	Self-Insured	X

POLICY:

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for Fotivda for GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 487.0 Quantity Limit Exceptions

REQUIRED DEFINITIONS:

1. **Attachment** – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. **Exhibit** – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
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4. **Revised** – the date of every revision to the policy, including typographical and grammatical changes.
5. **Reviewed** – the date documenting the annual review if the policy has no revisions necessary.

ADDITIONAL DEFINITIONS:

1. **Formulary** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. **Non-formulary products** – those medications that are not included in the Formulary.
3. **Healthcare provider** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
4. **NCQA** – National Committee for Quality Assurance.
5. **Medically Necessary or Medical Necessity** – covered services rendered by a provider that the Health Plan determines are:



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 663.0

**SECTION: Commercial Drug
SUBJECT: Fotivda**

- A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
- B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
- C. In accordance with current standards of medical practice;
- D. Not primarily for the convenience of the Member, or the Member's Provider; and
- E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

PROCEDURE:

New members to the plan already established on therapy may be eligible for continuity of care coverage as long as there is medical record documentation that the safety and effectiveness of use for the prescribed indication is supported by Food and Drug Administration (FDA) approval or adequate medical and scientific evidence in the medical literature.

An exception for coverage of Fotivda may be made for members who meet the following criteria:

- Medical record documentation that Fotivda is prescribed by a hematologist or oncologist **AND**
- Medical record documentation of age greater than or equal to 18 years **AND**
- Medical record documentation of a diagnosis of relapsed or refractory advanced renal cell carcinoma (RCC) **AND**
- Medical record documentation of treatment with two or more prior systemic therapies

MEDISPAN AUTHORIZATION LEVEL: GPI-12, number of claims authorized = 1, enter for the remainder of the calendar year

QUANTITY LIMIT: *No QLs need to be entered within the authorization unless the requested quantity exceeds the QL.*

- **QL FOR LETTER ONLY:** 21 tablets per 28 days



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 663.0

**SECTION: Commercial Drug
SUBJECT: Fotivda**

RE-AUTHORIZATION CRITERIA: Fotivda is configured as a prior authorization for new starts only. Fotivda will no longer be covered if it is identified that the member is not receiving appropriate follow-up care from the prescribing specialist or if the member has greater than or equal to a 90 day break in therapy.

- Medical record documentation that the member is receiving appropriate follow-up care from the prescribing specialist

If a formulary exception is approved, Fotivda will be paid for under the member's prescription drug benefit.

Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.

FORMULARY ALTERNATIVES:

everolimus*, Cabometyx*, Inlyta*, Lenvima*, Nexavar*, sunitinib*

*prior authorization required

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE
STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND
FEDERAL REGULATORY ENTITIES.**

**THIS POLICY WILL BE REVISED AS NECESSARY AND
REVIEWED NO LESS THAN ANNUALLY.**

Signed: _____

Title: Director, Pharmacy Services

Date: March 1, 2022

Devised: 7/1/21

Revised: 11/24/21 – added one-time PA to approval crit., removed auth duration & added re-auth crit., updated FA

Revised: 3/1/22 – annual review, updated referenced policies & covered LOBs, updated FA



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 664.0

**SECTION: Commercial Drug
SUBJECT: Imcivree**

Applicable line of business:

Commercial	X	Medicaid	
Medicare		ACA	
GHP Kids		Self-Insured	X

*This policy is only applicable to those members whose coverage does not exclude medications for weight management.

POLICY:

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for Imcivree for GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 487.0 Quantity Limit Exceptions

REQUIRED DEFINITIONS:

1. **Attachment** – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. **Exhibit** – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. **Devised** – the date the policy was implemented.
4. **Revised** – the date of every revision to the policy, including typographical and grammatical changes.
5. **Reviewed** – the date documenting the annual review if the policy has no revisions necessary.

ADDITIONAL DEFINITIONS:

1. **Formulary** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. **Non-formulary products** – those medications that are not included in the Formulary.
3. **Healthcare provider** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
4. **NCQA** – National Committee for Quality Assurance.



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 664.0

**SECTION: Commercial Drug
SUBJECT: Imcivree**

5. **Medically Necessary or Medical Necessity** – covered services rendered by a provider that the Health Plan determines are:
- A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
 - B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
 - C. In accordance with current standards of medical practice;
 - D. Not primarily for the convenience of the Member, or the Member's Provider; and
 - E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

PROCEDURE:

An exception for coverage of Imcivree may be made for members who meet the following criteria:

- Medical record documentation of age greater than or equal to 6 years **AND**
- Medical record documentation of one of the following:
 - For patients 18 years and older: Medical record documentation of body mass index (BMI) of greater than or equal to 30 kg/m²
 - For patients age 6 years to less than 18 years: Medical record documentation of weight greater than or equal to 95th percentile using growth chart assessments

AND

- Medical record documentation of a proopiomelanocortin (POMC), proprotein convertase subtilisin/kexin type 1 (PCSK1), or leptin receptor (LEPR) deficiency **AND**
- Medical record confirmation of genetic testing demonstrating variants in POMC, PCSK1, or LEPR genes that are interpreted as pathogenic, likely pathogenic, or of uncertain significance (VUS)*

***NOTE:** Imcivree is not indicated for treatment of:

- Obesity due to suspected POMC-, PCSK1-, or LEPR-deficiency with POMC, PCSK1, or LEPR variants classified as benign or likely benign
- Other types of obesity not related to POMC, PCSK1 or LEPR deficiency, including obesity associated with other genetic syndromes and general (polygenic) obesity

MEDISPAN AUTHORIZATION LEVEL: GPI-12



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 664.0

**SECTION: Commercial Drug
SUBJECT: Imcivree**

QUANTITY LIMIT: *No QLs need to be entered within the authorization unless the requested quantity exceeds the QL.*

- QL FOR LETTER ONLY: 0.3 mL per day

If a formulary exception is approved, Imcivree will be paid for under the member's prescription drug benefit.

Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.

FORMULARY ALTERNATIVES:

none

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE
STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND
FEDERAL REGULATORY ENTITIES.**

**THIS POLICY WILL BE REVISED AS NECESSARY AND
REVIEWED NO LESS THAN ANNUALLY.**

Signed: _____

Title: Director, Pharmacy Services

Date: March 1, 2022

Devised: 7/1/21

Revised: 3/1/22 – annual review, updated referenced policies & covered LOBs



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 665.0

**SECTION: Commercial Drug
SUBJECT: Klisyri**

Applicable line of business:

Commercial	X	Medicaid	
Medicare		ACA	X
GHP Kids	X	Self-Insured	X

POLICY:

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for Klisyri for GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 487.0 Quantity Limit Exceptions

REQUIRED DEFINITIONS:

1. **Attachment** – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. **Exhibit** – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. **Devised** – the date the policy was implemented.
4. **Revised** – the date of every revision to the policy, including typographical and grammatical changes.
5. **Reviewed** – the date documenting the annual review if the policy has no revisions necessary.

ADDITIONAL DEFINITIONS:

1. **Formulary** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. **Non-formulary products** – those medications that are not included in the Formulary.
3. **Healthcare provider** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
4. **NCQA** – National Committee for Quality Assurance.
5. **Medically Necessary or Medical Necessity** – covered services rendered by a provider that the Health Plan determines are:



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 665.0

**SECTION: Commercial Drug
SUBJECT: Klisyri**

- A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
- B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
- C. In accordance with current standards of medical practice;
- D. Not primarily for the convenience of the Member, or the Member's Provider; and
- E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

PROCEDURE:

An exception for coverage of Klisyri may be made for members who meet the following criteria:

- Medical record documentation that Klisyri is prescribed by a dermatologist **AND**
- Medical record documentation of actinic keratosis of the face or scalp **AND**
- Medical record documentation of greater than or equal to 4 lesions within a contiguous 25 cm² area **AND**
- Medical record documentation of a therapeutic failure on, intolerance to, or contraindication to topical fluorouracil **AND** imiquimod

MEDISPAN AUTHORIZATION LEVEL: GPI-12

QUANTITY LIMIT: *No QLs need to be entered within the authorization unless the requested quantity exceeds the QL.*

- **QL FOR LETTER ONLY:** 1 package (5 packets) per fill

If a formulary exception is approved, Klisyri will be paid for under the member's prescription drug benefit.

Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.

FORMULARY ALTERNATIVES:

fluorouracil cream/solution, imiquimod cream, Picato gel*

*prior authorization required



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 665.0

**SECTION: Commercial Drug
SUBJECT: Klisyri**

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE
STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND
FEDERAL REGULATORY ENTITIES.**

**THIS POLICY WILL BE REVISED AS NECESSARY AND
REVIEWED NO LESS THAN ANNUALLY.**

Signed: _____

Title: Director, Pharmacy Services

Date: March 1, 2022

Devised: 7/1/21

Revised: 3/1/22 – annual review, updated referenced policies & covered LOBs



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 666.0

**SECTION: Commercial Drug
SUBJECT: Diclofenac 3% Gel**

Applicable line of business:

Commercial	X	Medicaid	
Medicare		ACA	X
GHP Kids	X	Self-Insured	X

POLICY:

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for diclofenac 3% gel for GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 487.0 Quantity Limit Exceptions

REQUIRED DEFINITIONS:

1. **Attachment** – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. **Exhibit** – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. **Devised** – the date the policy was implemented.
4. **Revised** – the date of every revision to the policy, including typographical and grammatical changes.
5. **Reviewed** – the date documenting the annual review if the policy has no revisions necessary.

ADDITIONAL DEFINITIONS:

1. **Formulary** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. **Non-formulary products** – those medications that are not included in the Formulary.
3. **Healthcare provider** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
4. **NCQA** – National Committee for Quality Assurance.
5. **Medically Necessary or Medical Necessity** – covered services rendered by a provider that the Health Plan determines are:



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 666.0

**SECTION: Commercial Drug
SUBJECT: Diclofenac 3% Gel**

- A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
- B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
- C. In accordance with current standards of medical practice;
- D. Not primarily for the convenience of the Member, or the Member's Provider; and
- E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

PROCEDURE:

An exception for coverage of diclofenac 3% gel may be made for members who meet the following criteria:

- Medical record documentation of a diagnosis of actinic keratosis **AND**
- Medical record documentation of a therapeutic failure on, intolerance to, or contraindication to topical fluorouracil **AND** imiquimod

MEDISPAN AUTHORIZATION LEVEL: GPI-12, generic only

If a formulary exception is approved, diclofenac 3% gel will be paid for under the member's prescription drug benefit.

Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.

FORMULARY ALTERNATIVES:

fluorouracil cream/solution, imiquimod cream, Picato gel*

*prior authorization required

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE
STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND
FEDERAL REGULATORY ENTITIES.**

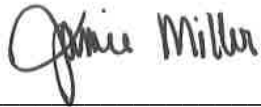
**THIS POLICY WILL BE REVISED AS NECESSARY AND
REVIEWED NO LESS THAN ANNUALLY.**

Geisinger

**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 666.0

**SECTION: Commercial Drug
SUBJECT: Diclofenac 3% Gel**



Signed: _____

Title: Director, Pharmacy Services

Date: March 1, 2022

Devised: 7/1/21

Revised: 3/1/22 – annual review, updated referenced policies & covered LOBs



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 667.0

**SECTION: Commercial Drug
SUBJECT: Verquvo**

Applicable line of business:

Commercial	X	Medicaid	
Medicare		ACA	X
GHP Kids	X	Self-Insured	X

POLICY:

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for Verquvo for GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 487.0 Quantity Limit Exceptions

REQUIRED DEFINITIONS:

1. **Attachment** – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. **Exhibit** – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. **Devised** – the date the policy was implemented.
4. **Revised** – the date of every revision to the policy, including typographical and grammatical changes.
5. **Reviewed** – the date documenting the annual review if the policy has no revisions necessary.

ADDITIONAL DEFINITIONS:

1. **Formulary** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. **Non-formulary products** – those medications that are not included in the Formulary.
3. **Healthcare provider** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
4. **NCQA** – National Committee for Quality Assurance.
5. **Medically Necessary or Medical Necessity** – covered services rendered by a provider that the Health Plan determines are:



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 667.0

**SECTION: Commercial Drug
SUBJECT: Verquvo**

- A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
- B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
- C. In accordance with current standards of medical practice;
- D. Not primarily for the convenience of the Member, or the Member's Provider; and
- E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

PROCEDURE:

An exception for coverage of Verquvo may be made for members who meet the following criteria:

- Medical record documentation that Verquvo is prescribed by a cardiologist **AND**
- Medical record documentation of age greater than or equal to 18 years **AND**
- Medical record documentation of symptomatic chronic New York Heart Association Class II-IV heart failure **AND**
- Medical record documentation of one of the following:
 - Medical record documentation of hospital admission due to heart failure within the previous 6 months **OR**
 - Medical record documentation of outpatient intravenous (IV) diuretic treatment for heart failure within the previous 3 months

AND

- Medical record documentation of a left ventricular ejection fraction (LVEF) less than or equal to 45% **AND**
- Medical record documentation of therapeutic failure on, intolerance to, or contraindication to at least one formulary angiotensin converting enzyme inhibitor (ACEi), angiotensin receptor blocker (ARB) or angiotensin receptor and neprilysin inhibitor (ARNI) **AND**
- Medical record documentation of therapeutic failure on, intolerance to, or contraindication to at least one formulary beta-blocker

MEDISPAN AUTHORIZATION LEVEL: GPI-12

QUANTITY LIMIT: *No QLs need to be entered within the authorization unless the requested quantity exceeds the QL.*

- **QL FOR LETTER ONLY:** 1 tablet per day



POLICY NUMBER: 667.0

**POLICY AND PROCEDURE
PHARMACY
MANUAL**

**SECTION: Commercial Drug
SUBJECT: Verquvo**

If a formulary exception is approved, Verquvo will be paid for under the member's prescription drug benefit.

Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.

FORMULARY ALTERNATIVES:

Angiotensin Converting Enzyme Inhibitor (ACEi)/Angiotensin Receptor Blocker (ARB): amlodipine/benazepril, benazepril, benazepril/hctz, candesartan, candesartan/hctz, captopril, captopril/hctz, enalapril, enalapril/hctz, fosinopril, irbesartan, irbesartan/hctz, lisinopril, lisinopril/hctz, losartan, losartan/hctz, moexipril, moexipril/hctz, olmesartan, olmesartan/hctz, quinapril, telmisartan, telmisartan/hctz, trandolapril, ramipril, valsartan, valsartan/hctz

Angiotensin Receptor and Neprilysin Inhibitor (ARNI): Entresto

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE
STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND
FEDERAL REGULATORY ENTITIES.**

**THIS POLICY WILL BE REVISED AS NECESSARY AND
REVIEWED NO LESS THAN ANNUALLY.**

Signed: _____

Title: Director, Pharmacy Services

Date: March 1, 2022

Devised: 7/1/21

Revised: 3/1/22 – annual review, updated referenced policies & covered LOBs



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 668.0

**SECTION: Commercial Drug
SUBJECT: Zokinvy**

Applicable line of business:

Commercial	X	Medicaid	
Medicare		ACA	X
GHP Kids	X	Self-Insured	X

POLICY:

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for Zokinvy for GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 487.0 Quantity Limit Exceptions

REQUIRED DEFINITIONS:

1. **Attachment** – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. **Exhibit** – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. **Devised** – the date the policy was implemented.
4. **Revised** – the date of every revision to the policy, including typographical and grammatical changes.
5. **Reviewed** – the date documenting the annual review if the policy has no revisions necessary.

ADDITIONAL DEFINITIONS:

1. **Formulary** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. **Non-formulary products** – those medications that are not included in the Formulary.
3. **Healthcare provider** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
4. **NCQA** – National Committee for Quality Assurance.
5. **Medically Necessary or Medical Necessity** – covered services rendered by a provider that the Health Plan determines are:



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 668.0

**SECTION: Commercial Drug
SUBJECT: Zokinvy**

- A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
- B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
- C. In accordance with current standards of medical practice;
- D. Not primarily for the convenience of the Member, or the Member's Provider; and
- E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

PROCEDURE:

An exception for coverage of Zokinvy may be made for members who meet the following criteria:

- Medical record documentation of a confirmed diagnosis through genetic testing of one of the following:
 - Hutchinson-Gilford Progeria Syndrome
 - Processing-deficient progeroid laminopathy with either:
 - Heterozygous LMNA mutation with progerin-like protein accumulation
 - Homozygous or compound heterozygous ZMPSTE24 mutations

AND

- Medical record documentation of age greater than or equal to 12 months **AND**
- Medical record documentation of body surface area of at least 0.39m² **AND**
- Medical record documentation that the requested dose is appropriate based on the patient's body surface area **AND**
- Medical record documentation that all potential drug interactions have been addressed by the prescriber (such as discontinuation of the interacting drug, dose reduction of the interacting drug, or counseling of the beneficiary of the risks associated with the use of both medications when they interact)

MEDISPAN AUTHORIZATION LEVEL: GPI-12

AUTHORIZATION DURATION: Initial approval will be for 12 months or less if the reviewing provider feels it is medically appropriate. Subsequent approvals will be for an additional 12 months or less if the reviewing provider feels it is medically appropriate and will require the following:

- Medical record documentation that the requested dose is appropriate based on the patient's body surface area **AND**



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 668.0

**SECTION: Commercial Drug
SUBJECT: Zokinvy**

- Medical record documentation that all potential drug interactions have been addressed by the prescriber (such as discontinuation of the interacting drug, dose reduction of the interacting drug, or counseling of the beneficiary of the risks associated with the use of both medications when they interact)

If a formulary exception is approved, Zokinvy will be paid for under the member's prescription drug benefit.

Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.

FORMULARY ALTERNATIVES:

none

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE
STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND
FEDERAL REGULATORY ENTITIES.**

**THIS POLICY WILL BE REVISED AS NECESSARY AND
REVIEWED NO LESS THAN ANNUALLY.**

Signed: _____

Title: Director, Pharmacy Services

Date: March 1, 2022

Devised: 7/1/21

Revised: 3/1/22 – annual review, updated referenced policies & covered LOBs



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 669.0

**SECTION: Commercial Drug
SUBJECT: Carbaglu**

Applicable line of business:

Commercial	X	Medicaid	
Medicare		ACA	X
GHP Kids	X	Self-Insured	X

POLICY:

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for Carbaglu for GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 487.0 Quantity Limit Exceptions

REQUIRED DEFINITIONS:

1. **Attachment** – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. **Exhibit** – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. **Devised** – the date the policy was implemented.
4. **Revised** – the date of every revision to the policy, including typographical and grammatical changes.
5. **Reviewed** – the date documenting the annual review if the policy has no revisions necessary.

ADDITIONAL DEFINITIONS:

1. **Formulary** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. **Non-formulary products** – those medications that are not included in the Formulary.
3. **Healthcare provider** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
4. **NCQA** – National Committee for Quality Assurance.
5. **Medically Necessary or Medical Necessity** – covered services rendered by a provider that the Health Plan determines are:



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 669.0

**SECTION: Commercial Drug
SUBJECT: Carbaglu**

- A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
- B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
- C. In accordance with current standards of medical practice;
- D. Not primarily for the convenience of the Member, or the Member's Provider; and
- E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

PROCEDURE:

An exception for coverage of Carbaglu may be made for members who meet the following criteria:

N-acetylglutamate synthase (NAGS) deficiency

- Medical record documentation that Carbaglu is prescribed by a metabolic disorder specialist **AND**
- Medical record documentation of a diagnosis of hyperammonemia due to the deficiency of the hepatic enzyme N-acetylglutamate synthase (NAGS) **AND**
- Medical record documentation that Carbaglu is prescribed with a dose of therapy that is consistent with FDA-approved package labeling, nationally recognized compendia, or peer-reviewed medical literature

AUTHORIZATION DURATION: 6 months

Propionic Acidemia (PA) or Methylmalonic Acidemia (MMA)

- Medical record documentation that Carbaglu is prescribed by a metabolic disorder specialist **AND**
- Medical record documentation of a diagnosis of propionic acidemia (PA) or methylmalonic acidemia (MMA) **AND**
- Medical record documentation of plasma ammonia level greater than or equal to 50 micromol/L **AND**
- Medical record documentation that Carbaglu is being prescribed as adjunctive treatment to standard of care (including but not limited to intravenous glucose, insulin, L-carnitine, protein restriction, and dialysis) **AND**
- Medical record documentation that Carbaglu is prescribed with a dose and duration of therapy that is consistent with FDA-approved package labeling, nationally recognized compendia, or peer-reviewed medical literature



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 669.0

**SECTION: Commercial Drug
SUBJECT: Carbaglu**

AUTHORIZATION DURATION: 7 days

If a formulary exception is approved, Carbaglu will be paid for under the member's prescription drug benefit.

Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.

FORMULARY ALTERNATIVES:

none

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE
STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND
FEDERAL REGULATORY ENTITIES.**

**THIS POLICY WILL BE REVISED AS NECESSARY AND
REVIEWED NO LESS THAN ANNUALLY.**

Signed: _____

Title: Director, Pharmacy Services

Date: March 1, 2022

Devised: 7/1/21

Revised: 3/1/22 – annual review, updated referenced policies & covered LOBs



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 670.0

**SECTION: Commercial Drug
SUBJECT: Asmanex and Qvar**

Applicable line of business:

Commercial	X	Medicaid	
Medicare		ACA	X
GHP Kids	X	Self-Insured	X

POLICY:

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for Asmanex and Qvar for GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 487.0 Quantity Limit Exceptions

REQUIRED DEFINITIONS:

1. **Attachment** – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. **Exhibit** – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. **Devised** – the date the policy was implemented.
4. **Revised** – the date of every revision to the policy, including typographical and grammatical changes.
5. **Reviewed** – the date documenting the annual review if the policy has no revisions necessary.

ADDITIONAL DEFINITIONS:

1. **Formulary** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. **Non-formulary products** – those medications that are not included in the Formulary.
3. **Healthcare provider** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
4. **NCQA** – National Committee for Quality Assurance.
5. **Medically Necessary or Medical Necessity** – covered services rendered by a provider that the Health Plan determines are:



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 670.0

**SECTION: Commercial Drug
SUBJECT: Asmanex and Qvar**

- A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
- B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
- C. In accordance with current standards of medical practice;
- D. Not primarily for the convenience of the Member, or the Member's Provider; and
- E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

PROCEDURE:

An exception for coverage of Asmanex or Qvar may be made for members who meet the following criteria:

- Electronic step therapy of on-line prescription drug claims history showing 15 days use of Arnuity Ellipta or Flovent Diskus/HFA **AND** Pulmicort Flexhaler within the previous 180 days. If this electronic step is met, the claim will automatically adjudicate **OR**
- If the electronic step therapy criteria are not met, prescribing provider should request an exception for coverage indicating therapeutic failure on, intolerance to, or contraindication to Arnuity Ellipta or Flovent Diskus/HFA **AND** Pulmicort Flexhaler

MEDISPAN AUTHORIZATION LEVEL:

- Asmanex – GPI-10
- Qvar – GPI-12

If a formulary exception is approved, Asmanex or Qvar will be paid for under the member's prescription drug benefit.

Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.

FORMULARY ALTERNATIVES:

Arnuity Ellipta, Flovent Diskus, Flovent HFA, Pulmicort Flexhaler



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 670.0

**SECTION: Commercial Drug
SUBJECT: Asmanex and Qvar**

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE
STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND
FEDERAL REGULATORY ENTITIES.**

**THIS POLICY WILL BE REVISED AS NECESSARY AND
REVIEWED NO LESS THAN ANNUALLY.**

Signed: _____

Title: Director, Pharmacy Services

Date: March 1, 2022

Devised: 7/1/21

Revised: 3/1/22 – annual review, updated referenced policies & covered LOBs



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 671.0

**SECTION: Commercial Drug
SUBJECT: Lupkynis**

Applicable line of business:

Commercial	X	Medicaid	
Medicare		ACA	X
GHP Kids	X	Self-Insured	X

POLICY:

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for Lupkynis for GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 487.0 Quantity Limit Exceptions

REQUIRED DEFINITIONS:

1. **Attachment** – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. **Exhibit** – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. **Devised** – the date the policy was implemented.
4. **Revised** – the date of every revision to the policy, including typographical and grammatical changes.
5. **Reviewed** – the date documenting the annual review if the policy has no revisions necessary.

ADDITIONAL DEFINITIONS:

1. **Formulary** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. **Non-formulary products** – those medications that are not included in the Formulary.
3. **Healthcare provider** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
4. **NCQA** – National Committee for Quality Assurance.
5. **Medically Necessary or Medical Necessity** – covered services rendered by a provider that the Health Plan determines are:



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 671.0

**SECTION: Commercial Drug
SUBJECT: Lupkynis**

- A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
- B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
- C. In accordance with current standards of medical practice;
- D. Not primarily for the convenience of the Member, or the Member's Provider; and
- E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

PROCEDURE:

An exception for coverage of Lupkynis may be made for members who meet the following criteria:

- Medical record documentation that Lupkynis is prescribed by or in consultation with a rheumatologist or nephrologist **AND**
- Medical record documentation of age greater than or equal to 18 years **AND**
- Medical record documentation of a diagnosis of active lupus nephritis, Class III, IV, V alone or in combination, confirmed by a kidney biopsy **AND**
- Medical record documentation that Lupkynis will be prescribed in combination with a background immunosuppressive therapy regimen (e.g. mycophenolate mofetil (MMF) and corticosteroids) **AND**
- Medical record documentation of therapeutic failure on, intolerance to, or contraindication to Benlysta

MEDISPAN AUTHORIZATION LEVEL: GPI-12

AUTHORIZATION DURATION: Initial approval will be for 6 months. Subsequent approvals will be for 12 months. Re-authorization will require the following:

- Medical record documentation of a positive clinical response to Lupkynis (e.g. improvement/stabilization in UPCR, eGFR, renal-related events) **AND**
- Medical record documentation that Lupkynis will be prescribed in combination with a background immunosuppressive therapy regimen (e.g. mycophenolate mofetil (MMF) and corticosteroids)

QUANTITY LIMIT: *No QLs need to be entered within the authorization unless the requested quantity exceeds the QL.*

- **QL FOR LETTER ONLY:** 6 capsules per day, 30 day supply per fill



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 671.0

**SECTION: Commercial Drug
SUBJECT: Lupkynis**

If a formulary exception is approved, Lupkynis will be paid for under the member's prescription drug benefit.

Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.

FORMULARY ALTERNATIVES:

Benlysta*

*prior authorization required

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE
STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND
FEDERAL REGULATORY ENTITIES.**

**THIS POLICY WILL BE REVISED AS NECESSARY AND
REVIEWED NO LESS THAN ANNUALLY.**

Signed: _____

Title: Director, Pharmacy Services

Date: March 1, 2022

Devised: 7/22/21

Revised: 3/1/22 – annual review, updated referenced policies & covered LOBs



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 672.0

**SECTION: Commercial Drug
SUBJECT: Metformin Extended Release
(generic Fortamet and Glumetza)**

Applicable line of business:

Commercial	X	Medicaid	
Medicare		ACA	X
GHP Kids	X	Self-Insured	X

POLICY:

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for metformin extended release (generic Fortamet and Glumetza) for GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 487.0 Quantity Limit Exceptions

REQUIRED DEFINITIONS:

1. **Attachment** – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. **Exhibit** – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. **Devised** – the date the policy was implemented.
4. **Revised** – the date of every revision to the policy, including typographical and grammatical changes.
5. **Reviewed** – the date documenting the annual review if the policy has no revisions necessary.

ADDITIONAL DEFINITIONS:

1. **Formulary** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. **Non-formulary products** – those medications that are not included in the Formulary.
3. **Healthcare provider** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
4. **NCQA** – National Committee for Quality Assurance.
5. **Medically Necessary or Medical Necessity** – covered services rendered by a provider that the Health Plan determines are:



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 672.0

**SECTION: Commercial Drug
SUBJECT: Metformin Extended Release
(generic Fortamet and Glumetza)**

- A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
- B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
- C. In accordance with current standards of medical practice;
- D. Not primarily for the convenience of the Member, or the Member's Provider; and
- E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

PROCEDURE:

An exception for coverage of metformin extended release (generic Fortamet and Glumetza) may be made for members who meet the following criteria:

- Medical record documentation of therapeutic failure on, intolerance to, or contraindication to metformin immediate release tablets **AND** metformin extended release tablets (generic Glucophage XR) at maximum dosage (2 grams per day = 4 tablets of 500mg per day)

MEDISPAN AUTHORIZATION LEVEL: GPI-14, generic only

QUANTITY LIMIT: *No QLs need to be entered within the authorization unless the requested quantity exceeds the QL.*

- **QL FOR LETTER ONLY:** 2 tablets per day

If a formulary exception is approved, metformin extended release (generic Fortamet and Glumetza) will be paid for under the member's prescription drug benefit.

Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.

FORMULARY ALTERNATIVES:

metformin immediate release, metformin extended release (generic Glucophage XR)



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 672.0

**SECTION: Commercial Drug
SUBJECT: Metformin Extended Release
(generic Fortamet and Glumetza)**

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE
STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND
FEDERAL REGULATORY ENTITIES.**

**THIS POLICY WILL BE REVISED AS NECESSARY AND
REVIEWED NO LESS THAN ANNUALLY.**

Signed: _____

Title: Director, Pharmacy Services

Date: March 1, 2022

Devised: 8/24/21

Revised: 3/1/22 – annual review, updated referenced policies & covered LOBs, defined IR & ER



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 673.0

**SECTION: Commercial Drug
SUBJECT: Lumakras**

Applicable line of business:

Commercial	X	Medicaid	
Medicare		ACA	X
GHP Kids	X	Self-Insured	X

POLICY:

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for Lumakras for GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 487.0 Quantity Limit Exceptions

REQUIRED DEFINITIONS:

1. **Attachment** – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. **Exhibit** – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. **Devised** – the date the policy was implemented.
4. **Revised** – the date of every revision to the policy, including typographical and grammatical changes.
5. **Reviewed** – the date documenting the annual review if the policy has no revisions necessary.

ADDITIONAL DEFINITIONS:

1. **Formulary** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. **Non-formulary products** – those medications that are not included in the Formulary.
3. **Healthcare provider** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
4. **NCQA** – National Committee for Quality Assurance.
5. **Medically Necessary or Medical Necessity** – covered services rendered by a provider that the Health Plan determines are:



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 673.0

**SECTION: Commercial Drug
SUBJECT: Lumakras**

- A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
- B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
- C. In accordance with current standards of medical practice;
- D. Not primarily for the convenience of the Member, or the Member's Provider; and
- E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

PROCEDURE:

New members to the plan already established on therapy may be eligible for continuity of care coverage as long as there is medical record documentation that the safety and effectiveness of use for the prescribed indication is supported by Food and Drug Administration (FDA) approval or adequate medical and scientific evidence in the medical literature.

An exception for coverage of Lumakras may be made for members who meet the following criteria:

- Medical record documentation that Lumakras is prescribed by a hematologist or oncologist **AND**
- Medical record documentation of age greater than or equal to 18 years **AND**
- Medical record documentation of locally advanced or metastatic non-small cell lung cancer (NSCLC) **AND**
- Medical record documentation of a KRAS G12C mutation, as determined by a Food and Drug Administration (FDA)-approved test* **AND**
- Medical record documentation of treatment with at least one prior systemic therapy

***NOTE:** The Food and Drug Administration (FDA) approved tests for the detection of KRAS G12C mutation in NSCLC are the thescreen KRAS RGQ PCR Kit and Guardant 360® CDx.

MEDISPAN AUTHORIZATION LEVEL: GPI-12, number of claims authorized = 1, enter for the remainder of the calendar year

QUANTITY LIMIT: *No QLs need to be entered within the authorization unless the requested quantity exceeds the QL.*

- **QL FOR LETTER ONLY:** 8 tablets per day, 30 day supply per fill



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 673.0

**SECTION: Commercial Drug
SUBJECT: Lumakras**

RE-AUTHORIZATION CRITERIA: Lumakras is configured as a prior authorization for new starts only. Lumakras will no longer be covered if it is identified that the member is not receiving appropriate follow-up care from the prescribing specialist or if the member has greater than or equal to a 90 day break in therapy.

- Medical record documentation that the member is receiving appropriate follow-up care from the prescribing specialist

If a formulary exception is approved, Lumakras will be paid for under the member's prescription drug benefit.

Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.

FORMULARY ALTERNATIVES:

none

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE
STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND
FEDERAL REGULATORY ENTITIES.**

**THIS POLICY WILL BE REVISED AS NECESSARY AND
REVIEWED NO LESS THAN ANNUALLY.**

Signed: _____

Title: Director, Pharmacy Services

Date: March 1, 2022

Devised: 9/1/21

Revised: 11/29/21 – added one-time PA to approval crit., removed auth duration & added re-auth crit.

Revised: 3/1/22 – annual review, updated referenced policies & covered LOBs



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 674.0

**SECTION: Commercial Drug
SUBJECT: Truseltiq**

Applicable line of business:

Commercial	X	Medicaid	
Medicare		ACA	X
GHP Kids	X	Self-Insured	X

POLICY:

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for Truseltiq for GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 487.0 Quantity Limit Exceptions

REQUIRED DEFINITIONS:

1. **Attachment** – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. **Exhibit** – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. **Devised** – the date the policy was implemented.
4. **Revised** – the date of every revision to the policy, including typographical and grammatical changes.
5. **Reviewed** – the date documenting the annual review if the policy has no revisions necessary.

ADDITIONAL DEFINITIONS:

1. **Formulary** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. **Non-formulary products** – those medications that are not included in the Formulary.
3. **Healthcare provider** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
4. **NCQA** – National Committee for Quality Assurance.
5. **Medically Necessary or Medical Necessity** – covered services rendered by a provider that the Health Plan determines are:



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 674.0

**SECTION: Commercial Drug
SUBJECT: Truseltiq**

- A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
- B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
- C. In accordance with current standards of medical practice;
- D. Not primarily for the convenience of the Member, or the Member's Provider; and
- E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

PROCEDURE:

New members to the plan already established on therapy may be eligible for continuity of care coverage as long as there is medical record documentation that the safety and effectiveness of use for the prescribed indication is supported by Food and Drug Administration (FDA) approval or adequate medical and scientific evidence in the medical literature.

An exception for coverage of Truseltiq may be made for members who meet the following criteria:

- Medical record documentation that Truseltiq is prescribed by a hematologist or oncologist **AND**
- Medical record documentation of age greater than or equal to 18 years **AND**
- Medical record documentation of unresectable locally advanced or metastatic cholangiocarcinoma **AND**
- Medical record documentation of a fibroblast growth factor receptor 2 (FGFR2) fusion or other rearrangement as verified by a Food and Drug Administration (FDA) approved test* **AND**
- Medical record documentation of one prior line of therapy

***NOTE:** The Food and Drug Administration (FDA) approved test can be found at <http://www.fda.gov/CompanionDiagnostics>.

MEDISPAN AUTHORIZATION LEVEL: GPI-12, number of claims authorized = 1, enter for the remainder of the calendar year



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 674.0

**SECTION: Commercial Drug
SUBJECT: Truseltiq**

QUANTITY LIMIT: *No QLs need to be entered within the authorization unless the requested quantity exceeds the QL.*

- **QL FOR LETTER ONLY:**
 - Truseltiq 50 mg daily dose: 42 capsules per 28 days
 - Truseltiq 75 mg daily dose: 63 capsules per 28 days
 - Truseltiq 100 mg daily dose: 21 capsules per 28 days
 - Truseltiq 125 mg daily dose: 42 capsules per 28 days

RE-AUTHORIZATION CRITERIA: Truseltiq is configured as a prior authorization for new starts only. Truseltiq will no longer be covered if it is identified that the member is not receiving appropriate follow-up care from the prescribing specialist or if the member has greater than or equal to a 90 day break in therapy.

- Medical record documentation that the member is receiving appropriate follow-up care from the prescribing specialist

If a formulary exception is approved, Truseltiq will be paid for under the member's prescription drug benefit.

Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.

FORMULARY ALTERNATIVES:

Pemazyre*

*prior authorization required

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE
STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND
FEDERAL REGULATORY ENTITIES.**

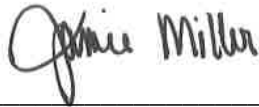
**THIS POLICY WILL BE REVISED AS NECESSARY AND
REVIEWED NO LESS THAN ANNUALLY.**

Geisinger

**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 674.0

**SECTION: Commercial Drug
SUBJECT: Truseltiq**



Signed: _____

Title: Director, Pharmacy Services

Date: March 1, 2022

Devised: 9/1/21

Revised: 12/1/21 – added one-time PA to approval crit., removed auth duration & added re-auth crit.

Revised: 3/1/22 – annual review, updated referenced policies & covered LOBs



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 675.0

**SECTION: Commercial Drug
SUBJECT: Qelbree**

Applicable line of business:

Commercial	X	Medicaid	
Medicare		ACA	X
GHP Kids	X	Self-Insured	X

POLICY:

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for Qelbree for GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 487.0 Quantity Limit Exceptions

REQUIRED DEFINITIONS:

1. **Attachment** – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. **Exhibit** – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. **Devised** – the date the policy was implemented.
4. **Revised** – the date of every revision to the policy, including typographical and grammatical changes.
5. **Reviewed** – the date documenting the annual review if the policy has no revisions necessary.

ADDITIONAL DEFINITIONS:

1. **Formulary** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. **Non-formulary products** – those medications that are not included in the Formulary.
3. **Healthcare provider** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
4. **NCQA** – National Committee for Quality Assurance.
5. **Medically Necessary or Medical Necessity** – covered services rendered by a provider that the Health Plan determines are:



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 675.0

**SECTION: Commercial Drug
SUBJECT: Qelbree**

- A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
- B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
- C. In accordance with current standards of medical practice;
- D. Not primarily for the convenience of the Member, or the Member's Provider; and
- E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

PROCEDURE:

New members to the plan already established on therapy may be eligible for continuity of care coverage as long as there is medical record documentation that the safety and effectiveness of use for the prescribed indication is supported by Food and Drug Administration (FDA) approval or adequate medical and scientific evidence in the medical literature.

An exception for coverage of Qelbree may be made for members who meet the following criteria:

- Medical record documentation of a diagnosis of attention deficit disorder (ADD) or attention deficit hyperactivity disorder (ADHD) **AND**
- Medical record documentation of therapeutic failure on, intolerance to, or contraindication to atomoxetine OR documentation that member has difficulty swallowing **AND**
- Medical record documentation of therapeutic failure on, intolerance to, or contraindication to amphetamine-dextroamphetamine ER **AND** methylphenidate ER unless precluded by a valid pre-existing medical condition (e.g., personal or family history of substance use disorder, substance misuse, etc.).

MEDISPAN AUTHORIZATION LEVEL: GPI-12

QUANTITY LIMIT: *No QLs need to be entered within the authorization unless the requested quantity exceeds the QL.*

- **QL FOR LETTER ONLY:**
 - Qelbree 100mg: 1 tablet per day
 - Qelbree 150 mg: 2 tablets per day
 - Qelbree 200 mg: 2 tablets per day



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 675.0

**SECTION: Commercial Drug
SUBJECT: Qelbree**

If a formulary exception is approved, Qelbree will be paid for under the member's prescription drug benefit.

Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.

FORMULARY ALTERNATIVES:

atomoxetine, dextroamphetamine, dextroamphetamine/amphetamine combination, dextroamphetamine/amphetamine SR combination, methylphenidate, methylphenidate sustained-release, methylphenidate extended-release, Metadate CD

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE
STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND
FEDERAL REGULATORY ENTITIES.**

**THIS POLICY WILL BE REVISED AS NECESSARY AND
REVIEWED NO LESS THAN ANNUALLY.**

Signed: _____

Title: Director, Pharmacy Services

Date: March 1, 2022

Devised: 11/1/21

Revised: 3/1/22 – annual review, updated referenced policies & covered LOBs



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 676.0

**SECTION: Commercial Drug
SUBJECT: Roszet**

Applicable line of business:

Commercial	X	Medicaid	
Medicare		ACA	X
GHP Kids	X	Self-Insured	X

POLICY:

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for Roszet for GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 469.0 Statin Quantity Limit Exceptions
- Policy 487.0 Quantity Limit Exceptions

REQUIRED DEFINITIONS:

1. **Attachment** – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. **Exhibit** – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. **Devised** – the date the policy was implemented.
4. **Revised** – the date of every revision to the policy, including typographical and grammatical changes.
5. **Reviewed** – the date documenting the annual review if the policy has no revisions necessary.

ADDITIONAL DEFINITIONS:

1. **Formulary** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. **Non-formulary products** – those medications that are not included in the Formulary.
3. **Healthcare provider** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
4. **NCQA** – National Committee for Quality Assurance.



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 676.0

**SECTION: Commercial Drug
SUBJECT: Roszet**

5. **Medically Necessary or Medical Necessity** – covered services rendered by a provider that the Health Plan determines are:
- A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
 - B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
 - C. In accordance with current standards of medical practice;
 - D. Not primarily for the convenience of the Member, or the Member's Provider; and
 - E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

PROCEDURE:

An exception for coverage of Roszet may be made for members who meet the following criteria:

- Medical record documentation of a diagnosis of primary non-familial hyperlipidemia or homozygous familial hypercholesterolemia **AND**
- Medical record documentation of age greater than or equal to 18 years **AND**
- Medical record documentation of therapeutic failure on or intolerance to rosuvastatin **AND** ezetimibe used in combination

MEDISPAN AUTHORIZATION LEVEL: GPI-12

QUANTITY LIMIT: *No QLs need to be entered within the authorization unless the requested quantity exceeds the QL.*

- **QL FOR LETTER ONLY:** 1 tablet per day

If a formulary exception is approved, Roszet will be paid for under the member's prescription drug benefit.

Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.

FORMULARY ALTERNATIVES:

rosuvastatin, ezetimibe, atorvastatin, fluvastatin, lovastatin, pravastatin, simvastatin



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 676.0

**SECTION: Commercial Drug
SUBJECT: Roszet**

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE
STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND
FEDERAL REGULATORY ENTITIES.**

**THIS POLICY WILL BE REVISED AS NECESSARY AND
REVIEWED NO LESS THAN ANNUALLY.**

Signed: _____

Title: Director, Pharmacy Services

Date: March 1, 2022

Devised: 11/1/21

Revised: 3/1/22 – annual review, updated referenced policies & covered LOBs



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 677.0

**SECTION: Commercial Drug
SUBJECT: Zegalogue**

Applicable line of business:

Commercial	X	Medicaid	
Medicare		ACA	X
GHP Kids	X	Self-Insured	X

POLICY:

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for Zegalogue for GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 487.0 Quantity Limit Exceptions

REQUIRED DEFINITIONS:

1. **Attachment** – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. **Exhibit** – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. **Devised** – the date the policy was implemented.
4. **Revised** – the date of every revision to the policy, including typographical and grammatical changes.
5. **Reviewed** – the date documenting the annual review if the policy has no revisions necessary.

ADDITIONAL DEFINITIONS:

1. **Formulary** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. **Non-formulary products** – those medications that are not included in the Formulary.
3. **Healthcare provider** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
4. **NCQA** – National Committee for Quality Assurance.
5. **Medically Necessary or Medical Necessity** – covered services rendered by a provider that the Health Plan determines are:



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 677.0

**SECTION: Commercial Drug
SUBJECT: Zegalogue**

- A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
- B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
- C. In accordance with current standards of medical practice;
- D. Not primarily for the convenience of the Member, or the Member's Provider; and
- E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

PROCEDURE:

An exception for coverage of Zegalogue may be made for members who meet the following criteria:

- Medical record documentation of a therapeutic failure on, intolerance to, or contraindication to Glucagon emergency kit/injection **AND** Gvoke **AND** Baqsimi

MEDISPAN AUTHORIZATION LEVEL: GPI-10

QUANTITY LIMIT: *No QLs need to be entered within the authorization unless the requested quantity exceeds the QL.*

- **QL FOR LETTER ONLY:** 2 units per fill (1.2 mL per fill)

If a formulary exception is approved, Zegalogue will be paid for under the member's prescription drug benefit.

Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.

FORMULARY ALTERNATIVES:

Gvoke, Baqsimi, Glucagon

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE
STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND
FEDERAL REGULATORY ENTITIES.**

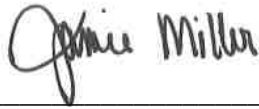
**THIS POLICY WILL BE REVISED AS NECESSARY AND
REVIEWED NO LESS THAN ANNUALLY.**

Geisinger

**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 677.0

**SECTION: Commercial Drug
SUBJECT: Zegalogue**



Signed: _____

Title: Director, Pharmacy Services

Date: March 1, 2022

Devised: 11/1/21

Revised: 3/1/22 – annual review, updated referenced policies & covered LOBs



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 678.0

**SECTION: Commercial Drug
SUBJECT: Zeposia**

Applicable line of business:

Commercial	X	Medicaid	
Medicare		ACA	X
GHP Kids	X	Self-Insured	X

POLICY:

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for Zeposia for GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 487.0 Quantity Limit Exceptions

REQUIRED DEFINITIONS:

1. **Attachment** – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. **Exhibit** – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. **Devised** – the date the policy was implemented.
4. **Revised** – the date of every revision to the policy, including typographical and grammatical changes.
5. **Reviewed** – the date documenting the annual review if the policy has no revisions necessary.

ADDITIONAL DEFINITIONS:

1. **Formulary** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. **Non-formulary products** – those medications that are not included in the Formulary.
3. **Healthcare provider** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
4. **NCQA** – National Committee for Quality Assurance.
5. **Medically Necessary or Medical Necessity** – covered services rendered by a provider that the Health Plan determines are:



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 678.0

**SECTION: Commercial Drug
SUBJECT: Zeposia**

- A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
- B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
- C. In accordance with current standards of medical practice;
- D. Not primarily for the convenience of the Member, or the Member's Provider; and
- E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

PROCEDURE:

New members to the plan already established on therapy may be eligible for continuity of care coverage as long as there is medical record documentation that the safety and effectiveness of use for the prescribed indication is supported by Food and Drug Administration (FDA) approval or adequate medical and scientific evidence in the medical literature.

An exception for coverage of Zeposia may be made for members who meet the following criteria:

Multiple Sclerosis

Note: Prior authorization is not required for diagnosis code G35. In the event a requestor would like a medical necessity review completed the following criteria would apply:

- Medical record documentation of a diagnosis of Multiple Sclerosis

MEDISPAN AUTHORIZATION LEVEL: GPI-10

QUANTITY LIMIT: *No QLs need to be entered within the authorization unless the requested quantity exceeds the QL.*

- **QL FOR LETTER ONLY:**
 - 7 Day Starter Pack: 7 capsules per 180 days
 - Starter Kit (7 Day Starter Pack and 0.92 mg 30 count bottle): 37 capsules per 180 days
 - 0.92 mg capsules: 1 capsule per day

AUTHORIZATION DURATION: Approval will be entered as an open-ended authorization.



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 678.0

**SECTION: Commercial Drug
SUBJECT: Zeposia**

Ulcerative Colitis

- Medical record documentation that Zeposia is prescribed by a gastroenterologist **AND**
- Medical record documentation of a diagnosis of moderate to severe ulcerative colitis **AND**
- Medical record documentation of age greater than or equal to 18 years **AND**
- Medical record documentation of therapeutic failure on, intolerance to, or contraindication to Humira **AND** Entyvio **AND** infliximab **AND**
- Medical record documentation that Zeposia is not being used concurrently with a TNF blocker or other biologic agent

MEDISPAN AUTHORIZATION LEVEL: GPI-10

QUANTITY LIMIT: *No QLs need to be entered within the authorization unless the requested quantity exceeds the QL.*

- **QL FOR LETTER ONLY:**
 - 7 Day Starter Pack: 7 capsules per 180 days
 - Starter Kit (7 Day Starter Pack and 0.92 mg 30 count bottle): 37 capsules per 180 days
 - 0.92 mg capsules: 1 capsule per day

AUTHORIZATION DURATION: Approval will be given for an initial duration of six (6) months. For continuation of coverage, medical record documentation of clinical improvement or lack of progression in the signs and symptoms of ulcerative colitis at six (6) months of Zeposia therapy is required.

After the initial six (6) month approval, subsequent approvals for coverage will be for a duration of one (1) year requiring medical record documentation of continued or sustained improvement in the signs and symptoms of ulcerative colitis while on Zeposia therapy.

If a formulary exception is approved, Zeposia will be paid for under the member's prescription drug benefit.

Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 678.0

**SECTION: Commercial Drug
SUBJECT: Zeposia**

FORMULARY ALTERNATIVES:

Ulcerative Colitis: Humira*

*prior authorization required

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE
STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND
FEDERAL REGULATORY ENTITIES.**

**THIS POLICY WILL BE REVISED AS NECESSARY AND
REVIEWED NO LESS THAN ANNUALLY.**

Signed: _____

Title: Director, Pharmacy Services

Date: March 1, 2022

Devised: 11/1/21

Revised: 3/1/22 – annual review, updated referenced policies & covered LOBs



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 679.0

**SECTION: Commercial Drug
SUBJECT: Desvenlafaxine ER
(generic Khedezla)**

Applicable line of business:

Commercial	X	Medicaid	
Medicare		ACA	X
GHP Kids	X	Self-Insured	X

POLICY:

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for desvenlafaxine ER (generic Khedezla) for GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 487.0 Quantity Limit Exceptions

REQUIRED DEFINITIONS:

1. **Attachment** – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. **Exhibit** – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. **Devised** – the date the policy was implemented.
4. **Revised** – the date of every revision to the policy, including typographical and grammatical changes.
5. **Reviewed** – the date documenting the annual review if the policy has no revisions necessary.

ADDITIONAL DEFINITIONS:

1. **Formulary** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. **Non-formulary products** – those medications that are not included in the Formulary.
3. **Healthcare provider** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
4. **NCQA** – National Committee for Quality Assurance.
5. **Medically Necessary or Medical Necessity** – covered services rendered by a provider that the Health Plan determines are:



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 679.0

**SECTION: Commercial Drug
SUBJECT: Desvenlafaxine ER
(generic Khedezla)**

- A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
- B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
- C. In accordance with current standards of medical practice;
- D. Not primarily for the convenience of the Member, or the Member's Provider; and
- E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

PROCEDURE:

New members to the plan already established on therapy may be eligible for continuity of care coverage as long as there is medical record documentation that the safety and effectiveness of use for the prescribed indication is supported by Food and Drug Administration (FDA) approval or adequate medical and scientific evidence in the medical literature.

An exception for coverage of desvenlafaxine ER (generic Khedezla) may be made for members who meet the following criteria:

- Medical record documentation of therapeutic failure on, intolerance to, or contraindication to desvenlafaxine succinate ER (generic Pristiq)

MEDISPAN AUTHORIZATION LEVEL: GPI-12, generic only

QUANTITY LIMIT: *No QLs need to be entered within the authorization unless the requested quantity exceeds the QL.*

- QL FOR LETTER ONLY: 1 tablet per day

If a formulary exception is approved, desvenlafaxine ER (generic Khedezla) will be paid for under the member's prescription drug benefit.

Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.

FORMULARY ALTERNATIVES:

desvenlafaxine succinate ER (generic Pristiq)



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 679.0

**SECTION: Commercial Drug
SUBJECT: Desvenlafaxine ER
(generic Khedezla)**

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE
STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND
FEDERAL REGULATORY ENTITIES.**

**THIS POLICY WILL BE REVISED AS NECESSARY AND
REVIEWED NO LESS THAN ANNUALLY.**

Signed: _____

Title: Director, Pharmacy Services

Date: March 1, 2022

Devised: 11/12/21

Revised: 3/1/22 – annual review, updated referenced policies & covered LOBs



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 680.0

**SECTION: Commercial Drug
SUBJECT: Welireg**

Applicable line of business:

Commercial	X	Medicaid	
Medicare		ACA	X
GHP Kids	X	Self-Insured	X

POLICY:

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for Welireg for GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 487.0 Quantity Limit Exceptions

REQUIRED DEFINITIONS:

1. **Attachment** – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. **Exhibit** – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
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4. **Revised** – the date of every revision to the policy, including typographical and grammatical changes.
5. **Reviewed** – the date documenting the annual review if the policy has no revisions necessary.

ADDITIONAL DEFINITIONS:

1. **Formulary** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. **Non-formulary products** – those medications that are not included in the Formulary.
3. **Healthcare provider** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
4. **NCQA** – National Committee for Quality Assurance.
5. **Medically Necessary or Medical Necessity** – covered services rendered by a provider that the Health Plan determines are:



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 680.0

**SECTION: Commercial Drug
SUBJECT: Welireg**

- A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
- B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
- C. In accordance with current standards of medical practice;
- D. Not primarily for the convenience of the Member, or the Member's Provider; and
- E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

PROCEDURE:

New members to the plan already established on therapy may be eligible for continuity of care coverage as long as there is medical record documentation that the safety and effectiveness of use for the prescribed indication is supported by Food and Drug Administration (FDA) approval or adequate medical and scientific evidence in the medical literature.

An exception for coverage of Welireg may be made for members who meet the following criteria:

- Medical record documentation that Welireg is prescribed by a hematologist or oncologist **AND**
- Medical record documentation of age greater than or equal to 18 years **AND**
- Medical record documentation of a diagnosis of von Hippel-Lindau (VHL) disease confirmed with a germline VHL alteration and at least one of the following:
 - associated renal cell carcinoma (RCC) **OR**
 - associated central nervous system (CNS) hemangioblastomas **OR**
 - associated pancreatic neuroendocrine tumors (pNET)

AND

- Medical record documentation that patient does not require immediate surgery

MEDISPAN APPROVAL LEVEL: GPI-12, number of claims authorized = 1, enter for the remainder of the calendar year

QUANTITY LIMIT: *No QLs need to be entered within the authorization unless the requested quantity exceeds the QL.*

- QL FOR LETTER ONLY: 90 tablets per 30 days



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 680.0

**SECTION: Commercial Drug
SUBJECT: Welireg**

RE-AUTHORIZATION CRITERIA: Welireg is configured as a prior authorization for new starts only. Welireg will no longer be covered if it is identified that the member is not receiving appropriate follow-up care from the prescribing specialist or if the member has greater than or equal to a 90 day break in therapy.

- Medical record documentation that the member is receiving appropriate follow-up care from the prescribing specialist

If a formulary exception is approved, Welireg will be paid for under the member's prescription drug benefit.

Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.

FORMULARY ALTERNATIVES:

none

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE
STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND
FEDERAL REGULATORY ENTITIES.**

**THIS POLICY WILL BE REVISED AS NECESSARY AND
REVIEWED NO LESS THAN ANNUALLY.**

Signed: _____

Title: Director, Pharmacy Services

Date: March 1, 2022

Devised: 11/19/21

Revised: 3/1/22 – annual review, updated referenced policies & covered LOBs



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 681.0

**SECTION: Commercial Drug
SUBJECT: InPen**

Applicable line of business:

Commercial	X	Medicaid	
Medicare		ACA	X
GHP Kids	X	Self-Insured	X

POLICY:

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for InPen for GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 487.0 Quantity Limit Exceptions

REQUIRED DEFINITIONS:

1. **Attachment** – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. **Exhibit** – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. **Devised** – the date the policy was implemented.
4. **Revised** – the date of every revision to the policy, including typographical and grammatical changes.
5. **Reviewed** – the date documenting the annual review if the policy has no revisions necessary.

ADDITIONAL DEFINITIONS:

1. **Formulary** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. **Non-formulary products** – those medications that are not included in the Formulary.
3. **Healthcare provider** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
4. **NCQA** – National Committee for Quality Assurance.
5. **Medically Necessary or Medical Necessity** – covered services rendered by a provider that the Health Plan determines are:



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 681.0

**SECTION: Commercial Drug
SUBJECT: InPen**

- A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
- B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
- C. In accordance with current standards of medical practice;
- D. Not primarily for the convenience of the Member, or the Member's Provider; and
- E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

PROCEDURE:

An exception for coverage of InPen may be made for members who meet the following criteria:

- Medical record documentation of a diagnosis of diabetes mellitus **AND**
- Medical record documentation that InPen is prescribed by or in consultation with an endocrinologist **AND**
- Medical record documentation of age greater than or equal to 7 years OR age less than 7 years and documentation that InPen will be utilized with adult supervision **AND**
- Medical record documentation that member has access to a device with the ability to install and use the InPen app (e.g., smartphone, tablet, etc. with iOS 10 or later or Android 6 or later) **AND**
- Medical record documentation that member has utilized multiple daily injections of insulin (i.e., at least 3 injections per day), with frequent self-adjustments of insulin dose for at least 6 months **AND**
- Medical record documentation that member has suboptimal blood sugar control despite appropriate management as demonstrated by at least one of the following:
 - Glycosylated hemoglobin level (HbA1c) greater than 7.0%
 - History of recurring hypoglycemia
 - Wide fluctuations in blood glucose before mealtime
 - History of severe glycemic excursions

MEDISPAN APPROVAL LEVEL: NDC-11

QUANTITY LIMIT: *No QLs need to be entered within the authorization unless the requested quantity exceeds the QL.*

- **QL FOR LETTER ONLY:** 1 pen per 365 days



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 681.0

**SECTION: Commercial Drug
SUBJECT: InPen**

If a formulary exception is approved, InPen will be paid for under the member's prescription drug benefit.

Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.

FORMULARY ALTERNATIVES:

none

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE
STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND
FEDERAL REGULATORY ENTITIES.**

**THIS POLICY WILL BE REVISED AS NECESSARY AND
REVIEWED NO LESS THAN ANNUALLY.**

Signed: _____

Title: Director, Pharmacy Services

Date: March 1, 2022

Devised: 11/19/21

Revised: 3/1/22 – annual review, updated referenced policies & covered LOBs



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 682.0

**SECTION: Commercial Drug
SUBJECT: Kerendia**

Applicable line of business:

Commercial	X	Medicaid	
Medicare		ACA	X
GHP Kids	X	Self-Insured	X

POLICY:

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for Kerendia for GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 487.0 Quantity Limit Exceptions

REQUIRED DEFINITIONS:

1. **Attachment** – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. **Exhibit** – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. **Devised** – the date the policy was implemented.
4. **Revised** – the date of every revision to the policy, including typographical and grammatical changes.
5. **Reviewed** – the date documenting the annual review if the policy has no revisions necessary.

ADDITIONAL DEFINITIONS:

1. **Formulary** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. **Non-formulary products** – those medications that are not included in the Formulary.
3. **Healthcare provider** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
4. **NCQA** – National Committee for Quality Assurance.
5. **Medically Necessary or Medical Necessity** – covered services rendered by a provider that the Health Plan determines are:



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 682.0

**SECTION: Commercial Drug
SUBJECT: Kerendia**

- A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
- B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
- C. In accordance with current standards of medical practice;
- D. Not primarily for the convenience of the Member, or the Member's Provider; and
- E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

PROCEDURE:

An exception for coverage of Kerendia may be made for members who meet the following criteria:

- Medical record documentation of a diagnosis of chronic kidney disease associated with type 2 diabetes **AND**
- Medical record documentation of age greater than or equal to 18 years **AND**
- Medical record documentation of serum potassium less than or equal to 5.0 mEq/L **AND**
- Medical record documentation of therapeutic failure on, intolerance to, or contraindication to two (2) of the preferred sodium-glucose cotransporter 2 (SGLT-2) inhibitors Food and Drug Administration (FDA)-approved for the member's diagnosis

MEDISPAN APPROVAL LEVEL: GPI-12

QUANTITY LIMIT: *No QLs need to be entered within the authorization unless the requested quantity exceeds the QL.*

- **QL FOR LETTER ONLY:** 1 tablet per day

If a formulary exception is approved, Kerendia will be paid for under the member's prescription drug benefit.

Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.

FORMULARY ALTERNATIVES:

Invokana



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 682.0

**SECTION: Commercial Drug
SUBJECT: Kerendia**

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE
STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND
FEDERAL REGULATORY ENTITIES.**

**THIS POLICY WILL BE REVISED AS NECESSARY AND
REVIEWED NO LESS THAN ANNUALLY.**

Signed: _____

Title: Director, Pharmacy Services

Date: March 1, 2022

Devised: 11/19/21

Revised: 3/1/22 – annual review, updated referenced policies & covered LOBs



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 683.0

**SECTION: Commercial Drug
SUBJECT: Lybalvi**

Applicable line of business:

Commercial	X	Medicaid	
Medicare		ACA	X
GHP Kids	X	Self-Insured	X

POLICY:

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for Lybalvi for GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 487.0 Quantity Limit Exceptions

REQUIRED DEFINITIONS:

1. **Attachment** – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. **Exhibit** – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. **Devised** – the date the policy was implemented.
4. **Revised** – the date of every revision to the policy, including typographical and grammatical changes.
5. **Reviewed** – the date documenting the annual review if the policy has no revisions necessary.

ADDITIONAL DEFINITIONS:

1. **Formulary** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. **Non-formulary products** – those medications that are not included in the Formulary.
3. **Healthcare provider** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
4. **NCQA** – National Committee for Quality Assurance.
5. **Medically Necessary or Medical Necessity** – covered services rendered by a provider that the Health Plan determines are:



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 683.0

**SECTION: Commercial Drug
SUBJECT: Lybalvi**

- A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
- B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
- C. In accordance with current standards of medical practice;
- D. Not primarily for the convenience of the Member, or the Member's Provider; and
- E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

PROCEDURE:

New members to the plan already established on therapy may be eligible for continuity of care coverage as long as there is medical record documentation that the safety and effectiveness of use for the prescribed indication is supported by Food and Drug Administration (FDA) approval or adequate medical and scientific evidence in the medical literature.

An exception for coverage of Lybalvi may be made for members who meet the following criteria:

- Medical record documentation of age greater than or equal to 18 years **AND**
- Medical record documentation that Lybalvi is being used for one of the following:
 - Schizophrenia **OR**
 - Acute treatment of manic or mixed episodes associated with bipolar I disorder **OR**
 - Maintenance treatment of bipolar I disorder

AND

- Medical record documentation of a therapeutic failure on, intolerance to, or contraindication to three (3) generic, formulary atypical antipsychotics, one of which must be olanzapine

MEDISPAN APPROVAL LEVEL: GPI-12

QUANTITY LIMIT: *No QLs need to be entered within the authorization unless the requested quantity exceeds the QL.*

- **QL FOR LETTER ONLY:** 1 tablet per day



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 683.0

**SECTION: Commercial Drug
SUBJECT: Lybalvi**

If a formulary exception is approved, Lybalvi will be paid for under the member's prescription drug benefit.

Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.

FORMULARY ALTERNATIVES:

aripiprazole, Caplyta*, Fanapt*, Latuda*, Vraylar*, olanzapine, paliperidone*, quetiapine, risperidone, ziprasidone

*prior authorization required

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE
STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND
FEDERAL REGULATORY ENTITIES.**

**THIS POLICY WILL BE REVISED AS NECESSARY AND
REVIEWED NO LESS THAN ANNUALLY.**

Signed: _____

Title: Director, Pharmacy Services

Date: March 1, 2022

Devised: 11/22/21

Revised: 3/1/22 – annual review, updated referenced policies & covered LOBs



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 684.0

**SECTION: Commercial Drug
SUBJECT: Myfembree**

Applicable line of business:

Commercial	X	Medicaid	
Medicare		ACA	X
GHP Kids	X	Self-Insured	X

POLICY:

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for Myfembree for GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 487.0 Quantity Limit Exceptions

REQUIRED DEFINITIONS:

1. **Attachment** – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. **Exhibit** – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. **Devised** – the date the policy was implemented.
4. **Revised** – the date of every revision to the policy, including typographical and grammatical changes.
5. **Reviewed** – the date documenting the annual review if the policy has no revisions necessary.

ADDITIONAL DEFINITIONS:

1. **Formulary** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. **Non-formulary products** – those medications that are not included in the Formulary.
3. **Healthcare provider** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
4. **NCQA** – National Committee for Quality Assurance.
5. **Medically Necessary or Medical Necessity** – covered services rendered by a provider that the Health Plan determines are:



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 684.0

**SECTION: Commercial Drug
SUBJECT: Myfembree**

- A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
- B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
- C. In accordance with current standards of medical practice;
- D. Not primarily for the convenience of the Member, or the Member's Provider; and
- E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

PROCEDURE:

An exception for coverage of Myfembree may be made for members who meet the following criteria:

- Medical record documentation that Myfembree is prescribed by a gynecologist **AND**
- Medical record documentation of age greater than or equal to 18 years **AND**
- Medical record documentation that patient is premenopausal **AND**
- Medical record documentation of a diagnosis of heavy menstrual bleeding associated with uterine leiomyomas (fibroids) **AND**
- Medical record documentation of therapeutic failure on, intolerance to, or contraindication to at least one prior treatment to reduce menstrual bleeding, including but not limited to:
 - Oral contraceptives **OR**
 - Oral or injectable progesterone **OR**
 - Progestin-releasing intrauterine system **OR**
 - Tranexamic acid tablets **OR**
 - Gonadotropin-releasing hormone (GnRH) agonists

MEDISPAN APPROVAL LEVEL: GPI-12

QUANTITY LIMIT: *No QLs need to be entered within the authorization unless the requested quantity exceeds the QL.*

- **QL FOR LETTER ONLY:** 28 capsules per 28 days

AUTHORIZATION DURATION: Initial authorization will be 24 months (or less if there is medical record documentation of a previous incomplete course of therapy with a gonadotropin-releasing hormone (GnRH) receptor antagonist (i.e., relugolix or elagolix).



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 684.0

**SECTION: Commercial Drug
SUBJECT: Myfembree**

REAUTHORIZATION:

- Medical record documentation that the patient has not been treated for more than a total of 24 months with a gonadotropin-releasing hormone (GnRH) receptor antagonist (i.e., relugolix or elagolix) **OR**
- Documentation of medical or scientific literature to support the use of this agent beyond the Food and Drug Administration (FDA)-approved treatment duration.

If a formulary exception is approved, Myfembree will be paid for under the member's prescription drug benefit.

Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.

FORMULARY ALTERNATIVES:

Afirmelle, Altavera, Alyacen, Amethia, Amethyst, Apri, Aranelle, Ashlyna, Aubra, Aurovela, Aurovela 24 FE, Aurovela DE, Aviane, Ayuna, Azurette, Balcoltra, Balziva, Bekyree, Blisovi 24 FE, Blisovi FE, Briellyn, Camila, Camrese, Camrese Lo, Caziant, Charlotte 24 FE, Chateal, Cryselles, Cyclofem, Cyred, Dasetta, Daysee, Deblitane, Delyla, Desogestrel/ethinyl estradiol, Dolishale, drospirenone/ethinyl estradiol/levomefolate, drospirenone/ethinyl estradiol, Elinest, Emoquette, Enpresse, Enskyce, Errin, Estarylla, ethynodiol/ethinyl estradiol, Falmina, Fayosim, Femynor, Gemmily, Hailey, Hailey 24 FE, Hailey FE, Heather, Iclevia, Incassia, Introvale, Isibloom, Jaimiess, Jasmiel, Jencycla, Jolessa, Juleber, Junel, Junel FE, Junel FE 24, Kaitlib FE, Kalliga, Kariva, Kelnor, Kurvelo, Larin, Larin 24 FE, Larissia, Layolis FE, Leena, Lessina, Levonest, levonorgestrel/ethinyl estradiol, Levora, Lillow, LoJaimiess, Lo Loestrin FE, Loryna, Low-Ogestrel, Lo-Zumandimine, Lutera, Lyleq, Lyza, Marlissa, Merzee, Microgestin, Microgestin FE, Mili, Mono-Linyah, Natazia, Necon, Nextstellis, Nikki, Nora-Be, norethindrone, norethindrone/ethinyl estradiol, norethindrone/ethinyl estradiol/ferrous fumarate, norgestimate/ethinyl estradiol, Norlyda, Norlyroc, Nortrel, Ocella, Orsythia, Philith, Pimtree, Pirmella, Portia, Previfem, Reclipsen, Rivelsa, Setlakin, Sharobel, Simliya, Simpesse, Slynd, Sprintec, Sronyx, Syeda, Tarina 24 FE, Tarina FE, Taytulla, Tilia FE, Tri-Femynor, Tri-Estarylla, Tri-Legest FE, Tri-Linyah, Tri-Lo-Estarylla, Tri-Lo-Marzia, Tri-Lo-Mili, Tri-Lo-Sprintec, Tri-Mili, Tri-Nymyo, Tri-Previfem, Tri-Sprintec, Trivora-28, Tri-VyLibra, Tri-VyLibra Lo, Tulana, Tyblume, Tydemy, Velivet, Vestura, Vienva, Viorele, Volnea, Vyfemla, VyLibra, Wera, Wymzya FE, Zarah, Zovia 1-35E, Zumandimine, medroxyprogesterone intramuscular suspension, tranexamic acid, Lupron Depot



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 684.0

**SECTION: Commercial Drug
SUBJECT: Myfembree**

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE
STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND
FEDERAL REGULATORY ENTITIES.**

**THIS POLICY WILL BE REVISED AS NECESSARY AND
REVIEWED NO LESS THAN ANNUALLY.**

Signed: _____

Title: Director, Pharmacy Services

Date: March 1, 2022

Devised: 11/22/21

Revised: 3/1/22 – annual review, updated referenced policies & covered LOBs



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 685.0

**SECTION: Commercial Drug
SUBJECT: Oriahnn**

Applicable line of business:

Commercial	X	Medicaid	
Medicare		ACA	X
GHP Kids	X	Self-Insured	X

POLICY:

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for Oriahnn for GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 487.0 Quantity Limit Exceptions

REQUIRED DEFINITIONS:

1. **Attachment** – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. **Exhibit** – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. **Devised** – the date the policy was implemented.
4. **Revised** – the date of every revision to the policy, including typographical and grammatical changes.
5. **Reviewed** – the date documenting the annual review if the policy has no revisions necessary.

ADDITIONAL DEFINITIONS:

1. **Formulary** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. **Non-formulary products** – those medications that are not included in the Formulary.
3. **Healthcare provider** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
4. **NCQA** – National Committee for Quality Assurance.
5. **Medically Necessary or Medical Necessity** – covered services rendered by a provider that the Health Plan determines are:



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 685.0

**SECTION: Commercial Drug
SUBJECT: Oriahnn**

- A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
- B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
- C. In accordance with current standards of medical practice;
- D. Not primarily for the convenience of the Member, or the Member's Provider; and
- E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

PROCEDURE:

An exception for coverage of Oriahnn may be made for members who meet the following criteria:

- Medical record documentation that Oriahnn is prescribed by a gynecologist **AND**
- Medical record documentation of age greater than or equal to 18 years **AND**
- Medical record documentation that patient is premenopausal **AND**
- Medical record documentation of a diagnosis of heavy menstrual bleeding associated with uterine leiomyomas (fibroids) **AND**
- Medical record documentation of therapeutic failure on, intolerance to, or contraindication to at least one prior treatment to reduce menstrual bleeding, including but not limited to:
 - Oral contraceptives **OR**
 - Oral or injectable progesterone **OR**
 - Progestin-releasing intrauterine system **OR**
 - Tranexamic acid tablets **OR**
 - Gonadotropin-releasing hormone (GnRH) agonists

MEDISPAN APPROVAL LEVEL: GPI-12

QUANTITY LIMIT: *No QLs need to be entered within the authorization unless the requested quantity exceeds the QL.*

- **QL FOR LETTER ONLY:** 56 capsules per 28 days

AUTHORIZATION DURATION: Initial authorization will be 24 months (or less if there is medical record documentation of a previous incomplete course of therapy with a gonadotropin-releasing hormone (GnRH) receptor antagonist (i.e., relugolix or elagolix).



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 685.0

**SECTION: Commercial Drug
SUBJECT: Oriahnn**

REAUTHORIZATION:

- Medical record documentation that the patient has not been treated for more than a total of 24 months with a gonadotropin-releasing hormone (GnRH) receptor antagonist (i.e., relugolix or elagolix) **OR**
- Documentation of medical or scientific literature to support the use of this agent beyond the Food and Drug Administration (FDA)-approved treatment duration.

If a formulary exception is approved, Oriahnn will be paid for under the member's prescription drug benefit.

Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.

FORMULARY ALTERNATIVES:

Afirmelle, Altavera, Alyacen, Amethia, Amethyst, Apri, Aranelle, Ashlyna, Aubra, Aurovela, Aurovela 24 FE, Aurovela DE, Aviane, Ayuna, Azurette, Balcoltra, Balziva, Bekyree, Blisovi 24 FE, Blisovi FE, Briellyn, Camila, Camrese, Camrese Lo, Caziant, Charlotte 24 FE, Chateal, Cryselles, Cyclofem, Cyred, Dasetta, Daysee, Deblitane, Delyla, Desogestrel/ethinyl estradiol, Dolishale, drospirenone/ethinyl estradiol/levomefolate, drospirenone/ethinyl estradiol, Elinest, Emoquette, Enpresse, Enskyce, Errin, Estarylla, ethynodiol/ethinyl estradiol, Falmina, Fayosim, Femynor, Gemmily, Hailey, Hailey 24 FE, Hailey FE, Heather, Iclevia, Incassia, Introvale, Isibloom, Jaimiess, Jasmiel, Jencycla, Jolessa, Juleber, Junel, Junel FE, Junel FE 24, Kaitlib FE, Kalliga, Kariva, Kelnor, Kurvelo, Larin, Larin 24 FE, Larissia, Layolis FE, Leena, Lessina, Levonest, levonorgestrel/ethinyl estradiol, Levora, Lillow, LoJaimiess, Lo Loestrin FE, Loryna, Low-Ogestrel, Lo-Zumandimine, Lutera, Lyleq, Lyza, Marlissa, Merzee, Microgestin, Microgestin FE, Mili, Mono-Linyah, Natazia, Necon, Nextstellis, Nikki, Nora-Be, norethindrone, norethindrone/ethinyl estradiol, norethindrone/ethinyl estradiol/ferrous fumarate, norgestimate/ethinyl estradiol, Norlyda, Norlyroc, Nortrel, Ocella, Orsythia, Philith, Pimtree, Pirmella, Portia, Previfem, Reclipsen, Rivelsa, Setlakin, Sharobel, Simliya, Simpesse, Slynd, Sprintec, Sronyx, Syeda, Tarina 24 FE, Tarina FE, Taytulla, Tilia FE, Tri-Femynor, Tri-Estarylla, Tri-Legest FE, Tri-Linyah, Tri-Lo-Estarylla, Tri-Lo-Marzia, Tri-Lo-Mili, Tri-Lo-Sprintec, Tri-Mili, Tri-Nymyo, Tri-Previfem, Tri-Sprintec, Trivora-28, Tri-VyLibra, Tri-VyLibra Lo, Tulana, Tyblume, Tydemy, Velivet, Vestura, Vienva, Viorele, Volnea, Vyfemla, VyLibra, Wera, Wymzya FE, Zarah, Zovia 1-35E, Zumandimine, medroxyprogesterone intramuscular suspension, tranexamic acid, Lupron Depot



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 685.0

**SECTION: Commercial Drug
SUBJECT: Oriahnn**

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE
STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND
FEDERAL REGULATORY ENTITIES.**

**THIS POLICY WILL BE REVISED AS NECESSARY AND
REVIEWED NO LESS THAN ANNUALLY.**

Signed: _____

Title: Director, Pharmacy Services

Date: March 1, 2022

Devised: 11/22/21

Revised: 3/1/22 – annual review, updated referenced policies & covered LOBs



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 686.0

**SECTION: Commercial Drug
SUBJECT: Wegovy**

Applicable line of business:

Commercial	X	Medicaid	
Medicare		ACA	
GHP Kids		Self-Insured	X

*This policy is only applicable to those members whose coverage does not exclude medications for weight management.

POLICY:

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for agents to treat insomnia for GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 487.0 Quantity Limit Exceptions

REQUIRED DEFINITIONS:

1. **Attachment** – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. **Exhibit** – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. **Devised** – the date the policy was implemented.
4. **Revised** – the date of every revision to the policy, including typographical and grammatical changes.
5. **Reviewed** – the date documenting the annual review if the policy has no revisions necessary.

ADDITIONAL DEFINITIONS:

1. **Formulary** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. **Non-formulary products** – those medications that are not included in the Formulary.
3. **Healthcare provider** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
4. **NCQA** – National Committee for Quality Assurance.

5. **Medically Necessary or Medical Necessity** – covered services rendered by a provider that the Health Plan determines are:
- A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
 - B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
 - C. In accordance with current standards of medical practice;
 - D. Not primarily for the convenience of the Member, or the Member's Provider; and
 - E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

PROCEDURE:

Pharmaceuticals for chronic weight management are not covered, except for certain clients that request this benefit.

An exception for coverage of Wegovy may be made for members who meet the following criteria:

- Medical record documentation of age greater than or equal to 18 years **AND**
- Medical record documentation of use as adjunct therapy to reduced calorie diet and increased physical activity for chronic weight management **AND**
- Medical record documentation of one of the following:
 - Medical record documentation of body mass index (BMI) greater than or equal to 30 kg/m² **OR**
 - Medical record documentation of body mass index (BMI) greater than or equal to 27 kg/m² and at least one weight-related comorbid condition (e.g., hypertension, type 2 diabetes mellitus, or dyslipidemia)

NOTE: Wegovy is not indicated for treatment of chronic weight management:

- In combination with semaglutide containing products or any other GLP-1 receptor agonist
- In combination with other products for weight loss, as safety and efficacy or coadministration has not been established
- In patients with a history of pancreatitis

MEDISPAN APPROVAL LEVEL: GPI-12



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 686.0

**SECTION: Commercial Drug
SUBJECT: Wegovy**

QUANTITY LIMIT: *No QLs need to be entered within the authorization unless the requested quantity exceeds the QL.*

- **QL FOR LETTER ONLY:** 3 mL per 28 days

If an exception is made, Wegovy will be paid for under the member's prescription drug benefit.

Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.

FORMULARY ALTERNATIVES:

phentermine, Qsymia, Contrave, Saxenda

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE
STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND
FEDERAL REGULATORY ENTITIES.**

**THIS POLICY WILL BE REVISED AS NECESSARY AND
REVIEWED NO LESS THAN ANNUALLY.**

Signed: _____

Title: Director, Pharmacy Services

Date: March 1, 2022

Devised: 11/22/21

Revised: 3/1/22 – annual review, updated referenced policies & covered LOBs, updated FA



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 687.0

**SECTION: Commercial Drug
SUBJECT: Brexafemme**

Applicable line of business:

Commercial	X	Medicaid	
Medicare		ACA	X
GHP Kids	X	Self-Insured	X

POLICY:

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for Brexafemme for GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 487.0 Quantity Limit Exceptions

REQUIRED DEFINITIONS:

1. **Attachment** – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. **Exhibit** – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. **Devised** – the date the policy was implemented.
4. **Revised** – the date of every revision to the policy, including typographical and grammatical changes.
5. **Reviewed** – the date documenting the annual review if the policy has no revisions necessary.

ADDITIONAL DEFINITIONS:

1. **Formulary** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. **Non-formulary products** – those medications that are not included in the Formulary.
3. **Healthcare provider** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
4. **NCQA** – National Committee for Quality Assurance.
5. **Medically Necessary or Medical Necessity** – covered services rendered by a provider that the Health Plan determines are:



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 687.0

**SECTION: Commercial Drug
SUBJECT: Brexafemme**

- A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
- B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
- C. In accordance with current standards of medical practice;
- D. Not primarily for the convenience of the Member, or the Member's Provider; and
- E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

PROCEDURE:

An exception for coverage of Brexafemme may be made for members who meet the following criteria:

- Medical record documentation of a diagnosis of vulvovaginal candidiasis (VVC) **AND**
- Medical record documentation that member is greater than or equal to 12 years of age and post-menarchal **AND**
- Medical record documentation of therapeutic failure, contraindication, or intolerance to oral fluconazole tablets **AND** one formulary topical antifungal indicated for the treatment of vulvovaginal candidiasis

MEDISPAN AUTHORIZATION LEVEL: GPI-12

QUANTITY LIMIT: *No QLs need to be entered within the authorization unless the requested quantity exceeds the QL.*

- QL FOR LETTER ONLY: 4 tablets per day, 1 fill

AUTHORIZATION DURATION: 1 month, number of claims authorized = 1

If a formulary exception is approved, Brexafemme will be paid for under the member's prescription drug benefit.

Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.

FORMULARY ALTERNATIVES:

fluconazole, miconazole 3 200 mg vaginal suppository, terconazole 0.41% cream, terconazole 0.8% cream, terconazole suppository



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 687.0

**SECTION: Commercial Drug
SUBJECT: Brexafemme**

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE
STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND
FEDERAL REGULATORY ENTITIES.**

**THIS POLICY WILL BE REVISED AS NECESSARY AND
REVIEWED NO LESS THAN ANNUALLY.**

Signed: _____

Title: Director, Pharmacy Services

Date: March 1, 2022

Devised: 1/4/22

Revised: 3/1/22 – annual review, updated referenced policies & covered LOBs



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 688.0

**SECTION: Commercial Drug
SUBJECT: Bylvay**

Applicable line of business:

Commercial	X	Medicaid	
Medicare		ACA	X
GHP Kids	X	Self-Insured	X

POLICY:

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for Bylvay for GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 487.0 Quantity Limit Exceptions

REQUIRED DEFINITIONS:

1. **Attachment** – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. **Exhibit** – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. **Devised** – the date the policy was implemented.
4. **Revised** – the date of every revision to the policy, including typographical and grammatical changes.
5. **Reviewed** – the date documenting the annual review if the policy has no revisions necessary.

ADDITIONAL DEFINITIONS:

1. **Formulary** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. **Non-formulary products** – those medications that are not included in the Formulary.
3. **Healthcare provider** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
4. **NCQA** – National Committee for Quality Assurance.
5. **Medically Necessary or Medical Necessity** – covered services rendered by a provider that the Health Plan determines are:



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 688.0

**SECTION: Commercial Drug
SUBJECT: Bylvay**

- A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
- B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
- C. In accordance with current standards of medical practice;
- D. Not primarily for the convenience of the Member, or the Member's Provider; and
- E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

PROCEDURE:

An exception for coverage of Bylvay may be made for members who meet the following criteria:

- Medical record documentation that Bylvay is prescribed by or consultation with a hepatologist or gastroenterologist **AND**
- Medical record documentation of a diagnosis of progressive familial intrahepatic cholestasis (PFIC) confirmed by genetic testing **AND**
- Medical record documentation of the presence of moderate to severe pruritus **AND**
- Medical record documentation of age greater than or equal to 3 months **AND**
- Medical record documentation that the member is receiving an appropriate dose* based on the patient's weight **AND**
- Medical record documentation of concurrent use or therapeutic failure on, intolerance to, or contraindication to ursodiol

***NOTE:** The recommended dosage of Bylvay is 40 mcg/kg once daily. If there is no improvement in pruritus after 3 months, the dosage may be increased in 40 mcg/kg increments up to 120 mcg/kg once daily not to exceed a total daily dose of 6 mg (6000 mcg). See https://bylvay.com/pdf/021066_Bylvay_Dosing_Guide.pdf

MEDISPAN AUTHORIZATION LEVEL: GPI-10

QUANTITY LIMIT: *No QLs need to be entered within the authorization unless the requested quantity exceeds the QL.*

- **QL FOR LETTER ONLY:**
 - 200 mcg pellets: 30 capsules per day, up to a 34 day supply per fill
 - 600 mcg pellets: 10 capsules per day, up to a 34 day supply per fill
 - 400 mcg capsules: 15 capsules per day, up to a 34 day supply per fill
 - 1200 mcg capsules: 5 capsules per day, up to a 34 day supply per fill



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 688.0

**SECTION: Commercial Drug
SUBJECT: Bylvay**

AUTHORIZATION DURATION: Initial approval will be for 6 months or less if the reviewing provider feels it is medically appropriate. Subsequent approvals will be for an additional 6 months or less if the reviewing provider feels it is medically appropriate and will require the following:

- Medical record documentation of improvement in pruritus and/or reduction in serum bile acid **AND**
- Medical record documentation that the member is receiving an appropriate dose* based on the patient's weight

If a formulary exception is approved, Bylvay will be paid for under the member's prescription drug benefit.

Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.

FORMULARY ALTERNATIVES:
ursodiol

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE
STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND
FEDERAL REGULATORY ENTITIES.**

**THIS POLICY WILL BE REVISED AS NECESSARY AND
REVIEWED NO LESS THAN ANNUALLY.**

Signed: _____

Title: Director, Pharmacy Services

Date: March 1, 2022

Devised: 1/4/22

Revised: 3/1/22 – annual review, updated referenced policies & covered LOBs



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 689.0

**SECTION: Commercial Drug
SUBJECT: Exkivity**

Applicable line of business:

Commercial	X	Medicaid	
Medicare		ACA	X
GHP Kids	X	Self-Insured	X

POLICY:

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for Exkivity for GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 487.0 Quantity Limit Exceptions

REQUIRED DEFINITIONS:

1. **Attachment** – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. **Exhibit** – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. **Devised** – the date the policy was implemented.
4. **Revised** – the date of every revision to the policy, including typographical and grammatical changes.
5. **Reviewed** – the date documenting the annual review if the policy has no revisions necessary.

ADDITIONAL DEFINITIONS:

1. **Formulary** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. **Non-formulary products** – those medications that are not included in the Formulary.
3. **Healthcare provider** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
4. **NCQA** – National Committee for Quality Assurance.
5. **Medically Necessary or Medical Necessity** – covered services rendered by a provider that the Health Plan determines are:



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 689.0

**SECTION: Commercial Drug
SUBJECT: Exkivity**

- A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
- B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
- C. In accordance with current standards of medical practice;
- D. Not primarily for the convenience of the Member, or the Member's Provider; and
- E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

PROCEDURE:

New members to the plan already established on therapy may be eligible for continuity of care coverage as long as there is medical record documentation that the safety and effectiveness of use for the prescribed indication is supported by Food and Drug Administration (FDA) approval or adequate medical and scientific evidence in the medical literature.

An exception for coverage of Exkivity may be made for members who meet the following criteria:

- Medical record documentation that Exkivity is prescribed by a hematologist or oncologist **AND**
- Medical record documentation of age greater than or equal to 18 years **AND**
- Medical record documentation of a diagnosis of locally advanced or metastatic non-small cell lung cancer (NSCLC) **AND**
- Medical record documentation of epidermal growth factor receptor (EGFR) exon 20 insertion mutations, as detected by a Food and Drug Administration (FDA)-approved test* **AND**
- Medical record documentation of disease progression on or after platinum-based chemotherapy

***NOTE:** The FDA approved test for detection of epidermal growth factor receptor (EGFR) exon 20 insertion mutations for Exkivity is the Oncomine Dx Target Test.

MEDISPAN AUTHORIZATION LEVEL: GPI-12

QUANTITY LIMIT: *No QLs need to be entered within the authorization unless the requested quantity exceeds the QL.*

- **QL FOR LETTER ONLY:** 4 capsules per day, 30 day supply per fill



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 689.0

**SECTION: Commercial Drug
SUBJECT: Exkivity**

RE-AUTHORIZATION CRITERIA: Exkivity will be configured as a prior authorization for new starts only. Exkivity will no longer be covered if it is identified that the member is not receiving appropriate follow-up care from the prescribing specialist or if the member has greater than or equal to a 90 day break in therapy.

- Medical record documentation that the member is receiving appropriate follow-up care from the prescribing specialist

If a formulary exception is approved, Exkivity will be paid for under the member's prescription drug benefit.

Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.

FORMULARY ALTERNATIVES:

none

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE
STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND
FEDERAL REGULATORY ENTITIES.**

**THIS POLICY WILL BE REVISED AS NECESSARY AND
REVIEWED NO LESS THAN ANNUALLY.**

Signed: _____

Title: Director, Pharmacy Services

Date: March 1, 2022

Devised: 1/4/22

Revised: 3/1/22 – annual review, updated referenced policies & covered LOBs



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 690.0

**SECTION: Commercial Drug
SUBJECT: Besremi**

Applicable line of business:

Commercial	X	Medicaid	
Medicare		ACA	X
GHP Kids	X	Self-Insured	X

POLICY:

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for Besremi for GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 487.0 Quantity Limit Exceptions

REQUIRED DEFINITIONS:

1. **Attachment** – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. **Exhibit** – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. **Devised** – the date the policy was implemented.
4. **Revised** – the date of every revision to the policy, including typographical and grammatical changes.
5. **Reviewed** – the date documenting the annual review if the policy has no revisions necessary.

ADDITIONAL DEFINITIONS:

1. **Formulary** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. **Non-formulary products** – those medications that are not included in the Formulary.
3. **Healthcare provider** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
4. **NCQA** – National Committee for Quality Assurance.
5. **Medically Necessary or Medical Necessity** – covered services rendered by a provider that the Health Plan determines are:



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 690.0

**SECTION: Commercial Drug
SUBJECT: Besremi**

- A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
- B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
- C. In accordance with current standards of medical practice;
- D. Not primarily for the convenience of the Member, or the Member's Provider; and
- E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

PROCEDURE:

New members to the plan already established on therapy may be eligible for continuity of care coverage as long as there is medical record documentation that the safety and effectiveness of use for the prescribed indication is supported by Food and Drug Administration (FDA) approval or adequate medical and scientific evidence in the medical literature.

An exception for coverage of Besremi may be made for members who meet the following criteria:

- Medical record documentation that Besremi is prescribed by a hematologist or oncologist **AND**
- Medical record documentation of age greater than or equal to 18 years **AND**
- Medical record documentation of a diagnosis of polycythemia vera **AND**
- Medical record documentation of an inadequate response or intolerance to hydroxyurea

MEDISPAN AUTHORIZATION LEVEL: GPI-12

QUANTITY LIMIT: *No QLs need to be entered within the authorization unless the requested quantity exceeds the QL.*

- QL FOR LETTER ONLY: 2 mL per 28 days, 28 day supply per fill

RE-AUTHORIZATION CRITERIA: Besremi will be configured as a prior authorization for new starts only. Besremi will no longer be covered if it is identified that the member is not receiving appropriate follow-up care from the prescribing specialist or if the member has greater than or equal to a 90 day break in therapy.

- Medical record documentation that the member is receiving appropriate follow-up care from the prescribing specialist



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 690.0

**SECTION: Commercial Drug
SUBJECT: Besremi**

If a formulary exception is approved, Besremi will be paid for under the member's prescription drug benefit.

Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.

FORMULARY ALTERNATIVES:

hydroxyurea

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE
STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND
FEDERAL REGULATORY ENTITIES.**

**THIS POLICY WILL BE REVISED AS NECESSARY AND
REVIEWED NO LESS THAN ANNUALLY.**

Signed: _____

Title: Director, Pharmacy Services

Date: March 1, 2022

Devised: 1/21/22

Revised: 3/1/22 – annual review, updated referenced policies & covered LOBs



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 691.0

**SECTION: Commercial Drug
SUBJECT: Eprontia**

Applicable line of business:

Commercial	X	Medicaid	
Medicare		ACA	X
GHP Kids	X	Self-Insured	X

POLICY:

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for Eprontia for GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 487.0 Quantity Limit Exceptions

REQUIRED DEFINITIONS:

1. **Attachment** – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. **Exhibit** – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. **Devised** – the date the policy was implemented.
4. **Revised** – the date of every revision to the policy, including typographical and grammatical changes.
5. **Reviewed** – the date documenting the annual review if the policy has no revisions necessary.

ADDITIONAL DEFINITIONS:

1. **Formulary** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. **Non-formulary products** – those medications that are not included in the Formulary.
3. **Healthcare provider** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
4. **NCQA** – National Committee for Quality Assurance.
5. **Medically Necessary or Medical Necessity** – covered services rendered by a provider that the Health Plan determines are:

- A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
- B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
- C. In accordance with current standards of medical practice;
- D. Not primarily for the convenience of the Member, or the Member's Provider; and
- E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

PROCEDURE:

New members to the plan already established on therapy may be eligible for continuity of care coverage as long as there is medical record documentation that the safety and effectiveness of use for the prescribed indication is supported by Food and Drug Administration (FDA) approval or adequate medical and scientific evidence in the medical literature.

An exception for coverage of Eprontia may be made for members who meet the following criteria:

Seizures

- Medical record documentation of a diagnosis of partial onset seizures, primary generalized tonic-clonic seizures, or Lennox Gastaut syndrome **AND**
- Medical record documentation of age greater than or equal to 2 years **AND**
- Medical record documentation of one of the following:
 - Therapeutic failure on, intolerance to, or contraindication to three formulary alternatives, one of which must be topiramate immediate release tablets or topiramate immediate release sprinkle capsules **OR**
 - Medical record documentation of difficulty swallowing tablets **AND** therapeutic failure on, intolerance to, or contraindication to three formulary alternatives, one of which must be topiramate immediate release sprinkle capsules

For Migraine prophylaxis

- Medical record documentation of a diagnosis of use for migraine prophylaxis **AND**
- Medical record documentation of age greater than or equal to 12 years **AND**
- Medical record documentation of one of the following:
 - Therapeutic failure on, intolerance to, or contraindication to three formulary alternatives, one of which must be topiramate immediate release tablets or topiramate immediate release sprinkle capsule **OR**

- Medical record documentation of difficulty swallowing tablets **AND** therapeutic failure on, intolerance to, or contraindication to three formulary alternatives, one of which must be topiramate immediate release sprinkle capsules

NOTE: Topiramate immediate release sprinkle capsules may be opened and sprinkled over one teaspoon of soft food for immediate administration without chewing.

QUANTITY LIMIT: *No QLs need to be entered within the authorization unless the requested quantity exceeds the QL.*

- 16 mL per day

MEDISPAN AUTHORIZATION LEVEL: GPI-12

If an exception is made, Eprontia will be paid for under the member's prescription drug benefit.

Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.

FORMULARY ALTERNATIVES:

Seizures

For patients aged ≥ 2 years: topiramate immediate release tablets, topiramate immediate release sprinkle capsules, lamotrigine immediate release sprinkle capsules, carbamazepine, levetiracetam IR, phenobarbital, phenytoin, pregabalin, topiramate extended release*

Additional Formulary Alternatives: gabapentin (3+), oxcarbazepine (4+), divalproex (10+), levetiracetam ER (12+), tiagabine (12+), lamotrigine ER (13+), felbamate (14+), and zonisamide (16+)

*prior authorization required

Migraine Prophylaxis

topiramate immediate release tablets, topiramate immediate release sprinkle capsules, metoprolol, propranolol, timolol, atenolol, nadolol, divalproex, sodium valproate, amitriptyline, venlafaxine, topiramate extended release*

*prior authorization required

Geisinger

**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 691.0

**SECTION: Commercial Drug
SUBJECT: Eprontia**

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE
STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND
FEDERAL REGULATORY ENTITIES.**

**THIS POLICY WILL BE REVISED AS NECESSARY AND
REVIEWED NO LESS THAN ANNUALLY.**



Signed: _____

Title: Director, Pharmacy Services

Date: March 1, 2022

Devised: 1/21/22

Revised: 3/1/22 – annual review, updated referenced policies & covered LOBs, updated how QL is entered,
updated FA



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 692.0

**SECTION: Commercial Drug
SUBJECT: Rezurock**

Applicable line of business:

Commercial	X	Medicaid	
Medicare		ACA	X
GHP Kids	X	Self-Insured	X

POLICY:

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for Rezurock for GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 487.0 Quantity Limit Exceptions

REQUIRED DEFINITIONS:

1. **Attachment** – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. **Exhibit** – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. **Devised** – the date the policy was implemented.
4. **Revised** – the date of every revision to the policy, including typographical and grammatical changes.
5. **Reviewed** – the date documenting the annual review if the policy has no revisions necessary.

ADDITIONAL DEFINITIONS:

1. **Formulary** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. **Non-formulary products** – those medications that are not included in the Formulary.
3. **Healthcare provider** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
4. **NCQA** – National Committee for Quality Assurance.
5. **Medically Necessary or Medical Necessity** – covered services rendered by a provider that the Health Plan determines are:



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 692.0

**SECTION: Commercial Drug
SUBJECT: Rezurock**

- A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
- B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
- C. In accordance with current standards of medical practice;
- D. Not primarily for the convenience of the Member, or the Member's Provider; and
- E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

PROCEDURE:

An exception for coverage of Rezurock may be made for members who meet the following criteria:

- Medical record documentation that Rezurock is prescribed by a hematologist, oncologist, or transplant specialist **AND**
- Medical record documentation of age greater than or equal to 12 years **AND**
- Medical record documentation of a diagnosis of steroid refractory graft-versus-host disease (GVHD) b
- Medical record documentation of therapeutic failure of two or more prior lines of systemic therapy **AND**
- If request is for 200mg twice daily dosing, one of the following applies:
 - Medical record documentation that member is concurrently receiving a strong CYP3A4 inducer **OR**
 - If concurrently taking with a proton pump inhibitor (PPI), medical record documentation that treatment with a PPI is medically necessary **AND** medical record documentation of therapeutic failure on, intolerance to, or contraindication to a H2 blocker

MEDISPAN AUTHORIZATION LEVEL: GPI-12

QUANTITY LIMIT:

- 200 mg once daily: No QLs need to be entered within the authorization unless the requested quantity exceeds the QL. QL FOR LETTER ONLY: 1 tablet per day, 30 day supply per fill
- 200 mg twice daily: Only enter PA, OQL, max daily dose 2. QL FOR LETTER: 2 tablets per day, 30 day supply per fill



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 692.0

**SECTION: Commercial Drug
SUBJECT: Rezurock**

AUTHORIZATION DURATION: Initial approval given for 6 months or less if the reviewing provider feels it is appropriate. The medication will no longer be covered if the member experiences unacceptable toxicity or worsening of disease. Subsequent approvals for an additional 12 months or less if the reviewing provider feels it is medically appropriate and will require the following:

- Medical record documentation of continued disease improvement or lack of disease progression **AND**
- If request is for 200mg twice daily dosing, one of the following applies:
 - Medical record documentation that member is concurrently receiving a strong CYP3A4 inducer **OR**
 - If concurrently taking with a proton pump inhibitor (PPI), medical record documentation that treatment with a PPI is medically necessary **AND** medical record documentation of therapeutic failure on, intolerance to, or contraindication to a H2 blocker

If a formulary exception is approved, Rezurock will be paid for under the member's prescription drug benefit.

Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.

FORMULARY ALTERNATIVES:

Tacrolimus, cyclosporine, hydroxychloroquine, methotrexate, mycophenolate, sirolimus*, imatinib, Imbruvica*, Jakafi*, Rituxan*, Enbrel*, Lemtrada*, Orencia*

*prior authorization required

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE
STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND
FEDERAL REGULATORY ENTITIES.**

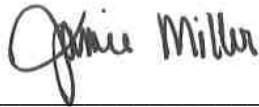
**THIS POLICY WILL BE REVISED AS NECESSARY AND
REVIEWED NO LESS THAN ANNUALLY.**

Geisinger

**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 692.0

**SECTION: Commercial Drug
SUBJECT: Rezurock**



Signed: _____

Title: Director, Pharmacy Services

Date: March 1, 2022

Devised: 1/21/22

Revised: 3/1/22 – annual review, updated referenced policies & covered LOBs, corrected typo



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 693.0

**SECTION: Commercial Drug
SUBJECT: Scemblix**

Applicable line of business:

Commercial	X	Medicaid	
Medicare		ACA	X
GHP Kids	X	Self-Insured	X

POLICY:

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for Scemblix for GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 487.0 Quantity Limit Exceptions

REQUIRED DEFINITIONS:

1. **Attachment** – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. **Exhibit** – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. **Devised** – the date the policy was implemented.
4. **Revised** – the date of every revision to the policy, including typographical and grammatical changes.
5. **Reviewed** – the date documenting the annual review if the policy has no revisions necessary.

ADDITIONAL DEFINITIONS:

1. **Formulary** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. **Non-formulary products** – those medications that are not included in the Formulary.
3. **Healthcare provider** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
4. **NCQA** – National Committee for Quality Assurance.
5. **Medically Necessary or Medical Necessity** – covered services rendered by a provider that the Health Plan determines are:



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 693.0

**SECTION: Commercial Drug
SUBJECT: Scemblix**

- A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
- B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
- C. In accordance with current standards of medical practice;
- D. Not primarily for the convenience of the Member, or the Member's Provider; and
- E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

PROCEDURE:

New members to the plan already established on therapy may be eligible for continuity of care coverage as long as there is medical record documentation that the safety and effectiveness of use for the prescribed indication is supported by Food and Drug Administration (FDA) approval or adequate medical and scientific evidence in the medical literature.

An exception for coverage of Scemblix may be made for members who meet the following criteria:

- Medical record documentation that Scemblix is prescribed by a hematologist or oncologist **AND**
- Medical record documentation of age greater than or equal to 18 years **AND**
- Medical record documentation of a diagnosis of Philadelphia chromosome-positive chronic myeloid leukemia (Ph+ CML) in chronic phase (CP) **AND** one of the following:
 - Medical record documentation of previous treatment with two or more tyrosine kinase inhibitors (TKIs) **OR**
 - Medical record documentation of a T315I cell mutation

AND

- If the requested dose is 200 mg twice daily: Medical record documentation of a T315I cell mutation

MEDISPAN AUTHORIZATION LEVEL: GPI-12

QUANTITY LIMIT:

- 40 mg per day or 80 mg per day: No QLs need to be entered within the authorization unless the requested quantity exceeds the QL. **QL FOR LETTER ONLY: 2 tablets per day, 30 day supply per fill**



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 693.0

**SECTION: Commercial Drug
SUBJECT: Scemblix**

- 200 mg twice daily (40 mg tablets): Only enter PA, OQL, max daily dose 10. QL FOR LETTER: 10 tablets per day, 30 day supply per fill

RE-AUTHORIZATION CRITERIA: Scemblix will be configured as a prior authorization for new starts only. Scemblix will no longer be covered if it is identified that the member is not receiving appropriate follow-up care from the prescribing specialist or if the member has greater than or equal to a 90 day break in therapy.

- Medical record documentation that the member is receiving appropriate follow-up care from the prescribing specialist

If a formulary exception is approved, Scemblix will be paid for under the member's prescription drug benefit.

Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.

FORMULARY ALTERNATIVES:

imatinib, Bosulif*, Iclusig*, Sprycel*, Tassigna*

*prior authorization required

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE
STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND
FEDERAL REGULATORY ENTITIES.**

**THIS POLICY WILL BE REVISED AS NECESSARY AND
REVIEWED NO LESS THAN ANNUALLY.**

Signed: _____

Title: Director, Pharmacy Services

Date: March 1, 2022

Devised: 1/21/22

Revised: 3/1/22 – annual review, updated referenced policies & covered LOBs

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Dev. 1/21/22

Rev. 3/1/22



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 694.0

**SECTION: Commercial Drug
SUBJECT: Livmarli**

Applicable line of business:

Commercial	X	Medicaid	
Medicare		ACA	X
GHP Kids	X	Self-Insured	X

POLICY:

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for Livmarli for GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 487.0 Quantity Limit Exceptions

REQUIRED DEFINITIONS:

1. **Attachment** – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. **Exhibit** – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. **Devised** – the date the policy was implemented.
4. **Revised** – the date of every revision to the policy, including typographical and grammatical changes.
5. **Reviewed** – the date documenting the annual review if the policy has no revisions necessary.

ADDITIONAL DEFINITIONS:

1. **Formulary** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. **Non-formulary products** – those medications that are not included in the Formulary.
3. **Healthcare provider** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
4. **NCQA** – National Committee for Quality Assurance.
5. **Medically Necessary or Medical Necessity** – covered services rendered by a provider that the Health Plan determines are:



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 694.0

**SECTION: Commercial Drug
SUBJECT: Livmarli**

- A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
- B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
- C. In accordance with current standards of medical practice;
- D. Not primarily for the convenience of the Member, or the Member's Provider; and
- E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

PROCEDURE:

An exception for coverage of Livmarli may be made for members who meet the following criteria:

- Medical record documentation that Livmarli is prescribed by or in consultation with a hepatologist or gastroenterologist **AND**
- Medical record documentation of diagnosis of Alagille Syndrome (ALGS) **AND**
- Medical record documentation of the presence of moderate to severe pruritus **AND**
- Medical record documentation of age greater than or equal to 1 year **AND**
- Medical record documentation that the member is receiving an appropriate dose* based on the member's weight **AND**
- Medical record documentation of therapeutic failure on, intolerance to, or contraindication to ursodiol **AND** one of the following: cholestyramine, rifampin, naltrexone, sertraline

NOTE:

Patient Weight (kg)	Days 1-7 (190 mcg/kg once daily)		Beginning Day 8 (380 mcg/kg once daily)	
	Volume QD (mL)	Dosing dispenser size (mL)	Volume QD (mL)	Dosing dispenser size (mL)
5 to 6	0.1	0.5	0.2	0.5
7 to 9	0.15		0.3	
10 to 12	0.2		0.45	
13 to 15	0.3		0.6	1
16 to 19	0.35		0.7	
20 to 24	0.45		0.9	
25 to 29	0.5	1		
30 to 34	0.6	1	1.25	3
35 to 39	0.7		1.5	
40 to 49	0.9		1.75	
50 to 59	1		2.25	
60 to 69	1.25		2.5	
70 or higher	1.5		3	



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 694.0

**SECTION: Commercial Drug
SUBJECT: Livmarli**

MEDISPAN AUTHORIZATION LEVEL: GPI-12

QUANTITY LIMIT: No QLs need to be entered within the authorization unless the requested quantity exceeds the QL.

- QL for letter only: 3 mL per day, 30 day supply per fill

RE-AUTHORIZATION CRITERIA: Initial approval will be for 6 months or less if the reviewing provider feels it is medically appropriate. Subsequent approvals will be for an additional 6 months or less if the reviewing provider feels it is medically appropriate and will require the following:

- Medical record documentation of improvement in pruritus from baseline **AND**
- Medical record documentation that the member is receiving an appropriate dose* based on the patient's weight

If a formulary exception is approved, Livmarli will be paid for under the member's prescription drug benefit.

Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.

FORMULARY ALTERNATIVES:

ursodiol, cholestyramine, rifampin, naltrexone, sertraline, Bylvay*

*prior authorization required

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE
STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND
FEDERAL REGULATORY ENTITIES.**

**THIS POLICY WILL BE REVISED AS NECESSARY AND
REVIEWED NO LESS THAN ANNUALLY.**



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 694.0

**SECTION: Commercial Drug
SUBJECT: Livmarli**

Signed: _____

Title: Director, Pharmacy Services

Date: April 4, 2022

Devised: 4/4/22



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 695.0

**SECTION: Commercial Drug
SUBJECT: Opzelura**

Applicable line of business:

Commercial	X	Medicaid	
Medicare		ACA	X
GHP Kids	X	Self-Insured	X

POLICY:

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for Opzelura for GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 487.0 Quantity Limit Exceptions

REQUIRED DEFINITIONS:

1. **Attachment** – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. **Exhibit** – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
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5. **Reviewed** – the date documenting the annual review if the policy has no revisions necessary.

ADDITIONAL DEFINITIONS:

1. **Formulary** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. **Non-formulary products** – those medications that are not included in the Formulary.
3. **Healthcare provider** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
4. **NCQA** – National Committee for Quality Assurance.
5. **Medically Necessary or Medical Necessity** – covered services rendered by a provider that the Health Plan determines are:



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 695.0

**SECTION: Commercial Drug
SUBJECT: Opzelura**

- A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
- B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
- C. In accordance with current standards of medical practice;
- D. Not primarily for the convenience of the Member, or the Member's Provider; and
- E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

PROCEDURE:

An exception for coverage of Opzelura may be made for members who meet the following criteria:

- Medical record documentation that Opzelura is prescribed by or in consultation with a dermatologist, allergist, or immunologist **AND**
- Medical record documentation of a diagnosis of mild to moderate atopic dermatitis **AND**
- Medical record documentation of age greater than or equal to 12 years **AND**
- Medical record documentation that member is immunocompetent **AND**
- Medical record documentation of Body Surface Area (BSA) less than or equal to 20% **AND**
- Medical record documentation that Opzelura is NOT being used in combination with therapeutic biologics, other Janus-associated kinase (JAK) inhibitors or potent immunosuppressants such as azathioprine or cyclosporine **AND**
- Medical record documentation of therapeutic failure on, intolerance to, or contraindication to ALL of the following:
 - One formulary topical calcineurin inhibitor **AND**
 - One formulary topical corticosteroid unless deemed inadvisable due to potential risks such as (a) use on sensitive skin areas (face, axillae, or groin) **OR** (b) member is less than 15 years of age **AND**
 - Eucrisa

MEDISPAN AUTHORIZATION LEVEL: GPI-12

QUANTITY LIMIT: No QLs need to be entered within the authorization unless the requested quantity exceeds the QL.

- QL for letter only: 240 grams per 28 days

AUTHORIZATION DURATION: Initial approval will be for 3 months or less if the reviewing provider feels it is medically appropriate. The medication will no longer be covered if patient experiences resolution of symptoms of atopic dermatitis. Subsequent approvals will be for an additional 6 months and will require:

- Medical record documentation of tolerability and positive clinical response to Opzelura **AND**
- Medical record documentation of symptomatic atopic dermatitis that requires additional treatment with Opzelura **AND**
- Medical record documentation that Opzelura is NOT being used in combination with therapeutic biologics, other Janus-associated kinase (JAK) inhibitors or potent immunosuppressants such as azathioprine or cyclosporine

If a formulary exception is approved, Opzelura will be paid for under the member's prescription drug benefit.

Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.

FORMULARY ALTERNATIVES:

Calcineurin Inhibitors: tacrolimus ointment, pimecrolimus cream*
Eucrisa*

Low-potency topical corticosteroids: alclometasone dipropionate 0.5% cream and ointment (Aclovate); fluocinolone acetonide 0.01% soln. (Synalar); hydrocortisone 2.5% cream, ointment, and lotion (Hytone)

Medium-potency topical corticosteroids: betamethasone valerate 0.1% cream (Valisone); fluocinolone acetonide 0.025% cream and ointment (Synalar); fluticasone propionate 0.05% cream, ointment, and lotion (Cutivate); triamcinolone 0.1% cream, ointment and lotion (Kenalog); triamcinolone acetonide 0.025% cream, ointment and lotion (Kenalog); triamcinolone acetonide 0.147 mg/g aerosol (Kenalog Spray)

High-potency topical corticosteroids: augmented betamethasone dipropionate 0.05% cream (Diprolene AF); betamethasone valerate 0.1% ointment (Valisone); triamcinolone 0.5% cream (Kenalog); fluocinonide 0.05% cream, ointment and gel (Lidex)

Very high-potency topical corticosteroids: augmented betamethasone dipropionate 0.05% ointment, gel and lotion (Diprolene); clobetasol 0.05% cream, ointment, and scalp lotion (Temovate) diflorasone diacetate 0.05% cream and ointment (ApexiCon/Psorcon)

*prior authorization required



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 695.0

**SECTION: Commercial Drug
SUBJECT: Opzelura**

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE
STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND
FEDERAL REGULATORY ENTITIES.**

**THIS POLICY WILL BE REVISED AS NECESSARY AND
REVIEWED NO LESS THAN ANNUALLY.**

Signed: _____

Title: Director, Pharmacy Services

Date: June 6, 2022

Devised: 4/4/22

Revised: 6/6/22 – removed references to Livmarli



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 696.0

**SECTION: Commercial Drug
SUBJECT: Qulipta**

Applicable line of business:

Commercial	X	Medicaid	
Medicare		ACA	X
GHP Kids	X	Self-Insured	X

POLICY:

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for Qulipta for GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 487.0 Quantity Limit Exceptions

REQUIRED DEFINITIONS:

1. **Attachment** – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. **Exhibit** – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. **Devised** – the date the policy was implemented.
4. **Revised** – the date of every revision to the policy, including typographical and grammatical changes.
5. **Reviewed** – the date documenting the annual review if the policy has no revisions necessary.

ADDITIONAL DEFINITIONS:

1. **Formulary** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. **Non-formulary products** – those medications that are not included in the Formulary.
3. **Healthcare provider** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
4. **NCQA** – National Committee for Quality Assurance.
5. **Medically Necessary or Medical Necessity** – covered services rendered by a provider that the Health Plan determines are:

- A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
- B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
- C. In accordance with current standards of medical practice;
- D. Not primarily for the convenience of the Member, or the Member's Provider; and
- E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

PROCEDURE:

An exception for coverage of Qulipta may be made for members who meet the following criteria:

- Medical record documentation that Qulipta is prescribed by or in consultation with a neurologist or headache specialist **AND**
- Medical record documentation of age greater than or equal to 18 years **AND**
- Medical record documentation of a diagnosis of migraine with or without aura, based on the International Classification of Headache Disorders (ICHD)-III diagnostic criteria **AND**
- Medical record documentation of number of baseline migraine or headache days per month **AND**
- Medical record documentation of diagnosis of episodic migraine (no more than 14 headache days per month) **AND**
- Medical record documentation that Qulipta will not be used concomitantly with another calcitonin gene-related peptide (CGRP) receptor antagonist indicated for the preventive treatment of migraine (e.g., Aimovig, Ajovy, Emgality, Vyepti, Nurtec ODT) **AND**
- Medical record documentation of therapeutic failure on, intolerance to, or contraindication to at least three (3) of the following:
 - One (1) beta blocker (metoprolol, propranolol, timolol, atenolol, nadolol)
 - Topiramate
 - Divalproex/sodium valproate
 - Amitriptyline
 - Venlafaxine **AND**
- Medical record documentation of therapeutic failure on, intolerance to, or contraindication to Aimovig **AND** Emgality **AND**
- Medical record documentation that Qulipta will not be used in combination with botulinum toxin for the preventive treatment **OR**

- Medical record documentation of therapeutic failure on a minimum 3 month trial of at least one CGRP antagonists without the concomitant use of Botox **AND**
- Medical record documentation of therapeutic failure on a minimum 6 month trial of Botox without the concomitant use of a CGRP antagonist

MEDISPAN AUTHORIZATION LEVEL: GPI-12

QUANTITY LIMIT: No QLs need to be entered within the authorization unless the requested quantity exceeds the QL.

- QL FOR LETTER ONLY: 1 tablet per day

AUTHORIZATION DURATION: Initial approval will be for six (6) months and subsequent approvals will be for twelve (12) months. Requests for continuation of coverage will be approved for members who meet the following criteria:

- Medical record documentation of continued or sustained reduction in migraine or headache frequency or has experienced a decrease in severity or duration of migraine **AND**
- Medical record documentation that Qulipta will not be used concomitantly with another calcitonin gene-related peptide (CGRP) receptor antagonist indicated for the preventive treatment of migraine (e.g., Aimovig, Ajovy, Emgality, Vyepti, Nurtec ODT) **AND**
- Medical record documentation that Qulipta will not be used in combination with botulinum toxin for preventive treatment **OR**
 - Medical record documentation of a therapeutic failure on a minimum 3 month trial of at least one CGRP antagonists without the concomitant use of Botox **AND**
 - Medical record documentation of therapeutic failure on a minimum 6 month trial of Botox without the concomitant use of a CGRP antagonist

If a formulary exception is approved, Qulipta will be paid for under the member's prescription drug benefit.

Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 696.0

**SECTION: Commercial Drug
SUBJECT: Qulipta**

FORMULARY ALTERNATIVES:

metoprolol, propranolol, timolol, atenolol, nadolol, topiramate, divalproex, sodium valproate, amitriptyline, venlafaxine, Aimovig*, Emgality*

*prior authorization required

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE
STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND
FEDERAL REGULATORY ENTITIES.**

**THIS POLICY WILL BE REVISED AS NECESSARY AND
REVIEWED NO LESS THAN ANNUALLY.**

Signed: _____

Title: Director, Pharmacy Services

Date: April 4, 2022

Devised: 4/4/22



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 697.0

**SECTION: Commercial Drug
SUBJECT: Tavneos**

Applicable line of business:

Commercial	X	Medicaid	
Medicare		ACA	X
GHP Kids	X	Self-Insured	X

POLICY:

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for Tavneos for GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 487.0 Quantity Limit Exceptions

REQUIRED DEFINITIONS:

1. **Attachment** – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. **Exhibit** – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. **Devised** – the date the policy was implemented.
4. **Revised** – the date of every revision to the policy, including typographical and grammatical changes.
5. **Reviewed** – the date documenting the annual review if the policy has no revisions necessary.

ADDITIONAL DEFINITIONS:

1. **Formulary** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. **Non-formulary products** – those medications that are not included in the Formulary.
3. **Healthcare provider** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
4. **NCQA** – National Committee for Quality Assurance.
5. **Medically Necessary or Medical Necessity** – covered services rendered by a provider that the Health Plan determines are:



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 697.0

**SECTION: Commercial Drug
SUBJECT: Tavneos**

- A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
- B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
- C. In accordance with current standards of medical practice;
- D. Not primarily for the convenience of the Member, or the Member's Provider; and
- E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

PROCEDURE:

An exception for coverage of Tavneos may be made for members who meet the following criteria:

- Medical record documentation of age greater than or equal to 18 years **AND**
- Medical record documentation of severe active anti-neutrophil cytoplasmic autoantibody (ANCA)-associated vasculitis classified as one of the following variants:
 - granulomatosis with polyangiitis (GPA) **OR**
 - microscopic polyangiitis (MPA)

AND

- Medical record documentation of both of the following:
 - Medical record documentation of a positive test for anti-proteinase 3 (PR3) or anti-myeloperoxidase (MPO) **AND**
 - Medical record documentation of at least 1 major item, 3 non-major items, or 2 renal items of proteinuria and hematuria on the Birmingham Vasculitis Activity Score (BVAS)

AND

- Medical record documentation that Tavneos will be administered in combination with standard therapy such as, but not limited to rituximab, cyclophosphamide, methotrexate, mycophenolate, or azathioprine, and/or glucocorticoids

MEDISPAN AUTHORIZATION LEVEL: GPI-12

QUANTITY LIMIT: No QLs need to be entered within the authorization unless the requested quantity exceeds the QL.

- **QL FOR LETTER ONLY:** 6 capsules per day, 30 day supply per fill



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 697.0

**SECTION: Commercial Drug
SUBJECT: Tavneos**

AUTHORIZATION DURATION: Initial approval will be given for six months. Subsequent approvals will be for an additional twelve months and will require:

- Medical record documentation of continued disease improvement or lack of disease progression **AND**
- Medical record documentation that the member is responding positively to therapy as evidenced by a reduction in the Birmingham Vasculitis Activity Score (BVAS) **AND**
- Medical record documentation that Tavneos will continue to be administered in combination with standard therapy such as, but not limited to rituximab, cyclophosphamide, methotrexate, mycophenolate, or azathioprine, and/or glucocorticoids

The medication will no longer be covered if patient experiences toxicity or worsening of disease.

If a formulary exception is approved, Tavneos will be paid for under the member's prescription drug benefit.

Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.

FORMULARY ALTERNATIVES:

azathioprine, oral cyclophosphamide, methotrexate, mycophenolate, prednisone

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE
STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND
FEDERAL REGULATORY ENTITIES.**

**THIS POLICY WILL BE REVISED AS NECESSARY AND
REVIEWED NO LESS THAN ANNUALLY.**

Signed: _____

Title: Director, Pharmacy Services

Date: April 4, 2022



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 697.0

**SECTION: Commercial Drug
SUBJECT: Tavneos**

Devised: 4/4/22



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 698.0

**SECTION: Commercial Drug
SUBJECT: Trudhesa**

Applicable line of business:

Commercial	X	Medicaid	
Medicare		ACA	X
GHP Kids	X	Self-Insured	X

POLICY:

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for Trudhesa for GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 487.0 Quantity Limit Exceptions

REQUIRED DEFINITIONS:

1. **Attachment** – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. **Exhibit** – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. **Devised** – the date the policy was implemented.
4. **Revised** – the date of every revision to the policy, including typographical and grammatical changes.
5. **Reviewed** – the date documenting the annual review if the policy has no revisions necessary.

ADDITIONAL DEFINITIONS:

1. **Formulary** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. **Non-formulary products** – those medications that are not included in the Formulary.
3. **Healthcare provider** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
4. **NCQA** – National Committee for Quality Assurance.
5. **Medically Necessary or Medical Necessity** – covered services rendered by a provider that the Health Plan determines are:



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 698.0

**SECTION: Commercial Drug
SUBJECT: Trudhesa**

- A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
- B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
- C. In accordance with current standards of medical practice;
- D. Not primarily for the convenience of the Member, or the Member's Provider; and
- E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

PROCEDURE:

An exception for coverage of Trudhesa may be made for members who meet the following criteria:

- Medical record documentation of age greater than or equal to 18 years **AND**
- Medical record documentation that Trudhesa will be used for the acute treatment of moderate to severe migraine headaches with or without aura **AND**
- Medical record documentation of therapeutic failure on, in tolerance to, or contraindication to three (3) formulary alternatives, one of which must be dihydroergotamine nasal spray

MEDISPAN AUTHORIZATION LEVEL: GPI-12

QUANTITY LIMIT: No QLs need to be entered within the authorization unless the requested quantity exceeds the QL.

- QL FOR LETTER ONLY: 12 mL per 28 days

If a formulary exception is approved, Trudhesa will be paid for under the member's prescription drug benefit.

Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 698.0

**SECTION: Commercial Drug
SUBJECT: Trudhesa**

FORMULARY ALTERNATIVES:

dihydroergotamine nasal spray, zolmitriptan nasal spray, sumatriptan nasal spray, zolmitriptan tablets, sumatriptan tablets, naratriptan, rizatriptan, almotriptan*, eletriptan*, frovatriptan tablets*^, Nurtec ODT*, Ubrelvy*

*prior authorization required

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE
STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND
FEDERAL REGULATORY ENTITIES.**

**THIS POLICY WILL BE REVISED AS NECESSARY AND
REVIEWED NO LESS THAN ANNUALLY.**

Signed: _____

Title: Director, Pharmacy Services

Date: April 4, 2022

Devised: 4/4/22



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 699.0

**SECTION: Commercial Drug
SUBJECT: Tyrvaya**

Applicable line of business:

Commercial	X	Medicaid	
Medicare		ACA	X
GHP Kids	X	Self-Insured	X

POLICY:

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for Tyrvaya for GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 487.0 Quantity Limit Exceptions

REQUIRED DEFINITIONS:

1. **Attachment** – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. **Exhibit** – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. **Devised** – the date the policy was implemented.
4. **Revised** – the date of every revision to the policy, including typographical and grammatical changes.
5. **Reviewed** – the date documenting the annual review if the policy has no revisions necessary.

ADDITIONAL DEFINITIONS:

1. **Formulary** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. **Non-formulary products** – those medications that are not included in the Formulary.
3. **Healthcare provider** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
4. **NCQA** – National Committee for Quality Assurance.
5. **Medically Necessary or Medical Necessity** – covered services rendered by a provider that the Health Plan determines are:



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 699.0

**SECTION: Commercial Drug
SUBJECT: Tyrvaya**

- A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
- B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
- C. In accordance with current standards of medical practice;
- D. Not primarily for the convenience of the Member, or the Member's Provider; and
- E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

PROCEDURE:

An exception for coverage of Tyrvaya may be made for members who meet the following criteria:

- Medical record documentation of a diagnosis of dry eye disease **AND**
- Medical record documentation of a therapeutic failure on, intolerance to, or contraindication to Xiidra **AND** cyclosporine (generic Restasis)

MEDISPAN AUTHORIZATION LEVEL: GPI-12

QUANTITY LIMIT: No QLs need to be entered within the authorization unless the requested quantity exceeds the QL.

- QL FOR LETTER ONLY: 8.4 mL per 30 days

If a formulary exception is approved, Tyrvaya will be paid for under the member's prescription drug benefit.

Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.

FORMULARY ALTERNATIVES:

Xiidra, cyclosporine (generic Restasis)



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 699.0

**SECTION: Commercial Drug
SUBJECT: Tyrvaya**

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE
STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND
FEDERAL REGULATORY ENTITIES.**

**THIS POLICY WILL BE REVISED AS NECESSARY AND
REVIEWED NO LESS THAN ANNUALLY.**

Signed: _____

Title: Director, Pharmacy Services

Date: April 4, 2022

Devised: 4/4/22



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 700.0

**SECTION: Commercial Drug
SUBJECT: Vuity**

Applicable line of business:

Commercial	X	Medicaid	
Medicare		ACA	X
GHP Kids	X	Self-Insured	X

POLICY:

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for Vuity for GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 487.0 Quantity Limit Exceptions

REQUIRED DEFINITIONS:

1. **Attachment** – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. **Exhibit** – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. **Devised** – the date the policy was implemented.
4. **Revised** – the date of every revision to the policy, including typographical and grammatical changes.
5. **Reviewed** – the date documenting the annual review if the policy has no revisions necessary.

ADDITIONAL DEFINITIONS:

1. **Formulary** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. **Non-formulary products** – those medications that are not included in the Formulary.
3. **Healthcare provider** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
4. **NCQA** – National Committee for Quality Assurance.
5. **Medically Necessary or Medical Necessity** – covered services rendered by a provider that the Health Plan determines are:



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 700.0

**SECTION: Commercial Drug
SUBJECT: Vuity**

- A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
- B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
- C. In accordance with current standards of medical practice;
- D. Not primarily for the convenience of the Member, or the Member's Provider; and
- E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

PROCEDURE:

An exception for coverage of Vuity may be made for members who meet the following criteria:

- Medical record documentation that Vuity is prescribed by or in consultation with an optometrist or ophthalmologist **AND**
- Medical record documentation of a diagnosis of presbyopia **AND**
- Medical record documentation of age greater than or equal to 40 years **AND**
- Medical record documentation of intolerance to or contraindication to corrective lenses

MEDISPAN AUTHORIZATION LEVEL: GPI-14

QUANTITY LIMIT: No QLs need to be entered within the authorization unless the requested quantity exceeds the QL.

- QL FOR LETTER ONLY: 2.5 mL per 30 days

If a formulary exception is approved, Vuity will be paid for under the member's prescription drug benefit.

Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.

FORMULARY ALTERNATIVES:

none



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 700.0

**SECTION: Commercial Drug
SUBJECT: Vuity**

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE
STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND
FEDERAL REGULATORY ENTITIES.**

**THIS POLICY WILL BE REVISED AS NECESSARY AND
REVIEWED NO LESS THAN ANNUALLY.**

Signed: _____

Title: Director, Pharmacy Services

Date: April 4, 2022

Devised: 4/4/22



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 701.0

**SECTION: Commercial Drug
SUBJECT: Adbry**

Applicable line of business:

Commercial	X	Medicaid	
Medicare		ACA	X
GHP Kids	X	Self-Insured	X

POLICY:

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for Adbry for GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 487.0 Quantity Limit Exceptions

REQUIRED DEFINITIONS:

1. **Attachment** – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. **Exhibit** – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. **Devised** – the date the policy was implemented.
4. **Revised** – the date of every revision to the policy, including typographical and grammatical changes.
5. **Reviewed** – the date documenting the annual review if the policy has no revisions necessary.

ADDITIONAL DEFINITIONS:

1. **Formulary** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. **Non-formulary products** – those medications that are not included in the Formulary.
3. **Healthcare provider** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
4. **NCQA** – National Committee for Quality Assurance.
5. **Medically Necessary or Medical Necessity** – covered services rendered by a provider that the Health Plan determines are:



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 701.0

**SECTION: Commercial Drug
SUBJECT: Adbry**

- A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
- B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
- C. In accordance with current standards of medical practice;
- D. Not primarily for the convenience of the Member, or the Member's Provider; and
- E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

PROCEDURE:

An exception for coverage of Adbry may be made for members who meet the following criteria:

- Medical record documentation of a diagnosis of moderate to severe atopic dermatitis **AND**
- Medical record documentation that Adbry is prescribed by or in consultation with an allergist, dermatologist, or immunologist **AND**
- Medical record documentation of age greater than or equal to 18 years **AND**
- Medical record documentation of contraindication to, intolerance to, or therapeutic failure on an adequate trial of phototherapy (UVA/UVB treatment) **AND**
- Medical record documentation of one of the following:
 - Therapeutic failure on an adequate trial of at least one medium (or higher) potency topical corticosteroid OR
 - For members with an intolerance or contraindication to topical corticosteroids or for members in whom topical corticosteroids are inadvisable, therapeutic failure on, intolerance to, or contraindication to a topical calcineurin inhibitor.

MEDISPAN AUTHORIZATION LEVEL: GPI-12

AUTHORIZATION DURATION: Initial approval will be for 6 months or less if the reviewing provider feels it is medically appropriate. Subsequent approvals for the medication will be for 12 months or less if the reviewing provider feels it is medically appropriate and will require medical record documentation of continued disease improvement or lack of disease progression. The medication will no longer be covered if the patient experiences toxicity or worsening of disease.

QUANTITY LIMIT:

Initial Approval – Two authorizations must be entered.

- 600mg once, followed by 300mg every other week
 1. In Darwin: Add PA, OQL, DS, enter 1 in max number of claims authorized, max quantity of 6, minimum day supply 28, and maximum day supply 28 with a duration of 2 weeks.
 2. In PA Hub: Add PA, OQL, and max quantity 4 with a start date 1 day after the loading dose for remainder of the authorization.
 - QL FOR LETTER: Loading Dose: 6 mL per 28 days;
Maintenance Dose: 4 mL per 28 days

Renewal

- 300mg every other week
 1. In PA Hub: Add PA, OQL, and max quantity 4.
 - QL FOR LETTER: 4 mL per 28 days
- 300mg every 4 weeks
 1. In PA Hub: Add PA, OQL, and max quantity 2.
 - QL FOR LETTER: 2 mL per 28 days

If a formulary exception is approved, Adbry will be paid for under the member's prescription drug benefit.

Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.

FORMULARY ALTERNATIVES:

tacrolimus ointment

Low-potency topical corticosteroids: alclometasone dipropionate 0.5% cream and ointment (Acloivate); fluocinolone acetonide 0.01% soln. (Synalar); hydrocortisone 2.5% cream, ointment, and lotion (Hytone)

Medium-potency topical corticosteroids: betamethasone valerate 0.1% cream (Valisone); fluocinolone acetonide 0.025% cream and ointment (Synalar); fluticasone propionate 0.05% cream, ointment, and lotion (Cutivate); triamcinolone 0.1% cream, ointment and lotion (Kenalog); triamcinolone acetonide 0.025% cream, ointment and lotion (Kenalog); triamcinolone acetonide 0.147 mg/g aerosol (Kenalog Spray)

High-potency topical corticosteroids: augmented betamethasone dipropionate 0.05% cream (Diprolene AF); betamethasone valerate 0.1% ointment (Valisone); triamcinolone 0.5% cream (Kenalog); fluocinonide 0.05% cream, ointment and gel (Lidex)

Very high-potency topical corticosteroids: augmented betamethasone dipropionate 0.05% ointment, gel and lotion (Diprolene); clobetasol 0.05% cream, ointment, and scalp lotion (Temovate) diflorasone diacetate 0.05% cream and ointment (ApexiCon/Psorcon)



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 701.0

**SECTION: Commercial Drug
SUBJECT: Adbry**

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE
STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND
FEDERAL REGULATORY ENTITIES.**

**THIS POLICY WILL BE REVISED AS NECESSARY AND
REVIEWED NO LESS THAN ANNUALLY.**

Signed: _____

Title: Director, Pharmacy Services

Date: May 31, 2022

Devised: 5/31/22



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 702.0

**SECTION: Commercial Drug
SUBJECT: Dhivy**

Applicable line of business:

Commercial	X	Medicaid	
Medicare		ACA	X
GHP Kids	X	Self-Insured	X

POLICY:

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for Dhivy for GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 487.0 Quantity Limit Exceptions

REQUIRED DEFINITIONS:

1. **Attachment** – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. **Exhibit** – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. **Devised** – the date the policy was implemented.
4. **Revised** – the date of every revision to the policy, including typographical and grammatical changes.
5. **Reviewed** – the date documenting the annual review if the policy has no revisions necessary.

ADDITIONAL DEFINITIONS:

1. **Formulary** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. **Non-formulary products** – those medications that are not included in the Formulary.
3. **Healthcare provider** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
4. **NCQA** – National Committee for Quality Assurance.
5. **Medically Necessary or Medical Necessity** – covered services rendered by a provider that the Health Plan determines are:



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 702.0

**SECTION: Commercial Drug
SUBJECT: Dhivy**

- A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
- B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
- C. In accordance with current standards of medical practice;
- D. Not primarily for the convenience of the Member, or the Member's Provider; and
- E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

PROCEDURE:

An exception for coverage of Dhivy may be made for members who meet the following criteria:

- Medical record documentation of a diagnosis of Parkinson's disease, post-encephalitis parkinsonism, **OR** parkinsonism which may follow carbon monoxide intoxication or manganese intoxication **AND**
- Medical record documentation of therapeutic failure on, intolerance to, or contraindication to three (3) formulary alternatives, one of which must be immediate release carbidopa/levodopa

MEDISPAN AUTHORIZATION LEVEL: GPI-14

QUANTITY LIMIT: No QLs need to be entered within the authorization unless the requested quantity exceeds the QL.

- QL for letter only: 8 tablets per day

If a formulary exception is approved, Dhivy will be paid for under the member's prescription drug benefit.

Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.

FORMULARY ALTERNATIVES:

carbidopa/levodopa ODT, carbidopa/levodopa tablet, carbidopa/levodopa ER tablet, carbidopa/levodopa/entacapone, pramipexole, ropinirole, ropinirole ER, bromocriptine, selegiline, amantadine, benzotropine, trihexyphenidyl, rasagiline



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 702.0

**SECTION: Commercial Drug
SUBJECT: Dhivy**

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE
STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND
FEDERAL REGULATORY ENTITIES.**

**THIS POLICY WILL BE REVISED AS NECESSARY AND
REVIEWED NO LESS THAN ANNUALLY.**

Signed: _____

Title: Director, Pharmacy Services

Date: May 31, 2022

Devised: 5/31/22



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 703.0

**SECTION: Commercial Drug
SUBJECT: Livtency**

Applicable line of business:

Commercial	X	Medicaid	
Medicare		ACA	X
GHP Kids	X	Self-Insured	X

POLICY:

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for Livtency for GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 487.0 Quantity Limit Exceptions

REQUIRED DEFINITIONS:

1. **Attachment** – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. **Exhibit** – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
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4. **Revised** – the date of every revision to the policy, including typographical and grammatical changes.
5. **Reviewed** – the date documenting the annual review if the policy has no revisions necessary.

ADDITIONAL DEFINITIONS:

1. **Formulary** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. **Non-formulary products** – those medications that are not included in the Formulary.
3. **Healthcare provider** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
4. **NCQA** – National Committee for Quality Assurance.
5. **Medically Necessary or Medical Necessity** – covered services rendered by a provider that the Health Plan determines are:



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 703.0

**SECTION: Commercial Drug
SUBJECT: Livtency**

- A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
- B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
- C. In accordance with current standards of medical practice;
- D. Not primarily for the convenience of the Member, or the Member's Provider; and
- E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

PROCEDURE:

An exception for coverage of Livtency may be made for members who meet the following criteria:

- Medical record documentation that Livtency is prescribed by a transplant surgeon, infectious disease specialist, or hematologist/oncologist. **AND**
- Medical record documentation of age greater than or equal to 12 years of age and weighs over 35 kg **AND**
- Medical record documentation that patient has received a hematopoietic stem cell transplant (HSCT), or solid organ transplant (SOT) **AND**
- Medical record documentation of a diagnosis of post-transplant cytomegalovirus (CMV) infection **AND**
- Medical record documentation that the members CMV infection is refractory to previous treatment with ganciclovir, valganciclovir, cidofovir, or foscarnet **AND**
- Medical record documentation that medication will not be used in combination with another CMV antiviral **AND**
- If request is above 400mg twice daily dosing, medical record documentation of one of the following:
 - For requests of 800mg twice daily dosing: Medical record documentation that member is concurrently receiving carbamazepine **OR**
 - For requests of 1200mg twice daily dosing: Medical record documentation that member is concurrently receiving phenytoin or phenobarbital

MEDISPAN AUTHORIZATION LEVEL: GPI-12

AUTHORIZATION DURATION: 8 weeks



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 703.0

**SECTION: Commercial Drug
SUBJECT: Livtency**

NOTE: Livtency has not been studied in clinical trials for longer than 8 weeks and should only be used for treatment of active infection. Livtency is not approved for prophylaxis of CMV infections.

QUANTITY LIMIT: 4 tablets per day, 28 day supply per fill

- 400 mg twice daily (given as two 200mg tablets twice daily): No QLs need to be entered within the authorization unless the requested quantity exceeds the QL. QL FOR LETTER ONLY: 4 tablets per day
- 800 mg twice daily (given as four 200mg tablets twice daily): Only enter PA, OQL, max daily dose 8. QL FOR LETTER: 8 tablets per day
- 1200mg twice daily (given as six 200mg tablets twice daily): Only enter PA, OQL, max daily dose 12. QL FOR LETTER: 12 tablets per day

If a formulary exception is approved, Livtency will be paid for under the member's prescription drug benefit.

Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.

FORMULARY ALTERNATIVES:

valganciclovir

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE
STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND
FEDERAL REGULATORY ENTITIES.**

**THIS POLICY WILL BE REVISED AS NECESSARY AND
REVIEWED NO LESS THAN ANNUALLY.**

Signed: _____

Title: Director, Pharmacy Services

Date: May 31, 2022



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 703.0

**SECTION: Commercial Drug
SUBJECT: Livtencity**

Devised: 5/31/22



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 704.0

**SECTION: Commercial Drug
SUBJECT: Recorlev**

Applicable line of business:

Commercial	X	Medicaid	
Medicare		ACA	X
GHP Kids	X	Self-Insured	X

POLICY:

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for Recorlev for GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 487.0 Quantity Limit Exceptions

REQUIRED DEFINITIONS:

1. **Attachment** – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. **Exhibit** – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. **Devised** – the date the policy was implemented.
4. **Revised** – the date of every revision to the policy, including typographical and grammatical changes.
5. **Reviewed** – the date documenting the annual review if the policy has no revisions necessary.

ADDITIONAL DEFINITIONS:

1. **Formulary** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. **Non-formulary products** – those medications that are not included in the Formulary.
3. **Healthcare provider** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
4. **NCQA** – National Committee for Quality Assurance.
5. **Medically Necessary or Medical Necessity** – covered services rendered by a provider that the Health Plan determines are:



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 704.0

**SECTION: Commercial Drug
SUBJECT: Recorlev**

- A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
- B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
- C. In accordance with current standards of medical practice;
- D. Not primarily for the convenience of the Member, or the Member's Provider; and
- E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

PROCEDURE:

An exception for coverage of Recorlev may be made for members who meet the following criteria:

- Medical record documentation of endogenous hypercortisolemia associated with Cushing's syndrome **AND**
- Medical record documentation of age greater than or equal to 18 years older **AND**
- Medical record documentation that Recorlev is prescribed by or in consultation with an endocrinologist **AND**
- Medical record documentation that pituitary surgery is not an option or has not been curative **AND**
- Medical record documentation of therapeutic failure on, intolerance to, or contraindication to two (2) of the following: ketoconazole, Metopirone, Signifor, Signifor LAR

MEDISPAN AUTHORIZATION LEVEL: GPI-12

AUTHORIZATION DURATION: 12 months. Subsequent approvals will be for an additional 12 months or less if the reviewing provider feels it is medically appropriate. Reauthorization requires medical record documentation of improvement in urinary free cortisol levels compared to baseline.



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 704.0

**SECTION: Commercial Drug
SUBJECT: Recorlev**

QUANTITY LIMIT: No QLs need to be entered within the authorization unless the requested quantity exceeds the QL.

- QL for letter only: 8 tablets per day, up to a 31 day supply per fill

If a formulary exception is approved, Recorlev will be paid for under the member's prescription drug benefit.

Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.

FORMULARY ALTERNATIVES:

ketoconazole oral tablets, Signifor LAR*, Signifor*

*prior authorization required

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE
STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND
FEDERAL REGULATORY ENTITIES.**

**THIS POLICY WILL BE REVISED AS NECESSARY AND
REVIEWED NO LESS THAN ANNUALLY.**

Signed: _____

Title: Director, Pharmacy Services

Date: May 31, 2022

Devised: 5/31/22



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 705.0

**SECTION: Commercial Drug
SUBJECT: Soanz**

Applicable line of business:

Commercial	X	Medicaid	
Medicare		ACA	X
GHP Kids	X	Self-Insured	X

POLICY:

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for Soanz for GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 487.0 Quantity Limit Exceptions

REQUIRED DEFINITIONS:

1. **Attachment** – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. **Exhibit** – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. **Devised** – the date the policy was implemented.
4. **Revised** – the date of every revision to the policy, including typographical and grammatical changes.
5. **Reviewed** – the date documenting the annual review if the policy has no revisions necessary.

ADDITIONAL DEFINITIONS:

1. **Formulary** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. **Non-formulary products** – those medications that are not included in the Formulary.
3. **Healthcare provider** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
4. **NCQA** – National Committee for Quality Assurance.
5. **Medically Necessary or Medical Necessity** – covered services rendered by a provider that the Health Plan determines are:



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 705.0

**SECTION: Commercial Drug
SUBJECT: Soanz**

- A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
- B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
- C. In accordance with current standards of medical practice;
- D. Not primarily for the convenience of the Member, or the Member's Provider; and
- E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

PROCEDURE:

An exception for coverage of Soanz may be made for members who meet the following criteria:

- Medical record documentation of age greater than or equal to 18 years **AND**
- Medical record documentation that Soanz will be used for the treatment of edema associated with heart failure **OR** renal disease **AND**
- Medical record documentation of therapeutic failure on, intolerance to, or contraindication to three (3) formulary alternatives, one of which must be generic torsemide

MEDISPAN AUTHORIZATION LEVEL: GPI-12

QUANTITY LIMIT: No QLs need to be entered within the authorization unless the requested quantity exceeds the QL.

- QL for letter only:
 - 20 mg tablets: 1 tablet per day
 - 40 mg tablets: 2 tablets per day
 - 60 mg tablets: 3 tablets per day

If a formulary exception is approved, Soanz will be paid for under the member's prescription drug benefit.

Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.

FORMULARY ALTERNATIVES:

torsemide, furosemide, bumetanide



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 705.0

**SECTION: Commercial Drug
SUBJECT: Soanz**

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE
STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND
FEDERAL REGULATORY ENTITIES.**

**THIS POLICY WILL BE REVISED AS NECESSARY AND
REVIEWED NO LESS THAN ANNUALLY.**

Signed: _____

Title: Director, Pharmacy Services

Date: June 7, 2022

Devised: 6/7/22



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 706.0

**SECTION: Commercial Drug
SUBJECT: Vonjo**

Applicable line of business:

Commercial	X	Medicaid	
Medicare		ACA	X
GHP Kids	X	Self-Insured	X

POLICY:

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for Vonjo for GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 487.0 Quantity Limit Exceptions

REQUIRED DEFINITIONS:

1. **Attachment** – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. **Exhibit** – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. **Devised** – the date the policy was implemented.
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5. **Reviewed** – the date documenting the annual review if the policy has no revisions necessary.

ADDITIONAL DEFINITIONS:

1. **Formulary** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. **Non-formulary products** – those medications that are not included in the Formulary.
3. **Healthcare provider** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
4. **NCQA** – National Committee for Quality Assurance.
5. **Medically Necessary or Medical Necessity** – covered services rendered by a provider that the Health Plan determines are:

- A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
- B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
- C. In accordance with current standards of medical practice;
- D. Not primarily for the convenience of the Member, or the Member's Provider; and
- E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

PROCEDURE:

An exception for coverage of Vonjo may be made for members who meet the following criteria:

- Medical record documentation that Vonjo is prescribed by a hematologist or oncologist **AND**
- Medical record documentation of age greater than or equal to 18 years **AND**
- Medical record documentation of a diagnosis of intermediate or high-risk myelofibrosis, including primary myelofibrosis, post-polycythemia vera myelofibrosis or post-essential thrombocythemia myelofibrosis **AND**
- Medical record documentation of severe thrombocytopenia with platelet count less than or equal to $50 \times 10^9/L$ **AND**
- Medical record documentation of splenomegaly as measured by computed tomography (CT), magnetic resonance imaging (MRI), or ultrasound **AND**
- Medical record documentation of baseline total symptom score as measured by the modified Myelofibrosis Symptom Assessment Form (MFSAF) **AND**
- Medical record documentation that Vonjo will not be used concurrently with other kinase inhibitors

NOTE: Intermediate or High-Risk Myelofibrosis is defined by having at least 2 of the following factors:

- ✓ Age > 65 years
- ✓ $WBC > 25 \times 10^9/L$
- ✓ Hemoglobin < 10 g/dL
- ✓ Blood Blasts $\geq 1\%$
- ✓ Presence of Constitutional Symptoms (weight loss, fever, excessive sweats, etc.)
- ✓ Transfusion dependency
- ✓ Platelets less than $100 \times 10^9/L$
- ✓ Unfavorable karyotype



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 706.0

**SECTION: Commercial Drug
SUBJECT: Vonjo**

MEDISPAN AUTHORIZATION LEVEL: GPI-12

QUANTITY LIMIT: No QLs need to be entered within the authorization unless the requested quantity exceeds the QL.

- QL for letter only: 4 capsules per day, 30 day supply per fill

AUTHORIZATION DURATION: Each treatment period will be defined as six (6) months. Re-review with occur every six (6) months. Vonjo will no longer be covered if medical record documentation does not show:

- Medical record documentation of platelet count less than or equal to $50 \times 10^9/L$
AND
- The member has achieved a reduction from pretreatment baseline of at least 35% in spleen volume as measured by computed tomography (CT), magnetic resonance imaging (MRI), or ultrasound **OR**
- The member has achieved a 50% or greater reduction in the Total Symptom Score from baseline as measured by the modified Myelofibrosis Symptom Assessment Form (MFSAF)

If a formulary exception is approved, Vonjo will be paid for under the member's prescription drug benefit.

Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.

FORMULARY ALTERNATIVES:

Jakafi*, Inrebic*

*prior authorization required

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE
STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND
FEDERAL REGULATORY ENTITIES.**

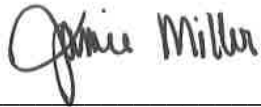
**THIS POLICY WILL BE REVISED AS NECESSARY AND
REVIEWED NO LESS THAN ANNUALLY.**

Geisinger

**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 706.0

**SECTION: Commercial Drug
SUBJECT: Vonjo**



Signed: _____

Title: Director, Pharmacy Services

Date: June 7, 2022

Devised: 6/7/22



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 707.0

**SECTION: Commercial Drug
SUBJECT: Voxzogo**

Applicable line of business:

Commercial	X	Medicaid	
Medicare		ACA	X
GHP Kids	X	Self-Insured	X

POLICY:

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for Voxzogo GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 487.0 Quantity Limit Exceptions

REQUIRED DEFINITIONS:

1. **Attachment** – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. **Exhibit** – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. **Devised** – the date the policy was implemented.
4. **Revised** – the date of every revision to the policy, including typographical and grammatical changes.
5. **Reviewed** – the date documenting the annual review if the policy has no revisions necessary.

ADDITIONAL DEFINITIONS:

1. **Formulary** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. **Non-formulary products** – those medications that are not included in the Formulary.
3. **Healthcare provider** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
4. **NCQA** – National Committee for Quality Assurance.
5. **Medically Necessary or Medical Necessity** – covered services rendered by a provider that the Health Plan determines are:



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 707.0

**SECTION: Commercial Drug
SUBJECT: Voxzogo**

- A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
- B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
- C. In accordance with current standards of medical practice;
- D. Not primarily for the convenience of the Member, or the Member's Provider; and
- E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

PROCEDURE:

An exception for coverage of Voxzogo may be made for members who meet the following criteria:

- Medical record documentation of a diagnosis of achondroplasia with genetic testing confirming a mutation of FGFR3 **AND**
- Medical record documentation that Voxzogo is prescribed by a pediatric endocrinologist **AND**
- Medical record documentation that member is 5 to 18 years of age **AND**
- Medical record documentation of evidence that patient has open epiphyses **AND**
- Medical record patient has not received (within the past 18 months) or plans to receive limb-lengthening surgery **AND**
- Medical record documentation that Voxzogo will not be used in combination with human growth hormone products **AND**
- Medical record documentation of glomerular filtration rate (GFR) greater than 60ml/min/1.73m² **AND**
- Medical record documentation of member's current weight **AND**
- Medical record documentation that prescribed dose is appropriate for patient's current weight **AND**
- Medical record documentation of baseline annualized growth velocity (AGV), calculated based on standing height measured over the course of 6 months prior to request

MEDISPAN AUTHORIZATION LEVEL: GPI-12

QUANTITY LIMIT: No QLs need to be entered within the authorization unless the requested quantity exceeds the QL.

- QL for letter only: 1 vial per day, 30 day supply per fill



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 707.0

**SECTION: Commercial Drug
SUBJECT: Voxzogo**

AUTHORIZATION DURATION: Each treatment period will be defined as six (6) months. Re-review will occur every six (6) months. Voxzogo will no longer be covered if medical record documentation does not show:

- Medical record documentation of positive response to Voxzogo, as evidenced by improvement in annualized growth velocity (AGV) from baseline **AND**
- Medical record documentation of evidence that patient continues to have open epiphyses **AND**
- Medical record patient has not received (within the past 18 months) or plans to receive limb-lengthening surgery **AND**
- Medical record documentation that Voxzogo will not be used in combination with human growth hormone products **AND**
- Medical record documentation of glomerular filtration rate (GFR) greater than 60ml/min/1.73m² **AND**
- Medical record documentation of patient's current weight **AND**
- Medical record documentation that prescribed dose is appropriate for patient's current weight

If a formulary exception is approved, Voxzogo will be paid for under the member's prescription drug benefit.

Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.

FORMULARY ALTERNATIVES:

none

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE
STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND
FEDERAL REGULATORY ENTITIES.**

**THIS POLICY WILL BE REVISED AS NECESSARY AND
REVIEWED NO LESS THAN ANNUALLY.**

Signed: _____

Title: Director, Pharmacy Services



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 707.0

**SECTION: Commercial Drug
SUBJECT: Voxzogo**

Date: June 7, 2022

Devised: 6/7/22



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 708.0

**SECTION: Commercial Drug
SUBJECT: Duloxetine 40 mg
(generic Irenka)**

Applicable line of business:

Commercial	X	Medicaid	
Medicare		ACA	X
GHP Kids	X	Self-Insured	X

POLICY:

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is developed and applied according to the processes outlined in Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Policy 143.0OT Formulary Development by the Pharmacy & Therapeutics Committee. The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for duloxetine 40 mg (generic Irenka) GHP members who have prescription drug benefits, including Commercial, ACA, GHP Kids, and Self-Insured plans, unless a specific limitation or exception exists. Additional policies that may be referenced as part of a coverage decision include:

- Policy 9.0 Brand
- Policy 487.0 Quantity Limit Exceptions

REQUIRED DEFINITIONS:

1. **Attachment** – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
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ADDITIONAL DEFINITIONS:

1. **Formulary** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. **Non-formulary products** – those medications that are not included in the Formulary.
3. **Healthcare provider** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
4. **NCQA** – National Committee for Quality Assurance.
5. **Medically Necessary or Medical Necessity** – covered services rendered by a provider that the Health Plan determines are:



**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 708.0

**SECTION: Commercial Drug
SUBJECT: Duloxetine 40 mg
(generic Irenka)**

- A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
- B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
- C. In accordance with current standards of medical practice;
- D. Not primarily for the convenience of the Member, or the Member's Provider; and
- E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

PROCEDURE:

An exception for coverage of duloxetine 40 mg (generic Irenka) may be made for members who meet the following criteria:

- Medical record documentation of therapeutic failure on, intolerance to, or contraindication to duloxetine (generic Cymbalta) at the same dose as requested

MEDISPAN AUTHORIZATION LEVEL: GPI-14, generic only

If a formulary exception is approved, duloxetine 40 mg (generic Irenka) will be paid for under the member's prescription drug benefit.

Reviewer should refer to the process and procedure in Pharmacy Policy 3.0 (Geisinger Health Plan (GHP) Formulary Exception) for additional information.

FORMULARY ALTERNATIVES:
duloxetine (generic Cymbalta)

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE
STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND
FEDERAL REGULATORY ENTITIES.**

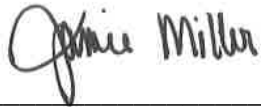
**THIS POLICY WILL BE REVISED AS NECESSARY AND
REVIEWED NO LESS THAN ANNUALLY.**

Geisinger

**POLICY AND PROCEDURE
PHARMACY
MANUAL**

POLICY NUMBER: 708.0

**SECTION: Commercial Drug
SUBJECT: Duloxetine 40 mg
(generic Irenka)**



Signed: _____

Title: Director, Pharmacy Services

Date: June 7, 2022

Devised: 6/7/22