POLICY AND PROCEDURE
PHARMACY
MANUAL

POLICY NUMBER: 3.0
SECTION: Commercial Drug
SUBJECT: Geisinger Health Plan (GHP) Formulary Exception

Applicable line of business:

<table>
<thead>
<tr>
<th>Line of Business</th>
<th>Commercial</th>
<th>Medicaid</th>
<th>Medicare</th>
<th>ACA</th>
<th>GHP Kids</th>
</tr>
</thead>
</table>

POLICY:
The Plan’s Department of Pharmacy maintains a process by which healthcare providers 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. 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.

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 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).
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** – The 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, online 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.

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
For initial requests, Geisinger Health Plan will not require new members (members who have enrolled with the plan in the last 120 days) to meet prior authorization or step therapy criteria if medical record documentation of the following is provided:

- Member has been utilizing the requested medication for greater than or equal to six (6) months AND
- Member was not stabilized on samples of the requested medication 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

The following medications are specifically excluded from continuity of care. All other categories are subject to the discretion of the reviewing provider.

<table>
<thead>
<tr>
<th>• Acthar</th>
<th>• GLP-1 Agonists</th>
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</thead>
<tbody>
<tr>
<td>• Active Ingredients on Formulary as a Different Formulation (e.g., Lialda vs. Delzicol)</td>
<td>• High Risk Medications in the Elderly</td>
</tr>
<tr>
<td>• Allergy Eye Drops</td>
<td>• Nasal Steroids</td>
</tr>
<tr>
<td>• Asthma/COPD Inhalers</td>
<td>• Oral Contraceptives</td>
</tr>
</tbody>
</table>
### POLICY AND PROCEDURE

**PHARMACY MANUAL**

**SECTION:** Commercial Drug

**SUBJECT:** Geisinger Health Plan (GHP) Formulary Exception

<table>
<thead>
<tr>
<th>• Brands with a Generic</th>
<th>• Pancreatic Enzymes</th>
</tr>
</thead>
<tbody>
<tr>
<td>• Combination Agents when all ingredient are on formulary (e.g., Vytorin)</td>
<td>• Proton Pump Inhibitors</td>
</tr>
<tr>
<td>• Compounds</td>
<td>• SGLT2 Inhibitors</td>
</tr>
<tr>
<td>• Diabetic Testing Supplies When Not Used in Conjunction with a Pump</td>
<td>• Testosterone Products</td>
</tr>
<tr>
<td>• DPP4 Inhibitors</td>
<td>• Topical Acne Products</td>
</tr>
<tr>
<td></td>
<td>• Topical Antifungals</td>
</tr>
<tr>
<td></td>
<td>• Topical Steroids</td>
</tr>
</tbody>
</table>

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

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

Signed: ____________________________

Title: Director, Pharmacy Services

Date: August 10, 2020

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
POLICY AND PROCEDURE
PHARMACY
MANUAL

POLICY NUMBER: 3.0

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

Reviewed: 3/08 – annual review
Reviewed: 4/09 – annual review
Reviewed: 4/09 – clarified 48 business hours
Reviewed: 3/10 – annual review
Reviewed: 3/1/11 – annual review
Reviewed: 1/30/12 – changed title and signature
Reviewed: 1/30/13 – annual review
Reviewed: 1/30/14 – annual review
Reviewed: 1/30/15 – annual review, updated signature
Reviewed: 6/1/15 – annual review
Reviewed: 6/1/15 – updated format, logo, & procedure
Reviewed: 6/1/16 – annual review
Reviewed: 6/1/17 – annual review, update standard Marketplace timeline
Reviewed: 6/1/18 – annual review, updated hours & sig., added continuity of care language, updated procedure 6
Reviewed: 8/24/18 – updated notification, verbal and written, will be within the specified time frame from the request date.
Reviewed: 3/13/19 – moved policy from technical/operational to Commercial Clinical policies
Reviewed: 3/1/20 – annual review, added GHP Kids
Reviewed: 8/6/20 – updated date received definition, added written notification date definition, added activity log to PA Hub definition
Reviewed: 8/10/20 – added CPhT and LPN definitions, added LPN as a reviewer
POLICY:
Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of formulary. The formulary is applied according to the formulary review process (see Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Part D Policy 143.0 D Geisinger Health Plan (GHP) and Geisinger Indemnity Insurance Company (GIIC) Formulary Development by the Pharmacy). The results of this process determine the development and application 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 treatment insomnia for GHP members who have prescription drug benefits, including all lines of business, unless a specific limitation or exception exists.

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

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

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

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: November 18, 2020

Devised: 7/99
Effective: 7/99
Reviewed: 12/99
Reviewed: 12/99
Reviewed: 11/00
Reviewed: 3/01
Reviewed: 2/02
Reviewed: 4/02
Reviewed: 3/03
Reviewed: 3/04
Reviewed: 3/05-updated title
Reviewed: 3/06-updated title
Reviewed: 4/06-updated criteria for coverage of this class of drugs
Reviewed: 3/07
Reviewed: 4/07 added signature
Reviewed: 8/07 corrected typo
Reviewed: 3/08 – annual review
Reviewed: 4/09 – annual review – updated alt (zaleplon)
Reviewed: 3/10 – annual review
Reviewed: 3/11 – annual review, updated with generic Ambien & removed old criterion
Reviewed: 3/12 – annual review, updated signature
Reviewed: 3/16/12 – fixed typo, zolpidem CR missing **
Reviewed: 3/29/12 – added Intermezzo to policy
Reviewed: 3/1/13 – annual review, updated logo and definitions, fixed typo
Reviewed: 3/1/14 – annual review, updated formatting, changed ER to CR for zolpidem
POLICY NUMBER: 8.0

SECTION: Commercial Drug
SUBJECT: Ramelteon, doxepin (generic Silenor), and Sublingual 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
Reviewed: 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
POLICY NUMBER: 9.0

APPLICATION AND PROCEDURE
PHARMACY
MANUAL

SECTION: Commercial Drug
SUBJECT: Brand

Applicable line of business:

<table>
<thead>
<tr>
<th>Business</th>
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</thead>
<tbody>
<tr>
<td>Commercial</td>
<td>X</td>
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<tr>
<td>Medicaid</td>
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POLICY:
Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of formulary. The formulary is applied according to the formulary review process (see Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Part D Policy 143.0 D Geisinger Health Plan (GHP) and Geisinger Indemnity Insurance Company (GIIC) Formulary Development by the Pharmacy). The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for branded medications with an AB-rated formulary generic available for GHP members who have prescription drug benefits, including all lines of business, unless a specific limitation or exception exists.

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).
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 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

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POLICY AND PROCEDURE
PHARMACY
MANUAL

POLICY NUMBER: 9.0

SECTION: Commercial Drug
SUBJECT: Brand

Signed: ______________________________

Title: Director, Pharmacy Services

Date: March 1, 2020

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: 3/11 – annual review; clarified introduction
Revised: 3/12 – annual review, updated signature
Revised: 3/13 – annual review, updated logo and definitions
Revised: 3/14 – annual review, updated formatting
Revised: 5/28/14 – updated to require failure on generic & failure on FA, updated signature
Revised: 3/15 – annual review
Reviewed: 3/16 – annual review
Revised: 5/16 – updated format, logo, and procedure
Reviewed: 3/17 – annual review
Revised: 3/18 – annual review, updated signature
Reviewed: 3/19 – annual review
Revised: 3/20 – annual review, added GHP Kids
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B. Provided for the diagnosis, or the direct care and treatment of the Member’s condition, illness, disease or injury;
C. In accordance with current standards of medical practice;
D. Not primarily for the convenience of the Member, or the Member's Provider; and
E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due 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 pneumonia* 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**
- 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

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, 2020
POLICY NUMBER: 26.0

POLICY AND PROCEDURE
PHARMACY
MANUAL

SECTION: Commercial Drug
SUBJECT: Striant

Applicable line of business:

<table>
<thead>
<tr>
<th>Line of Business</th>
<th>Commercial</th>
<th>Medicaid</th>
<th>Medicare</th>
<th>ACA</th>
<th>GHP Kids</th>
</tr>
</thead>
<tbody>
<tr>
<td>Commercial</td>
<td>X</td>
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<td>GHP Kids</td>
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</table>

POLICY:
Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of formulary. The formulary is applied according to the formulary review process (see Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Part D Policy 143.0 D Geisinger Health Plan (GHP) and Geisinger Indemnity Insurance Company (GIIC) Formulary Development by the Pharmacy). The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for Striant for GHP members who have prescription drug benefits, including all lines of business, unless a specific limitation or exception exists.

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

ADDITIONAL DEFINITIONS:
1. Formulary – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. Non-formulary products – those medications that are not included in the Formulary.
3. Healthcare provider – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
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 Striant may be made for members who meet the following criteria:

- Medical record documentation of a diagnosis which is consistent with an FDA approved treatment indication, AND
- Medical record documentation of a therapeutic failure on, intolerance to, or contraindication to formulary testosterone patch (Androderm Patch) and Androgel

QUANTITY LIMIT: Striant will be restricted to a monthly quantity of 68 tablets per co-pay.

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

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

FORMULARY ALTERNATIVES:
Androderm Patch, testosterone gel, testosterone axillary solution, testosterone cypionate injection, testosterone enanthate injection

THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE STANDARDS 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: 26.0
SECTION: Commercial Drug
SUBJECT: Striant

Signed: ____________________________________________

Title: Director, Pharmacy Services
Date: March 1, 2020

Devised: 1/01
Effective: 2/01
Revised: 3/01
Revised: 2/02
Reviewed: 4/02
Revised: 3/03
Revised: 3/04 – edited verbiage of “documentation” for grammatical purposes
Revised: 10/04 – added Striant 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
Reviewed: 3/10 – annual review
Reviewed: 3/11 – annual review
Revised: 9/11 – added Fortesta to policy
Revised: 3/12 – annual review, updated sig, removed Androgel
Revised: 3/13 – annual review, updated logo and definitions, updated Striant QL
Revised: 5/13 – added Fortesta and Testim to policy
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, and procedure
Revised: 3/17 – annual review, updated FA
Revised: 3/18 – annual review, updated signature, corrected typo
Revised: 3/19 – annual review, removed Axiron, Fortesta, and Testim from policy, updated FA
Revised: 3/20 – annual review, added GHP Kids
POLICY:
Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of formulary. The formulary is applied according to the formulary review process (see Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Part D Policy 143.0 D Geisinger Health Plan (GHP) and Geisinger Indemnity Insurance Company (GIIC) Formulary Development by the Pharmacy). The results of this process determine the development and application 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 all lines of business, unless a specific limitation or exception exists.

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

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

**QUANTITY LIMIT:** 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
- **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, 2020

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
Revised: 3/10 – annual review
Revised: 4/10 – updated alternatives
Revised: 3/11 – 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
valsartan HCT, updated title
Revised: 7/29/13 – removed generic valsartan/hctz & added Diovan HCT, updated criteria for
Diovan HCT
Revised: 3/14 – annual review

HPRX02
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Dev. 5/01
Rev. 3/1/20
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
POLICY:
Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of formulary. The formulary is applied according to the formulary review process (see Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Part D Policy 143.0 D Geisinger Health Plan (GHP) and Geisinger Indemnity Insurance Company (GIIC) Formulary Development by the Pharmacy). The results of this process determine the development and application 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 all lines of business, unless a specific limitation or exception exists.

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

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

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.

FDA Approved Indications:
Pediatric Growth Hormone Deficiency: Norditropin, Genotropin, Humatrope, Nutropin AQ, Omnitrope, Saizen, 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. There is a minimum 20% copayment for this medication. For those members who have a 50% copayment, they will be responsible for 50% of the cost.

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

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**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE STANDARDS OF NCQA AND ANY OTHER 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 NUMBER: 29.0

SECTION: Commercial Drug
SUBJECT: Human Growth Hormone

Date: March 1, 2020

Devised: 4/97
Revised: 1/99
Reviewed: 12/00
Revised: 3/01
Reviewed: 2/02
Revised: 4/02
Reviewed: 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
Reviewed: 3/1/13 – annual review, updated logo and definitions
Revised: 3/1/14 – annual review, updated formatting
Reviewed: 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
Reviewed: 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
Reviewed: 3/1/19 – annual review
Revised: 3/1/20 – annual review, added GHP Kids
POLICY:
Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of formulary. The formulary is applied according to the formulary review process (see Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Part D Policy 143.0 D Geisinger Health Plan (GHP) and Geisinger Indemnity Insurance Company (GIIC) Formulary Development by the Pharmacy). The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for topical tretinoin for GHP members who have prescription drug benefits, including all lines of business, unless a specific limitation or exception exists.

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

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

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

THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE STANDARDS 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: 30.0

POLICY AND PROCEDURE
PHARMACY
MANUAL

SECTION: Commercial Drug
SUBJECT: Topical Tretinoin

Signed:_______________________________________________
Title: Director, Pharmacy Services
Date: March 1, 2020

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
Reviewed: 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
Reviewed: 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
POLICY:
Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of formulary. The formulary is applied according to the formulary review process (see Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Part D Policy 143.0 D Geisinger Health Plan (GHP) and Geisinger Indemnity Insurance Company (GIIC) Formulary Development by the Pharmacy). The results of this process determine the development and application 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 all lines of business, unless a specific limitation or exception exists.

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

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

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, 2020

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: 3/11 – annual review—updated informational section
Revised: 3/12 – annual review and updated signature
Revised: 9/17/12 – updated criteria for coverage and updated location
Revised: 3/13 – annual review, updated logo and definitions, corrected signature title
Revised: 3/14 – annual review, updated formatting
Revised: 3/15 – annual review, updated signature
Revised: 3/16 – annual review, updated payment logic to reflect pay as calculated
Revised: 5/16 – updated format, logo, and procedure
POLICY:
Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of formulary. The formulary is applied according to the formulary review process (see Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Part D Policy 143.0 D Geisinger Health Plan (GHP) and Geisinger Indemnity Insurance Company (GIIC) Formulary Development by the Pharmacy). The results of this process determine the development and application 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 all lines of business, unless a specific limitation or exception exists.

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

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

If an exception is made, itraconazole will be paid for under the member's prescription 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, 2020

Devised: 1/98
Reviewed: 3/99
Reviewed: 6/01
Revised: 7/01
Revised: 10/01
Reviewed: 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
Reviewed: 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
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
POLICY:
Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of formulary. The formulary is applied according to the formulary review process (see Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Part D Policy 143.0 D Geisinger Health Plan (GHP) and Geisinger Indemnity Insurance Company (GIIC) Formulary Development by the Pharmacy). The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for Avandia for GHP members who have prescription drug benefits, including all lines of business, unless a specific limitation or exception exists.

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

ADDITIONAL DEFINITIONS:
1. Formulary – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. Non-formulary products – those medications that are not included in the Formulary.
3. Healthcare provider – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
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 Avandia may be made for members who meet the following criteria:

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

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

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

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

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

Signed: John Miller

Title: Director, Pharmacy Services
Date: March 1, 2020

Devised: 7/99
Effective: 7/99
Revised: 10/01
Reviewed: 1/02
Revised: 2/02
Reviewed: 6/02
Revised: 3/03
Revised: 10/03 – updated to reflect Novo Nordisk vialled Insulin as formulary alternatives
Revised: 3/04 – updated to reflect generic availability of Glucotrol XL in FA section.
Revised: 3/05 – updated title
Revised: 11/05 – updated to reflect generic availability of Amaryl in the FA section.
Revised: 3/06 – updated title
Revised: 3/07 – updated Avandia criteria
Revised: 4/07 – added signature
Reviewed: 3/08 – annual review, updated alternatives
Revised: 4/09 – annual review; updated alternatives
Reviewed: 3/10 – annual review
Revised: 8/10 – removed Actos from policy and updated criteria
Revised: 3/11 – annual review, updated alternative section
Revised: 3/12 – annual review updated signature
Revised: 3/13 – annual review, updated logo & definitions, updated alternatives to pioglitazone
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
Reviewed: 3/17 – annual review
Revised: 3/18 – annual review, updated signature
Reviewed: 3/19 – annual review
Revised: 3/20 – annual review, added GHP Kids
Applicable line of business:

<table>
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<tr>
<th></th>
<th>Commercial</th>
<th>Medicare</th>
<th>Medicaid</th>
<th>ACA</th>
<th>GHP Kids</th>
</tr>
</thead>
</table>

POLICY:
Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of formulary. The formulary is applied according to the formulary review process (see Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Part D Policy 143.0 D Geisinger Health Plan (GHP) and Geisinger Indemnity Insurance Company (GIIC) Formulary Development by the Pharmacy). The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for Dexilant or omeprazole/sodium bicarbonate for GHP members who have prescription drug benefits, including all lines of business, unless a specific limitation or exception exists.

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

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

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, Dexilant*, and esomeprazole (in that order)

QUANTITY LIMIT: Pharmacist note to CSR: Authorization should be entered by HICL and only checking the Formulary PA required box (no QLs need to be entered within the authorization).

- Dexilant: 1 capsule per day

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.
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, 2020

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: 3/11 – annual review
Revised: 3/12 – annual review updated signature
POLICY: Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of formulary. The formulary is applied according to the formulary review process (see Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Part D Policy 143.0 D Geisinger Health Plan (GHP) and Geisinger Indemnity Insurance Company (GIIC) Formulary Development by the Pharmacy). The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for Tazorac Gel for GHP members who have prescription drug benefits, including all lines of business, unless a specific limitation or exception exists.

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

ADDITIONAL DEFINITIONS:
1. **Formulary** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. **Non-formulary products** – those medications that are not included in the Formulary.
3. **Healthcare provider** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
5. **Medically Necessary or Medical Necessity** – covered services rendered by a provider that the Health Plan determines are:
   - Appropriate for the symptoms and diagnosis or treatment of the Member’s condition, illness, disease or injury;
B. Provided for the diagnosis, or the direct care and treatment of the Member’s condition, illness, disease or injury;
C. In accordance with current standards of medical practice;
D. Not primarily for the convenience of the Member, or the Member's Provider; and
E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

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

**Acne Vulgaris**
- Medical record documentation of a diagnosis of acne, acne vulgaris, or adult onset acne **AND**
- Medical record documentation that Tazorac Gel is being prescribed by a dermatologist **AND**
- Medical record documentation of a contraindication to, intolerance to, or therapeutic failure on three (3) formulary alternatives for the treatment of acne

**Plaque Psoriasis**
- Medical record documentation of a diagnosis of plaque psoriasis **AND**
- Medical record documentation that Tazorac Gel is being prescribed by a dermatologist **AND**
- Medical record documentation of a contraindication to, intolerance to, or therapeutic failure on one (1) topical anti-psoriatic therapy **AND** at least 2 to 3 months of methotrexate or phototherapy

If an exception is made, Tazorac 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:**
- **Antipsoriatrics**: calcipotriene, topical calcitriol, Drithocreme HP, methotrexate
Acne Treatment: 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.

Signed: __________________________
Title: Director, Pharmacy Services
Date: March 1, 2020

Reviewed: 10/01
Revised: 11/01
Revised: 2/02
Revised: 6/02
Revised: 3/03
Revised: 3/04 – updated formulary alternative section to reflect the manufacturer discontinuation of Drithocreme products.
Revised: 3/05 – 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
Reviewed: 3/10 – annual review
Revised: 3/11 – annual review, updated formulary alt section
Revised: 3/12 – annual review updated signature
Revised: 3/13 – annual review, updated logo, definitions, and alternatives
Revised: 3/14 – annual review, updated formatting
Revised: 3/15 – annual review, updated signature, changed Differin 0.3% gel to adapalene, removed Retin-A Microgel, added tretinoin microsphere gel to alternatives
Revised: 5/16 – updated format, logo, & procedure
Revised: 3/17 – annual review, updated FA
Revised: 3/27/17 – updated alternative criteria, added MTX to FA
Revised: 3/18 – annual review, updated signature, updated cream to gel
Reviewed: 3/19 – annual review
Revised: 3/1/20 – annual review, added GHP Kids
Applicable line of business:

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<thead>
<tr>
<th>Line of Business</th>
<th>Medicaid</th>
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<th>GHP Kids</th>
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<td>GHP Kids</td>
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</tbody>
</table>

POLICY:
Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of formulary. The formulary is applied according to the formulary review process (see Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Part D Policy 143.0 D Geisinger Health Plan (GHP) and Geisinger Indemnity Insurance Company (GIIC) Formulary Development by the Pharmacy). The results of this process determine the development and application 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 all lines of business, unless a specific limitation or exception exists.

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

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

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 signs and symptoms of rheumatoid arthritis on six (6) months of etanercept therapy 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 continued or sustained improvement in the signs and symptoms of rheumatoid arthritis while on etanercept therapy.
QUANTITY LIMIT: Pharmacist note to CSR: Authorization should be entered by HICL and only checking the Formulary PA required box (no QLs need to be entered within the authorization).
  - 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:
  Humira*, Rinvoq*, Xeljanz*

  *prior authorization required
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

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 signs and symptoms of polyarticular juvenile idiopathic arthritis or juvenile rheumatoid arthritis on six (6) months of etanercept therapy 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 continued or sustained improvement in the signs and symptoms of polyarticular juvenile idiopathic arthritis or juvenile rheumatoid arthritis while on etanercept therapy.

QUANTITY LIMIT: Pharmacist note to CSR: Authorization should be entered by HICL and only checking the Formulary PA required box (no QLs need to be entered within the authorization).
- 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
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

**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 psoriatic arthritis on six (6) months of etanercept therapy.

After the initial six (6) month approval, subsequent approvals will be for a duration of one (1) year requiring medical record documentation of continued or sustained improvement in the signs and symptoms of psoriatic arthritis while on etanercept therapy.

**QUANTITY LIMIT:** Pharmacist note to CSR: Authorization should be entered by HICL and only checking the Formulary PA required box (no QLs need to be entered within the authorization).

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

\textbf{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 ankylosing spondylitis is required.

After the initial six (6) month approval, subsequent approvals will be for a duration of one (1) year requiring medical record documentation of continued or sustained improvement in the signs and symptoms of ankylosing spondylitis while on etanercept therapy.

\textbf{QUANTITY LIMIT:} Pharmacist note to CSR: \textit{Authorization should be entered by HICL and only checking the Formulary PA required box (no QLs need to be entered within the authorization).}

- 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

\textbf{FORMULARY ALTERNATIVES:}

Cosentyx*, Humira*

*prior authorization required
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

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 signs and symptoms of psoriasis on six (6) months of etanercept therapy is required.

After the initial six (6) month approval, subsequent approvals will be for a duration of one (1) year, requiring medical record documentation of continued or sustained improvement in the signs and symptoms of psoriasis while on etanercept therapy.

QUANTITY LIMIT/AUTHORIZATION PARAMETERS:

<table>
<thead>
<tr>
<th>If requesting a dose of:</th>
<th>Initial – 3 months authorization</th>
<th>Remainder/Subsequent</th>
</tr>
</thead>
<tbody>
<tr>
<td>50 mg syringe/pen</td>
<td>Quantity limit: 8 mL per 28 days</td>
<td>Quantity limit: 4 mL per 28 days</td>
</tr>
<tr>
<td></td>
<td>Max quantity supply: 8</td>
<td>Authorization should be entered by HICL and only checking the Formulary box (no QLs need to be entered within the authorization).</td>
</tr>
<tr>
<td></td>
<td>Min day supply: 28</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Max day supply: 28</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Enter by GPID</td>
<td></td>
</tr>
<tr>
<td>25 mg syringe</td>
<td>Quantity limit: 8 mL per 28 days</td>
<td>Quantity limit: 4 mL per 28 days</td>
</tr>
<tr>
<td></td>
<td>Max quantity supply: 8</td>
<td>Authorization should be entered by HICL and only checking the Formulary box (no QLs need to be entered within the authorization).</td>
</tr>
<tr>
<td></td>
<td>Min day supply: 28</td>
<td></td>
</tr>
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<td>Max day supply: 28</td>
<td></td>
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<tr>
<td></td>
<td>Enter by GPID</td>
<td></td>
</tr>
<tr>
<td>25 mg vial</td>
<td>Quantity limit: 16 mL per 28 days</td>
<td>Quantity limit: 8 mL per 28 days</td>
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<tr>
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<td>Max quantity supply: 16</td>
<td>Authorization should be entered by HICL and only checking the Formulary box (no QLs need to be entered within the authorization).</td>
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<tr>
<td></td>
<td>Min day supply: 28</td>
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<td>Max day supply: 28</td>
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<tr>
<td></td>
<td>Enter by GPID</td>
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</tbody>
</table>
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

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 signs and symptoms of psoriasis on six (6) months of etanercept therapy is required.

After the initial six (6) month approval, subsequent approvals will be for a duration of one (1) year, requiring medical record documentation of continued or sustained improvement in the signs and symptoms of psoriasis while on etanercept therapy.

QUANTITY LIMIT: Pharmacist note to CSR: Authorization should be entered by HICL and only checking the Formulary PA required box (no QLs need to be entered within the authorization).

- 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)
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, 2020

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%
Revised: 5/08 – updated criteria
Reviewed: 4/09 – annual review
Reviewed: 3/10 – annual review
Reviewed: 3/11 – annual review
Reviewed: 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: 9/25/19 – 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
Applicable line of business:

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POLICY:
Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of formulary. The formulary is applied according to the formulary review process (see Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Part D Policy 143.0 D Geisinger Health Plan (GHP) and Geisinger Indemnity Insurance Company (GIIC) Formulary Development by the Pharmacy). The results of this process determine the development and application 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 all lines of business, unless a specific limitation or exception exists.

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

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

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.

Signed:_______________________________________________
Title: Director, Pharmacy Services
Date: March 1, 2020

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: 3/11 – annual review
Revised: 3/12 – annual review
Revised: 3/13 – annual review, updated logo and definitions
Revised: 3/14 – annual review, updated formatting
Revised: 3/15 – annual review, updated signature
Revised: 3/16 – annual review, added formulary alternative section
Revised: 5/16 – updated format, logo, & procedure
Reviewed: 3/17 – annual review
Revised: 6/2/17 – removed age restriction
Revised: 3/18 – annual review, updated signature, updated formatting
Reviewed: 3/19 – annual review
Revised: 3/20 – annual review, added GHP Kids
POLICY AND PROCEDURE
PHARMACY
MANUAL

POLICY NUMBER: 47.0
SECTION: Commercial Drug
SUBJECT: Tazorac Cream

Applicable line of business:

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<tr>
<th>Line of Business</th>
<th>Commercial</th>
<th>Medicaid</th>
<th>Medicare</th>
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<tr>
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<td></td>
<td>X</td>
</tr>
<tr>
<td>GHP Kids</td>
<td></td>
<td></td>
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<td>X</td>
</tr>
</tbody>
</table>

POLICY:
Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of formulary. The formulary is applied according to the formulary review process (see Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Part D Policy 143.0 D Geisinger Health Plan (GHP) and Geisinger Indemnity Insurance Company (GIIC) Formulary Development by the Pharmacy). The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for Tazorac Cream for GHP members who have prescription drug benefits, including all lines of business, unless a specific limitation or exception exists.

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

ADDITIONAL DEFINITIONS:
1. Formulary – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. Non-formulary products – those medications that are not included in the Formulary.
3. Healthcare provider – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
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;
POLICY NUMBER: 47.0

POLICY AND PROCEDURE
PHARMACY
MANUAL

SECTION: Commercial Drug
SUBJECT: Tazorac Cream

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

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

**Acne Vulgaris**
- Medical record documentation of a diagnosis of acne, acne vulgaris, or adult onset acne **AND**
- Medical record documentation that Tazorac Cream is prescribed by a dermatologist **AND**
- Medical record documentation of a contraindication to, intolerance to, or therapeutic failure on three (3) formulary alternatives for the treatment of acne

**Plaque Psoriasis**
- Medical record documentation of a diagnosis of plaque psoriasis **AND**
- Medical record documentation that Tazorac Cream is prescribed by a dermatologist **AND**
- Medical record documentation of a contraindication to, intolerance to, or therapeutic failure on one (1) topical anti-psoriatic therapy **AND** at least 2 to 3 months of methotrexate or phototherapy

If an exception is made, Tazorac 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:**
- **Antipsoriatics:** calcipotriene, topical calcitriol, Drithocreme HP, methotrexate
Acne Treatment: 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.

Signed: _______________________________________________

Title: Director, Pharmacy Services

Date: March 1, 2020
Revised: 3/1/20 – annual review, added GHP Kids
Applicable line of business:

<table>
<thead>
<tr>
<th>Line of Business</th>
<th>Commercial</th>
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POLICY:
Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of formulary. The formulary is applied according to the formulary review process (see Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Part D Policy 143.0 D Geisinger Health Plan (GHP) and Geisinger Indemnity Insurance Company (GIIC) Formulary Development by the Pharmacy). The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for inhaled tobramycin for GHP members who have prescription drug benefits, including all lines of business, unless a specific limitation or exception exists.

REQUIRED DEFINITIONS:
1. Attachment – a supporting document that is developed and maintained by the policy writer or 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).
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 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

QUANTITY LIMIT/AUTHORIZATION PARAMETERS:

<table>
<thead>
<tr>
<th>If requesting:</th>
<th>Remainder/Subsequent</th>
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<tbody>
<tr>
<td>Tobramycin inhalation solution</td>
<td>Quantity limit: 280 mL per 56 days</td>
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<td></td>
<td>Max quantity supply: 280</td>
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<td>Min day supply: 56</td>
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<tr>
<td>Tobi PodHaler</td>
<td>Quantity limit: 224 mL per 56 days</td>
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<td>Max quantity supply: 224</td>
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<td>Min day supply: 56</td>
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<td>Max day supply: 56</td>
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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

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

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

Signed: ____________________________________________

Title: Director, Pharmacy Services

Date: March 1, 2020
Applicable line of business:

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POLICY:
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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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3. **Healthcare provider** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
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 darifenacin ER, 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 Vesicare

If a formulary exception is approved darifenacin ER, 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, tolterodine, Myrbetriq, Vesicare

THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE STANDARDS 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: 48.0

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

Signed: ________________________________
Title: Director, Pharmacy Services
Date: March 1, 2020

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: 3/11 – annual review
Revised: 3/12 – 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
**POLICY NUMBER: 50.0**

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

### Applicable line of business:

<table>
<thead>
<tr>
<th>Line of Business</th>
<th>Commercial</th>
<th>Medicaid</th>
<th>Medicare</th>
<th>ACA</th>
<th>GHP Kids</th>
</tr>
</thead>
<tbody>
<tr>
<td>Policy Applies</td>
<td>X</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

### POLICY:

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of formulary. The formulary is applied according to the formulary review process (see Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Part D Policy 143.0 D Geisinger Health Plan (GHP) and Geisinger Indemnity Insurance Company (GIIC) Formulary Development by the Pharmacy). The results of this process determine the development and application 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 all lines of business, unless a specific limitation or exception exists.

### REQUIRED DEFINITIONS:

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

### ADDITIONAL DEFINITIONS:

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

<table>
<thead>
<tr>
<th>Antihemophilic Agent</th>
<th>Routine Prophylaxis</th>
<th>On-Demand/ Perioperative</th>
</tr>
</thead>
<tbody>
<tr>
<td>Alphanine SD</td>
<td>X</td>
<td></td>
</tr>
<tr>
<td>Alprolix</td>
<td>X</td>
<td>X</td>
</tr>
<tr>
<td>Bebulin</td>
<td>X</td>
<td></td>
</tr>
<tr>
<td>BeneFIX</td>
<td>X</td>
<td></td>
</tr>
<tr>
<td>Idelvion</td>
<td>X</td>
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<td>Profilnine</td>
<td>X</td>
<td></td>
</tr>
<tr>
<td>Rebinyn</td>
<td>X</td>
<td></td>
</tr>
<tr>
<td>Rixubis</td>
<td>X</td>
<td>X</td>
</tr>
</tbody>
</table>

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, 2020
Reviewed: 3/1/19 – annual review
Revised: 3/1/20 – annual review, added GHP Kids
POLICY NUMBER: 63.0

POLICY AND PROCEDURE
PHARMACY
MANUAL

SECTION: Commercial Drug
SUBJECT: Elmiron

Applicable line of business:

<table>
<thead>
<tr>
<th>Line of Business</th>
<th>Commercial</th>
<th>Medicaid</th>
<th>Medicare</th>
<th>ACA</th>
<th>GHP Kids</th>
</tr>
</thead>
<tbody>
<tr>
<td>X</td>
<td></td>
<td>X</td>
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</tbody>
</table>

POLICY:
Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of formulary. The formulary is applied according to the formulary review process (see Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Part D Policy 143.0 D Geisinger Health Plan (GHP) and Geisinger Indemnity Insurance Company (GIIIC) Formulary Development by the Pharmacy). The results of this process determine the development and application 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 all lines of business, unless a specific limitation or exception exists.

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

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

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.

Signed: [Signature]
Title: Director, Pharmacy Services
Date: March 1, 2020

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
POLICY: Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of formulary. The formulary is applied according to the formulary review process (see Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Part D Policy 143.0 D Geisinger Health Plan (GHP) and Geisinger Indemnity Insurance Company (GIIC) Formulary Development by the Pharmacy). The results of this process determine the development and application 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 all lines of business, unless a specific limitation or exception exists.

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

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

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 (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 01, 2020

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: 3/11 – annual review
Revised: 3/12 – annual review, updated signature
Revised: 3/13 – annual review, updated logo and definitions
Revised: 3/14 – 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
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
POLICY:
Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of formulary. The formulary is applied according to the formulary review process (see Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Part D Policy 143.0 D Geisinger Health Plan (GHP) and Geisinger Indemnity Insurance Company (GIIC) Formulary Development by the Pharmacy). The results of this process determine the development and application 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 all lines of business, unless a specific limitation or exception exists.

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

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

QUANTITY LIMIT: 0.67 mL per day, 28 day supply per fill

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 signs and symptoms of rheumatoid arthritis on six (6) months of anakinra therapy 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 continued or sustained improvement in the signs and symptoms of rheumatoid arthritis while on anakinra therapy.

FORMULARY ALTERNATIVES:
   Humira*, Rinvoq*, Xeljanz*

*prior authorization required
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

**AUTHORIZATION DURATION**
The initial approval will be for a time period of 12 weeks, requiring medical record documentation of improvement in signs and symptoms of NOMID. Kineret will then require approval on a yearly basis.

**FORMULARY ALTERNATIVES:**
none
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 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

**AUTHORIZATION DURATION**
The initial approval will be for a time period of 12 weeks, requiring medical record documentation of improvement in signs and symptoms of CAPS. Kineret will then require approval on a yearly basis.

**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 ANNNUALLY.**
POLICY AND PROCEDURE
PHARMACY
MANUAL

POLICY NUMBER: 71.0
SECTION: Commercial Drug
SUBJECT: Kineret

Signed: _______________________________________
Title: Director, Pharmacy Services
Date: March 1, 2020

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: 3/11 – annual review
Revised: 3/12 – annual review, updated sig
Revised: 9/17/12 – updated authorization duration and file location
Revised: 3/13 – annual review, updated logo and definitions
Revised: 5/13 – added NOMID indication
Revised: 3/14 – 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: 3/15 – annual review
Revised: 9/19/15 – removed joint count criteria from initial and renewal requirements
Revised: 3/16 – annual review, updated policy format to improve readability
Revised: 5/16 – updated format, logo, & procedure
Review: 3/17 – 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: 3/18 – 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: 3/19 – 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

HPRX02
geisinger.edu/dfs/0004/0142/142006/COMMERCIAL\Commercial 2020-2021\Policy 71.0 Kineret.docx
Rev. 7/02
Rev. 3/1/20
Applicable line of business:

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<tr>
<th>Line of Business</th>
<th>X</th>
<th>Medicaid</th>
<th>Medicare</th>
<th>ACA</th>
<th>GHP Kids</th>
</tr>
</thead>
</table>

POLICY:
Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of formulary. The formulary is applied according to the formulary review process (see Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Part D Policy 143.0 D Geisinger Health Plan (GHP) and Geisinger Indemnity Insurance Company (GIIC) Formulary Development by the Pharmacy). The results of this process determine the development and application 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 all lines of business, unless a specific limitation or exception exists.

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

ADDITIONAL DEFINITIONS:
1. **Formulary** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. **Non-formulary products** – those medications that are not included in the Formulary.
3. **Healthcare provider** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
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 Actimmune may be made for members who meet the following criterion:

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

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.

Signed: ________________________________
Title: Director, Pharmacy Services
Date: March 1, 2020
POLICY NUMBER: 72.0

SECTION: Commercial Drug

SUBJECT: Actimmune
Applicable line of business:

<table>
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<tr>
<th>Line of Business</th>
<th>Medicaid</th>
<th>ACA</th>
<th>GHP Kids</th>
</tr>
</thead>
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<tr>
<td>Commercial</td>
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</tr>
<tr>
<td>GHP Kids</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

POLICY:
Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of formulary. The formulary is applied according to the formulary review process (see Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Part D Policy 143.0 Geisinger Health Plan (GHP) and Geisinger Indemnity Insurance Company (GlIIC) Formulary Development by the Pharmacy). The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for Rapamune Solution and sirolimus tablets for GHP members who have prescription drug benefits, including all lines of business, unless a specific limitation or exception exists.

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

ADDITIONAL DEFINITIONS:
1. **Formulary** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. **Non-formulary products** – those medications that are not included in the Formulary.
3. **Healthcare provider** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
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 Rapamune Solution or sirolimus tablets 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
If an exception is made, Rapamune Solution or sirolimus 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:**
- 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: June 9, 2020

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
POLICY NUMBER: 73.0

SECTION: Commercial Drug
SUBJECT: Rapamune Solution and Sirolimus Tablets

Revised: 3/1/15 – annual review, added sirolimus tablets to policy, updated signature
Revised: 7/22/15 – added lymphangioleiomyomatosis indication, updated 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, 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
Applicable line of business:

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<tr>
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<tr>
<td>Medicaid</td>
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</tr>
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<td>GHP Kids</td>
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</table>

POLICY:
Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is applied according to the formulary review process (see Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Part D Policy 143.0 D Geisinger Health Plan (GHP) and Geisinger Indemnity Insurance Company (GIIC) Formulary Development by the Pharmacy). The results of this process determine the development and application 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 all lines of business, unless a specific limitation or exception exists.

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

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

QUANTITY LIMIT: Pharmacist note to CSR: Authorization should be entered by HICL and only checking the Formulary PA required box (no QLs need to be entered within the authorization).
- 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:
Amitiza, 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, 2020

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
Applicable line of business:

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POLICY:
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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.
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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;
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** Travatan Z 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** Travatan Z

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), Travatan Z, 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.**
Signed:_______________________________________________

Title: Director, Pharmacy Services

Date: March 1, 2020

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: 3/11 – 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
Applicable line of business:

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<th>Commercial</th>
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<tr>
<td>POLICY NUMBER</td>
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POLICY:
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REQUIRED DEFINITIONS:
1. Attachment – a supporting document that is developed and maintained by the policy writer or 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).
5. Medically Necessary or Medical Necessity – covered services rendered by a provider that the Health Plan determines are:
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B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
C. In accordance with current standards of medical practice;
D. Not primarily for the convenience of the Member, or the Member's Provider; and
E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to 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

**AUTHORIZATION DURATION:**
**For biweekly or weekly administration:**
Approval for new starts and dose increases (biweekly to weekly), adalimumab 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 signs and symptoms of rheumatoid arthritis on six (6) months of adalimumab therapy 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 continued or sustained improvement in the signs and symptoms of rheumatoid arthritis while on adalimumab therapy.

**QUANTITY LIMIT/AUTHORIZATION PARAMETERS:**

<table>
<thead>
<tr>
<th>If requesting a dose of:</th>
<th>Quantity limit: 2 syringes per 28 days</th>
</tr>
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<tbody>
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<td>Max quantity supply: 2</td>
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<tr>
<td></td>
<td>Min day supply: 28</td>
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<table>
<thead>
<tr>
<th>Weekly dosing</th>
<th>Quantity limit: 4 syringes per 28 days</th>
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<tbody>
<tr>
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<td>Max quantity supply: 4</td>
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<tr>
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<td>Min day supply: 28</td>
</tr>
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<td></td>
<td>Max day supply: 28</td>
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</tbody>
</table>
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

AUTHORIZATION DURATION:
For biweekly administration: 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 signs and symptoms of polyarticular juvenile idiopathic arthritis or juvenile rheumatoid arthritis on six (6) months of adalimumab therapy 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 continued or sustained improvement in the signs and symptoms of polyarticular juvenile idiopathic arthritis or juvenile rheumatoid while on adalimumab therapy.

QUANTITY LIMIT/AUTHORIZATION PARAMETERS:
2 syringes per 28 days
Max quantity supply: 2
Min day supply: 28
Max day supply: 28
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

AUTHORIZATION DURATION (For biweekly administration):
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 psoriatic arthritis on six (6) months of adalimumab therapy 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 continued or sustained improvement in the signs and symptoms of psoriatic arthritis while on adalimumab therapy.
QUANTITY LIMIT/AUTHORIZATION PARAMETERS:
- 2 syringes per 28 days
- Max quantity supply: 2
- Min day supply: 28
- Max day supply: 28

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

**AUTHORIZATION DURATION:**
**For biweekly administration:**
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 ankylosing spondylitis on six (6) months of adalimumab therapy is required.

After the initial six (6) month approval, subsequent approvals will be for a duration of one (1) year requiring medical record documentation of continued or sustained improvement in the signs and symptoms of ankylosing spondylitis while on adalimumab therapy.

**QUANTITY LIMIT/AUTHORIZATION PARAMETERS:**
- 2 syringes per 28 days
- Max quantity supply: 2
  - Min day supply: 28
  - Max day supply: 28
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
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.

**AUTHORIZATION DURATION:**
**For biweekly or weekly administration:**
Approval for new starts and dose increases (biweekly to weekly), adalimumab 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 signs and symptoms of Crohn’s disease on six (6) months of adalimumab therapy is required.

After the initial six (6) month approval, subsequent approvals will be for a duration of one (1) year requiring medical record documentation of continued or sustained improvement in the signs and symptoms of Crohn’s disease while on adalimumab therapy.
**QUANTITY LIMIT/AUTHORIZATION PARAMETERS:**

<table>
<thead>
<tr>
<th>If requesting</th>
<th>Product</th>
<th>Initial – One-week authorization</th>
<th>Remainder/Subsequent</th>
</tr>
</thead>
</table>
| Adults and pediatric ≥ 40 kg biweekly dosing | Humira Pen Crohn’s, UC-HS 40 mg/0.8 mL (6 pack pen kit) starter | Quantity limit: 6 per 28 days  
Max quantity supply: 6  
Min day supply: 28  
Max day supply: 28  
Enter by GPID | Quantity limit: 2 per 28 days  
Max quantity supply: 2  
Min day supply: 28  
Max day supply: 28 |
| | Humira CF Crohn’s-UC-HS 80 mg/0.8 mL (3 pack pen kit) or Humira CF pediatric Crohn’s 80/0.8 mL (3 pack syringe kit) starter | Quantity limit: 3 per 28 days  
Max quantity supply: 3  
Min day supply: 28  
Max day supply: 28  
Enter by GPID | Quantity limit: 2 per 28 days  
Max quantity supply: 2  
Min day supply: 28  
Max day supply: 28 |
| Pediatrics < 40 kg biweekly dosing | Humira Pediatric Crohn’s 40 mg/0.8 mL (3 pack syringe kit) starter | Quantity limit: 3 per 28 days  
Max quantity supply: 3  
Min day supply: 28  
Max day supply: 28  
Enter by GPID | Quantity limit: 2 per 28 days  
Max quantity supply: 2  
Min day supply: 28  
Max day supply: 28 |
| | Humira CF Pediatric Crohn’s 80 mg-40 mg syringe (2 pack syringe kit) starter | N/A | Quantity limit: 2 per 28 days  
Max quantity supply: 2  
Min day supply: 28  
Max day supply: 28 |
| Weekly dosing | N/A | N/A | Quantity limit: 4 per 28 days  
Max quantity supply: 4  
Min day supply: 28  
Max day supply: 28 |

**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

AUTHORIZATION DURATION:
For biweekly administration:
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 signs and symptoms of psoriasis on six (6) months of adalimumab therapy is required.

After the initial six (6) month approval, subsequent approvals will be for a duration of one (1) year, requiring medical record documentation of continued or sustained improvement in the signs and symptoms of psoriasis while on adalimumab therapy.

QUANTITY LIMIT/AUTHORIZATION PARAMETERS:

<table>
<thead>
<tr>
<th>If requesting</th>
<th>Initial – One-week authorization</th>
<th>Remainder/Subsequent</th>
</tr>
</thead>
<tbody>
<tr>
<td>Humira Pen Psor-uveitis-adol HS 40mg/0.8 mL (4 pack pen kit) starter</td>
<td>Quantity limit: 4 per 28 days Max quantity supply: 4 Min day supply: 28 Max day supply: 28 Enter by GPID</td>
<td>Quantity limit: 2 per 28 days Max quantity supply: 2 Min day supply: 28 Max day supply: 28</td>
</tr>
</tbody>
</table>
FORMULARY ALTERNATIVES:
cyclosporine, methotrexate

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

**Medium-potency topical corticosteroids:** betamethasone valerate 0.1% cream (Valisone); flucinolone 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) diflorsone 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 18 years **AND**
- Medical record documentation of a therapeutic failure on, intolerance to, or contraindication to azathioprine or 6-mercaptopurine (6-MP) **OR** medical record documentation of a therapeutic failure on or intolerance to prior biologic therapy. **AND**
- Medical record documentation that Humira is not being used concurrently with a tumor necrosis factor (TNF) blocker or other biologic agent **AND**

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 18 years **AND**
- Medical record documentation of a therapeutic failure on, intolerance to, or contraindication to azathioprine or 6-mercaptopurine (6-MP) **OR** medical record documentation of a therapeutic failure on or intolerance to prior biologic therapy **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.

**AUTHORIZATION DURATION:**

**For biweekly or weekly administration:**

Approval for new starts and dose increases (biweekly to weekly), adalimumab 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 signs and symptoms of ulcerative colitis on six (6) months of adalimumab therapy is required.

After the initial six (6) month approval, subsequent approvals 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 adalimumab therapy.

**QUANTITY LIMIT/AUTHORIZATION PARAMETERS:**

<table>
<thead>
<tr>
<th>If requesting:</th>
<th>Product</th>
<th>Initial – One-week authorization</th>
<th>Remainder/Subsequent</th>
</tr>
</thead>
<tbody>
<tr>
<td>Biweekly Dosing</td>
<td>Humira Pen Crohn’s, UC-HS 40 mg/0.8 mL (6 pack pen kit) starter</td>
<td>Quantity limit: 6 per 28 days Max quantity supply: 6 Min day supply: 28 Max day supply: 28 Enter by GPID</td>
<td>Quantity limit: 2 per 28 days Max quantity supply: 2 Min day supply: 28 Max day supply: 28</td>
</tr>
<tr>
<td></td>
<td>Humira CF Crohn’s-UC-HS 80 mg/0.8 mL (3 pack pen kit) starter</td>
<td>Quantity limit: 3 per 28 days Max quantity supply: 3 Min day supply: 28 Max day supply: 28 Enter by GPID</td>
<td>Quantity limit: 2 per 28 days Max quantity supply: 2 Min day supply: 28 Max day supply: 28</td>
</tr>
<tr>
<td>Weekly dosing</td>
<td>N/A</td>
<td>N/A</td>
<td>Quantity limit: 4 per 28 days Max quantity supply: 4 Min day supply: 28 Max day supply: 28</td>
</tr>
</tbody>
</table>

**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* **AND**
- 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.

**AUTHORIZATION DURATION:**
**For weekly administration:**
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 hidradenitis suppurativa on six (6) months of adalimumab therapy is required.

After the initial six (6) month approval, subsequent approvals will be for a duration of one (1) year requiring medical record documentation of continued or sustained improvement in the signs and symptoms of hidradenitis suppurativa while on adalimumab therapy.
# QUANTITY LIMIT/AUTHORIZATION PARAMETERS:

<table>
<thead>
<tr>
<th>If requesting</th>
<th>Product</th>
<th>Initial – One-week authorization</th>
<th>Remainder/Subsequent</th>
</tr>
</thead>
</table>
| Adult Hidradenitis Suppurativa | Humira Pen Crohn’s, UC-HS 40 mg/0.8 mL (6 pack pen kit) starter       | Quantity limit: 6 per 28 days
Min day supply: 6
Max day supply: 28
Enter by GPID                                           | Quantity limit: 4 per 28 days
Max quantity supply: 4
Min day supply: 28
Max day supply: 28                                        |
|                        | Humira CF Crohn’s-UC-HS 80 mg/0.8 mL (3 pack pen kit) starter         | Quantity limit: 3 per 28 days
Max quantity supply: 3
Min day supply: 28
Max day supply: 28
Enter by GPID                                           | Quantity limit: 4 per 28 days
Max quantity supply: 4
Min day supply: 28
Max day supply: 28                                        |
| Age 12 – 18 years weighing 30 to <60 kg Hidradenitis Suppurativa | Humira Psor-Uveitis-Adol-HS starter 40 mg/0.8 mL (4 pack kit)       | Quantity limit: 4 per 28 days
Max quantity supply: 4
Min day supply: 28
Max day supply: 28
Enter by GPID                                           | Quantity limit: 2 per 28 days
Max quantity supply: 2
Min day supply: 28
Max day supply: 28                                        |
|                        | Humira CF Pen Psor-UV-Adol HS 80 mg-40 mg (3 pack kit) starter        | Quantity limit: 3 per 28 days
Max quantity supply: 3
Min day supply: 28
Max day supply: 28
Enter by GPID                                           | Quantity limit: 2 per 28 days
Max quantity supply: 2
Min day supply: 28
Max day supply: 28                                        |
| Age 12 – 18 years weighing >60 kg Hidradenitis Suppurativa | Humira Pen Crohn’s, UC-HS 40 mg/0.8 mL (6 pack pen kit) starter       | Quantity limit: 6 per 28 days
Max quantity supply: 6
Min day supply: 28
Max day supply: 28
Enter by GPID                                           | Quantity limit: 4 per 28 days
Max quantity supply: 4
Min day supply: 28
Max day supply: 28                                        |
|                        | Humira CF Crohn’s-UC-HS 80 mg/0.8 mL (3 pack pen kit) starter         | Quantity limit: 3 per 28 days
Max quantity supply: 3
Min day supply: 28
Max day supply: 28
Enter by GPID                                           | Quantity limit: 4 per 28 days
Max quantity supply: 4
Min day supply: 28
Max day supply: 28                                        |

## 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

AUTHORIZATION DURATION:
For biweekly administration:
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 signs and symptoms of uveitis on six (6) months of adalimumab therapy is required.

After the initial six (6) month approval, subsequent approvals will be for a duration of one (1) year, requiring medical record documentation of continued or sustained improvement in the signs and symptoms of uveitis while on adalimumab therapy.

QUANTITY LIMIT/AUTHORIZATION PARAMETERS:

<table>
<thead>
<tr>
<th>If requesting</th>
<th>Product</th>
<th>Initial – One-week authorization</th>
<th>Remainder/Subsequent</th>
</tr>
</thead>
<tbody>
<tr>
<td>Adult Uveitis</td>
<td>Humira Pen Psor-uveitis-adol HS 40 mg/0.8 mL (4 pack pen kit)</td>
<td>Quantity limit: 4 per 28 days Max quantity supply: 4 Min day supply: 28 Max day supply: 28 Enter by GPID</td>
<td>Quantity limit: 2 per 28 days Max quantity supply: 2 Min day supply: 28 Max day supply: 28</td>
</tr>
</tbody>
</table>
### Humira CF Pen
Psor-UV-Adol-HS  
80 mg-40 mg pen kit (3 pack pen kit):  
**Quantity limit:** 3 per 28 days  
**Max quantity supply:** 3  
**Min day supply:** 28  
**Max day supply:** 28  
**Enter by GPID**

### Pediatric Uveitis
**Quantity limit:** 2 per 28 days  
**Max quantity supply:** 2  
**Min day supply:** 28  
**Max day supply:** 28

### FORMULARY ALTERNATIVES:

- **Immunosuppressants**: methotrexate, azathioprine, mycophenolate, cyclosporine, tacrolimus

- **Steroids**: prednisone, methylprednisolone, dexamethasone, prednisolone, budesonide
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: [Signature]

Title: Director, Pharmacy Services

Date: March 1, 2020
updated signature, added or capitalized AND between criteria for each indication

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
POLICY NUMBER: 93.0

POLICY AND PROCEDURE
PHARMACY
MANUAL

SECTION: Commercial Drug
SUBJECT: Voriconazole

Applicable line of business:

<table>
<thead>
<tr>
<th>Line of Business</th>
<th>Medicaid</th>
<th>ACA</th>
<th>GHP Kids</th>
</tr>
</thead>
<tbody>
<tr>
<td>Commercial</td>
<td>X</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Medicare</td>
<td></td>
<td>ACA</td>
<td>X</td>
</tr>
<tr>
<td>GHP Kids</td>
<td></td>
<td></td>
<td>X</td>
</tr>
</tbody>
</table>

POLICY:
Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of formulary. The formulary is applied according to the formulary review process (see Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Part D Policy 143.0 D Geisinger Health Plan (GHP) and Geisinger Indemnity Insurance Company (GIIC) Formulary Development by the Pharmacy). The results of this process determine the development and application 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 all lines of business, unless a specific limitation or exception exists.

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

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

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.

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, 2020

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
Revised: 3/07
Revised: 5/07 – added signature
Revised: 3/08 – annual review; updated alternatives
Revised: 4/09 – annual review
Revised: 3/10 – annual review
Revised: 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
Revised: 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: 3/18 – annual review, updated signature, updated formatting
Revised: 3/19 – annual review
Revised: 3/20 – annual review, added GHP Kids

HPRX02
\geisinger.edu\dfs\0004\0142\142006\COMMERCIAL\Commercial 2020-2021\Policy 93.0 Voriconazole.docx
Dev. 7/03
Rev. 3/1/200
POLICY AND PROCEDURE
PHARMACY
MANUAL

POLICY NUMBER: 94.0
SECTION: Commercial Drug
SUBJECT: Adhansia XR, Aptensio XR, Daytrana, Jornay PM, Dexamethylphenidate HCl ER, QuilliChew ER, and Quillivant XR

Applicable line of business:

<table>
<thead>
<tr>
<th>Commercial</th>
<th>X</th>
</tr>
</thead>
<tbody>
<tr>
<td>Medicare</td>
<td></td>
</tr>
<tr>
<td>GHP Kids</td>
<td>X</td>
</tr>
</tbody>
</table>

POLICY:
Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of formulary. The formulary is applied according to the formulary review process (see Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Part D Policy 143.0 D Geisinger Health Plan (GHP) and Geisinger Indemnity Insurance Company (GIIIC) Formulary Development by the Pharmacy). The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for Adhansia XR, Aptensio XR, Daytrana, dexamethylphenidate HCl ER, Jornay PM, QuilliChew ER, and Quillivant XR for GHP members who have prescription drug benefits, including all lines of business, unless a specific limitation or exception exists.

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

ADDITIONAL DEFINITIONS:
1. Formulary – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. Non-formulary products – those medications that are not included in the Formulary.
3. Healthcare provider – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
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 Adhansia XR, Aptensio XR, Daytrana, dexmethylphenidate HCl ER, Jornay PM, Quillivant XR, or QuilliChew ER 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\(^\) AND amphetamine/dextroamphetamine SR combination

\(\) 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.”

QUANTITY LIMIT: Pharmacist note to CSR: Authorization should be entered by HICL and only checking the Formulary PA required box (no QLs need to be entered within the authorization).

Adhansia XR: 1 capsule per day
Jornay PM: 1 capsule per day
POLICY NUMBER: 94.0
SECTION: Commercial Drug
SUBJECT: Adhansia XR, Aptensio XR, Daytrana, Jornay PM, Dexmethylphenidate HCl ER, QuilliChew ER, and Quillivant XR

If an exception is made, Adhansia XR, Aptensio XR, Daytrana, dexamethasone, hydrochloride, PM, 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, 2020

Devised: 7/03
Effective: 7/03
Revised: 3/04 – updated formulary alternative section
Revised: 3/05 – updated title
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
POLICY NUMBER: 94.0

SECTION: Commercial Drug

SUBJECT: Adhansia XR, Aptensio XR, Daytrana, Jornay PM, Dexmethylphenidate HCl ER, QuilliChew ER, and Quillivant XR

Revised: 6/10 – updated criteria, added Concerta and Vyvanse to policy
Revised: 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
Revised: 3/1/14 – annual review
Revised: 3/1/15 – annual review, updated signature, added dexamethasone HCl ER
Revised: 7/22/15 – moved Vyvanse to policy 384.0
Revised: 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
Revised: 3/1/19 – annual review
Revised: 01/16/20 – added Adhansia XR and Jornay PM
Revised: 3/1/20 – annual review, added GHP Kids

Dev. 7/03
Rev. 3/1/20
POLICY:  
Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of formulary. The formulary is applied according to the formulary review process (see Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Part D Policy 143.0 D Geisinger Health Plan (GHP) and Geisinger Indemnity Insurance Company (GIIC) Formulary Development by the Pharmacy). The results of this process determine the development and application 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 all lines of business, unless a specific limitation or exception exists.

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

ADDITIONAL DEFINITIONS:
1. Formulary – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. Non-formulary products – those medications that are not included in the Formulary.
3. Healthcare provider – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
5. Medically Necessary or Medical Necessity – covered services rendered by a provider that the Health Plan determines are:
   - Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
C. In accordance with current standards of medical practice;
D. Not primarily for the convenience of the Member, or the Member's Provider; and
E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services 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

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, 2020

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
Revised: 3/07
Revised: 5/07 – added signature
Revised: 3/08 – annual review
Revised: 1/09 – added Omnaris
Revised: 4/09 – annual review
Revised: 3/10 – annual review
Revised: 3/11/11 – 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
Revised: 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
Revised: 3/1/19 – annual review
Revised: 7/16/19 – removed Veramyst from policy (product discontinued)
Revised: 09/25/19 – removed budesonide from criteria and formulary alternatives (product discontinued)
Revised: 3/1/20 – annual review, added GHP Kids
Applicable line of business:

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<th>Line of Business</th>
<th>Commercial</th>
<th>Medicaid</th>
<th>Medicare</th>
<th>ACA</th>
<th>GHP Kids</th>
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POLICY:
Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of formulary. The formulary is applied according to the formulary review process (see Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Part D Policy 143.0 D Geisinger Health Plan (GHP) and Geisinger Indemnity Insurance Company (GIIC) Formulary Development by the Pharmacy). The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for Lilly Insulin for GHP members who have prescription drug benefits, including all lines of business, unless a specific limitation or exception exists.

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

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

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.

Signed: ____________________________________________
Title: Director, Pharmacy Services
Date: March 1, 2020

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 vialed 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
POLICY:
Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of formulary. The formulary is applied according to the formulary review process (see Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Part D Policy 143.0 D Geisinger Health Plan (GHP) and Geisinger Indemnity Insurance Company (GIIC) Formulary Development by the Pharmacy). The results of this process determine the development and application 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 all lines of business, unless a specific limitation or exception exists.

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

ADDITIONAL DEFINITIONS:
1. Formulary – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. Non-formulary products – those medications that are not included in the Formulary.
3. Healthcare provider – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
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 Iressa may be made for members who meet the following criteria:

- Medical record documentation that Iressa is prescribed by a hematologist/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

QUANTITY LIMIT: Pharmacist note to CSR: Authorization should be entered by HICL and only checking the Formulary PA required box (no QLs need to be entered within the authorization).

- 1 tablet per day, 30 day supply per fill

AUTHORIZATION DURATION: If approved, approval will be for a period of twelve (12) months. Re-review will be every twelve (12) months. Iressa will no longer be covered if there is medical record documentation of disease progression.

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*, Tarceva*

  *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, 2020

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
Reviewed: 3/07
Revised: 5/07 – added signature
Reviewed: 3/08 – annual review
Reviewed: 4/09 – annual review
Reviewed: 3/10 – annual review
Reviewed: 3/11 – annual review
Reviewed: 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
POLICY:
Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of formulary. The formulary is applied according to the formulary review process (see Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Part D Policy 143.0 D Geisinger Health Plan (GHP) and Geisinger Indemnity Insurance Company (GIIC) Formulary Development by the Pharmacy). The results of this process determine the development and application 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 all lines of business, unless a specific limitation or exception exists.

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

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

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

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

THIS POLICY WILL BE REVISED AS NECESSARY AND REVIEWED NO LESS THAN ANNUALLY.
Signed: John Miller

Title: Director, Pharmacy Services

Date: March 1, 2020
Applicable line of business:

<table>
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<tr>
<th>Line of Business</th>
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<td>Medicare</td>
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<td>ACA</td>
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<tr>
<td>GHP Kids</td>
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<td>X</td>
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</tbody>
</table>

**POLICY:**

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of formulary. The formulary is applied according to the formulary review process (see Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Part D Policy 143.0 D Geisinger Health Plan (GHP) and Geisinger Indemnity Insurance Company (GIIC) Formulary Development by the Pharmacy). The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for Forteo for GHP members who have prescription drug benefits, including all lines of business, unless a specific limitation or exception exists.

**REQUIRED DEFINITIONS:**

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

**ADDITIONAL DEFINITIONS:**

1. **Formulary** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. **Non-formulary products** – those medications that are not included in the Formulary.
3. **Healthcare provider** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
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 Forteo 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:
  o There is medical record documentation of a diagnosis of osteoporosis AND
  o There is medical record documentation of postmenopausal status or glucocorticoid induced osteoporosis AND
  o There is medical record documentation that member has not previously been on a parathyroid hormone analog for greater than 2 years AND
  o There is medical record documentation of an attempt of therapy with or contraindication to bisphosphonates OR
  o 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:
  o There is medical record documentation of a diagnosis of osteoporosis AND
  o There is medical record documentation of an attempt of therapy with or contraindication to bisphosphonate therapy OR
  o There is medical record documentation of a previous osteoporotic fracture or high risk of fracture (T-score <-2.5)

QUANTITY LIMIT: Pharmacist note to CSR: Authorization should be entered by HICL and only checking the Formulary PA required box (no QLs need to be entered within the authorization).
- 2.4 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)

From: WHO Technical Report 8

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

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

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

THIS POLICY WILL BE REVISED AS NECESSARY AND REVIEWED NO LESS THAN ANNUALLY.
Signed:_______________________________________________

Title: Director, Pharmacy Services

Date: March 1, 2020

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.
Reviewed: 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
Reviewed: 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
POLICY:
Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of formulary. The formulary is applied according to the formulary review process (see Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Part D Policy 143.0 D Geisinger Health Plan (GHP) and Geisinger Indemnity Insurance Company (GIIC) Formulary Development by the Pharmacy). The results of this process determine the development and application 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 all lines of business, unless a specific limitation or exception exists.

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

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

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.

Signed: ____________________________________________
Title: Director, Pharmacy Services
Date: March 1, 2020
POLICY:  
Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of formulary. The formulary is applied according to the formulary review process (see Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Part D Policy 143.0 D Geisinger Health Plan (GHP) and Geisinger Indemnity Insurance Company (GIIC) Formulary Development by the Pharmacy). The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for Finacea for GHP members who have prescription drug benefits, including all lines of business, unless a specific limitation or exception exists.

REQUIRED DEFINITIONS:
1. **Attachment** – a supporting document that is developed and maintained by the policy writer or 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).
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 Finacea may be made for members who meet the following criteria:

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

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

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.**

Signed:____________________________
Title: Director, Pharmacy Services
Date: March 1, 2020
POLICY:
Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of formulary. The formulary is applied according to the formulary review process (see Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Part D Policy 143.0 D Geisinger Health Plan (GHP) and Geisinger Indemnity Insurance Company (GIIC) Formulary Development by the Pharmacy). The results of this process determine the development and application 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 all lines of business, unless a specific limitation or exception exists.

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

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

THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE STANDARDS 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: 118.0

POLICY AND PROCEDURE
PHARMACY
MANUAL

SECTION: Commercial Drug
SUBJECT: Modafinil

Signed: ____________________________________________

Title: Director, Pharmacy Services

Date: March 1, 2020

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.
Reviewed: 1/10 – removed failure on stimulant for narcolepsy, removed formulary alt.
Reviewed: 3/10 – annual review
Reviewed: 3/11/10 – annual review
Revised: 3/1/12 – annual review, updated signature
Reviewed: 6/5/12 – added generic modafinil to policy
Revised: 3/1/13 – annual review, updated logo & definitions, removed brand Provigil from policy
Reviewed: 11/15/13 – added shift-work disorder & fatigue assoc. with multiple sclerosis indications
Reviewed: 3/1/14 – annual review, updated formatting
Reviewed: 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
Applicable line of business:

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<th>Line of Business</th>
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<td>Commercial</td>
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<tr>
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<td></td>
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<tr>
<td>Medicare</td>
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<td>GHP Kids</td>
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POLICY:

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of formulary. The formulary is applied according to the formulary review process (see Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Part D Policy 143.0 D Geisinger Health Plan (GHP) and Geisinger Indemnity Insurance Company (GIIC) Formulary Development by the Pharmacy). The results of this process determine the development and application 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 all lines of business, unless a specific limitation or exception exists.

REQUIRED DEFINITIONS:

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

ADDITIONAL DEFINITIONS:

1. **Formulary** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. **Non-formulary products** – those medications that are not included in the Formulary.
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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

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
POLICY NUMBER: 120.0

POLICY AND PROCEDURE SECTION: Commercial Drug
PHARMACY SUBJECT: Ezetimibe/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.

Signed:_______________________________________________

Title: Director, Pharmacy Services

Date: March 1, 2020

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: 9/11 – added criteria for high dose simvastatin
Revised: 11/12 – annual review, updated signature
Revised: 8/21/12 – changed Lipitor to atorvastatin
Revised: 11/13 – annual review, updated logo and definitions, fixed typo, updated alternatives
Reviewed: 3/14 – annual review
Revised: 3/15 – annual review, updated signature
Revised: 3/16 – annual review, update policy formatting
Revised: 5/16 – updated format, logo, & procedure
Revised: 5/27/16 – updated Crestor to rosuvastatin
Revised: 3/17 – annual review, updated Zetia to ezetimibe
Revised: 3/18 – annual review, updated signature, updated Vytorin to ezetimibe/simvastatin
Reviewed: 3/19 – annual review
Revised: 3/20 – annual review, added GHP Kids
POLICY NUMBER: 121.0

POLICY AND PROCEDURE
PHARMACY
MANUAL

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

Applicable line of business:

<table>
<thead>
<tr>
<th>Line of Business</th>
<th>GHP X</th>
<th>Medicaid</th>
<th>Medicare</th>
<th>ACA X</th>
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</table>

POLICY:
Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of formulary. The formulary is applied according to the formulary review process (see Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Part D Policy 143.0 D Geisinger Health Plan (GHP) and Geisinger Indemnity Insurance Company (GIIC) Formulary Development by the Pharmacy). The results of this process determine the development and application 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 all lines of business, unless a specific limitation or exception exists.

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

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

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)

THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE STANDARDS 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: 121.0

POLICY AND PROCEDURE
PHARMACY
MANUAL

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

Signed:_______________________________________________
Title: Director, Pharmacy Services
Date: March 1, 2020

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: 3/11/11 – annual review; updated criteria and als. to reflect generics
Revised: 9/11 – added Lastacaft, removed epinastine (now generic), updated alternatives
Revised: 3/12 – annual review, updated signature, logo, fixed typo, updated alternatives
Revised: 3/13 – annual review, updated logo, definitions, and signature
Reviewed: 3/14 – annual review
Revised: 3/15 – annual review, updated signature
Reviewed: 3/16 – 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,
oloapatadine (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
POLICY AND PROCEDURE
PHARMACY
MANUAL

POLICY NUMBER: 124.0
SECTION: Commercial Drug
SUBJECT: Revlimid

Applicable line of business:

<table>
<thead>
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POLICY:
Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of formulary. The formulary is applied according to the formulary review process (see Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Part D Policy 143.0 D Geisinger Health Plan (GHP) and Geisinger Indemnity Insurance Company (GIIC) Formulary Development by the Pharmacy). The results of this process determine the development and application 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 all lines of business, unless a specific limitation or exception exists.

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

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

- Medical record documentation that Revlimid is prescribed by a hematologist/oncologist AND

For Myelodysplastic Syndromes (MDS)
- 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

For Multiple Myeloma
- Medical record documentation of a diagnosis of multiple myeloma
OR

For Non-Hodgkin Lymphomas (NHL)
• 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 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 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 of a diagnosis of marginal zone 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

QUANTITY LIMIT: Pharmacist note to CSR: Authorization should be entered by HICL and only checking the Formulary PA required box (no QLs need to be entered within the authorization).
• 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
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.

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: August 4, 2020

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
Reviewed: 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
Reviewed: 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
Reviewed: 8/4/20 – corrected typo
POLICY NUMBER: 125.0

SECTION: Commercial Drug
SUBJECT: Sprycel

Applicable line of business:

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POLICY:
Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is applied according to the formulary review process (see Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Part D Policy 143.0 D Geisinger Health Plan (GHP) and Geisinger Indemnity Insurance Company (GIIC) Formulary Development by the Pharmacy). The results of this process determine the development and application 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 all lines of business, unless a specific limitation or exception exists.

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

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

AUTHORIZATION DURATION: Treatment period will be defined as 12 months. Review will be every 12 months. Sprycel will no longer be covered if there is medical record documentation of disease progression.
QUANTITY LIMIT: Pharmacist note to CSR: Authorization should be entered by HICL and only checking the Formulary PA required box (no QLs need to be entered within the authorization).

- 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

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, 2020

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
POLICY:
Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of formulary. The formulary is applied according to the formulary review process (see Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Part D Policy 143.0 D Geisinger Health Plan (GHP) and Geisinger Indemnity Insurance Company (GIIC) Formulary Development by the Pharmacy). The results of this process determine the development and application 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 all lines of business, unless a specific limitation or exception exists.

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

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

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.

Signed: ______________________________
Title: Director, Pharmacy Services
Date: March 1, 2020
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
POLICY AND PROCEDURE
PHARMACY
MANUAL

POLICY NUMBER: 129.0
SECTION: Commercial Drug
SUBJECT: Apidra

Applicable line of business:

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POLICY:
Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of formulary. The formulary is applied according to the formulary review process (see Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Part D Policy 143.0 D Geisinger Health Plan (GHP) and Geisinger Indemnity Insurance Company (GIIC) Formulary Development by the Pharmacy). The results of this process determine the development and application 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 all lines of business, unless a specific limitation or exception exists.

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

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

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

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

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

Signed:_______________________________
Title: Director, Pharmacy Services
Date: March 1, 2020

Devised: 10/06
Reviewed: 3/07
Revised: 5/07 – added signature
Reviewed: 3/08 – annual review
Revised: 4/09 – annual review
Reviewed: 3/10 – annual review
Revised: 3/11/11 – annual review
Reviewed: 3/1/12 – annual review, updated signature
Revised: 3/1/13 – annual review, updated logo and definitions
Reviewed: 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, 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
Applicable line of business:

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POLICY:
Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of formulary. The formulary is applied according to the formulary review process (see Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Part D Policy 143.0 D Geisinger Health Plan (GHP) and Geisinger Indemnity Insurance Company (GIIC) Formulary Development by the Pharmacy). The results of this process determine the development and application 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 all lines of business, unless a specific limitation or exception exists.

REQUIRED DEFINITIONS:
1. **Attachment** – a supporting document that is developed and maintained by the policy writer or 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).
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 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

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
Novo Nordisk insulins: Novolin N, Novolin R, Novolin 70/30, Novolog, Novolog 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.
Signed: __________________________________________________________________________

Title: Director, Pharmacy Services

Date: March 1, 2020

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
Reviewed: 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
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POLICY:
Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of formulary. The formulary is applied according to the formulary review process (see Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Part D Policy 143.0 D Geisinger Health Plan (GHP) and Geisinger Indemnity Insurance Company (GIIC) Formulary Development by the Pharmacy). The results of this process determine the development and application 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 all lines of business, unless a specific limitation or exception exists.

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

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

QUANTITY LIMIT: Pharmacist note to CSR: Authorization should be entered by HICL and only checking the Formulary box (no QLs need to be entered within the authorization).

- 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.

FORMULARY ALTERNATIVES:
metformin, glyburide, glipizide, glipizide sustained-release, chlorpropamide, glimepiride, acarbose, Glyset, repaglinide, pioglitazone, Avandia*, Jardiance, Synjardy, Invokana, Invokamet, Tradjenta, Jentadueto, Glyxambi, Ozempic, Victoza, Xultophy*, Lantus, Toujeo, Tresiba, Leveimir, Rybelsus
NovoNordisk insulins: Novolin N, Novolin R, Novolin 70/30, Novolog, Novolog 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, 2020

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: 3/11 – annual review
Revised: 3/12 – annual review, updated signature
Revised: 6/21/12 – added Bydureon to policy
Revised: 3/13 – annual review, updated logo and definitions, updated alternatives
Revised: 1/2/14 – added failure of Victoza to Byetta criteria, updated formulary alternatives
Revised: 3/14 – 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
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 authorization, 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: 01/28/20 – added failure of Rybelus and updated FA
Reviewed: 3/1/20 – annual review, added GHP Kids
Applicable line of business:

<table>
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<tr>
<th>Line of Business</th>
<th>Commercial</th>
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<th>GHP Kids</th>
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POLICY:
Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of formulary. The formulary is applied according to the formulary review process (see Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Part D Policy 143.0 D Geisinger Health Plan (GHP) and Geisinger Indemnity Insurance Company (GIIC) Formulary Development by the Pharmacy). The results of this process determine the development and application 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 all lines of business, unless a specific limitation or exception exists.

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

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

AUTHORIZATION DURATION: Each treatment period will be defined as 12 months. Review will occur every 12 months. Nexavar will no longer be covered if there is medical record documentation of disease progression.

QUANTITY LIMIT: Pharmacist note to CSR: Authorization should be entered by HICL and only checking the Formulary PA required box (no(QLs need to be entered within the authorization).

- 4 tablets per day, 30 day supply per fill

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.

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, 2020

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: 3/01/11 – annual review
Revised: 3/01/12 – annual review, updated signature
Revised: 3/01/13 – annual review, updated logo and definitions
Revised: 3/01/14 – annual review, updated formatting, corrected typo, added approval statement
Revised: 3/01/15 – annual review, updated signature
Reviewed: 3/01/16 – 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
Reviewed: 6/1/18 – added QL
Revised: 3/1/19 – annual review, added QL approval note
Revised: 3/1/20 – annual review, added GHP Kids
POLICY: Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of formulary. The formulary is applied according to the formulary review process (see Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Part D Policy 143.0 D Geisinger Health Plan (GHP) and Geisinger Indemnity Insurance Company (GIIC) Formulary Development by the Pharmacy). The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for Sutent for GHP members who have prescription drug benefits, including all lines of business, unless a specific limitation or exception exists.

REQUIRED DEFINITIONS:
1. **Attachment** – a supporting document that is developed and maintained by the policy writer or 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).
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 Sutent may be made for members who meet all the following criteria:

**Gastrointestinal Stromal Tumor (GIST)**
- Medical record documentation that Sutent 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 Sutent 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 Sutent is prescribed by an oncologist AND
- Medical record documentation of a diagnosis of advanced renal cell carcinoma
Renal Cell Carcinoma, adjuvant treatment

- Medical record documentation that Sutent 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.

**QUANTITY LIMIT:** Pharmacist note to CSR: *Authorization should be entered by HICL and only checking the Formulary PA required box (no QLs need to be entered within the authorization).*

- 1 capsule per day, 28 day supply per fill

**AUTHORIZATION DURATION:** Each treatment period will be defined as 12 months. Review will occur every 12 months. Sutent will no longer be covered if there is medical record documentation of disease progression.

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

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.
Signed:_______________________________________________

Title: Director, Pharmacy Services

Date: March 1, 2020

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
Reviewed: 3/1/13 – annual review, updated logo and definitions
Revised: 3/1/14 – annual review, corrected typo, added approval statement
Reviewed: 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
### POLICY NUMBER: 135.0

**POLICY AND PROCEDURE**  
**PHARMACY**  
**MANUAL**

**SECTION:** Commercial Drug  
**SUBJECT:** Ranolazine ER

**Applicable line of business:**

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<th>Line of Business</th>
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**POLICY:**
Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of formulary. The formulary is applied according to the formulary review process (see Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Part D Policy 143.0 D Geisinger Health Plan (GHP) and Geisinger Indemnity Insurance Company (GIIC) Formulary Development by the Pharmacy). The results of this process determine the development and application 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 all lines of business, unless a specific limitation or exception exists.

**REQUIRED DEFINITIONS:**

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

**ADDITIONAL DEFINITIONS:**

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

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

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

Signed: ________________________________
Title: Director, Pharmacy Services
Date: March 1, 2020

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: 3/11 – annual review
Revised: 3/12 – annual review, updated signature
Revised: 3/13 – annual review, updated logo and definitions
Revised: 3/14 – annual review, updated formatting, added approval statement
Revised: 3/15 – annual review, updated signature
Reviewed: 3/16 – annual review
Revised: 5/16 – updated format, logo, & procedure
Revised: 3/17 – annual review
Revised: 3/18 – annual review, updated signature, updated format of prescriber criteria
Reviewed: 3/19 – annual review
Revised: 11/21/19 – updated Ranexa to generic ranolazine ER
Revised: 3/1/20 – annual review, added GHP Kids
Applicable line of business:

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<tr>
<th>Line of Business</th>
<th>Commercial</th>
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<th>GHP Kids</th>
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POLICY:
Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of formulary. The formulary is applied according to the formulary review process (see Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Part D Policy 143.0 D Geisinger Health Plan (GHP) and Geisinger Indemnity Insurance Company (GIIC) Formulary Development by the Pharmacy). The results of this process determine the development and application 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 all lines of business, unless a specific limitation or exception exists.

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

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

QUANTITY LIMIT: Pharmacist note to CSR: Authorization should be entered by HICL and only checking the Formulary PA required box (no QLs need to be entered within the authorization).
- 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.
THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND FEDERAL REGULATORY ENTITIES.

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

Signed:_______________________________________________
Title: Director, Pharmacy Services
Date: March 1, 2020

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: 3/11 – annual review-updated criteria to add metabolic specialist
Revised: 3/12 – annual review, updated signature
Revised: 3/13 – annual review, updated logo and definitions, updated alternatives
Revised: 3/14 – annual review, updated formatting, added approval statement
Revised: 3/15 – annual review, updated signature
Revised: 3/16 – annual review
Revised: 5/16 – updated format, logo, & procedure
Reviewed: 3/17 – annual review
Revised: 3/18 – annual review, updated signature
Revised: 6/18 – added QL
Revised: 3/19 – annual review, added QL approval note
Revised: 11/21/19 – updated Zavesca to generic miglustat
Revised: 3/20 – annual review, added GHP Kids
POLICY NUMBER: 140.0

SECTION: Commercial Drug
SUBJECT: Quinine Sulfate

Applicable line of business:

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<th>Line of Business</th>
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POLICY:
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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).
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 quinine sulfate may be made for members who meet the following criteria:

- Medical record documentation of a diagnosis of malaria or babesiosis

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, Daraprim, chloroquine, mefloquine

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

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

Signed:_______________________________________________
Title: Director, Pharmacy Services
Date: March 1, 2020
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 Qualaquin to quinine sulfate, removed Fansidar from alternatives 
Reviewed: 3/1/16 – annual review 
Revised: 5/1/16 – updated format, logo, & procedure, updated Qualaquin 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
POLICY AND PROCEDURE
PHARMACY
MANUAL

POLICY NUMBER: 141.0
SECTION: Commercial Drug
SUBJECT: Januvia

Applicable line of business:

<table>
<thead>
<tr>
<th>Line of Business</th>
<th>Medicaid</th>
<th>Medicare</th>
<th>ACA</th>
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POLICY:
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REQUIRED DEFINITIONS:
1. **Attachment** – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. **Exhibit** – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. **Devised** – the date the policy was implemented.
4. **Revised** – the date of every revision to the policy, including typographical and grammatical changes.
5. **Reviewed** – the date documenting the annual review if the policy has no revisions necessary.

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C. In accordance with current standards of medical practice;
D. Not primarily for the convenience of the Member, or the Member’s Provider; and
E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services 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

QUANTITY LIMIT: Pharmacist note to CSR: Authorization should be entered by HICL and only checking the Formulary box (no QLs need to be entered within the authorization).
- 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

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

THIS POLICY WILL BE REVISED AS NECESSARY AND REVIEWED NO LESS THAN ANNUALLY.
Signed: _____________________________________________

Title: Director, Pharmacy Services

Date: March 1, 2020

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: 3/1/16 – 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
Applicable line of business:

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POLICY:

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of formulary. The formulary is applied according to the formulary review process (see Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Part D Policy 143.0 D Geisinger Health Plan (GHP) and Geisinger Indemnity Insurance Company (GIIC) Formulary Development by the Pharmacy). The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for Noxafil for GHP members who have prescription drug benefits, including all lines of business, unless a specific limitation or exception exists.

REQUIRED DEFINITIONS:

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

ADDITIONAL DEFINITIONS:

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

PROCEDURE:
An exception for coverage of Noxafil 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 that Noxafil 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

OR
- Medical record documentation of treatment of oropharyngeal candidiasis with therapeutic failure on, contraindication to, or intolerance to fluconazole* or itraconazole*

QUANTITY LIMIT: Enter by GPID.
- 100 mg tablets: one-time, one week authorization for QL 93 tablets per 30 days, for the remainder of the authorization, the QL of 90 tablets per 30 days will apply
- 200 mg/5 mL suspension: 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 oropharyngeal candidiasis: One-time, 28 days authorization

If an exception is made, Noxafil will be paid for under the member’s prescription drug benefit.
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, 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, 2020

Devised: 5/07
Reviewed: 3/08 – annual review
Reviewed: 4/09 – annual review
Reviewed: 3/10 – annual review
Reviewed: 3/1/11 – annual review
Reviewed: 3/1/12 – annual review, updated signature & alternatives
Reviewed: 3/1/13 – annual review, updated logo and definitions, updated alternatives
Reviewed: 3/1/14 – annual review, added approval statement
Reviewed: 3/1/15 – annual review, update signature
Reviewed: 3/1/16 – annual review
Reviewed: 5/1/16 – updated format, logo, & procedure
Reviewed: 3/1/17 – annual review
Reviewed: 3/1/18 – annual review, updated signature, updated formatting
Reviewed: 3/1/19 – annual review
Reviewed: 5/29/19 – added auth duration and QL
Reviewed: 3/1/20 – annual review, added GHP Kids
Applicable line of business:

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POLICY:

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of formulary. The formulary is applied according to the formulary review process (see Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Part D Policy 143.0 D Geisinger Health Plan (GHP) and Geisinger Indemnity Insurance Company (GIIC) Formulary Development by the Pharmacy). The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for Bravelle for GHP members who have prescription drug benefits, including all lines of business, unless a specific limitation or exception exists.

REQUIRED DEFINITIONS:

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

- Medical record documentation that Bravelle 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
  - Bravelle 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 Bravelle 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 Bravelle 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

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

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

Date: March 1, 2020

Devised: 5/07
Reviewed: 3/08 – annual review
Reviewed: 4/09 – annual review
Reviewed: 3/10 – annual review
Reviewed: 3/1/11 – annual review
Reviewed: 3/1/12 – annual review, updated signature
Reviewed: 3/1/13 – annual review, updated logo and definitions
Reviewed: 3/1/14 – annual review, added approval statement
Reviewed: 3/1/15 – annual review, updated signature
Reviewed: 3/1/16 – annual review, updated policy formatting
Reviewed: 5/1/16 – updated format, logo, & procedure
Reviewed: 3/1/17 – annual review
POLICY NUMBER: 143.0

SECTION: Commercial Drug
SUBJECT: Bravelle

Revised: 3/1/18 – annual review, updated signature, updated FA (Repronex D/C)
Reviewed: 3/1/19 – annual review
Revised: 9/20/19 – removed PA from Gonal-F, replaced existing PA criteria with new criteria
Revised: 3/1/20 – annual review, added GHP Kids
POLICY NUMBER: 147.0

SECTION: Commercial Drug

SUBJECT: Epogen, Procrit, Aranesp, and Retacrit

Applicable line of business:

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REQUIRED DEFINITIONS:

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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/dL 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 100 ng/mL or transferrin saturation level 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 100 ng/mL or transferrin saturation level 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.

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

Response (hemoglobin increase by 1 g/dL) → Titrate dosage to maintain optimal hemoglobin (11-12 g/dL)

No response at 4 weeks for epoetin alfa and 6 weeks for darbepoetin → Increase dose of erythropoietic agent +/- iron supplementation as indicated

Response (hemoglobin increase by 1 g/dL) at 8-12 wks → Titrate dosage to maintain optimal hemoglobin (11-12 g/dL)

Stable hemoglobin level (within 1-2 g/dL of baseline) while receiving chemotherapy → Continue erythropoietic therapy

No hemoglobin response at 8-12 wks → Discontinue erythropoietic therapy

Transfuse as indicated based upon symptoms and institutional guidelines

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.
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:
Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of formulary. The formulary is applied according to the formulary review process (see Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Part D Policy 143.0 D Geisinger Health Plan (GHP) and Geisinger Indemnity Insurance Company (GIIC) Formulary Development by the Pharmacy). The results of this process determine the development and application 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 all lines of business, unless a specific limitation or exception exists.

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

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

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

THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE STANDARDS 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: 148.0

SECTION: Commercial Drug
SUBJECT: Paliperidone Extended Release

Signed: ____________________________________________

Title: Director, Pharmacy Services

Date: March 1, 2020

Devised: 7/07
Reviewed: 3/08 – annual review
Revised: 4/09 – annual review, updated alt.
Reviewed: 3/10 – annual review
Revised: 3/1/11 – annual review
Reviewed: 3/1/12 – annual review, updated signature & alternatives
Revised: 3/1/13 – annual review, updated logo and definitions, updated alternatives
Reviewed: 3/1/14 – annual review, added approval statement
Revised: 3/1/15 – annual review, updated signature
Reviewed: 3/1/16 – annual review, updated policy formatting, changed Abilify to aripiprazole
Revised: 5/1/16 – updated format, logo, & procedure, changed Seroquel to quetiapine
Reviewed: 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
Applicable line of business:

<table>
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<tr>
<th>Line of Business</th>
<th>Commercial</th>
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<th>GHP Kids</th>
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**POLICY:**
Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of formulary. The formulary is applied according to the formulary review process (see Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Part D Policy 143.0 D Geisinger Health Plan (GHP) and Geisinger Indemnity Insurance Company (GIIC) Formulary Development by the Pharmacy). The results of this process determine the development and application 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 all lines of business, unless a specific limitation or exception exists.

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

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

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.

Signed: ________________________________
Title: Director, Pharmacy Services
Date: March 1, 2020

Devised: 7/07
Reviewed: 3/08 – Annual review
Reviewed: 4/09 – annual review
Reviewed: 3/10 – annual review
Reviewed: 3/11 – annual review
Reviewed: 3/12 – annual review, updated signature
Reviewed: 3/13 – annual review, updated logo & definitions
Reviewed: 3/14 – annual review, added approval statement
Reviewed: 3/15 – annual review, updated signature, updated formatting
Reviewed: 3/16 – annual review, removed extra roman numeral from FA
Reviewed: 5/16 – updated format, logo, & procedure
Reviewed: 3/17 – annual review, updated FA
Reviewed: 3/18 – annual review, updated signature
Reviewed: 3/19 – annual review
Reviewed: 3/20 – annual review, added GHP Kids
POLICY: Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of formulary. The formulary is applied according to the formulary review process (see Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Part D Policy 143.0 D Geisinger Health Plan (GHP) and Geisinger Indemnity Insurance Company (GIIC) Formulary Development by the Pharmacy). The results of this process determine the development and application 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 all lines of business, unless a specific limitation or exception exists.

REQUIRED DEFINITIONS:
1. **Attachment** – a supporting document that is developed and maintained by the policy writer or 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).
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   A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
   B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
C. In accordance with current standards of medical practice;
D. Not primarily for the convenience of the Member, or the Member's Provider; and
E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to 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

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.

QUANTITY LIMIT: Pharmacist note to CSR: Authorization should be entered by HICL and only checking the Formulary PA required box (no QLs need to be entered within the authorization).

- 4 capsules per day, 30 day supply per fill

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, 2020

Devised: 7/07
Reviewed: 3/08 – annual review
Reviewed: 4/09 – annual review
Reviewed: 3/10 – annual review
Reviewed: 3/11 – annual review
Reviewed: 3/12 – annual review, updated signature
Reviewed: 3/13 – annual review, updated logo and definitions
Reviewed: 3/14 – annual review, updated formatting, added approval statement
Reviewed: 3/15 – annual review, updated signature
Reviewed: 3/16 – annual review, updated policy formatting
Reviewed: 5/16 – updated format, logo, & procedure
Reviewed: 3/17 – annual review
Reviewed: 10/10/17 – added authorization duration
Reviewed: 3/18 – annual review, updated signature & format, added grandfather language
Reviewed: 6/18 – added QL
Reviewed: 3/19 – annual review, added QL approval note
Reviewed: 3/20 – annual review, added GHP Kids
POLICY NUMBER: 154.0

SECTION: Commercial Drug
SUBJECT: Aliskiren

Applicable line of business:

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POLICY:
Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of formulary. The formulary is applied according to the formulary review process (see Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Part D Policy 143.0 D Geisinger Health Plan (GHP) and Geisinger Indemnity Insurance Company (GIIC) Formulary Development by the Pharmacy). The results of this process determine the development and application 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 all lines of business, unless a specific limitation or exception exists.

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).
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. **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)

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
- **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, 2020

Devised: 10/07
Revised: 3/08 – annual review; updated alternatives
Revised: 3/10 – added Valturna to policy
Reviewed: 4/10 – updated alternatives
Revised: 3/11 – annual review
Revised: 3/12 – annual review, updated signature and alternatives
Revised: 3/13 – annual review, updated logo and definitions
Revised: 3/14 – annual review, updated formatting, added valsartan/hctz to FA, corrected two typos, Valturna D/C by manufacturer and removed from policy
Revised: 3/15 – annual review, updated signature, added irbesartan & irbesartan/hctz as FA
Reviewed: 3/16 – annual review
Revised: 5/16 – updated format, logo, & procedure, added ACE & ARB to definitions
Revised: 3/17 – annual review, updated FA
Revised: 3/18 – annual review, updated signature, corrected typo, updated FA
Revised: 3/19 – annual review, defined abbreviations
Revised: 11/21/19 – updated Tekturna to generic Aliskiren
Revised: 3/1/20 – annual review, added GHP Kids
Applicable line of business:

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**POLICY:**
Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of formulary. The formulary is applied according to the formulary review process (see Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Part D Policy 143.0 D Geisinger Health Plan (GHP) and Geisinger Indemnity Insurance Company (GIIC) Formulary Development by the Pharmacy). The results of this process determine the development and application 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 all lines of business, unless a specific limitation or exception exists.

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

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

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

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

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

Title: Director, Pharmacy Services

Date: March 1, 2020

Devised: 10/07
Reviewed: 3/08 – annual review
Reviewed: 4/09 – annual review
Reviewed: 3/10 – annual review
Reviewed: 3/11/11 – 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
POLICY AND PROCEDURE
PHARMACY
MANUAL

POLICY NUMBER: 159.0

SECTION: Commercial Drug
SUBJECT: Amlodipine/valsartan and Amlodipine/valsartan/hctz

Applicable line of business:

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<thead>
<tr>
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POLICY:
Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of formulary. The formulary is applied according to the formulary review process (see Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Part D Policy 143.0 D Geisinger Health Plan (GHP) and Geisinger Indemnity Insurance Company (GIIC) Formulary Development by the Pharmacy). The results of this process determine the development and application 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 all lines of business, unless a specific limitation or exception exists.

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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3. **Devised** – the date the policy was implemented.
4. **Revised** – the date of every revision to the policy, including typographical and grammatical changes.
5. **Reviewed** – the date documenting the annual review if the policy has no revisions necessary.

ADDITIONAL DEFINITIONS:

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

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

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

Signed: __________________________________________________________________________

Title: Director, Pharmacy Services

Date: March 1, 2020

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
Applicable line of business:

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POLICY:
Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of formulary. The formulary is applied according to the formulary review process (see Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Part D Policy 143.0 D Geisinger Health Plan (GHP) and Geisinger Indemnity Insurance Company (GIIC) Formulary Development by the Pharmacy). The results of this process determine the development and application 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 all lines of business, unless a specific limitation or exception exists.

REQUIRED DEFINITIONS:
1. Attachment – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. Exhibit – a 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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ADDITIONAL DEFINITIONS:
1. Formulary – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. Non-formulary products – those medications that are not included in the Formulary.
3. Healthcare provider – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
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
• 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.

**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.

AUTHORIZATION DURATION: 6 months

NEULASTA/FULPHILA/ZIEXTENZO/UDENYCA QUANTITY LIMIT: Pharmacist note to CSR: Authorization should be entered by HICL and only checking the Formulary PA required box (no QLs need to be entered within the authorization).

- 1 syringe per 14 days (0.043 mL per day)

If an exception is made, Neupogen, Neulasta, Fulphila, 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 NUMBER: 162.0

SECTION: Commercial Drug Pharmacy

SUBJECT: Neupogen, Neulasta, Fulphila, Udenyca, Ziextenzo, Leukine, Zarxio, Granix, and Nivestym

Signed: ____________________________________________________________

Title: Director, Pharmacy Services

Date: July 28, 2020

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: 12/28/15 – add: “uses supported by clinical guidelines” to policy
Reviewed: 3/1/16 – annual review, added Zarxio to approval statement
Reviewed: 5/1/16 – updated format, logo, & procedure
Reviewed: 3/1/17 – annual review
Reviewed: 3/1/18 – annual review, updated signature
Reviewed: 6/1/18 – updated TC regimen, added notes regarding 20% risk regimens not listed, added additional risk factors to primary prophylaxis, added hospitalized treatment to 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
Applicable line of business:

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POLICY:
Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of formulary. The formulary is applied according to the formulary review process (see Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Part D Policy 143.0 D Geisinger Health Plan (GHP) and Geisinger Indemnity Insurance Company (GIIC) Formulary Development by the Pharmacy). The results of this process determine the development and application 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 all lines of business, unless a specific limitation or exception exists.

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

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

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.

Signed: _________________________________
Title: Director, Pharmacy Services
Date: March 1, 2020

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
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, corrected typo
Reviewed: 3/1/19 – annual review
Revised: 3/1/20 – annual review, added GHP Kids
POLICY NUMBER: 164.0

POLICY AND PROCEDURE
PHARMACY
MANUAL

SECTION: Commercial Drug
SUBJECT: Veregen

Applicable line of business:

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POLICY:
Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of formulary. The formulary is applied according to the formulary review process (see Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Part D Policy 143.0 D Geisinger Health Plan (GHP) and Geisinger Indemnity Insurance Company (GIIC) Formulary Development by the Pharmacy). The results of this process determine the development and application 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 all lines of business, unless a specific limitation or exception exists.

REQUIRED DEFINITIONS:
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E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services 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)

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, 2020

Devised: 5/08
Reviewed: 4/09 – annual review
Reviewed: 3/10 – annual review
Revised: 3/11 – annual review-updated with generic Aldara
Revised: 3/12 – annual review, updated signature
Revised: 3/13 – annual review, updated logo and definitions
Revised: 10/7/13 – removed Neupro from policy
Revised: 3/14 – annual review, updated formatting
Revised: 3/15 – annual review, updated signature
Reviewed: 3/16 – annual review
Reviewed: 5/16 – updated format, logo, & procedure
Reviewed: 3/17 – annual review
Revised: 3/18 – annual review, updated signature, updated criteria format
Reviewed: 3/19 – annual review
Reviewed: 3/20 – annual review, added GHP Kids
POUCH POLICY: Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of formulary. The formulary is applied according to the formulary review process (see Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Part D Policy 143.0 D Geisinger Health Plan (GHP) and Geisinger Indemnity Insurance Company (GIIC) Formulary Development by the Pharmacy). The results of this process determine the development and application 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 all lines of business, unless a specific limitation or exception exists.

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

QUANTITY LIMIT: 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

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: November 18, 2020

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, updated 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
Applicable line of business:

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<tr>
<th>Line of Business</th>
<th>Commercial</th>
<th>Medicaid</th>
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<th>ACA</th>
<th>GHP Kids</th>
</tr>
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POLICY:
Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of formulary. The formulary is applied according to the formulary review process (see Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Part D Policy 143.0 D Geisinger Health Plan (GHP) and Geisinger Indemnity Insurance Company (GIIC) Formulary Development by the Pharmacy). The results of this process determine the development and application 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 all lines of business, unless a specific limitation or exception exists.

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

ADDITIONAL DEFINITIONS:
1. **Formulary** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. **Non-formulary products** – those medications that are not included in the Formulary.
3. **Healthcare provider** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
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;
POLICY NUMBER: 167.0

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

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

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

THIS POLICY WILL BE REVISED AS NECESSARY AND REVIEWED NO LESS THAN ANNUALLY.
Signed: ____________________________________________

Title: Director, Pharmacy Services

Date: March 1, 2020

Devised: 5/08
Reviewed: 4/09 – annual review
Reviewed: 3/10 – annual review
Reviewed: 6/10 – updated criteria to include pulm/cardio
Reviewed: 3/1/11 – annual review
Reviewed: 3/1/12 – annual review, updated signature & alternatives
Reviewed: 3/1/13 – annual review, updated logo and definitions
Reviewed: 3/1/14 – annual review, updated policy title based on generic availability
Reviewed: 9/22/14 – added Tracleer criteria, removed Tracleer as FA, updated signature
Reviewed: 3/1/15 – annual review
Reviewed: 3/1/16 – annual review
Reviewed: 5/1/16 – updated format, logo, & procedure
Reviewed: 7/21/16 – removed in combination with Tracleer
Reviewed: 3/1/17 – annual review, clarified that policy is for generic Revatio
Reviewed: 3/1/18 – annual review, updated signature, updated prescriber criteria
Reviewed: 3/1/19 – annual review
Reviewed: 3/1/20 – annual review, added GHP Kids
Applicable line of business:

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POLICY:
Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of formulary. The formulary is applied according to the formulary review process (see Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Part D Policy 143.0 D Geisinger Health Plan (GHP) and Geisinger Indemnity Insurance Company (GIIC) Formulary Development by the Pharmacy). The results of this process determine the development and application 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 all lines of business, unless a specific limitation or exception exists.

REQUIRED DEFINITIONS:

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

ADDITIONAL DEFINITIONS:

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

QUANTITY LIMIT: Pharmacist note to CSR: Authorization should be entered by HICL and only checking the Formulary PA required box (no QLs need to be entered within the authorization).

- 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.

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, 2020

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
POLICY NUMBER: 169.0

SECTION: Commercial Drug
SUBJECT: Ventavis

Applicable line of business:

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POLICY:
Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of formulary. The formulary is applied according to the formulary review process (see Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Part D Policy 143.0 D Geisinger Health Plan (GHP) and Geisinger Indemnity Insurance Company (GIIC) Formulary Development by the Pharmacy). The results of this process determine the development and application 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 all lines of business, unless a specific limitation or exception exists.

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

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

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*, Tracleer*

*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: John Miller

Title: Director, Pharmacy Services

Date: March 1, 2020

Devised: 5/08
Reviewed: 4/09 – annual review
Reviewed: 3/10 – annual review
Revised: 6/10 – updated criteria to include pulm/cardio
Reviewed: 3/11/11 – 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
POLICY:
Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of formulary. The formulary is applied according to the formulary review process (see Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Part D Policy 143.0 D Geisinger Health Plan (GHP) and Geisinger Indemnity Insurance Company (GIIC) Formulary Development by the Pharmacy). The results of this process determine the development and application 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 all lines of business, unless a specific limitation or exception exists.

REQUIRED DEFINITIONS:
1. **Attachment** – a supporting document that is developed and maintained by the policy writer or 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).
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 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)

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.

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, 2020

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 treprostinil, updated all others w/ available generics
Revised: 3/1/20 – annual review, added GHP Kids
POLICY: Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of formulary. The formulary is applied according to the formulary review process (see Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Part D Policy 143.0 D Geisinger Health Plan (GHP) and Geisinger Indemnity Insurance Company (GIIC) Formulary Development by the Pharmacy). The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for Kuvan for GHP members who have prescription drug benefits, including all lines of business, unless a specific limitation or exception exists.

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

ADDITIONAL DEFINITIONS:
1. **Formulary** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. **Non-formulary products** – those medications that are not included in the Formulary.
3. **Healthcare provider** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
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;
PROCEDURE:
An exception for coverage of Kuvan may be made for members who meet the following criteria:

- Medical record documentation that Kuvan 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 µmol/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

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 Kuvan 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

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

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

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, 2020

Devised: 7/08
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 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
Applicable line of business:

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POLICY:
Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of formulary. The formulary is applied according to the formulary review process (see Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Part D Policy 143.0 D Geisinger Health Plan (GHP) and Geisinger Indemnity Insurance Company (GIIC) Formulary Development by the Pharmacy). The results of this process determine the development and application 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 all lines of business, unless a specific limitation or exception exists.

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).
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 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

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.

Signed: ________________________________
Title: Director, Pharmacy Services
Date: March 1, 2020
Applicable line of business:

<table>
<thead>
<tr>
<th>Line of Business</th>
<th>Commercial</th>
<th>Medicaid</th>
<th>Medicare</th>
<th>ACA</th>
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POLICY:

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of formulary. The formulary is applied according to the formulary review process (see Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Part D Policy 143.0 D Geisinger Health Plan (GHP) and Geisinger Indemnity Insurance Company (GIIC) Formulary Development by the Pharmacy). The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for Tasigna for GHP members who have prescription drug benefits, including all lines of business, unless a specific limitation or exception exists.

REQUIRED DEFINITIONS:

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

ADDITIONAL DEFINITIONS:

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

AUTHORIZATION DURATION: Re-review for disease progression every 12 months. Tasigna will no longer be covered if disease progresses.

QUANTITY LIMIT: Pharmacist note to CSR: Authorization should be entered by HICL and only checking the Formulary PA required box (no QLs need to be entered within the authorization).

- 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
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.

Signed:_______________________________________________
Title: Director, Pharmacy Services
Date: March 1, 2020

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
POLICY:
Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of formulary. The formulary is applied according to the formulary review process (see Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Part D Policy 143.0 D Geisinger Health Plan (GHP) and Geisinger Indemnity Insurance Company (GIIC) Formulary Development by the Pharmacy). The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for Tykerb for GHP members who have prescription drug benefits, including all lines of business, unless a specific limitation or exception exists.

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

ADDITIONAL DEFINITIONS:
1. Formulary – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. Non-formulary products – those medications that are not included in the Formulary.
3. Healthcare provider – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
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 Tykerb may be made for members who meet the following criteria:

- Medical record documentation that Tykerb 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)

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.

QUANTITY LIMIT: Pharmacist note to CSR: Authorization should be entered by HICL and only checking the Formulary PA required box (no QLs need to be entered within the authorization).
- 6 tablets per day, 30 day supply per fill
If a formulary exception is approved Tykerb will be paid for under the member’s prescription drug benefit.

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, 2020
Applicable line of business:

<table>
<thead>
<tr>
<th>Line of Business</th>
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POLICY:
Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of formulary. The formulary is applied according to the formulary review process (see Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Part D Policy 143.0 D Geisinger Health Plan (GHP) and Geisinger Indemnity Insurance Company (GIIC) Formulary Development by the Pharmacy). The results of this process determine the development and application 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 all lines of business, unless a specific limitation or exception exists.

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

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

QUANTITY LIMIT: 3 tablets per day

AUTHORIZATION DURATION: 3 days, RX count 1

OR

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

OR

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

**QUANTITY LIMIT:** 3 tablets per day

**AUTHORIZATION DURATION:** 14 days, RX count 1, maximum 14 day supply, 3 tablets per day.

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

**QUANTITY LIMIT:** 3 tablets per day

**AUTHORIZATION DURATION:** 14 days, RX count 1, maximum 14 day supply, 3 tablets per day.

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, 2020

Devised: 11/08
Reviewed: 4/09 – annual review
Reviewed: 3/10 – annual review
Reviewed: 4/10 – updated criteria to include HE and updated alternatives
Reviewed: 3/11 – annual review
Reviewed: 3/12 – annual review, updated signature & alternatives
Reviewed: 3/13 – annual review, updated logo and definitions
Reviewed: 3/14 – annual review, updated formatting
Reviewed: 3/15 – annual review, updated signature
Reviewed: 9/18/15 – added IBS-D indication criteria, updated formulary alternatives
Reviewed: 3/16 – annual review
Reviewed: 5/16 – updated format, logo, & procedure
Reviewed: 3/17 – annual review, removed Unicode characters
Reviewed: 3/18 – annual review, updated signature, updated criteria format of travelers’ diarrhea
Reviewed: 3/19 – annual review, defined abbreviations, added IBS-D note
Reviewed: 5/24/19 – updated policy format, added QL/duration & clarified 1 FQ for travelers’ diarrhea
Reviewed: 7/24/19 – corrected typo, added SIBO indication
Reviewed: 01/21/20- updated authorization duration
Reviewed: 3/1/20 – annual review, added GHP Kids
Applicable line of business:

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<th>Line of Business</th>
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POLICY:
Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of formulary. The formulary is applied according to the formulary review process (see Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Part D Policy 143.0 D Geisinger Health Plan (GHP) and Geisinger Indemnity Insurance Company (GIIC) Formulary Development by the Pharmacy). The results of this process determine the development and application 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 all lines of business, unless a specific limitation or exception exists.

REQUIRED DEFINITIONS:
1. Attachment – a supporting document that is developed and maintained by the policy writer or 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.
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C. In accordance with current standards of medical practice;
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E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services 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

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

THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE STANDARDS 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: 179.0
SECTION: Commercial Drug
SUBJECT: Lidocaine Patch

Applicable line of business:

<table>
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<tr>
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<th>ACA</th>
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POLICY:
Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of formulary. The formulary is applied according to the formulary review process (see Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Part D Policy 143.0 D Geisinger Health Plan (GHP) and Geisinger Indemnity Insurance Company (GIIC) Formulary Development by the Pharmacy). The results of this process determine the development and application 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 all lines of business, unless a specific limitation or exception exists.

REQUIRED DEFINITIONS:
1. **Attachment** – a supporting document that is developed and maintained by the policy writer or 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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C. In accordance with current standards of medical practice;
D. Not primarily for the convenience of the Member, or the Member’s Provider; and
E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services 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)

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.

Signed: ________________________________________________
Title: Director, Pharmacy Services
Date: March 1, 2020
POLICY NUMBER: 180.0

SECTION: Commercial Drug
SUBJECT: Sumatriptan/Naproxen

Applicable line of business:

<table>
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<tr>
<th></th>
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POLICY:
Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of formulary. The formulary is applied according to the formulary review process (see Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Part D Policy 143.0 D Geisinger Health Plan (GHP) and Geisinger Indemnity Insurance Company (GIIC) Formulary Development by the Pharmacy). The results of this process determine the development and application 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 all lines of business, unless a specific limitation or exception exists.

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

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

QUANTITY LIMIT: 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.

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, 2020

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
POLICY NUMBER: 182.0

SECTION: Commercial Drug

SUBJECT: Amlodipine/Olmesartan

Applicable line of business:

<table>
<thead>
<tr>
<th>Commercial</th>
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<td>ACA</td>
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<td>GHP Kids</td>
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POLICY:
Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of formulary. The formulary is applied according to the formulary review process (see Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Part D Policy 143.0 D Geisinger Health Plan (GHP) and Geisinger Indemnity Insurance Company (GIIC) Formulary Development by the Pharmacy). The results of this process determine the development and application 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 all lines of business, unless a specific limitation or exception exists.

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

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

Signed:_______________________________________________
Title: Director, Pharmacy Services
POLICY AND PROCEDURE
PHARMACY
MANUAL

Applicable line of business:

<table>
<thead>
<tr>
<th>Line of Business</th>
<th>Medicaid</th>
<th>ACA</th>
<th>GHP Kids</th>
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</tr>
<tr>
<td>Medicare</td>
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<td>X</td>
</tr>
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</table>

POLICY:
Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of formulary. The formulary is applied according to the formulary review process (see Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Part D Policy 143.0 D Geisinger Health Plan (GHP) and Geisinger Indemnity Insurance Company (GIIC) Formulary Development by the Pharmacy). The results of this process determine the development and application 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 all lines of business, unless a specific limitation or exception exists.

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

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

**QUANTITY LIMIT:** Pharmacist note to CSR: Authorization should be entered by HICL and only checking the Formulary PA required box (no QLs need to be entered within the authorization).
- 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
THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE
STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND
FEDERAL REGULATORY ENTITIES.

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

Signed: ____________________________________________

Title: Director, Pharmacy Services

Date: March 1, 2020

Devised: 4/09
Reviewed: 3/10
Reviewed: 3/1/11 – annual review
Reviewed: 3/1/12 – annual review, updated signature
Reviewed: 3/1/13 – annual review, updated logo and definitions
Reviewed: 3/1/14 – annual review, updated formatting, updated Emend to a quantity limit
Reviewed: 3/1/15 – annual review, updated signature
Reviewed: 3/1/16 – annual review, added QL indicator to granisetron
Reviewed: 5/1/16 – updated format, logo, & procedure
Reviewed: 3/1/17 – annual review, updated Emend to aprepitant
Reviewed: 3/1/18 – annual review, updated signature
Reviewed: 6/1/18 – added QL
Reviewed: 3/1/19 – annual review, added QL approval note
Reviewed: 3/1/20 – annual review, added GHP Kids
POLICY:
Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of formulary. The formulary is applied according to the formulary review process (see Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Part D Policy 143.0 D Geisinger Health Plan (GHP) and Geisinger Indemnity Insurance Company (GIIC) Formulary Development by the Pharmacy). The results of this process determine the development and application 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 all lines of business, unless a specific limitation or exception exists.

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

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

Applicable line of business:
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POLICY NUMBER: 184.0
C. In accordance with current standards of medical practice;
D. Not primarily for the convenience of the Member, or the Member’s Provider; and
E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services 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 Amitiza **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

**QUANTITY LIMIT:** Pharmacist note to CSR: *Authorization should be entered by HICL and only checking the Formulary PA required box (no QLs need to be entered within the authorization).*
- 12 mg dose: 0.6 mL (1 syringe) per day
- 8 mg dose: 6 mL (15 syringes) per 30 days

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: Amitiza, 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, 2020

Devised: 4/09
Revised: 5/09 – fixed typo
Reviewed: 3/10 – annual review
Revised: 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
Revised: 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
Revised: 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
Revised: 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
Revised: 3/1/20 – annual review, added GHP Kids
POLICY:
Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of formulary. The formulary is applied according to the formulary review process (see Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Part D Policy 143.0 D Geisinger Health Plan (GHP) and Geisinger Indemnity Insurance Company (GIIC) Formulary Development by the Pharmacy). The results of this process determine the development and application 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 all lines of business, unless a specific limitation or exception exists.

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

ADDITIONAL DEFINITIONS:
1. Formulary – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. Non-formulary products – those medications that are not included in the Formulary.
3. Healthcare provider – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician’s assistant, certified registered nurse practitioner).
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 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 Rituxan* AND
- Symptomatic ITP with bleeding symptoms and a platelet count of less than 30,000/μL OR a platelet count of less than 20,000/μL and an increased risk of bleeding

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/μL. 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/μL and 100,000/μL.

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/μL AND
- Medical record documentation that Promacta is prescribed by a gastroenterologist, hematologist, hepatologist or infectious disease specialist

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/µL 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)

**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.

**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, 2020

Devised: 4/09
Reviewed: 3/10 – annual review
Reviewed: 3/1/11—annual review
Reviewed: 3/1/12 – annual review, updated signature
Reviewed: 3/1/13 – annual review, updated logo and definitions
Reviewed: 5/4/13 – added chronic hepatitis C indication
Reviewed: 10/7/13 – added prescribers and updated platelet units
Reviewed: 3/14/14 – annual review
Reviewed: 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
Reviewed: 2/9/15 – corrected typo, added aplastic anemia indication
Reviewed: 3/1/15 – annual review, updated formatting
Reviewed: 11/20/15 – removed failure of splenectomy for chronic ITP
Reviewed: 3/1/16 – annual review
Reviewed: 5/1/16 – updated format, logo, & procedure
Reviewed: 3/1/17 – annual review, removed Unicode characters, corrected typo
Reviewed: 3/1/18 – annual review, updated signature
Reviewed: 3/1/19 – annual review
Reviewed: 3/28/19 – added first line aplastic anemia indication, updated aplastic anemia auth duration to 6 months initial, added aplastic anemia note
Reviewed: 3/1/20 – annual review, added GHP Kids
POLICY:
Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of formulary. The formulary is applied according to the formulary review process (see Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Part D Policy 143.0 D Geisinger Health Plan (GHP) and Geisinger Indemnity Insurance Company (GIIC) Formulary Development by the Pharmacy). The results of this process determine the development and application 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 all lines of business, unless a specific limitation or exception exists.

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

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

- 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 a therapeutic failure on, intolerance to, or contraindication to three (3) formulary alternatives

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 > 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+), Gabitril (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, 2020

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
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
POLICY NUMBER: 188.0

POLICY AND PROCEDURE
PHARMACY
MANUAL

SECTION: Commercial Drug
SUBJECT: Afinitor

Applicable line of business:

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POLICY:
Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of formulary. The formulary is applied according to the formulary review process (see Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Part D Policy 143.0 D Geisinger Health Plan (GHP) and Geisinger Indemnity Insurance Company (GIIC) Formulary Development by the Pharmacy). The results of this process determine the development and application 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 for GHP members who have prescription drug benefits, including all lines of business, unless a specific limitation or exception exists.

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

ADDITIONAL DEFINITIONS:
1. **Formulary** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. **Non-formulary products** – those medications that are not included in the Formulary.
3. **Healthcare provider** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
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 Afinitor may be made for members who meet the following criteria:

**Renal Cell Cancer**
- Medical record documentation that 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 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 Afinitor being used in combination with an aromatase inhibitor
Neuroendocrine tumors of pancreatic origin
- Medical record documentation that 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 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 lymphangioleiomyomatosis
- Medical record documentation that Afinitor is prescribed by an oncologist, nephrologist, or urologist AND
- Medical record documentation of renal angiomyolipoma and tuberous sclerosis complex (TSC)/sporadic lymphangioleiomyomatosis, 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: 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.

AUTHORIZATION DURATION: Each treatment period will be defined as 12 months. Review will occur every 12 months. Afinitor will no longer be covered if there is medical record documentation of disease progression.

QUANTITY LIMIT: Pharmacist note to CSR: Authorization should be entered by HICL and only checking the Formulary PA required box (no QLs need to be entered within the authorization).
• 1 tablet per day, 28 day supply per fill
If a formulary exception is approved, 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 – Sutent*, 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, 2020

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
Applicable line of business:

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**POLICY:**

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of formulary. The formulary is applied according to the formulary review process (see Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Part D Policy 143.0 D Geisinger Health Plan (GHP) and Geisinger Indemnity Insurance Company (GIIC) Formulary Development by the Pharmacy). The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for Aplenzin for GHP members who have prescription drug benefits, including all lines of business, unless a specific limitation or exception exists.

**REQUIRED DEFINITIONS:**

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

**ADDITIONAL DEFINITIONS:**

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

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.

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
REVIEWS NO LESS THAN ANNUALLY.

Signed: ____________________________________________

Title: Director, Pharmacy Services

Date: March 1, 2020

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
POLICY:
Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of formulary. The formulary is applied according to the formulary review process (see Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Part D Policy 143.0 D Geisinger Health Plan (GHP) and Geisinger Indemnity Insurance Company (GIIC) Formulary Development by the Pharmacy). The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for Apriso for GHP members who have prescription drug benefits, including all lines of business, unless a specific limitation or exception exists.

REQUIRED DEFINITIONS:
1. Attachment – a supporting document that is developed and maintained by the policy writer or 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.
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3. Healthcare provider – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
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   A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
C. In accordance with current standards of medical practice;
D. Not primarily for the convenience of the Member, or the Member's Provider; and
E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

PROCEDURE:
An exception for coverage of 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

If an exception is made, 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, Delzicol, balsalazide, Canasa Suppositories, Dipentum, Lialda, 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, 2020

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
POLICY AND PROCEDURE
PHARMACY
MANUAL

POLICY NUMBER: 190.0

SECTION: Commercial Drug
SUBJECT: Mesalamine (generic Apriso)

Applicable line of business:

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<tr>
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POLICY:
Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of formulary. The formulary is applied according to the formulary review process (see Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Part D Policy 143.0 D Geisinger Health Plan (GHP) and Geisinger Indemnity Insurance Company (GIIC) Formulary Development by the Pharmacy). The results of this process determine the development and application 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 all lines of business, unless a specific limitation or exception exists.

REQUIRED DEFINITIONS:
1. Attachment – a supporting document that is developed and maintained by the policy writer or 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).
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;
POLICY AND PROCEDURE
PHARMACY
MANUAL

POLICY NUMBER: 190.0
SECTION: Commercial Drug
SUBJECT: Mesalamine (generic Apriso)

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

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, Delzicol, balsalazide, Canasa Suppositories, Dipentum, Lialda, 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.
POLICY NUMBER: 190.0

POLICY AND PROCEDURE
PHARMACY
MANUAL

SECTION: Commercial Drug
SUBJECT: Mesalamine (generic Apriso)

Signed: ____________________________________________________________

Title: Director, Pharmacy Services

Date: November 18, 2020

Devised: 11/09
Reviewed: 3/10 – annual review
Reviewed: 3/11 – annual review
Reviewed: 3/11 – annual review
Reviewed: 3/12 – annual review, updated signature
Reviewed: 3/13 – annual review, updated logo and definitions
Reviewed: 3/14 – annual review, updated Asacol to HD as immed. release was D/C by manuf.
Reviewed: 3/14 – annual review
Reviewed: 3/15 – annual review, updated signature, added Delzicol to formulary alternatives
Reviewed: 3/16 – annual review
Reviewed: 5/16 – updated format, logo, & procedure
Reviewed: 3/17 – annual review
Reviewed: 3/18 – annual review, updated signature, updated Asacol to generic
Reviewed: 3/19 – annual review
Reviewed: 3/20 – annual review, added GHP Kids
Reviewed: 11/18/20 – updated to generic
POLICY NUMBER: 191.0

**SECTION**: Commercial Drug
**SUBJECT**: Olopatadine Nasal Spray

**POLICY AND PROCEDURE**
**PHARMACY**
**MANUAL**

**Applicable line of business:**

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**POLICY:**
Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of formulary. The formulary is applied according to the formulary review process (see Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Part D Policy 143.0 D Geisinger Health Plan (GHP) and Geisinger Indemnity Insurance Company (GIIC) Formulary Development by the Pharmacy). The results of this process determine the development and application 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 all lines of business, unless a specific limitation or exception exists.

**REQUIRED DEFINITIONS:**
1. **Attachment** – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. **Exhibit** – a 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).
5. **Medically Necessary or Medical Necessity** – covered services rendered by a provider that the Health Plan determines are:
   - Appropriate for the symptoms and diagnosis or treatment of the Member’s condition, illness, disease or injury;
B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
C. In accordance with current standards of medical practice;
D. Not primarily for the convenience of the Member, or the Member's Provider; and
E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services 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** Nasonex **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

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

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

Signed: _________________________________

Title: Director, Pharmacy Services

Date: March 1, 2020

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
POLICY:  
Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of formulary. The formulary is applied according to the formulary review process (see Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Part D Policy 143.0 D Geisinger Health Plan (GHP) and Geisinger Indemnity Insurance Company (GIIC) Formulary Development by the Pharmacy). The results of this process determine the development and application 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 all lines of business, unless a specific limitation or exception exists.

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

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

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

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

THIS POLICY WILL BE REVISED AS NECESSARY AND REVIEWED NO LESS THAN ANNUALLY.
Signed:_______________________________________________

Title: Director, Pharmacy Services

Date: March 1, 2020

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
POLICY:
Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of formulary. The formulary is applied according to the formulary review process (see Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Part D Policy 143.0 D Geisinger Health Plan (GHP) and Geisinger Indemnity Insurance Company (GIIC) Formulary Development by the Pharmacy). The results of this process determine the development and application 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 all lines of business, unless a specific limitation or exception exists.

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

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

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.
Signed:_______________________________________________

Title:  Director, Pharmacy Services

Date:  March 1, 2020

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
Reviewed:   3/1/13 – annual review, updated logo and definitions
Revised:    3/1/14 – annual review, updated formatting
Reviewed:   3/1/15 – annual review, updated signature
Revised:    3/1/16 – annual review
Reviewed:   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
POLICY NUMBER: 196.0

SECTION: Commercial Drug

SUBJECT: Alogliptin and Onglyza

Applicable line of business:

<table>
<thead>
<tr>
<th></th>
<th>Commercial</th>
<th>Medicaid</th>
<th>Medicare</th>
<th>ACA</th>
<th>GHP Kids</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>X</td>
<td></td>
<td></td>
<td>X</td>
<td>X</td>
</tr>
</tbody>
</table>

POLICY:

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of formulary. The formulary is applied according to the formulary review process (see Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Part D Policy 143.0 D Geisinger Health Plan (GHP) and Geisinger Indemnity Insurance Company (GIIC) Formulary Development by the Pharmacy). The results of this process determine the development and application 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 and Onglyza for GHP members who have prescription drug benefits, including all lines of business, unless a specific limitation or exception exists.

REQUIRED DEFINITIONS:

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

ADDITIONAL DEFINITIONS:

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

ALOGLOPTIN QUANTITY LIMIT: Pharmacist note to CSR: *Authorization should be entered by HICL and only checking the Formulary box (no QLs need to be entered within the authorization).*
- 1 tablet per day

ONGLYZA QUANTITY LIMIT: Pharmacist note to CSR: *Authorization should be entered by HICL and only checking the Formulary PA Required box (no QLs need to be entered within the authorization).*
- 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
THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND FEDERAL REGULATORY ENTITIES.

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

Signed: _________________________________
Title: Director, Pharmacy Services
Date: March 1, 2020

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: 3/18 – 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
POLICY NUMBER: 197.0

SECTION: Commercial Drug

SUBJECT: Cimzia

Applicable line of business:

<table>
<thead>
<tr>
<th>Line of Business</th>
<th>Commercial</th>
<th>Medicaid</th>
<th>Medicare</th>
<th>ACA</th>
<th>GHP Kids</th>
</tr>
</thead>
<tbody>
<tr>
<td>Commercial</td>
<td>X</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Medicaid</td>
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<tr>
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POLICY:
Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of formulary. The formulary is applied according to the formulary review process (see Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Part D Policy 143.0 D Geisinger Health Plan (GHP) and Geisinger Indemnity Insurance Company (GIIC) Formulary Development by the Pharmacy). The results of this process determine the development and application 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 all lines of business, unless a specific limitation or exception exists.

REQUIRED DEFINITIONS:

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

ADDITIONAL DEFINITIONS:

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

**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 signs and symptoms of rheumatoid arthritis on six (6) months of certolizumab therapy 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 continued or sustained improvement in the signs and symptoms of rheumatoid arthritis while on certolizumab therapy.
QUANTITY LIMIT/AUTHORIZATION PARAMETERS:

<table>
<thead>
<tr>
<th>Initial – One-time, one-week authorization</th>
<th>Remainder/Subsequent</th>
</tr>
</thead>
<tbody>
<tr>
<td>Quantity limit: 3 kits per 28 days</td>
<td>Quantity limit: 1 kit per 28 days</td>
</tr>
<tr>
<td>Max quantity supply: 3</td>
<td>Authorization should be entered by HICL and only checking the Formulary box (no QLs need to be entered within the authorization).</td>
</tr>
<tr>
<td>Min day supply: 28</td>
<td></td>
</tr>
<tr>
<td>Max day supply: 28</td>
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</table>

**NOTE:** This product is billed per kit. Each kit contains two 200mg syringes.

**FORMULARY ALTERNATIVES:**
Humira*, Rinoq*, Xeljanz*

*prior authorization required*
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
- Medical record documentation of age greater than or equal to 18 years
- Medical record documentation that Cimzia is prescribed by a gastroenterologist
- 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

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 Crohn’s disease on six (6) months of Cimzia therapy is required.

After the initial six (6) month approval, subsequent approvals for coverage will be for duration of 1 year requiring medical record documentation of continued or sustained improvement in the signs and symptoms of Crohn’s disease while on Cimzia therapy.

QUANTITY LIMIT/AUTHORIZATION PARAMETERS:

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</table>

NOTE: This product is billed per kit. Each kit contains two 200mg syringes.

FORMULARY ALTERNATIVES:
- Humira*

*prior authorization required
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:
  o 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

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 signs and symptoms of psoriatic arthritis on six (6) months of Cimzia therapy 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 continued or sustained improvement in the signs and symptoms of psoriatic arthritis while on Cimzia therapy.

QUANTITY LIMIT/AUTHORIZATION PARAMETERS:

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</table>

NOTE: This product is billed per kit. Each kit contains two 200mg syringes.

FORMULARY ALTERNATIVES:
Cosentyx*, Humira*

*prior authorization required
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

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 ankylosing spondylitis on six (6) months of Cimzia therapy is required.

After the initial six (6) month approval, subsequent approvals will be for a duration of one (1) year requiring medical record documentation of continued or sustained improvement in the signs and symptoms of ankylosing spondylitis while on Cimzia therapy.

QUANTITY LIMIT/AUTHORIZATION PARAMETERS:

<table>
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<td>within the authorization).</td>
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</tbody>
</table>

NOTE: This product is billed per kit. Each kit contains two 200mg syringes.

FORMULARY ALTERNATIVES:

Cosentyx*, Humira*

*prior authorization required
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

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 signs and symptoms of plaque psoriasis on six (6) months of Cimzia therapy 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 continued or sustained improvement in the signs and symptoms of plaque psoriasis while on Cimzia therapy.

QUANTITY LIMIT: 2 kits per 28 days

AUTHORIZATION PARAMETERS:
- Quantity supply max: 2
- Day supply min: 28
- Day supply max: 28

NOTE: This product is billed per kit. Each kit contains two 200mg syringes.

FORMULARY ALTERNATIVES:
Cosentyx*, Humira*

*prior authorization required
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)
- 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

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 non-radiographic axial spondylarthritis on six (6) months of Cimzia therapy is required.

After the initial six (6) month approval, subsequent approvals for coverage will be for duration of 1 year requiring medical record documentation of continued or sustained improvement in the signs and symptoms of non-radiographic axial spondylarthritis while on Cimzia therapy.

QUANTITY LIMIT/AUTHORIZATION PARAMETERS:

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<tbody>
<tr>
<td>Quantity limit: 3 kits per 28 days</td>
<td>Quantity limit: 1 kit per 28 days</td>
</tr>
<tr>
<td>Max quantity supply: 3</td>
<td>Authorization should be entered by</td>
</tr>
<tr>
<td>Min day supply: 28</td>
<td>HICL and only checking the</td>
</tr>
<tr>
<td>Max day supply: 28</td>
<td>Formulary box (no QLs need to be</td>
</tr>
<tr>
<td></td>
<td>entered within the authorization).</td>
</tr>
</tbody>
</table>

NOTE: This product is billed per kit. Each kit contains two 200mg syringes.

FORMULARY ALTERNATIVES: none
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, 2020

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
Revised: 10/1/19 – added non-radiographic axial spondylarthritis indication to policy
Revised: 01/28/20 – updated RA FA and added failure of Rinvoq and Xeljanz
Revised: 3/1/20 – annual review, added GHP Kids
POLICY:
Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of formulary. The formulary is applied according to the formulary review process (see Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Part D Policy 143.0 D Geisinger Health Plan (GHP) and Geisinger Indemnity Insurance Company (GIIC) Formulary Development by the Pharmacy). The results of this process determine the development and application 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 all lines of business, unless a specific limitation or exception exists.

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

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

QUANTITY LIMIT: Pharmacist note to CSR: Authorization should be entered by GPID and only checking the Formulary box (no QLs need to be entered within the authorization).
- 0.5 mL per 28 days

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 rheumatoid on six (6) months of Simponi therapy 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 continued or sustained improvement in the signs and symptoms of rheumatoid arthritis while on Simponi therapy.

**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

**QUANTITY LIMIT:** Pharmacist note to CSR: *Authorization should be entered by GPID and only checking the Formulary box (no QLs need to be entered within the authorization).*
- 0.5 mL per 28 days

**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 psoriatic arthritis on six (6) months of Simponi therapy 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 continued or sustained improvement in the signs and symptoms of psoriatic arthritis while on Simponi therapy.

**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

**QUANTITY LIMIT:** Pharmacist note to CSR: *Authorization should be entered by GPID and only checking the Formulary box (no QLs need to be entered within the authorization).*

- 0.5 mL per 28 days

**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 ankylosing spondylitis at six (6) months of Simponi 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 ankylosing spondylitis while on Simponi therapy.

**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

QUANTITY LIMIT/AUTHORIZATION PARAMETERS:

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<thead>
<tr>
<th>If requesting a dose of:</th>
<th>Initial – one-time, one-week authorization</th>
<th>Remainder/Subsequent</th>
</tr>
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<tbody>
<tr>
<td>100 mg/mL</td>
<td>Quantity limit: 3 mL per 28 days</td>
<td>Quantity limit: 1 mL per 28 days</td>
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<tr>
<td></td>
<td>Max quantity supply: 3</td>
<td>Authorization should be entered by GPID and only checking the Formulary box (no QLs need to be entered within the authorization).</td>
</tr>
<tr>
<td></td>
<td>Min day supply: 28</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Max day supply: 28</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Enter by GPID</td>
<td></td>
</tr>
</tbody>
</table>

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 Simponi 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 Simponi therapy.

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.

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

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

Signed:_______________________________________________
Title: Director, Pharmacy Services
Date: March 1, 2020

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
Revised: 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: 01/28/20 – updated RA FA and added failure of Rinvoq and Xeljanz
POLICY NUMBER: 199.0

SECTION: Commercial Drug
SUBJECT: Armodafinil

Applicable line of business:

<p>| | |</p>
<table>
<thead>
<tr>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Commercial</td>
<td>X</td>
</tr>
<tr>
<td>Medicaid</td>
<td></td>
</tr>
<tr>
<td>Medicare</td>
<td>ACA</td>
</tr>
<tr>
<td>GHP Kids</td>
<td>X</td>
</tr>
</tbody>
</table>

POLICY:
Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of formulary. The formulary is applied according to the formulary review process (see Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Part D Policy 143.0 D Geisinger Health Plan (GHP) and Geisinger Indemnity Insurance Company (GIIC) Formulary Development by the Pharmacy). The results of this process determine the development and application 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 all lines of business, unless a specific limitation or exception exists.

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

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

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:
medafinil*

*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: 199.0

SECTION: Commercial Drug
SUBJECT: Armodafinil

Signed: ______________________________
Title: Director, Pharmacy Services
Date: March 1, 2020

Devised: 1/10
Reviewed: 3/10 – annual review
Reviewed: 3/1/11 – annual review
Reviewed: 3/1/12 – annual review, updated signature
Reviewed: 6/28/12 – removed Provigil from alternatives and added modafinil
Reviewed: 3/1/13 – annual review, updated logo and definitions
Reviewed: 11/15/13 – fixed typographical error, updated criteria to failure of modafinil
Reviewed: 3/1/14 – annual review, updated formatting
Reviewed: 3/1/15 – annual review, updated signature
Reviewed: 3/1/16 – annual review, update policy formatting
Reviewed: 5/1/16 – updated format, logo, & procedure
Reviewed: 3/1/17 – annual review, updated Nuvigil to armodafinil
Reviewed: 3/1/18 – annual review, updated signature
Reviewed: 3/1/19 – annual review
Reviewed: 11/20/19 – removed failure of modafinil
Reviewed: 3/1/20 – annual review, added GHP Kids
Applicable line of business:

<table>
<thead>
<tr>
<th>Line of Business</th>
<th>Commercial</th>
<th>Medicaid</th>
<th>Medicare</th>
<th>ACA</th>
<th>GHP Kids</th>
</tr>
</thead>
</table>

POLICY:
Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of formulary. The formulary is applied according to the formulary review process (see Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Part D Policy 143.0 D Geisinger Health Plan (GHP) and Geisinger Indemnity Insurance Company (GIIC) Formulary Development by the Pharmacy). The results of this process determine the development and application 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 all lines of business, unless a specific limitation or exception exists.

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

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

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

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+), Gabitril (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: April 21, 2020

Devised: 1/10
Reviewed: 3/10 – annual review
Reviewed: 3/1/11 – annual review
Reviewed: 3/1/12 – annual review, updated signature & alternatives
Reviewed: 3/1/13 – annual review, updated logo and definitions
Reviewed: 3/1/14 – annual review, corrected typo
Reviewed: 3/1/15 – annual review, updated signature
Reviewed: 3/1/16 – annual review, removed carbatrol from FA, added tiagabine to FA
Reviewed: 5/1/16 – updated format, logo, & procedure
Reviewed: 3/1/17 – annual review
Reviewed: 3/1/18 – annual review, updated signature & prescriber, added grandfather language
Reviewed: 3/1/19 – annual review
Reviewed: 11/21/19 – updated Sabril to vigabatrin, updated FA
Reviewed: 3/1/20 – annual review, added GHP Kids
Reviewed: 4/21/20 – added indication headers, removed failure of all alternatives, added partial seizure diagnosis, adjunctive therapy, and failure of 3 criteria, updated FA
Applicable line of business:

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<tr>
<th>Line of Business</th>
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<th>Medicare</th>
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<td>GHP Kids</td>
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POLICY:
Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of formulary. The formulary is applied according to the formulary review process (see Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Part D Policy 143.0 D Geisinger Health Plan (GHP) and Geisinger Indemnity Insurance Company (GIIC) Formulary Development by the Pharmacy). The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for Saphris for GHP members who have prescription drug benefits, including all lines of business, unless a specific limitation or exception exists.

REQUIRED DEFINITIONS:

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

ADDITIONAL DEFINITIONS:

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

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

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

THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE STANDARDS 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: 202.0

POLICY AND PROCEDURE
PHARMACY
MANUAL

SECTION: Commercial Drug
SUBJECT: Saphris

Signed:  
Title: Director, Pharmacy Services
Date: March 1, 2020

Devised: 1/10
Reviewed: 3/10 – annual review
Reviewed: 3/1/11 – annual review
Reviewed: 3/1/12 – annual review, updated signature and alternatives
Reviewed: 3/1/13 – annual review, updated logo, alternatives, and definitions
Reviewed: 3/1/14 – annual review, updated alternatives based on generic Geodon and Seroquel
Reviewed: 3/20/14 – updated criteria to require failure on 3 formulary alternatives
Reviewed: 3/1/15 – annual review, updated signature
Reviewed: 3/1/16 – annual review, changed Abilify to aripiprazole
Reviewed: 5/1/16 – updated format, logo, & procedure
Reviewed: 3/1/17 – annual review
Reviewed: 3/1/18 – annual review, updated signature, added grandfather language
Reviewed: 3/1/19 – annual review
Reviewed: 3/1/20 – annual review, added GHP Kids
POLICY:
Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of formulary. The formulary is applied according to the formulary review process (see Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Part D Policy 143.0 D Geisinger Health Plan (GHP) and Geisinger Indemnity Insurance Company (GIIC) Formulary Development by the Pharmacy). The results of this process determine the development and application 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 all lines of business, unless a specific limitation or exception exists.

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

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

QUANTITY LIMIT: Pharmacist note to CSR: Authorization should be entered by HICL and only checking the Formulary PA required box (no QLs need to be entered within the authorization).
- 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
THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND FEDERAL REGULATORY ENTITIES.

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

Signed: [Signature]

Title: Director, Pharmacy Services

Date: March 1, 2020

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
Applicable line of business:

<table>
<thead>
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<td>Commercial</td>
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<td>Medicare</td>
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</tr>
<tr>
<td>GHP Kids</td>
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</tr>
</tbody>
</table>

POLICY:

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of formulary. The formulary is applied according to the formulary review process (see Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Part D Policy 143.0 D Geisinger Health Plan (GHP) and Geisinger Indemnity Insurance Company (GIIC) Formulary Development by the Pharmacy). The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for Banzel for GHP members who have prescription drug benefits, including all lines of business, unless a specific limitation or exception exists.

REQUIRED DEFINITIONS:

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

ADDITIONAL DEFINITIONS:

1. Formulary – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. Non-formulary products – those medications that are not included in the Formulary.
3. Healthcare provider – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
5. Medically Necessary or Medical Necessity – covered services rendered by a provider that the Health Plan determines are:
   - Appropriate for the symptoms and diagnosis or treatment of the Member’s condition, illness, disease or injury;
   - Provided for the diagnosis, or the direct care and treatment of the Member’s condition, illness, disease or injury;
C. In accordance with current standards of medical practice;
D. Not primarily for the convenience of the Member, or the Member's Provider; and
E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to 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 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 Banzel 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

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

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

THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE STANDARDS 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: 205.0

POLICY AND PROCEDURE
PHARMACY
MANUAL

SECTION: Commercial Drug
SUBJECT: Banzel

Signed: ___________________________________________

Title: Director, Pharmacy Services

Date: March 1, 2020

Devised: 1/10
Reviewed: 3/10 – annual review
Reviewed: 3/1/11 – annual review
Reviewed: 3/1/12 – annual review, updated signature
Reviewed: 3/1/13 – annual review, updated logo and definitions
Reviewed: 3/1/14 – annual review, updated formatting
Reviewed: 5/28/14 – added intractable epilepsy indication, updated signature
Reviewed: 3/1/15 – annual review
Reviewed: 6/8/15 – updated age requirement for LGS
Reviewed: 3/1/16 – annual review
Reviewed: 5/1/16 – updated format, logo, & procedure
Reviewed: 3/1/17 – annual review
Reviewed: 3/1/18 – annual review, updated signature, added grandfather language
Reviewed: 3/1/19 – annual review
Reviewed: 3/1/20 – annual review, added GHP Kids
POLICY:
Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of formulary. The formulary is applied according to the formulary review process (see Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Part D Policy 143.0 D Geisinger Health Plan (GHP) and Geisinger Indemnity Insurance Company (GIIC) Formulary Development by the Pharmacy). The results of this process determine the development and application 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 all lines of business, unless a specific limitation or exception exists.

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

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

**QUANTITY LIMIT:** Pharmacist note to CSR: *Authorization should be entered by HICL and only checking the Formulary PA required box (no QLs need to be entered within the authorization).*

- 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

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

**THIS POLICY WILL BE REVISED AS NECESSARY AND REVIEWED NO LESS THAN ANNUALLY.**
Signed: ________________________________  
Title: Director, Pharmacy Services  
Date:  March 1, 2020

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  
Reviewed:  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
POLICY NUMBER: 207.0

POLICY AND PROCEDURE
PHARMACY
MANUAL

SECTION: Commercial Drug
SUBJECT: Votrient

Applicable line of business:

<table>
<thead>
<tr>
<th>Line of Business</th>
<th>Commercial</th>
<th>Medicaid</th>
<th>Medicare</th>
<th>ACA</th>
<th>GHP Kids</th>
</tr>
</thead>
</table>

POLICY:
Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of formulary. The formulary is applied according to the formulary review process (see Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Part D Policy 143.0 D Geisinger Health Plan (GHP) and Geisinger Indemnity Insurance Company (GIIC) Formulary Development by the Pharmacy). The results of this process determine the development and application 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 all lines of business, unless a specific limitation or exception exists.

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

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

- 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

**OR**

- 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*

**OR**

- 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

**NOTE:** Will not be approved for gastrointestinal stromal tumors (GIST) or adipocytic sarcoma.
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.

QUANTITY LIMIT: Pharmacist note to CSR: Authorization should be entered by HICL and only checking the Formulary PA required box (no QLs need to be entered within the authorization).
  - 4 tablets per day, 30 day supply per fill

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:
  Sutent*, 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, 2020
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<th>Action</th>
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<td>Revised</td>
<td>7/18/12</td>
<td>– added advanced soft tissue sarcoma indication</td>
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<tr>
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<td>3/01/13</td>
<td>– annual review, updated logo and definitions</td>
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<td>3/01/16</td>
<td>– annual review</td>
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<td>3/24/16</td>
<td>– removed copay/15 day supply requirement, removed QL indicator from FA</td>
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<td>– updated format, logo, &amp; procedure</td>
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<td>– added authorization duration</td>
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<td>3/1/18</td>
<td>– annual review, updated signature, updated criteria format, added grandfather</td>
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<td>6/1/18</td>
<td>– added QL</td>
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<tr>
<td>Revised</td>
<td>3/1/19</td>
<td>– annual review, added QL approval note</td>
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<tr>
<td>Revised</td>
<td>3/1/20</td>
<td>– annual review, added GHP Kids</td>
</tr>
</tbody>
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Applicable line of business:

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<thead>
<tr>
<th>Line of Business</th>
<th>Commercial</th>
<th>Medicaid</th>
<th>Medicare</th>
<th>ACA</th>
<th>GHP Kids</th>
</tr>
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</table>

POLICY:
Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of formulary. The formulary is applied according to the formulary review process (see Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Part D Policy 143.0 D Geisinger Health Plan (GHP) and Geisinger Indemnity Insurance Company (GIIC) Formulary Development by the Pharmacy). The results of this process determine the development and application 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 all lines of business, unless a specific limitation or exception exists.

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

ADDITIONAL DEFINITIONS:
1. **Formulary** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. **Non-formulary products** – those medications that are not included in the Formulary.
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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:

- 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
- Must be prescribed by an immunologist, rheumatologist, or allergist AND
- Medical record documentation of therapeutic failure on, intolerance to, or contraindication to Kineret* AND Ilaris*

AUTHORIZATION DURATION: The initial approval will be for a time period of 12 weeks, requiring medical record documentation of improvement in signs and symptoms of CAPS. Arcalyst will then require approval on a yearly basis.

QUANTITY LIMIT/AUTHORIZATION PARAMETERS:

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<th>Initial – One-time, one-week authorization</th>
<th>Remainder/Subsequent</th>
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<td>Max quantity supply: 4</td>
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<td>Min day supply: 21</td>
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<tr>
<td>Max day supply: 21</td>
<td>Max day supply: 28</td>
</tr>
</tbody>
</table>

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:
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, 2020

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
Revised: 3/1/16 – annual review
Revised: 5/1/16 – updated format, logo, & procedure, added authorization duration indicator
Revised: 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
Revised: 3/1/18 – annual review, updated signature
Revised: 3/1/19 – annual review
Revised: 7/24/19 – added QL and authorization parameters
Revised: 3/1/20 – annual review, added GHP Kids
POLICY: Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of formulary. The formulary is applied according to the formulary review process (see Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Part D Policy 143.0 D Geisinger Health Plan (GHP) and Geisinger Indemnity Insurance Company (GIIC) Formulary Development by the Pharmacy). The results of this process determine the development and application 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 all lines of business, unless a specific limitation or exception exists.

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

ADDITIONAL DEFINITIONS:
1. **Formulary** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. **Non-formulary products** – those medications that are not included in the Formulary.
3. **Healthcare provider** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
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 (generic Adcirca) may be made for members who meet the following criteria:

- Medical record documentation that tadalafil is prescribed by a cardiologist or pulmonologist \textbf{AND}
- Medical record documentation of a diagnosis of functional class 2, 3, or 4 pulmonary arterial hypertension \textbf{AND}
- Medical record documentation of one of the following:
  - Therapeutic failure on, intolerance to, or contraindication to sildenafil* (generic Revatio) \textbf{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

**QUANTITY LIMIT:** Pharmacist note to CSR: \textit{Authorization should be entered by HICL and only checking the Formulary PA required box (no QLs need to be entered within the authorization).}

- 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.

**FORMULARY ALTERNATIVES:**
Uptravi®, Orenitram®, treprostinil® (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, 2020

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
POLICY:
Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of formulary. The formulary is applied according to the formulary review process (see Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Part D Policy 143.0 D Geisinger Health Plan (GHP) and Geisinger Indemnity Insurance Company (GIIC) Formulary Development by the Pharmacy). The results of this process determine the development and application 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 all lines of business, unless a specific limitation or exception exists.

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

ADDITIONAL DEFINITIONS:
1. **Formulary** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. **Non-formulary products** – those medications that are not included in the Formulary.
3. **Healthcare provider** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
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 Tyvaso may be made for members who meet the following criteria:

- 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 Tracleer*

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.

FORMULARY ALTERNATIVES:
- Uptravi®, Orenitram®, Remodulin®, Ventavis®, Adempas®, Opsumit®, Letairis®, Adcirca®, sildenafil®, Tracleer®

* 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:
Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of formulary. The formulary is applied according to the formulary review process (see Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Part D Policy 143.0 D Geisinger Health Plan (GHP) and Geisinger Indemnity Insurance Company (GIIC) Formulary Development by the Pharmacy). The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for Bystolic for GHP members who have prescription drug benefits, including all lines of business, unless a specific limitation or exception exists.

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

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

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

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.

Signed:_______________________________________________
Title: Director, Pharmacy Services

Date: March 1, 2020

Devised: 6/10
Reviewed: 3/1/11 – annual review
Revised: 3/1/12 – annual review, updated signature
Reviewed: 3/1/13 – annual review, updated logo and definitions
Revised: 3/1/14 – annual review
 Reviewed: 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
POLICY:
Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of formulary. The formulary is applied according to the formulary review process (see Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Part D Policy 143.0 D Geisinger Health Plan (GHP) and Geisinger Indemnity Insurance Company (GIIC) Formulary Development by the Pharmacy). The results of this process determine the development and application 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 all lines of business, unless a specific limitation or exception exists.

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

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

QUANTITY LIMIT: Pharmacist note to CSR: Authorization should be entered by HICL and only checking the Step Therapy box (no QLs need to be entered within the authorization).

- 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.

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: [Signature]

Title: Director, Pharmacy Services

Date: March 1, 2020

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
POLICY: 
Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of formulary. The formulary is applied according to the formulary review process (see Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Part D Policy 143.0 D Geisinger Health Plan (GHP) and Geisinger Indemnity Insurance Company (GIIC) Formulary Development by the Pharmacy). The results of this process determine the development and application 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 all lines of business, unless a specific limitation or exception exists.

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

ADDITIONAL DEFINITIONS:
1. Formulary – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. Non-formulary products – those medications that are not included in the Formulary.
3. Healthcare provider – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
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:
  o Medical record documentation of a diagnosis of Cold Sores (Herpes Simplex 1 or Herpes Labialis) in patients 12 years of age and older AND
  o 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:
  o Medical record documentation of a diagnosis of cold sores (Herpes Simplex 1 or Herpes Labialis) in patients 12 years of age and older AND
  o 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)

QUANTITY LIMIT: For acyclovir Cream: A quantity limit of 1 co-pay per package applies
For Denavir Cream: A quantity limit of 1 co-pay per package applies
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: July 29, 2020

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
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
POLICY NUMBER: 224.0

POLICY AND PROCEDURE
PHARMACY
MANUAL

SECTION: Commercial Drug
SUBJECT: Vimovo

Applicable line of business:

<table>
<thead>
<tr>
<th>Commercial</th>
<th>Medicaid</th>
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<tbody>
<tr>
<td>X</td>
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<tr>
<td>Medicare</td>
<td>ACA</td>
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<td></td>
<td>X</td>
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<tr>
<td>GHP Kids</td>
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</table>

POLICY:
Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of formulary. The formulary is applied according to the formulary review process (see Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Part D Policy 143.0 D Geisinger Health Plan (GHP) and Geisinger Indemnity Insurance Company (GIIC) Formulary Development by the Pharmacy). The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for Vimovo for GHP members who have prescription drug benefits, including all lines of business, unless a specific limitation or exception exists.

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

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

**QUANTITY LIMIT:** Pharmacist note to CSR: *Authorization should be entered by HICL and only checking the Formulary PA required box (no QLs need to be entered within the authorization).*
- 2 tablets per day, 28 day supply per fill

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

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
REVIEWS NO LESS THAN ANNUALLY.

Signed:_______________________________________________

Title: Director, Pharmacy Services

Date: March 1, 2020

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
POLICY AND PROCEDURE
PHARMACY MANUAL

POLICY NUMBER: 225.0
SECTION: Commercial Drug SUBJECT: Alogliptin/Metformin and Kombiglyze XR

Applicable line of business:

<table>
<thead>
<tr>
<th>Line of Business</th>
<th>Commercial</th>
<th>Medicaid</th>
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</table>

POLICY:
Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of formulary. The formulary is applied according to the formulary review process (see Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Part D Policy 143.0 D Geisinger Health Plan (GHP) and Geisinger Indemnity Insurance Company (GIIC) Formulary Development by the Pharmacy). The results of this process determine the development and application 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 all lines of business, unless a specific limitation or exception exists.

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

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

**KOMBIGLYZE QUANTITY LIMIT:** Pharmacist note to CSR: *Authorization should be entered by HICL and only checking the Formulary PA required box (no QLs need to be entered within the authorization).*
  - Kombiglyze XR 2.5-1000 mg: 2 tablets per day
  - Kombiglyze XR (all other strengths): 1 tablet per day

**ALOGLIPTIN/METFORMIN QUANTITY LIMIT:** Pharmacist note to CSR: *Authorization should be entered by HICL and only checking the Formulary box (no QLs need to be entered within the authorization).*
  - 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
THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND FEDERAL REGULATORY ENTITIES.

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

Signed: _____________________________________________

Title: Director, Pharmacy Services

Date: March 1, 2020

Devised: 3/11
Revised: 3/1/12 – annual review, updated signature
Revised: 7/18/12 – added Jentadueto 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: 2/8/18 – 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
Applicable line of business:

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**POLICY:**
Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of formulary. The formulary is applied according to the formulary review process (see Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Part D Policy 143.0 D Geisinger Health Plan (GHP) and Geisinger Indemnity Insurance Company (GIIC) Formulary Development by the Pharmacy). The results of this process determine the development and application 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 all lines of business, unless a specific limitation or exception exists.

**REQUIRED DEFINITIONS:**
1. **Attachment** – a supporting document that is developed and maintained by the policy writer or 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).
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 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, one of which is bupropion

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, 2020

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, updated FA
Reviewed: 3/1/19 – annual review
Revised: 3/1/20 – annual review, added GHP Kids
POLICY NUMBER: 229.0

SECTION: Commercial Drug

SUBJECT: Caprelsa

Applicable line of business:

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POLICY:
Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of formulary. The formulary is applied according to the formulary review process (see Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Part D Policy 143.0 D Geisinger Health Plan (GHP) and Geisinger Indemnity Insurance Company (GIIC) Formulary Development by the Pharmacy). The results of this process determine the development and application 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 all lines of business, unless a specific limitation or exception exists.

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

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

**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.

**QUANTITY LIMIT:** Pharmacist note to CSR: *Authorization should be entered by HICL and only checking the Formulary PA required box (noQLs need to be entered within the authorization)*.

- 100 mg tablet: 2 tablets per day, 30 day supply per fill
- 300 mg tablet: 1 tablet per day, 30 day supply per fill

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
REVIEWS NO LESS THAN ANNUALLY.

Signed:_______________________________________________

Title: Director, Pharmacy Services

Date: March 1, 2020

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
POLICY:  
Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of formulary. The formulary is applied according to the formulary review process (see Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Part D Policy 143.0 D Geisinger Health Plan (GHP) and Geisinger Indemnity Insurance Company (GIIC) Formulary Development by the Pharmacy). The results of this process determine the development and application 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 for GHP members who have prescription drug benefits, including all lines of business, unless a specific limitation or exception exists.

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

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

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

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

Signed: ________________________________________________

Title: Director, Pharmacy Services

Date: March 1, 2020

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
Applicable line of business:

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POLICY:

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of formulary. The formulary is applied according to the formulary review process (see Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Part D Policy 143.0 D Geisinger Health Plan (GHP) and Geisinger Indemnity Insurance Company (GIIC) Formulary Development by the Pharmacy). The results of this process determine the development and application 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 metered dose inhalers (MDI) for GHP members who have prescription drug benefits, including all lines of business, unless a specific limitation or exception exists.

REQUIRED DEFINITIONS:

1. **Attachment** – a supporting document that is developed and maintained by the policy writer or 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.
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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).
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 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

**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

SECTION: Commercial Drug

SUBJECT: Spacers for MDI

Signed: 

Title: Director, Pharmacy Services

Date: March 1, 2020

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
POLICY NUMBER: 237.0

SECTION: Commercial Drug

SUBJECT: Daliresp

Applicable line of business:

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POLICY:

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of formulary. The formulary is applied according to the formulary review process (see Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Part D Policy 143.0 D Geisinger Health Plan (GHP) and Geisinger Indemnity Insurance Company (GIIC) Formulary Development by the Pharmacy). The results of this process determine the development and application 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 all lines of business, unless a specific limitation or exception exists.

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.
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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

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

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

Signed: [signature]
Title: Director, Pharmacy Services
Date: October 12, 2020

Revised:
- 2/12
- 3/1/12 – annual review, updated signature
- 3/1/13 – annual review, updated logo and definitions
- 3/1/14 – annual review, removed Symbicort from FA, added Breo Ellipta & Tudorza to FA
- 3/1/15 – annual review, updated signature, remove Tudorza Pressair from alternatives
- 3/1/16 – annual review, updated FA bullet formatting
- 5/1/16 – updated format, logo, & procedure
- 12/7/16 – removed Foradil from FA
- 3/1/17 – annual review
- 3/1/18 – annual review, updated signature, defined COPD, updated FA
- 3/1/19 – annual review, updated FA
- 11/21/19 – updated FA
- 3/1/20 – annual review, added GHP Kids
- 10/12/20 – updated from failure of Spiriva to one LAMA, updated FA
POLICY NUMBER: 238.0

SECTION: Commercial Drug

SUBJECT: Dutasteride/Tamsulosin

Applicable line of business:

<table>
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<tr>
<th>Line of Business</th>
<th>Medicaid</th>
<th>Medicare</th>
<th>ACA</th>
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POLICY:
Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of formulary. The formulary is applied according to the formulary review process (see Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Part D Policy 143.0 D Geisinger Health Plan (GHP) and Geisinger Indemnity Insurance Company (GIIC) Formulary Development by the Pharmacy). The results of this process determine the development and application 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 all lines of business, unless a specific limitation or exception exists.

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

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

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 NUMBER: 239.0

SECTION: Commercial Drug

SUBJECT: Dificid

POLICY:

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of formulary. The formulary is applied according to the formulary review process (see Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Part D Policy 143.0 D Geisinger Health Plan (GHP) and Geisinger Indemnity Insurance Company (GIIC) Formulary Development by the Pharmacy). The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for Dificid for GHP members who have prescription drug benefits, including all lines of business, unless a specific limitation or exception exists.

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

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

QUANTITY LIMIT: Pharmacist note to CSR: Authorization should be entered by HICL and only checking the Formulary PA required box (no QLs need to be entered within the authorization).
- 20 tablets 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 NUMBER: 239.0

SECTION: Commercial Drug

SUBJECT: Dificid

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

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

Signed: ________________________________

Title: Director, Pharmacy Services

Date: July 28, 2020

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
Applicable line of business:

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<th>Medicaid</th>
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**POLICY:**
Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of formulary. The formulary is applied according to the formulary review process (see Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Part D Policy 143.0 D Geisinger Health Plan (GHP) and Geisinger Indemnity Insurance Company (GIIC) Formulary Development by the Pharmacy). The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for Forfivo XL for GHP members who have prescription drug benefits, including all lines of business, unless a specific limitation or exception exists.

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

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

QUANTITY LIMIT: Pharmacist note to CSR: Authorization should be entered by HICL and only checking the Formulary PA required box (no QLs need to be entered within the authorization).
- 1 tablet per day

If a formulary exception is approved 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.

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, 2020

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
Applicable line of business:

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**POLICY:**

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of formulary. The formulary is applied according to the formulary review process (see Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Part D Policy 143.0 D Geisinger Health Plan (GHP) and Geisinger Indemnity Insurance Company (GIIC) Formulary Development by the Pharmacy). The results of this process determine the development and application 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 all lines of business, unless a specific limitation or exception exists.

**REQUIRED DEFINITIONS:**

1. **Attachment** – a supporting document that is developed and maintained by the policy writer or 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).
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

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

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

THIS POLICY WILL BE REVISED AS NECESSARY AND
REVIEWS NO LESS THAN ANNUALLY.
Signed:  

Title:  Director, Pharmacy Services

Date:  March 1, 2020

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
POLICY AND PROCEDURE
PHARMACY
MANUAL

POLICY NUMBER: 244.0
SECTION: Commercial Drug
SUBJECT: Ferriprox

Applicable line of business:

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<tr>
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POLICY:
Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of formulary. The formulary is applied according to the formulary review process (see Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Part D Policy 143.0 D Geisinger Health Plan (GHP) and Geisinger Indemnity Insurance Company (GIIC) Formulary Development by the Pharmacy). The results of this process determine the development and application 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 all lines of business, unless a specific limitation or exception exists.

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).
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 thalassemia syndromes AND
- Medical record documentation of therapeutic failure on, intolerance to, or contraindication to Exjade AND
- Medical record documentation of absolute neutrophil count (ANC) greater than 1.5 x 10^9/L

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 mcg/L.

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

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

FORMULARY ALTERNATIVES:
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
REVIEWS NO LESS THAN ANNUALLY.

Signed: ________________________________

Title: Director, Pharmacy Services

Date: March 1, 2020

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

HPRX02
\geisinger.edu\dfs\0004\0142\142006\COMMERCIAL\Commercial 2020-2021\Policy 244.0 Ferriprox.docx
Dev. 3/29/12
Rev. 3/1/20
POLICY:
Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of formulary. The formulary is applied according to the formulary review process (see Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Part D Policy 143.0 D Geisinger Health Plan (GHP) and Geisinger Indemnity Insurance Company (GIIC) Formulary Development by the Pharmacy). The results of this process determine the development and application 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 all lines of business, unless a specific limitation or exception exists.

REQUIRED DEFINITIONS:
1. Attachment – a supporting document that is developed and maintained by the policy writer or 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).
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

AUTHORIZATION DURATION: Each treatment period will be defined as 12 months. Review will occur every 12 months. Erivedge will no longer be covered if there is medical record documentation of disease progression.

QUANTITY LIMIT: Pharmacist note to CSR: Authorization should be entered by HICL and only checking the Formulary PA required box (no QLs need to be entered within the authorization).
- 1 capsule per day, 30 day supply per fill

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, 2020

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
Revised: 5/1/16 – updated format, logo, & procedure, updated note to authorization duration
Reviewed: 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
POLICY AND PROCEDURE
PHARMACY
MANUAL

POLICY NUMBER: 246.0
SECTION: Commercial Drug
SUBJECT: Inlyta

Applicable line of business:

<table>
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<tr>
<th>Line of Business</th>
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<th>ACA</th>
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POLICY:
Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of formulary. The formulary is applied according to the formulary review process (see Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Part D Policy 143.0 D Geisinger Health Plan (GHP) and Geisinger Indemnity Insurance Company (GIIC) Formulary Development by the Pharmacy). The results of this process determine the development and application 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 all lines of business, unless a specific limitation or exception exists.

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

ADDITIONAL DEFINITIONS:
1. Formulary – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. Non-formulary products – those medications that are not included in the Formulary.
3. Healthcare provider – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
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;
POLICY NUMBER: 246.0

SECTION: Commercial Drug

SUBJECT: Inlyta

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

AUTHORIZATION DURATION: Each treatment period will be defined as 12 months. Review will occur every 12 months. Inlyta will no longer be covered if there is medical record documentation of disease progression.

QUANTITY LIMIT: Pharmacist note to CSR: Authorization should be entered by HICL and only checking the Formulary PA required box (no QLs need to be entered within the authorization).

- 1 mg tablet: 6 tablets per day, 30 day supply per fill
- 5 mg tablet: 4 tablets per day, 30 day supply per fill
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:**

Afinitor*, Avastin*, Nexavar*, Proleukin, Sutent*, 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: July 29, 2020
POLICY NUMBER: 247.0

POLICY AND PROCEDURE
PHARMACY
MANUAL

SECTION: Commercial Drug
SUBJECT: H.P. Acthar Gel

Applicable line of business:

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POLICY:

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of formulary. The formulary is applied according to the formulary review process (see Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Part D Policy 143.0 D Geisinger Health Plan (GHP) and Geisinger Indemnity Insurance Company (GIIC) Formulary Development by the Pharmacy). The results of this process determine the development and application 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 all lines of business, unless a specific limitation or exception exists.

REQUIRED DEFINITIONS:

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

ADDITIONAL DEFINITIONS:

1. **Formulary** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. **Non-formulary products** – those medications that are not included in the Formulary.
3. **Healthcare provider** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
5. **Medically Necessary or Medical Necessity** – covered services rendered by a provider that the Health Plan determines are:
   - Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
   - Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
C. In accordance with current standards of medical practice;
D. Not primarily for the convenience of the Member, or the Member’s Provider; and
E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services 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)

OR

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.

AUTHORIZATION DURATION: Treatment period is defined as 28 days; a re-review is required at that time.

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, 2020

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
POLICY NUMBER: 249.0

POLICY AND PROCEDURE
PHARMACY
MANUAL

SECTION: Commercial Drug
SUBJECT: Cycloset

Applicable line of business:

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POLICY:
Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of formulary. The formulary is applied according to the formulary review process (see Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Part D Policy 143.0 D Geisinger Health Plan (GHP) and Geisinger Indemnity Insurance Company (GIIC) Formulary Development by the Pharmacy). The results of this process determine the development and application 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 all lines of business, unless a specific limitation or exception exists.

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

ADDITIONAL DEFINITIONS:
1. Formulary – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. Non-formulary products – those medications that are not included in the Formulary.
3. Healthcare provider – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
5. Medically Necessary or Medical Necessity – covered services rendered by a provider that the Health Plan determines are:
   - Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
   - Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
C. In accordance with current standards of medical practice;
D. Not primarily for the convenience of the Member, or the Member’s Provider; and
E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services 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

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, Glyset, repaglinide, pioglitazone, Avandia*, Jardiance, Synjardy, Invokana, Invokamet, Tradjenta, Jentadueto

*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, 2020

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
Applicable line of business:

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POLICY:

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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).
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 thrombocytemia myelofibrosis AND
- Medical record documentation of platelet count greater than or equal to 50 x 10⁹/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 x 10⁹/L
- Hemoglobin < 10 g/dL
- Blood Blasts ≥ 1%
- Presence of Constitutional Symptoms (weight loss, fever, excessive sweats, etc.)
- Transfusion dependency
POLICY NUMBER: 250.0
SECTION: Commercial Drug
SUBJECT: Jakafi

✔ Platelets less than 100 x 10^9/L  
✔ Unfavorable karyotype

**AUTHORIZATION DURATION:** Each treatment period will be defined as six (6) months. Re-review will 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 x 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 if the reviewing provider feels it is medically appropriate. Subsequent approvals will be for 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.

**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)

**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.

**QUANTITY LIMIT (all indications):** Pharmacist note to CSR: *Authorization should be entered by HICL and only checking the Formulary PA required box (no QLs need to be entered within the authorization).*

- 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

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

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

Signed: [Signature]

Title: Director, Pharmacy Services

Date: March 1, 2020
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
POLICY NUMBER: 251.0

POLICY AND PROCEDURE
PHARMACY
MANUAL

SECTION: Commercial Drug
SUBJECT: Kalydeco

Applicable line of business:

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**POLICY:**
Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of formulary. The formulary is applied according to the formulary review process (see Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Part D Policy 143.0 D Geisinger Health Plan (GHP) and Geisinger Indemnity Insurance Company (GIIC) Formulary Development by the Pharmacy). The results of this process determine the development and application 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 all lines of business, unless a specific limitation or exception exists.

**REQUIRED DEFINITIONS:**
1. **Attachment** – a supporting document that is developed and maintained by the policy writer or 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).
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 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 6 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

NOTE:

<table>
<thead>
<tr>
<th>Mutation</th>
<th>D110H</th>
<th>F1052V</th>
<th>G551S</th>
<th>R117H</th>
<th>S549R</th>
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<tbody>
<tr>
<td>2789+5G→A</td>
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<tr>
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<td>D579G</td>
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<td>P67L</td>
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<td>E193K</td>
<td>G1349D</td>
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<td>A455E</td>
<td>E56K</td>
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<td>R1070W</td>
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<td></td>
</tr>
<tr>
<td>D110E</td>
<td>E831X</td>
<td>G551D</td>
<td>R117C</td>
<td>S549N</td>
<td></td>
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</tbody>
</table>

QUANTITY LIMIT: Pharmacist note to CSR: Authorization should be entered by HICL and only checking the Formulary PA required box (no QLs need to be entered within the authorization).

- 2 tablets or granule packets per day, 30 day supply per fill

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, 2020

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 vendor, updated signature  
Reviewed: 3/1/15 – annual review  
Revised: 4/13/15 – added R117H mutation to policy
<table>
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<tr>
<td>7/22/15</td>
<td>Updated age to 2 years for all mutations except R117H</td>
</tr>
<tr>
<td>11/20/15</td>
<td>Removed duplicate section referencing R117H</td>
</tr>
<tr>
<td>3/1/16</td>
<td>Annual Review</td>
</tr>
<tr>
<td>5/1/16</td>
<td>Updated format, logo, &amp; procedure</td>
</tr>
<tr>
<td>3/1/17</td>
<td>Annual Review, removed Unicode characters</td>
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<tr>
<td>10/3/17</td>
<td>Updated mutation chart</td>
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<tr>
<td>1/18/18</td>
<td>Updated format of prescriber &amp; age criteria, increased auth duration to 4 months, updated signature, removed QL indicators</td>
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<td>3/1/18</td>
<td>Annual Review</td>
</tr>
<tr>
<td>7/27/18</td>
<td>Added CF specialist, added per labeling to mutation crit., moved table to note</td>
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<tr>
<td>2/6/19</td>
<td>Updated age to 12 months, added QL note to CSR</td>
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<tr>
<td>3/1/19</td>
<td>Annual review, defined abbr., removed distribution information</td>
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<tr>
<td>10/1/19</td>
<td>Updated age to 6 months</td>
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<tr>
<td>3/1/20</td>
<td>Annual review, added GHP Kids</td>
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</tbody>
</table>
Applicable line of business:

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<tr>
<th>Line of Business</th>
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<th>ACA</th>
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<tbody>
<tr>
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<tr>
<td>Medicare</td>
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<td>X</td>
<td></td>
</tr>
<tr>
<td>GHP Kids</td>
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<td></td>
<td>X</td>
</tr>
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POLICY:
Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of formulary. The formulary is applied according to the formulary review process (see Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Part D Policy 143.0 D Geisinger Health Plan (GHP) and Geisinger Indemnity Insurance Company (GIIC) Formulary Development by the Pharmacy). The results of this process determine the development and application 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 all lines of business, unless a specific limitation or exception exists.

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

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

QUANTITY LIMIT: Pharmacist note to CSR: Authorization should be entered by HICL and only checking the Formulary PA required box (no QLs need to be entered within the authorization).

- 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.

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, 2020

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
Reviewed: 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
Applicable line of business:

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<tr>
<th>Line of Business</th>
<th>Commercial</th>
<th>Medicaid</th>
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POLICY:
Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of formulary. The formulary is applied according to the formulary review process (see Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Part D Policy 143.0 D Geisinger Health Plan (GHP) and Geisinger Indemnity Insurance Company (GIIC) Formulary Development by the Pharmacy). The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for Orencia SC for GHP members who have prescription drug benefits, including all lines of business, unless a specific limitation or exception exists.

REQUIRED DEFINITIONS:
1. **Attachment** – a supporting document that is developed and maintained by the policy writer or 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).
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*, Rinvoq*, OR Xeljanz* AND
- Medical record documentation that Orencia is not being used concurrently with a tumor necrosis factor (TNF) blocker or other biologic agent

QUANTITY LIMIT: Pharmacist note to CSR: Authorization should be entered by HICL and only checking the Formulary PA required box (no QLs need to be entered within the authorization).
- 4 syringes per 28 days

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 rheumatoid arthritis on six (6) months of abatacept therapy 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 required
medical record documentation of continued or sustained improvement in the signs and symptoms of rheumatoid arthritis while on abatacept therapy.

FORMULARY ALTERNATIVES:
Humira*, Rinvoq*, Xeljanz*

*prior authorization required
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

**QUANTITY LIMIT:** Pharmacist note to CSR: *Authorization should be entered by HICL and only checking the Formulary PA required box (no QLs need to be entered within the authorization).*

- 4 syringes per 28 days

**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 polyarticular juvenile idiopathic arthritis on six (6) months of abatacept therapy 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 required medical record documentation of continued or sustained improvement in the signs and symptoms of polyarticular juvenile idiopathic arthritis while on abatacept therapy.

**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
For treatment of psoriatic arthritis:

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 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 Orencia 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 Orencia is not being used concurrently with a tumor necrosis factor (TNF) blocker or other biologic agent

**QUANTITY LIMIT:** Pharmacist note to CSR: Authorization should be entered by HICL and only checking the Formulary PA required box (no QLs need to be entered within the authorization).

- 4 syringes per 28 days

**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 psoriatic arthritis on six (6) months of abatacept therapy 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 required medical record documentation of continued or sustained improvement in the signs and symptoms of psoriatic arthritis while on abatacept therapy.

**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:**

- Cosentyx*, Humira*

  *prior authorization required

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, 2020

Devised:  6/21/12
Revised:  3/1/13 – annual review, updated logo and definitions, fixed typo
Reviewed:  3/1/14
Revised:  9/22/14 – updated diagnosis, joint count, and alternatives criteria, modified auth duration wording, updated signature and FA
Reviewed:  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:  01/28/20 – updated RA FA and added failure of Rinvoq and Xeljanz
Revised:  3/1/20 – annual review, added GHP Kids
Applicable line of business:

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POLICY:
Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of formulary. The formulary is applied according to the formulary review process (see Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Part D Policy 143.0 D Geisinger Health Plan (GHP) and Geisinger Indemnity Insurance Company (GIIC) Formulary Development by the Pharmacy). The results of this process determine the development and application 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 all lines of business, unless a specific limitation or exception exists.

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).
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 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

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.

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
REVIEWS NO LESS THAN ANNUALLY.

Signed:_______________________________________________

Title: Director, Pharmacy Services

Date: March 1, 2019

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
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Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of formulary. The formulary is applied according to the formulary review process (see Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Part D Policy 143.0 D Geisinger Health Plan (GHP) and Geisinger Indemnity Insurance Company (GIIC) Formulary Development by the Pharmacy). The results of this process determine the development and application 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 all lines of business, unless a specific limitation or exception exists.

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:
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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

**NOTE:** The FDA approved test is the Vysis ALK Break-Apart FISH Probe Kit

**QUANTITY LIMIT:** Pharmacist note to CSR: *Authorization should be entered by HICL and only checking the Formulary PA required box (no QLs need to be entered within the authorization).*
- 2 capsules per day, 30 day supply per fill

**AUTHORIZATION DURATION:** Each treatment period will be defined as twelve (12) months. Re-review will occur every twelve (12) months. Xalkori will no longer be covered if there is medical record documentation of disease progression.
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

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

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

Signed:_______________________________________________

Title: Director, Pharmacy Services

Date: March 1, 2020
POLICY: Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of formulary. The formulary is applied according to the formulary review process (see Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Part D Policy 143.0 D Geisinger Health Plan (GHP) and Geisinger Indemnity Insurance Company (GIIC) Formulary Development by the Pharmacy). The results of this process determine the development and application 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 all lines of business, unless a specific limitation or exception exists.

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

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

**QUANTITY LIMIT:** Pharmacist note to CSR: *Authorization should be entered by HICL and only checking the Formulary PA required box (no QLs need to be entered within the authorization).*
- 8 tablets per day, 30 day supply per fill
AUTHORIZATION DURATION: Each treatment period will be defined as twelve (12) months. Re-review will occur every twelve (12) months. Zelboraf will no longer be covered if there is medical record documentation of disease progression.

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, 2020

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: 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
Applicable line of business:

| Line of Business | X | 
|------------------|---|---|
| Commercial       | X | Medicaid |
| Medicare         |   | ACA     |
| GHP Kids         |   | X       |

POLICY:
Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of formulary. The formulary is applied according to the formulary review process (see Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Part D Policy 143.0 D Geisinger Health Plan (GHP) and Geisinger Indemnity Insurance Company (GIIC) Formulary Development by the Pharmacy). The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for Zytiga for GHP members who have prescription drug benefits, including all lines of business, unless a specific limitation or exception exists.

REQUIRED DEFINITIONS:
1. **Attachment** – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. **Exhibit** – a 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).
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 Zytiga may be made for members who meet the following criteria:

- Medical record documentation that Zytiga 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 Zytiga 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.

QUANTITY LIMIT: Pharmacist note to CSR: Authorization should be entered by HICL and only checking the Formulary PA required box (no QLs need to be entered within the authorization).

- 250 mg tablet: 4 tablets per day, 30 day supply per fill
- 500 mg tablets: 2 tablets per day, 30 day supply per fill
AUTHORIZATION DURATION: Each treatment period will be defined as twelve (12) months. Re-review will occur every twelve (12) months. Zytiga will no longer be covered if there is medical record documentation of disease progression.

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

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, 2020

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
POLICY:
Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of formulary. The formulary is applied according to the formulary review process (see Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Part D Policy 143.0 D Geisinger Health Plan (GHP) and Geisinger Indemnity Insurance Company (GIIC) Formulary Development by the Pharmacy). The results of this process determine the development and application 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 all lines of business, unless a specific limitation or exception exists.

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

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

QUANTITY LIMIT: Pharmacist note to CSR: Authorization should be entered by HICL and only checking the Formulary PA required box (no QLs need to be entered within the authorization).

- 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

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

THIS POLICY WILL BE REVISED AS NECESSARY AND REVIEWED NO LESS THAN ANNUALLY.
Signed:_______________________________________________

Title: Director, Pharmacy Services

Date: March 1, 2020

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
Reviewed: 3/1/19 – annual review, added QL approval note
Revised: 3/1/20 – annual review, added GHP Kids
POLICY NUMBER: 259.0

POLICY AND PROCEDURE
PHARMACY
MANUAL

SECTiON: Commercial Drug
SUBJECT: Pancreaze, Pertzye, Viokace, and Zenpep

Applicable line of business:

<table>
<thead>
<tr>
<th>Business</th>
<th>Formulary</th>
<th>Medicaid</th>
<th>Medicare</th>
<th>ACA</th>
<th>GHP Kids</th>
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<tbody>
<tr>
<td>Commercial</td>
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<td>Medicare</td>
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POLICY:

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of formulary. The formulary is applied according to the formulary review process (see Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Part D Policy 143.0 D Geisinger Health Plan (GHP) and Geisinger Indemnity Insurance Company (GIIC) Formulary Development by the Pharmacy). The results of this process determine the development and application 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 all lines of business, unless a specific limitation or exception exists.

REQUIRED DEFINITIONS:

1. Attachment – a supporting document that is developed and maintained by the policy writer or 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).
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 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

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.

FORMULARY ALTERNATIVES:
pancrelipase, Creon
POLICY NUMBER: 259.0

SECTION: Commercial Drug
SUBJECT: Pancreaze, Pertzye, Viokace, and Zenpep

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

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

Signed: __________________________________________
Title: Director, Pharmacy Services
Date: October 12, 2020

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
Applicable line of business:

<table>
<thead>
<tr>
<th>Line of Business</th>
<th>Commercial</th>
<th>Medicaid</th>
<th>Medicare</th>
<th>ACA</th>
<th>GHP Kids</th>
</tr>
</thead>
</table>

POLICY:

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of formulary. The formulary is applied according to the formulary review process (see Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Part D Policy 143.0 D Geisinger Health Plan (GHP) and Geisinger Indemnity Insurance Company (GIIC) Formulary Development by the Pharmacy). The results of this process determine the development and application 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 all lines of business, unless a specific limitation or exception exists.

REQUIRED DEFINITIONS:

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

ADDITIONAL DEFINITIONS:

1. **Formulary** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. **Non-formulary products** – those medications that are not included in the Formulary.
3. **Healthcare provider** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
5. **Medically Necessary or Medical Necessity** – covered services rendered by a provider that the Health Plan determines are:
   - Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
   - Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
C. In accordance with current standards of medical practice;
D. Not primarily for the convenience of the Member, or the Member's Provider; and
E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to 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

**QUANTITY LIMIT:** Pharmacist note to CSR: Authorization should be entered by HICL and only checking the Formulary PA required box (no QLs need to be entered within the authorization).

- 4 tablets per day, 30 day supply per fill

**AUTHORIZATION DURATION:** Treatment period will be defined as 12 months. Review will occur every 12 months. Xtandi will no longer be covered if there is medical record documentation of disease progression.

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:**
- abiterone acetate*, Yonsa*, Zytiga*

*prior authorization required

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

**THESE POLICIES WILL BE REVISED AS NECESSARY AND REVIEWED NO LESS THAN ANNUALLY.**

Signed: ____________________________  
Title: Director, Pharmacy Services  
Date: March 1, 2020

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  
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: 01/28/20 – added indication for metastatic castration-sensitive prostate cancer  
Revised: 3/1/20 – annual review, added GHP Kids
POLICY:  
Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of formulary. The formulary is applied according to the formulary review process (see Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Part D Policy 143.0 D Geisinger Health Plan (GHP) and Geisinger Indemnity Insurance Company (GIIC) Formulary Development by the Pharmacy). The results of this process determine the development and application 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 all lines of business, unless a specific limitation or exception exists.

REQUIRED DEFINITIONS:
1. **Attachment** – a supporting document that is developed and maintained by the policy writer or 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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   A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
   B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
C. In accordance with current standards of medical practice;
D. Not primarily for the convenience of the Member, or the Member’s Provider; and
E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to 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
- 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
- Medical record documentation of chronic, accelerated, or blast phase Philadelphia chromosome-positive (Ph+) chronic myelogenous leukemia (CML)
- Medical record documentation of therapeutic failure on, intolerance to, or contraindication to one prior therapy (imatinib, Sprycel*, or Tasigna*)

**QUANTITY LIMIT:** Pharmacist note to CSR: *Authorization should be entered by HICL and only checking the Formulary PA required box (no QLs need to be entered within the authorization).*
- 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
AUTHORIZATION DURATION: Treatment period will be defined as 12 months. Review will be every 12 months. Bosulif will no longer be covered if there is medical record documentation of disease progression.

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, 2020

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
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
Applicable line of business:

<table>
<thead>
<tr>
<th>Line of Business</th>
<th>Medicaid</th>
<th>Medicare</th>
<th>ACA</th>
<th>GHP Kids</th>
</tr>
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<td>Medicaid</td>
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<tr>
<td>GHP Kids</td>
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</tr>
</tbody>
</table>

POLICY:
Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of formulary. The formulary is applied according to the formulary review process (see Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Part D Policy 143.0 D Geisinger Health Plan (GHP) and Geisinger Indemnity Insurance Company (GIIC) Formulary Development by the Pharmacy). The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for Dymista for GHP members who have prescription drug benefits, including all lines of business, unless a specific limitation or exception exists.

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

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

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

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.

Signed:______________________________
Title: Director, Pharmacy Services
Date: March 1, 2020

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
Applicable line of business:

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<tr>
<th>Line of Business</th>
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<th>Medicaid</th>
<th>Medicare</th>
<th>ACA</th>
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<td>X</td>
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</tbody>
</table>

**POLICY:**

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of formulary. The formulary is applied according to the formulary review process (see Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Part D Policy 143.0 D Geisinger Health Plan (GHP) and Geisinger Indemnity Insurance Company (GIIC) Formulary Development by the Pharmacy). The results of this process determine the development and application 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 all lines of business, unless a specific limitation or exception exists.

**REQUIRED DEFINITIONS:**

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

**ADDITIONAL DEFINITIONS:**

1. **Formulary** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. **Non-formulary products** – those medications that are not included in the Formulary.
3. **Healthcare provider** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
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;
POLICY NUMBER: 265.0

POLICY AND PROCEDURE
PHARMACY
MANUAL

SECTION: Commercial Drug

SUBJECT: Albendazole

C. In accordance with current standards of medical practice;
D. Not primarily for the convenience of the Member, or the Member's Provider; and
E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services 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)

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.

Signed: __________________________________________

Title: Director, Pharmacy Services

Date: 3/1/20
POLICY NUMBER: 265.0

SECTION: Commercial Drug

SUBJECT: Albendazole

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
POLICY:
Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of formulary. The formulary is applied according to the formulary review process (see Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Part D Policy 143.0 D Geisinger Health Plan (GHP) and Geisinger Indemnity Insurance Company (GIIC) Formulary Development by the Pharmacy). The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for Sklice for GHP members who have prescription drug benefits, including all lines of business, unless a specific limitation or exception exists.

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

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

If an exception is made, 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

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

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

Signed: ____________________________________________________________________________

Title: Director, Pharmacy Services
Date: March 1, 2020

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
Reviewed: 3/1/18 – annual review, updated signature
Revised: 3/1/19 – annual review, defined abbr.
Revised: 3/1/20 – annual review, added GHP Kids
POLICY:  
Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of formulary. The formulary is applied according to the formulary review process (see Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Part D Policy 143.0 D Geisinger Health Plan (GHP) and Geisinger Indemnity Insurance Company (GIIC) Formulary Development by the Pharmacy). The results of this process determine the development and application 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 5 mg for GHP members who have prescription drug benefits, including all lines of business, unless a specific limitation or exception exists.

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

ADDITIONAL DEFINITIONS:
1. **Formulary** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. **Non-formulary products** – those medications that are not included in the Formulary.
3. **Healthcare provider** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician’s assistant, certified registered nurse practitioner).
5. **Medically Necessary or Medical Necessity** – covered services rendered by a provider that the Health Plan determines are:
POLICY NUMBER: 268.0

SECTION: Commercial Drug

SUBJECT: Tadalafil 5 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 tadalafil 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

NOTE: Approve by GPID.

If an exception is made, tadalafil 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

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

THIS POLICY WILL BE REVISED AS NECESSARY AND REVIEWED NO LESS THAN ANNUALLY.
Signed: John Miller

Title: Director, Pharmacy Services

Date: March 1, 2020

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
POLICY:  
Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of formulary. The formulary is applied according to the formulary review process (see Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Part D Policy 143.0 D Geisinger Health Plan (GHP) and Geisinger Indemnity Insurance Company (GIIC) Formulary Development by the Pharmacy). The results of this process determine the development and application 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 all lines of business, unless a specific limitation or exception exists.

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

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

**OR**

**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)*
OR

**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)*

**QUANTITY LIMIT:** Pharmacist note to CSR: *Authorization should be entered by HICL and only checking the Formulary PA required box (no QLs need to be entered within the authorization).*
- 3 tablets per day, 28 day supply per fill

**AUTHORIZATION DURATION:** Treatment period will be defined as 12 months. Review will be every 12 months. Stivarga will no longer be covered if there is medical record documentation of disease progression.

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, Sutent*
- 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, 2020

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 Gleevec 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 grandchild language
Revised: 3/1/19 – annual review, added QL approval note
Revised: 3/1/20 – annual review, added GHP Kids
Policy Number: 271.0

Policy and Procedure Section: Commercial Drug Pharmacy

Subject: Binosto

Applicable line of business:

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<th>Line of Business</th>
<th>Commercial</th>
<th>Medicaid</th>
<th>Medicare</th>
<th>ACA</th>
<th>GHP Kids</th>
</tr>
</thead>
</table>

Policy:

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of formulary. The formulary is applied according to the formulary review process (see Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Part D Policy 143.0 D Geisinger Health Plan (GHP) and Geisinger Indemnity Insurance Company (GIIC) Formulary Development by the Pharmacy). The results of this process determine the development and application 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 all lines of business, unless a specific limitation or exception exists.

Required Definitions:

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

Additional Definitions:

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

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.

Signed: ____________________________________
Title: Director, Pharmacy Services

Date: March 1, 2019

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
Reviewed: 3/1/18 – annual review, updated signature
Reviewed: 3/1/19 – annual review
Revised: 3/1/20 – annual review, added GHP Kids
POLICY NUMBER: 272.0

POLICY AND PROCEDURE
PHARMACY
MANUAL

SECTION: Commercial Drug
SUBJECT: Latuda

Applicable line of business:

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<thead>
<tr>
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<th>Commercial</th>
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POLICY:
Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of formulary. The
formulary is applied according to the formulary review process (see Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Part D Policy 143.0 D Geisinger Health Plan (GHP) and Geisinger Indemnity Insurance Company (GIIC) Formulary Development by the Pharmacy). The results of this process determine the development and application 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 all lines of business, unless a specific limitation or exception exists.

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

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

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: May 1, 2020

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
Reviewed: 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
POLICY NUMBER: 273.0  
SECTION: Commercial Drug  
SUBJECT: Xeljanz and Xeljanz XR

Applicable line of business:

<table>
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<tr>
<th>Line of Business</th>
<th>Xeljanz</th>
<th>Xeljanz XR</th>
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**POLICY:**

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of formulary. The formulary is applied according to the formulary review process (see Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Part D Policy 143.0 D Geisinger Health Plan (GHP) and Geisinger Indemnity Insurance Company (GIIC) Formulary Development by the Pharmacy). The results of this process determine the development and application 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 all lines of business, unless a specific limitation or exception exists.

**REQUIRED DEFINITIONS:**

1. **Attachment** – a supporting document that is developed and maintained by the policy writer or 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).
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 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 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.
QUANTITY LIMIT: Pharmacist note to CSR: Authorization should be entered by GPID and only checking the Formulary PA required box (no QLs need to be entered within the authorization).
- 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

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 rheumatoid arthritis on six (6) months of Xeljanz 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 continued or sustained improvement in signs and symptoms of rheumatoid arthritis while on Xeljanz.

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/or 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 Xeljanx 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.

**QUANTITY LIMIT:** Pharmacist note to CSR: *Authorization should be entered by GPID and only checking the Formulary PA required box (no QLs need to be entered within the authorization).*
- 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

**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 rheumatoid arthritis on six (6) months of Xeljanz 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 continued or sustained improvement in signs and symptoms of rheumatoid arthritis while on Xeljanz.

**FORMULARY ALTERNATIVES:**

Cosentyx*, Humira*

*prior authorization required*
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

**QUANTITY LIMIT:** Pharmacist note to CSR: Authorization should be entered by HICL and only checking the Formulary PA required box (no QLs need to be entered within the authorization).

- 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

**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 rheumatoid arthritis on six (6) months of Xeljanz 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 continued or sustained improvement in signs and symptoms of rheumatoid arthritis while on Xeljanz.

**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
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:  July 29, 2020
POLICY AND PROCEDURE
PHARMACY
MANUAL

POLICY NUMBER: 273.0

SECTION: Commercial Drug
SUBJECT: Xeljanz and Xeljanz XR

Revised: 7/29/20 – added dosing criteria and note to RA AND PsA
POLICY NUMBER: 274.0

POLICY AND PROCEDURE
PHARMACY
MANUAL

SECTION: Commercial Drug
SUBJECT: Omeclamox

Applicable line of business:

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<td>POLICY:</td>
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| Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of formulary. The formulary is applied according to the formulary review process (see Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Part D Policy 143.0 D Geisinger Health Plan (GHP) and Geisinger Indemnity Insurance Company (GIIC) Formulary Development by the Pharmacy). The results of this process determine the development and application 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 all lines of business, unless a specific limitation or exception exists.

REQUIRED DEFINITIONS:
1. **Attachment** – a supporting document that is developed and maintained by the policy writer or 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).
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 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

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.**
POLICY NUMBER: 275.0

SECTION: Commercial Drug

SUBJECT: Aubagio 7 mg

Applicable line of business:

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POLICY:
Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of formulary. The formulary is applied according to the formulary review process (see Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Part D Policy 143.0 D Geisinger Health Plan (GHP) and Geisinger Indemnity Insurance Company (GIIC) Formulary Development by the Pharmacy). The results of this process determine the development and application 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 all lines of business, unless a specific limitation or exception exists.

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).
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

**QUANTITY LIMIT:** Pharmacist note to CSR: *Authorization should be entered by HICL and only checking the Formulary PA required box (no QLs need to be entered within the authorization).*

- 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, Plegridy, Rebif, Tecfidera
THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE
STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND
FEDERAL REGULATORY ENTITIES.

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

Signed:_______________________________________________

Title: Director, Pharmacy Services

Date: March 1, 2020

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
Revised: 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
Revised: 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
POLICY NUMBER: 276.0

POLICY AND PROCEDURE
PHARMACY
MANUAL

SECTION: Commercial Drug
SUBJECT: Absorica

Applicable line of business:

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POLICY:

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of formulary. The
formulary is applied according to the formulary review process (see Pharmacy Policy
2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0
Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Part D Policy 143.0 D
Geisinger Health Plan (GHP) and Geisinger Indemnity Insurance Company (GIIC) Formulary
Development by the Pharmacy). The results of this process determine the development and
application 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 all lines of business,
unless a specific limitation or exception exists.

REQUIRED DEFINITIONS:

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1. **Formulary** – a continually updated list of prescription medications that represents the
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2. **Non-formulary products** – those medications that are not included in the Formulary.
3. **Healthcare provider** – a person who is licensed, certified or otherwise regulated to
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   physician, physician's assistant, certified registered nurse practitioner).
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 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

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

THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE STANDARDS 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: 276.0

POLICY AND PROCEDURE
PHARMACY
MANUAL

POLICY NUMBER: 276.0

SECTION: Commercial Drug

SUBJECT: Absorica

Signed: ________________________________________

Title: Director, Pharmacy Services

Date: March 1, 2020

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
Reviewed: 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
POLICY NUMBER: 277.0

POLICY AND PROCEDURE
PHARMACY
MANUAL

SECTION: Commercial Drug
SUBJECT: Cometriq

Applicable line of business:

<table>
<thead>
<tr>
<th>Line of Business</th>
<th>Commercial</th>
<th>Medicaid</th>
<th>Medicare</th>
<th>ACA</th>
<th>GHP Kids</th>
</tr>
</thead>
</table>

POLICY:
Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of formulary. The formulary is applied according to the formulary review process (see Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Part D Policy 143.0 D Geisinger Health Plan (GHP) and Geisinger Indemnity Insurance Company (GIIC) Formulary Development by the Pharmacy). The results of this process determine the development and application 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 all lines of business, unless a specific limitation or exception exists.

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

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

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.

QUANTITY LIMIT: Pharmacist note to CSR: Authorization should be entered by HICL and only checking the Formulary PA required box (no QLs need to be entered within the authorization).

- 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

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, 2020

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
Reviewed: 6/1/18 – added QL
Revised: 3/1/19 – annual review, added QL approval note
Revised: 3/1/20 – annual review, added GHP Kids
POLICY NUMBER: 278.0

POLICY AND PROCEDURE
PHARMACY
MANUAL

SECTION: Commercial Drug
SUBJECT: Iclusig

Applicable line of business:

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<th>Line of Business</th>
<th>Commercial</th>
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<th>Medicare</th>
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<td>GHP Kids</td>
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</table>

POLICY:
Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of formulary. The formulary is applied according to the formulary review process (see Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Part D Policy 143.0 D Geisinger Health Plan (GHP) and Geisinger Indemnity Insurance Company (GIIC) Formulary Development by the Pharmacy). The results of this process determine the development and application 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 all lines of business, unless a specific limitation or exception exists.

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

ADDITIONAL DEFINITIONS:
1. Formulary – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. Non-formulary products – those medications that are not included in the Formulary.
3. Healthcare provider – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
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 adult patients with chronic phase, accelerated phase, 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 one prior tyrosine kinase inhibitor therapy OR medical record documentation of T315I mutation

AUTHORIZATION DURATION: Treatment period will be defined as 12 months. Review will be every 12 months. Iclusig will no longer be covered if there is medical record documentation of disease progression.

QUANTITY LIMIT: Pharmacist note to CSR: Authorization should be entered by HICL and only checking the Formulary PA required box (no QLs need to be entered within the authorization).

- 15 mg tablet: 2 tablets per day, 30 day supply per fill
- 45 mg tablet: 1 tablet per day, 30 day supply per fill

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, 2020

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
POLICY NUMBER: 279.0

POLICY AND PROCEDURE
PHARMACY
MANUAL

SECTION: Commercial Drug
SUBJECT: Linzess

Applicable line of business:

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<th>Commercial</th>
<th>Medicaid</th>
<th>Medicare</th>
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</table>

POLICY:
Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of formulary. The formulary is applied according to the formulary review process (see Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Part D Policy 143.0 D Geisinger Health Plan (GHP) and Geisinger Indemnity Insurance Company (GIIC) Formulary Development by the Pharmacy). The results of this process determine the development and application 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 all lines of business, unless a specific limitation or exception exists.

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

ADDITIONAL DEFINITIONS:
1. **Formulary** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. **Non-formulary products** – those medications that are not included in the Formulary.
3. **Healthcare provider** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
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;
POLICY AND PROCEDURE
PHARMACY
MANUAL

C. In accordance with current standards of medical practice;
D. Not primarily for the convenience of the Member, or the Member’s Provider; and
E. The most appropriate source or level of service that can safely be provided to the
Member. When applied to hospitalization, this further means that the Member
requires acute care as an inpatient due to the nature of the services 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 or 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

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
REVIEWS NO LESS THAN ANNUALLY.
Signed: 

Title: Director, Pharmacy Services

Date: March 1, 2020

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
Revised: 3/1/17 – annual review, removed Unicode characters
Reviewed: 3/1/18 – annual review, updated signature
Revised: 3/1/19 – annual review
Revised: 3/1/20 – annual review, added GHP Kids
Applicable line of business:

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<td>Medicare</td>
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**POLICY:**

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of formulary. The formulary is applied according to the formulary review process (see Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Part D Policy 143.0 D Geisinger Health Plan (GHP) and Geisinger Indemnity Insurance Company (GIIC) Formulary Development by the Pharmacy). The results of this process determine the development and application 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 all lines of business, unless a specific limitation or exception exists.

**REQUIRED DEFINITIONS:**

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

**ADDITIONAL DEFINITIONS:**

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

**QUANTITY LIMIT:** Pharmacist note to CSR: *Authorization should be entered by HICL and only checking the Formulary box (no QLs need to be entered within the authorization).*

- 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, Jentadueto, Jentadueto 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.**
POLICY NUMBER: 280.0

SECTION: Commercial Drug
SUBJECT: Alogliptin/Pioglitazone

Signed:_______________________________________________
Title: Director, Pharmacy Services
Date: March 1, 2020

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
POLICY AND PROCEDURE
PHARMACY
MANUAL

POLICY NUMBER: 281.0
SECTION: Commercial Drug
SUBJECT: Pomalyst

Applicable line of business:

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<tr>
<th>Line of Business</th>
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POLICY:
Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of formulary. The formulary is applied according to the formulary review process (see Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Part D Policy 143.0 D Geisinger Health Plan (GHP) and Geisinger Indemnity Insurance Company (GIIC) Formulary Development by the Pharmacy). The results of this process determine the development and application 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 all lines of business, unless a specific limitation or exception exists.

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

ADDITIONAL DEFINITIONS:
1. Formulary – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. Non-formulary products – those medications that are not included in the Formulary.
3. Healthcare provider – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
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**
  - 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
QUANTITY LIMIT: Pharmacist note to CSR: Authorization should be entered by HICL and only checking the Formulary PA required box (no QLs need to be entered within the authorization).
  • 21 tablets per 28 days

AUTHORIZATION DURATION: Treatment period will be defined as 12 months. Re-review will be every 12 months. Pomalyst will no longer be covered if there is medical record documentation of disease progression.

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.

Signed: ________________________________
Title: Director, Pharmacy Services
Date: July 29, 2020
POLICY NUMBER: 281.0

SECTION: Commercial Drug

SUBJECT: Pomalyst

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
Reviewed: 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
POLICY:
Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of formulary. The formulary is applied according to the formulary review process (see Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Part D Policy 143.0 D Geisinger Health Plan (GHP) and Geisinger Indemnity Insurance Company (GIIC) Formulary Development by the Pharmacy). The results of this process determine the development and application 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 all lines of business, unless a specific limitation or exception exists.

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

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

**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.

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, Rapamune 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.
POLICY NUMBER: 283.0

POLICY AND PROCEDURE
PHARMACY
MANUAL

SECTION: Commercial Drug
SUBJECT: Zortress

Signed: ________________________________
Title: Director, Pharmacy Services
Date: March 1, 2020

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
POLICY: 
Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of formulary. The formulary is applied according to the formulary review process (see Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Part D Policy 143.0 D Geisinger Health Plan (GHP) and Geisinger Indemnity Insurance Company (GIIC) Formulary Development by the Pharmacy). The results of this process determine the development and application 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 (generic Exjade) and Jadenu for GHP members who have prescription drug benefits, including all lines of business, unless a specific limitation or exception exists.

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

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

**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.

**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

**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 (generic Exjade) or Jadenu will be paid for under the member’s prescription drug benefit.

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, 2020

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
POLICY:
Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of formulary. The formulary is applied according to the formulary review process (see Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Part D Policy 143.0 D Geisinger Health Plan (GHP) and Geisinger Indemnity Insurance Company (GIIC) Formulary Development by the Pharmacy). The results of this process determine the development and application 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 all lines of business, unless a specific limitation or exception exists.

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

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

QUANTITY LIMIT: 3 syringes (9 mL) per 30 days. 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.

AUTHORIZATION DURATION: Initial authorization with 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, 2020

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
POLICY:
Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of formulary. The formulary is applied according to the formulary review process (see Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Part D Policy 143.0 D Geisinger Health Plan (GHP) and Geisinger Indemnity Insurance Company (GIIC) Formulary Development by the Pharmacy). The results of this process determine the development and application 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 all lines of business, unless a specific limitation or exception exists.

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

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

QUANTITY LIMIT: Pharmacist note to CSR: Authorization should be entered by HICL and only checking the Formulary PA required box (no QLs need to be entered within the authorization).

- 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.

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, 2020

Devised: 7/29/13
Reviewed: 3/1/14 – annual review
Reviewed: 3/1/15 – annual review, updated signature
Reviewed: 3/1/16 – annual review, corrected typo in authorization
Reviewed: 5/1/16 – updated format, logo, & procedure
Reviewed: 3/1/17 – annual review
Reviewed: 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
Reviewed: 10/1/19 – updated age to 1 year
Reviewed: 11/20/19 – revised parenteral nutrition requirements and separated by age
Reviewed: 3/1/20 – annual review, added GHP Kids
POLICY:
Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of formulary. The formulary is applied according to the formulary review process (see Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Part D Policy 143.0 D Geisinger Health Plan (GHP) and Geisinger Indemnity Insurance Company (GIIC) Formulary Development by the Pharmacy). The results of this process determine the development and application 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 all lines of business, unless a specific limitation or exception exists.

REQUIRED DEFINITIONS:
1. Attachment – a supporting document that is developed and maintained by the policy writer or 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).
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 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

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.
Signed: ______________________________________________________________________

Title: Director, Pharmacy Services

Date: March 1, 2020

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
POLICY: 
Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of formulary. The formulary is applied according to the formulary review process (see Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Part D Policy 143.0 D Geisinger Health Plan (GHP) and Geisinger Indemnity Insurance Company (GIIC) Formulary Development by the Pharmacy). The results of this process determine the development and application 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 all lines of business, unless a specific limitation or exception exists.

REQUIRED DEFINITIONS:
1. Attachment – a supporting document that is developed and maintained by the policy writer or 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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   A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
   B. Provided for the diagnosis, or the direct care and treatment of the Member’s condition, illness, disease or injury;
C. In accordance with current standards of medical practice;
D. Not primarily for the convenience of the Member, or the Member’s Provider; and
E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services 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 metrapone*

QUANTITY LIMIT: Pharmacist note to CSR: Authorization should be entered by HICL and only checking the Formulary PA required box (no QLs need to be entered within the authorization).

- 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.

FORMULARY ALTERNATIVES:
ketoconazole, metrapone*

*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, 2020

Devised: 7/29/13
Reviewed: 3/1/14 – annual review
Reviewed: 3/1/15 – annual review
Reviewed: 3/1/16 – annual review
Reviewed: 5/1/16 – updated format, logo, & procedure, corrected typo in authorization duration
Reviewed: 3/1/17 – annual review
Reviewed: 3/1/18 – annual review, updated signature, updated prescriber/diagnosis criteria, removed QL indicator
Reviewed: 3/1/19 – annual review, added QL approval note
Reviewed: 3/1/20 – annual review, added GHP Kids
Applicable line of business:

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<tr>
<th>Line of Business</th>
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<td>Commercial</td>
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<tr>
<td>GHP Kids</td>
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</table>

POLICY:
Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of formulary. The formulary is applied according to the formulary review process (see Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Part D Policy 143.0 D Geisinger Health Plan (GHP) and Geisinger Indemnity Insurance Company (GIIC) Formulary Development by the Pharmacy). The results of this process determine the development and application 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 all lines of business, unless a specific limitation or exception exists.

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

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

QUANTITY LIMIT: Pharmacist note to CSR: Authorization should be entered by HICL and only checking the Formulary PA required box (no QLs need to be entered within the authorization).
- 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, 2020

Devised: 7/29/13
Reviewed: 3/1/14 – annual review
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
POLICY NUMBER: 289.0

SECTION: Commercial Drug

SUBJECT: Kynamro

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
POLICY AND PROCEDURE
PHARMACY
MANUAL

POLICY NUMBER: 290.0
SECTION: Commercial Drug
SUBJECT: Ravicti

Applicable line of business:

<table>
<thead>
<tr>
<th>Line of Business</th>
<th>Commercial</th>
<th>Medicaid</th>
<th>Medicare</th>
<th>ACA</th>
<th>GHP Kids</th>
</tr>
</thead>
<tbody>
<tr>
<td>Geisinger Health Plan</td>
<td>X</td>
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POLICY:
Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of formulary. The formulary is applied according to the formulary review process (see Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Part D Policy 143.0 D Geisinger Health Plan (GHP) and Geisinger Indemnity Insurance Company (GIIC) Formulary Development by the Pharmacy). The results of this process determine the development and application 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 all lines of business, unless a specific limitation or exception exists.

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

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

**QUANTITY LIMIT:** Pharmacist note to CSR: *Authorization should be entered by HICL and only checking the Formulary box (no QLs need to be entered within the authorization).*

- 19 gm (17.3 mL) per day

**AUTHORIZATION DURATION:** Initial authorization will be for 6 months of therapy. 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.

**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, 2020

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
POLICY:
Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of formulary. The formulary is applied according to the formulary review process (see Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Part D Policy 143.0 D Geisinger Health Plan (GHP) and Geisinger Indemnity Insurance Company (GIIC) Formulary Development by the Pharmacy). The results of this process determine the development and application 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 all lines of business, unless a specific limitation or exception exists.

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

ADDITIONAL DEFINITIONS:
1. Formulary – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. Non-formulary products – those medications that are not included in the Formulary.
3. Healthcare provider – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
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
- Medical record documentation of erlotinib being prescribed in combination with gemcitabine
QUANTITY LIMIT: Pharmacist note to CSR: Authorization should be entered by HICL and only checking the Formulary PA required box (no QLs need to be entered within the authorization).
- 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

AUTHORIZATION DURATION: If approved, approval will be for a period of twelve (12) months. Re-review will be every twelve (12) months. Tarceva will no longer be covered if there is medical record documentation of disease progression.

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.

Signed: ____________________________
Title: Director, Pharmacy Services
Date: March 1, 2020
POLICY:  
Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of formulary. The formulary is applied according to the formulary review process (see Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Part D Policy 143.0 D Geisinger Health Plan (GHP) and Geisinger Indemnity Insurance Company (GIIC) Formulary Development by the Pharmacy). The results of this process determine the development and application 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 all lines of business, unless a specific limitation or exception exists.

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

ADDITIONAL DEFINITIONS:
1. **Formulary** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. **Non-formulary products** – those medications that are not included in the Formulary.
3. **Healthcare provider** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
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 that is caused by mutations of the low-density lipoprotein (LDL) receptor (LDLr) gene 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 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 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 Kynamro* AND
- Medical record documentation of therapeutic failure on, intolerance to, or contraindication to Repatha*

QUANTITY LIMIT: Pharmacist note to CSR: Authorization should be entered by HICL and only checking the Formulary PA required box (no QLs need to be entered within the authorization).
- 1 capsule 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, rosvastatin, Kynamro*, 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, 2020

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 rosvastatin
Revised: 3/1/17 – annual review, updated FA
Revised: 3/1/18 – annual review, updated signature, updated prescriber/age criteria, removed
Revised: 3/1/19 – annual review, added QL approval note, defined abbr.
Revised: 3/1/20 – annual review, added GHP Kids
POLICY AND PROCEDURE
PHARMACY
MANUAL

POLICY NUMBER: 294.0
SECTION: Commercial Drug
SUBJECT: Zomig Nasal Spray

Applicable line of business:

| Commercial | X | Medicaid | 
| Medicare  |   | ACA      | 
| GHP Kids  | X |         |

POLICY:
Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of formulary. The formulary is applied according to the formulary review process (see Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Part D Policy 143.0 D Geisinger Health Plan (GHP) and Geisinger Indemnity Insurance Company (GIIC) Formulary Development by the Pharmacy). The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for Zomig Nasal Spray for GHP members who have prescription drug benefits, including all lines of business, unless a specific limitation or exception exists.

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

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

QUANTITY LIMIT: 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 Zomig 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:
- 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, 2020

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
POLICY: Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of formulary. The formulary is applied according to the formulary review process (see Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Part D Policy 143.0 D Geisinger Health Plan (GHP) and Geisinger Indemnity Insurance Company (GIIC) Formulary Development by the Pharmacy). The results of this process determine the development and application 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 all lines of business, unless a specific limitation or exception exists.

REQUIRED DEFINITIONS:
1. Attachment – a supporting document that is developed and maintained by the policy writer or 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).
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

**QUANTITY LIMIT**: 16 doses per 28 days (Dose limit applies across all oral triptan products.)

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, 2020

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
POLICY: Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of formulary. The formulary is applied according to the formulary review process (see Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Part D Policy 143.0 D Geisinger Health Plan (GHP) and Geisinger Indemnity Insurance Company (GIIC) Formulary Development by the Pharmacy). The results of this process determine the development and application 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 all lines of business, unless a specific limitation or exception exists.

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

ADDITIONAL DEFINITIONS:
1. **Formulary** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. **Non-formulary products** – those medications that are not included in the Formulary.
3. **Healthcare provider** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
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 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
- 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.
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, 2020

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
POLICY: 
Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of formulary. The formulary is applied according to the formulary review process (see Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Part D Policy 143.0 D Geisinger Health Plan (GHP) and Geisinger Indemnity Insurance Company (GIIC) Formulary Development by the Pharmacy). The results of this process determine the development and application 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 all lines of business, unless a specific limitation or exception exists.

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:
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3. **Healthcare provider** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
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 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

QUANTITY LIMIT:
- 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

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: November 18, 2020

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: 01/28/20 – updated for new indication in patients 12 to less that 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
Applicable line of business:

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<tr>
<th>Line of Business</th>
<th>Medicaid</th>
<th>Medicare</th>
<th>ACA</th>
<th>GHP Kids</th>
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POLICY:
Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of formulary. The formulary is applied according to the formulary review process (see Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Part D Policy 143.0 D Geisinger Health Plan (GHP) and Geisinger Indemnity Insurance Company (GIIC) Formulary Development by the Pharmacy). The results of this process determine the development and application 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 all lines of business, unless a specific limitation or exception exists.

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

ADDITIONAL DEFINITIONS:
1. Formulary – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. Non-formulary products – those medications that are not included in the Formulary.
3. Healthcare provider – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
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 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 TPA 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**
- 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, Osphena will be paid for under the member’s prescription drug benefit.

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, Yuvafem

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

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

Signed:_______________________________________________
Title: Director, Pharmacy Services
Date: March 1, 2020

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
Reviewed: 3/1/17 – annual review, updated Vagifem to Yuvafem
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
POLICY:
Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of formulary. The formulary is applied according to the formulary review process (see Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Part D Policy 143.0 D Geisinger Health Plan (GHP) and Geisinger Indemnity Insurance Company (GIIC) Formulary Development by the Pharmacy). The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for Tafinlar and Mekinist for GHP members who have prescription drug benefits, including all lines of business, unless a specific limitation or exception exists.

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

QUANTITY LIMIT: Pharmacist note to CSR: Authorization should be entered by HICL and only checking the Formulary PA required box (no QLs need to be entered within the authorization).
• 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

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

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

Signed: ________________________________
Title: Director, Pharmacy Services
Date: March, 1 2020
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
POLICY NUMBER: 305.0

POLICY AND PROCEDURE
PHARMACY
MANUAL

SECTION: Commercial Drug
SUBJECT: Trokendi XR

Applicable line of business:

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POLICY:

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of formulary. The formulary is applied according to the formulary review process (see Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Part D Policy 143.0 D Geisinger Health Plan (GHP) and Geisinger Indemnity Insurance Company (GIIC) Formulary Development by the Pharmacy). The results of this process determine the development and application 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 all lines of business, unless a specific limitation or exception exists.

REQUIRED DEFINITIONS:

1. **Attachment** – a supporting document that is developed and maintained by the policy writer or 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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1. **Formulary** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
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   B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
C. In accordance with current standards of medical practice;
D. Not primarily for the convenience of the Member, or the Member’s Provider; and
E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to 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*

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, 2020

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
Reviewed: 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
POLICY:
Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of formulary. The formulary is applied according to the formulary review process (see Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Part D Policy 143.0 D Geisinger Health Plan (GHP) and Geisinger Indemnity Insurance Company (GIIC) Formulary Development by the Pharmacy). The results of this process determine the development and application 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 all lines of business, unless a specific limitation or exception exists.

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

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

DAY SUPPLY LIMIT: 34 day supply per fill

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
REVIEWS NO LESS THAN ANNUALLY.

Signed:_______________________________________________
Title: Director, Pharmacy Services
Date: July 29, 2020

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
Applicable line of business:

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**POLICY:**

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of formulary. The formulary is applied according to the formulary review process (see Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Part D Policy 143.0 D Geisinger Health Plan (GHP) and Geisinger Indemnity Insurance Company (GIIC) Formulary Development by the Pharmacy). The results of this process determine the development and application 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 all lines of business, unless a specific limitation or exception exists.

**REQUIRED DEFINITIONS:**

1. **Attachment** – a supporting document that is developed and maintained by the policy writer or 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).
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 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

QUANTITY LIMIT: Pharmacist note to CSR: Authorization should be entered by HICL and only checking the Formulary PA required box (no QLs need to be entered within the authorization).
- 1 tablet per day, 30 day supply per fill for each strength

AUTHORIZATION DURATION: Each authorization will be for 1 year. Re-review will occur each year. Gilotrif will no longer be covered if there is medical record documentation of disease progression.

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:
Tarceva*

*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, 2020

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
Revised: 3/1/20 – annual review, added GHP Kids
POLICY AND PROCEDURE
PHARMACY
MANUAL

POLICY NUMBER: 309.0
SECTION: Commercial Drug
SUBJECT: Trintellix

Applicable line of business:

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POLICY:
Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of formulary. The formulary is applied according to the formulary review process (see Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Part D Policy 143.0 D Geisinger Health Plan (GHP) and Geisinger Indemnity Insurance Company (GIIC) Formulary Development by the Pharmacy). The results of this process determine the development and application 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 all lines of business, unless a specific limitation or exception exists.

REQUIRED DEFINITIONS:
1. **Attachment** – a supporting document that is developed and maintained by the policy writer or 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).
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 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

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.

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, 2020

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
POLICY NUMBER: 310.0

POLICY AND PROCEDURE
PHARMACY
MANUAL

SECTION: Commercial Drug
SUBJECT: Rivastigmine Patch

Applicable line of business:

<table>
<thead>
<tr>
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POLICY:

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of formulary. The formulary is applied according to the formulary review process (see Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Part D Policy 143.0 D Geisinger Health Plan (GHP) and Geisinger Indemnity Insurance Company (GIIC) Formulary Development by the Pharmacy). The results of this process determine the development and application 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 all lines of business, unless a specific limitation or exception exists.

REQUIRED DEFINITIONS:

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

ADDITIONAL DEFINITIONS:

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

If an exception is made, rivastigmine 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:
- **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, 2020

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
Revised: 3/1/19 – annual review
Revised: 3/1/20 – annual review, added GHP Kids
POLICY NUMBER: 311.0

POLICY AND PROCEDURE
PHARMACY
MANUAL

SECTION: Commercial Drug
SUBJECT: Sucraid

Applicable line of business:

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POLICY:
Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of formulary. The formulary is applied according to the formulary review process (see Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Part D Policy 143.0 D Geisinger Health Plan (GHP) and Geisinger Indemnity Insurance Company (GIIC) Formulary Development by the Pharmacy). The results of this process determine the development and application 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 all lines of business, unless a specific limitation or exception exists.

REQUIRED DEFINITIONS:
1. **Attachment** – a supporting document that is developed and maintained by the policy writer or 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.
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   A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
   B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
C. In accordance with current standards of medical practice;
D. Not primarily for the convenience of the Member, or the Member's Provider; and
E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services 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

QUANTITY LIMIT: Pharmacist note to CSR: Authorization should be entered by HICL and only checking the Formulary PA required box (no QLs need to be entered within the authorization).

- 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.

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, 2020

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
POLICY NUMBER: 312.0

POLICY AND PROCEDURE
PHARMACY
MANUAL

SECTION: Commercial Drug
SUBJECT: Mirvaso

Applicable line of business:

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POLICY:
Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of formulary. The formulary is applied according to the formulary review process (see Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Part D Policy 143.0 D Geisinger Health Plan (GHP) and Geisinger Indemnity Insurance Company (GIIC) Formulary Development by the Pharmacy). The results of this process determine the development and application 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 all lines of business, unless a specific limitation or exception exists.

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:
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2. Non-formulary products – those medications that are not included in the Formulary.
3. Healthcare provider – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
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 Mirvaso may be made for members who meet the following criteria:

- Medical record documentation of a diagnosis or rosacea 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 topical metronidazole

QUANTITY LIMIT: Pharmacist note to CSR: Authorization should be entered by HICL and only checking the Formulary PA required box (no QLs need to be entered within the authorization).

- 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

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

THIS POLICY WILL BE REVISED AS NECESSARY AND REVIEWED NO LESS THAN ANNUALLY.
Signed: ________________________________

Title: Director, Pharmacy Services

Date: March 1, 2020

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
POLICY:
Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of formulary. The formulary is applied according to the formulary review process (see Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Part D Policy 143.0 D Geisinger Health Plan (GHP) and Geisinger Indemnity Insurance Company (GIIC) Formulary Development by the Pharmacy). The results of this process determine the development and application 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 all lines of business, unless a specific limitation or exception exists.

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

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

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, sulacetamide/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.
POLICY NUMBER: 314.0

POLICY AND PROCEDURE
PHARMACY
MANUAL

SECTION: Commercial Drug
SUBJECT: Bethkis

Applicable line of business:

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<th>GHP Kids</th>
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</table>

POLICY:
Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of formulary. The formulary is applied according to the formulary review process (see Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Part D Policy 143.0 D Geisinger Health Plan (GHP) and Geisinger Indemnity Insurance Company (GIIC) Formulary Development by the Pharmacy). The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for Bethkis for GHP members who have prescription drug benefits, including all lines of business, unless a specific limitation or exception exists.

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

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

QUANTITY LIMIT: 224 mL per 56 days

AUTHORIZATION PARAMETERS:
- Quantity supply max: 224 mL
- Day supply min: 56
- Day supply max: 56

If an exception is made, 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
THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND FEDERAL REGULATORY ENTITIES.

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

Signed: __________________________________________
Title: Director, Pharmacy Services
Date: March 1, 2020

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 nebulizers
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
Applicable line of business:

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<th>Line of Business</th>
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</table>

**POLICY:**

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of formulary. The formulary is applied according to the formulary review process (see Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Part D Policy 143.0 D Geisinger Health Plan (GHP) and Geisinger Indemnity Insurance Company (GIIC) Formulary Development by the Pharmacy). The results of this process determine the development and application 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 all lines of business, unless a specific limitation or exception exists.

**REQUIRED DEFINITIONS:**

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

**ADDITIONAL DEFINITIONS:**

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

**OR**

**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)

**OR**

**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
OR

**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

OR

**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

OR

**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

**QUANTITY LIMIT:** Pharmacist note to CSR: *Authorization should be entered by HICL and only checking the Formulary PA required box (no QLs need to be entered within the authorization).*
- 1 tablet or capsule per day, 28 day supply per fill

**AUTHORIZATION DURATION:** Each treatment period will be defined as 12 months. Re-review will occur every 12 months. Imbruvica will no longer be covered if there is medical record documentation of disease progression.

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.
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, 2020
POLICY:
Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of formulary. The formulary is applied according to the formulary review process (see Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Part D Policy 143.0 D Geisinger Health Plan (GHP) and Geisinger Indemnity Insurance Company (GIIC) Formulary Development by the Pharmacy). The results of this process determine the development and application 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 all lines of business, unless a specific limitation or exception exists.

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

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

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.

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
- 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, 2020

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
Reviewed: 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
POLICY NUMBER: 317.0

POLICY AND PROCEDURE
PHARMACY
MANUAL

SECTION: Commercial Drug
SUBJECT: Valchlor

Applicable line of business:

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POLICY:
Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of formulary. The formulary is applied according to the formulary review process (see Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Part D Policy 143.0 D Geisinger Health Plan (GHP) and Geisinger Indemnity Insurance Company (GIIC) Formulary Development by the Pharmacy). The results of this process determine the development and application 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 all lines of business, unless a specific limitation or exception exists.

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

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

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:** 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)

**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, 2020
Revised: 3/1/17 – annual review, updated FA
Revised: 10/10/17 – increased authorization duration to 12 months
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
POLICY: Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of formulary. The formulary is applied according to the formulary review process (see Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Part D Policy 143.0 D Geisinger Health Plan (GHP) and Geisinger Indemnity Insurance Company (GIIC) Formulary Development by the Pharmacy). The results of this process determine the development and application 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 all lines of business, unless a specific limitation or exception exists.

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

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

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 psoriasis on six (6) months of Stelara therapy is required.

After the initial six (6) month approval, subsequent approvals will be for a duration of one (1) year, requiring medical record documentation of continued or sustained improvement in signs and symptoms of psoriasis while on Stelara therapy.
NOTE:
- Plaque psoriasis
  - 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

QUANTITY LIMIT/AUTHORIZATION PARAMETERS: Authorization should be approved by GPID for the correct strength (as determined by weight).

<table>
<thead>
<tr>
<th>If requesting a dose of:</th>
<th>GPID</th>
<th>Initial – One-time, one-week authorization</th>
<th>Remainder/Subsequent</th>
</tr>
</thead>
<tbody>
<tr>
<td>100 kg or less</td>
<td>28158</td>
<td>Quantity limit: 0.5 ml per 28 days</td>
<td>Quantity limit: 0.5 mL per 84 days</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Max quantity supply: 0.5</td>
<td>Max quantity supply: 0.5</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Min day supply: 28</td>
<td>Min day supply: 84</td>
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<tr>
<td></td>
<td></td>
<td>Max day supply: 28</td>
<td>Max day supply: 84</td>
</tr>
<tr>
<td>Greater than 100 kg</td>
<td>28159</td>
<td>Quantity limit: 1 ml per 28 days</td>
<td>Quantity limit: 1 mL per 84 days</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Max quantity supply: 1</td>
<td>Max quantity supply: 1</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Min day supply: 28</td>
<td>Min day supply: 84</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Max day supply: 28</td>
<td>Max day supply: 84</td>
</tr>
</tbody>
</table>

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 12 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

AUTHORIZATION DURATION: Approval will be given for an initial duration of six (6) months. For continuation, medical record documentation of clinical improvement or lack of progression in the signs and symptoms of psoriasis on six (6) months of Stelara therapy is required.

After the initial six (6) month approval, subsequent approvals will be for a duration of one (1) year, requiring medical record documentation of improvement in the signs and symptoms of psoriasis while on Stelara therapy.

NOTE:
- Patients weighing over 100kg should receive 90 mg every 12 weeks
- Patients weighing ≥60kg to <100kg should receive 45 mg every 12 weeks
- Patients weighing less than 60kg should receive 0.75mg/kg every 12 weeks

QUANTITY LIMIT/AUTHORIZATION PARAMETERS: Authorization should be approved by GPID for the correct strength (as determined by weight).

<table>
<thead>
<tr>
<th>If requesting a dose of:</th>
<th>GPID</th>
<th>Initial – One-time, one-week authorization</th>
<th>Remainder/Subsequent</th>
</tr>
</thead>
<tbody>
<tr>
<td>Less than 60 kg</td>
<td>19903</td>
<td>Min day supply: 28 Max day supply: 28</td>
<td>Min day supply: 84 Max day supply: 84</td>
</tr>
<tr>
<td>Greater than or equal to 60 kg to less than 100 kg</td>
<td>28158</td>
<td>Quantity limit: 0.5 mL per 28 days Max quantity supply: 0.5 Min day supply: 28 Max day supply: 28</td>
<td>Quantity limit: 0.5 mL per 84 days Max quantity supply: 0.5 Min day supply: 84 Max day supply: 84</td>
</tr>
<tr>
<td>Greater than 100 kg</td>
<td>28159</td>
<td>Quantity limit: 1 mL per 28 days Max quantity supply: 1 Min day supply: 28 Max day supply: 28</td>
<td>Quantity limit: 1 mL per 84 days Max quantity supply: 1 Min day supply: 84 Max day supply: 84</td>
</tr>
</tbody>
</table>
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)

**High-potency topical corticosteroids**: augmented betamethasone dipropionate 0.05% cream (Diprolene AF); betamethasone valerate 0.1% ointment (Valisone); triamcinolone 0.5% cream (Kenalog); fluorocinolone 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) diflurarsone 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

**AUTHORIZED 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 psoriatic arthritis on six (6) months of Stelara therapy 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 continued or sustained improvement in the signs and symptoms of psoriatic arthritis while on Stelara therapy.

**NOTE:** Psoriatic arthritis

- 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.
### QUANTITY LIMIT/AUTHORIZATION PARAMETERS:
Authorization should be approved by GPID for the correct strength (as determined by weight).

<table>
<thead>
<tr>
<th>If requesting a dose of:</th>
<th>GPID</th>
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<td>Quantity limit: 1 mL per 84 days Max quantity supply: 1 Min day supply: 84 Max day supply: 84</td>
</tr>
</tbody>
</table>

### 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

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 Crohn’s disease on six (6) months of Stelara therapy 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 continued or sustained improvement in the signs and symptoms of Crohn’s disease while on Stelara therapy.

QUANTITY LIMIT/AUTHORIZATION PARAMETERS:

<table>
<thead>
<tr>
<th>Initial – One-time, RX count 1</th>
<th>Remainder/Subsequent</th>
</tr>
</thead>
<tbody>
<tr>
<td>104 mL per 56 days</td>
<td>QL: 1 mL per 56 days</td>
</tr>
<tr>
<td></td>
<td>Max quantity supply: 1</td>
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<tr>
<td></td>
<td>Min day supply: 56</td>
</tr>
<tr>
<td></td>
<td>Max day supply: 56</td>
</tr>
</tbody>
</table>

NOTE: Stelara 45 mg syringe is not indicated for use in Crohn’s disease.
### 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

### 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 on six (6) months of Stelara therapy 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 continued or sustained improvement in the signs and symptoms of ulcerative colitis while on Stelara therapy.

### QUANTITY LIMIT/AUTHORIZATION PARAMETERS:

<table>
<thead>
<tr>
<th>Initial – One-time, RX count 1</th>
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<tr>
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<td></td>
<td>Max quantity supply: 1</td>
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<tr>
<td></td>
<td>Min day supply: 56</td>
</tr>
<tr>
<td></td>
<td>Max day supply: 56</td>
</tr>
</tbody>
</table>

**NOTE:** Stelara 45 mg syringe is **not** indicated for use in ulcerative colitis.

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 21, 2020

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: 5/27/17 – 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
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
POLICY NUMBER: 319.0

POLICY AND PROCEDURE
PHARMACY
MANUAL

SECTION: Commercial Drug
SUBJECT: Symbicort

Applicable line of business:

<table>
<thead>
<tr>
<th>Line of Business</th>
<th>Coverage Status</th>
</tr>
</thead>
<tbody>
<tr>
<td>Commercial</td>
<td>X</td>
</tr>
<tr>
<td>Medicaid</td>
<td></td>
</tr>
<tr>
<td>Medicare</td>
<td>ACA</td>
</tr>
<tr>
<td>GHP Kids</td>
<td>X</td>
</tr>
</tbody>
</table>

POLICY:
Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of formulary. The formulary is applied according to the formulary review process (see Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Part D Policy 143.0 D Geisinger Health Plan (GHP) and Geisinger Indemnity Insurance Company (GIIC) Formulary Development by the Pharmacy). The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for Symbicort for GHP members who have prescription drug benefits, including all lines of business, unless a specific limitation or exception exists.

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

ADDITIONAL DEFINITIONS:
1. Formulary – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. Non-formulary products – those medications that are not included in the Formulary.
3. Healthcare provider – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
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 Symbicort 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 Advair Diskus* OR
- For ages greater than 12 years, medical record documentation of therapeutic failure on, intolerance to, or contraindication to Advair Diskus 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 Advair Diskus AND Breo Ellipta

*Note: Advair Diskus 100/50 is the only approved dose for patients 4 to 11 years old. The other formulations of Advair Diskus are approved for 12 years and older.

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

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: Advair Diskus, Dulera, Breo Ellipta
COPD: Advair Diskus, 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, 2020

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
POLICY:
Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of formulary. The formulary is applied according to the formulary review process (see Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Part D Policy 143.0 D Geisinger Health Plan (GHP) and Geisinger Indemnity Insurance Company (GIIC) Formulary Development by the Pharmacy). The results of this process determine the development and application 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 all lines of business, unless a specific limitation or exception exists.

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:
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2. **Non-formulary products** – those medications that are not included in the Formulary.
3. **Healthcare provider** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
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

QUANTITY LIMIT: Pharmacist note to CSR: Authorization should be entered by HICL and only checking the Formulary PA required box (no QLs need to be entered within the authorization).
- 3.6 mL per 28 days

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 signs and symptoms of rheumatoid arthritis on six (6) months of Actemra 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 continued or sustained improvement in the signs and symptoms of rheumatoid arthritis while on Actemra therapy.

**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

QUANTITY LIMIT: Pharmacist note to CSR: Authorization should be entered by HICL and only checking the Formulary PA required box (no QLs need to be entered within the authorization).
  - 3.6 mL per 28 days

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 signs and symptoms of rheumatoid arthritis on six (6) months of Actemra 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 continued or sustained improvement in the signs and symptoms of rheumatoid arthritis while on Actemra therapy.

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

**QUANTITY LIMIT:** Pharmacist note to CSR: *Authorization should be entered by HICL and only checking the Formulary PA required box (no QLs need to be entered within the authorization).*

- 3.6 mL per 28 days

**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 signs and symptoms of SJIA on six (6) months of Actemra 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 continued or sustained improvement in the signs and symptoms of SJIA while on Actemra therapy.

**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

QUANTITY LIMIT: Pharmacist note to CSR: *Authorization should be entered by HICL and only checking the Formulary PA required box (no QLs need to be entered within the authorization).*

- 3.6 mL per 28 days

AUTHORIZATION DURATION: Approval will be given for an initial duration of six (6) months. After the initial six (6) month approval, subsequent approvals for coverage will be for a duration of one (1) year. For continuation of coverage, medical record documentation of clinical improvement or lack of progression in signs and symptoms of giant cell arteritis and/or a decrease from baseline in the erythrocyte sedimentation rate (ESR) is required.

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

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 21, 2020

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: 01/28/20 – updated RA FA and added failure of Rinvoq and Xeljanz
Revised: 3/1/20 – annual review, added GHP Kids
POLICY:
Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of formulary. The formulary is applied according to the formulary review process (see Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Part D Policy 143.0 D Geisinger Health Plan (GHP) and Geisinger Indemnity Insurance Company (GIIC) Formulary Development by the Pharmacy). The results of this process determine the development and application 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 all lines of business, unless a specific limitation or exception exists.

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

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

**QUANTITY LIMIT:** Pharmacist note to CSR: *Authorization should be entered by HICL and only checking the Formulary PA required box (no QLs need to be entered within the authorization).*
- 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+), Gabitril (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, 2020

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
POLICY AND PROCEDURE
PHARMACY
MANUAL

POLICY NUMBER: 322.0

SECTION: Commercial Drug
SUBJECT: Fycompa

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
Applicable line of business:

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POLICY:
Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of formulary. The formulary is applied according to the formulary review process (see Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Part D Policy 143.0 D Geisinger Health Plan (GHP) and Geisinger Indemnity Insurance Company (GIIC) Formulary Development by the Pharmacy). The results of this process determine the development and application 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 all lines of business, unless a specific limitation or exception exists.

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

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

`QUANTITY LIMIT:` Pharmacist note to CSR: *Authorization should be entered by HICL and only checking the Formulary PA required box (no QLs need to be entered within the authorization).*

- 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.

`FORMULARY ALTERNATIVES:`

*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
REVIEWS NO LESS THAN ANNUALLY.

Signed:_______________________________________________

Title: Director, Pharmacy Services

Date: March 1, 2020

Revised: 3/1/14
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
POLICY NUMBER: 326.0

SECTION: Commercial Drug

SUBJECT: Sovaldi

POLICY AND PROCEDURE
PHARMACY
MANUAL

Applicable line of business:

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<tr>
<th>Line of Business</th>
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POLICY:
Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is applied according to the formulary review process (see Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Part D Policy 143.0 D Geisinger Health Plan (GHP) and Geisinger Indemnity Insurance Company (GIIC) Formulary Development by the Pharmacy). The results of this process determine the development and application 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 all lines of business, unless a specific limitation or exception exists.

REQUIRED DEFINITIONS:
1. **Attachment** – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. **Exhibit** – a 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).
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 ≥ 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 15mg/kg in pediatric patients < 47kg), 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
• 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:
  o Hepatitis B immunization series OR
  o 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:
  o Is being treated for human immunodeficiency virus (HIV) OR
  o 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. St Luke’s, AtlantiCare, Northern Light Health).

**TREATMENT DURATION:** Consistent with AASLD/ISDA Guidelines

**QUANTITY LIMIT:** Pharmacist note to CSR: *Authorization should be entered by HICL and only checking the Formulary box (no QLs need to be entered within the authorization).*

- 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

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE STANDARDS 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: 326.0

Section: Commercial Drug

Subject: Sovaldi

Signed: _________________________________
Title: Director, Pharmacy Services
Date: July 29, 2020

Revised:
5/28/14
Revised: 5/28/14 – 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
Revised: 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
Revised: 3/1/16 – annual review, defined abbreviations, removed Unicode characters
Revised: 3/27/17 – G3: removed peginterferon, added w/ Daklinza for post transplant
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: 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: 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: 3/1/18 – 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, added QL approval note, defined abbr., removed Olysio references (D/C)
Revised: 7/23/19 – added TPA COE exclusion
Revised: 3/1/20 – annual review, updated Hep B/HIV criteria to match DHS, corrected typo
Revised: 12/28/20 – added HCV positive transplant indication/FA criteria, added COE
Revised: 3/1/21 – annual review, added QL approval note, defined abbr., removed Olysio references (D/C)
Revised: 7/23/21 – 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
POLICY NUMBER: 327.0

SECTION: Commercial Drug
SUBJECT: Aptiom

Applicable line of business:

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POLICY:
Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of formulary. The formulary is applied according to the formulary review process (see Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Part D Policy 143.0 D Geisinger Health Plan (GHP) and Geisinger Indemnity Insurance Company (GIIC) Formulary Development by the Pharmacy). The results of this process determine the development and application 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 all lines of business, unless a specific limitation or exception exists.

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).
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 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

QUANTITY LIMIT: Pharmacist note to CSR: Authorization should be entered by HICL and only checking the Formulary PA required box (no QLs need to be entered within the authorization).
- 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.
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+), Gabitril (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: [Signature]
Title: Director, Pharmacy Services
Date: March 1, 2020

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
POLICY NUMBER: 328.0

SECTION: Commercial Drug

SUBJECT: Farxiga

Applicable line of business:

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POLICY:

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of formulary. The formulary is applied according to the formulary review process (see Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Part D Policy 143.0 D Geisinger Health Plan (GHP) and Geisinger Indemnity Insurance Company (GIIC) Formulary Development by the Pharmacy). The results of this process determine the development and application 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 all lines of business, unless a specific limitation or exception exists.

REQUIRED DEFINITIONS:

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

ADDITIONAL DEFINITIONS:

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

**QUANTITY LIMIT:** Pharmacist note to CSR: **Authorization should be entered by HICL and only checking the Formulary box (no QLs need to be entered within the authorization).**
- 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:
Jardiance, Synjardy, Invokana, Invokamet

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

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

Signed: __________________________________________________________

Title: Director, Pharmacy Services

Date: November 18, 2020

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
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
POLICY:

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of formulary. The formulary is applied according to the formulary review process (see Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Part D Policy 143.0 D Geisinger Health Plan (GHP) and Geisinger Indemnity Insurance Company (GIIC) Formulary Development by the Pharmacy). The results of this process determine the development and application 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 all lines of business, unless a specific limitation or exception exists.

REQUIRED DEFINITIONS:

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

ADDITIONAL DEFINITIONS:

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

- 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

QUANTITY LIMIT: Pharmacist note to CSR: Authorization should be entered by HICL
and only checking the Formulary box (no QLs need to be entered within the
authorization).

- 1 capsule per day, 30 day supply per fill

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.
POLICY NUMBER: 329.0

POLICY AND PROCEDURE
PHARMACY
MANUAL

SECTION: Commercial Drug
SUBJECT: Hetlioz

Signed: ____________________________________________

Title: Director, Pharmacy Services

Date: March 1, 2020

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
POLICY NUMBER: 330.0

POLICY AND PROCEDURE
PHARMACY
MANUAL

SECTION: Commercial Drug
SUBJECT: Zykadia

Applicable line of business:

<table>
<thead>
<tr>
<th>Line of Business</th>
<th>Commercial</th>
<th>Medicaid</th>
<th>Medicare</th>
<th>ACA</th>
<th>GHP Kids</th>
</tr>
</thead>
<tbody>
<tr>
<td>Commercial</td>
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<td>Medicaid</td>
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<td>Medicare</td>
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<td></td>
<td>X</td>
</tr>
<tr>
<td>GHP Kids</td>
<td></td>
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</tr>
</tbody>
</table>

POLICY:
Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of formulary. The formulary is applied according to the formulary review process (see Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Part D Policy 143.0 D Geisinger Health Plan (GHP) and Geisinger Indemnity Insurance Company (GIIC) Formulary Development by the Pharmacy). The results of this process determine the development and application 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 all lines of business, unless a specific limitation or exception exists.

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

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

QUANTITY LIMIT: Pharmacist note to CSR: Authorization should be entered by HICL and only checking the Formulary PA required box (no QLs need to be entered within the authorization).
- 3 capsules per day, 28 day supply per fill

AUTHORIZATION DURATION: Each treatment period will be defined as twelve (12) months. Re-review will occur every twelve (12) months. Zykadia will no longer be covered if there is medical record documentation of disease progression.

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, 2020

Devised: 7/22/14
Reviewed: 3/1/15 – annual review
Reviewed: 3/1/16 – annual review
Reviewed: 5/1/16 – updated format, logo, & procedure
Reviewed: 3/1/17 – annual review
Reviewed: 8/8/17 – removed failure of Xalkori, updated FA
Reviewed: 10/10/17 – increased authorization duration to 12 months
Reviewed: 1/17/18 – updated presc. criteria, updated QL, added failure of Alecensa, updated sig
Reviewed: 3/1/18– annual review, added grandfather language, defined FDA
Reviewed: 4/10/18 – updated QL
Reviewed: 3/1/19 – annual review, added QL approval note
Reviewed: 3/1/20 – annual review, added GHP Kids
POLICY NUMBER: 331.0

POLICY AND PROCEDURE
PHARMACY
MANUAL

SECTION: Commercial Drug
SUBJECT: Duavee

Applicable line of business:

<table>
<thead>
<tr>
<th></th>
<th>Commercial</th>
<th>Medicaid</th>
<th>Medicare</th>
<th>ACA</th>
<th>GHP Kids</th>
</tr>
</thead>
</table>

POLICY:

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of formulary. The formulary is applied according to the formulary review process (see Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Part D Policy 143.0 D Geisinger Health Plan (GHP) and Geisinger Indemnity Insurance Company (GIIC) Formulary Development by the Pharmacy). The results of this process determine the development and application 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 all lines of business, unless a specific limitation or exception exists.

REQUIRED DEFINITIONS:

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

ADDITIONAL DEFINITIONS:

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

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

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

THIS POLICY WILL BE REVISED AS NECESSARY AND REVIEWED NO LESS THAN ANNUALLY.
Signed:_______________________________________________
Title:  Director, Pharmacy Services
Date:  March 1, 2020
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
POLICY AND PROCEDURE
PHARMACY
MANUAL

POLICY NUMBER: 332.0
SECTION: Commercial Drug
SUBJECT: Adempas

Applicable line of business:

<table>
<thead>
<tr>
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POLICY:
Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of formulary. The formulary is applied according to the formulary review process (see Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Part D Policy 143.0 D Geisinger Health Plan (GHP) and Geisinger Indemnity Insurance Company (GIIC) Formulary Development by the Pharmacy). The results of this process determine the development and application 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 all lines of business, unless a specific limitation or exception exists.

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).
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 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 Tracleer*

**QUANTITY LIMIT:** Pharmacist note to CSR: *Authorization should be entered by HICL and only checking the Formulary PA required box (no QLs need to be entered within the authorization).*

- 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.

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*, Tracleer*

*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, 2020

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
Applicable line of business:

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<tr>
<th>Line of Business</th>
<th>Commercial</th>
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**POLICY:**

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of formulary. The formulary is applied according to the formulary review process (see Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Part D Policy 143.0 D Geisinger Health Plan (GHP) and Geisinger Indemnity Insurance Company (GIIC) Formulary Development by the Pharmacy). The results of this process determine the development and application 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 all lines of business, unless a specific limitation or exception exists.

**REQUIRED DEFINITIONS:**

1. **Attachment** – a supporting document that is developed and maintained by the policy writer or 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).
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 Xerese 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) **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

**OR**

- 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

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.

**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, 2020

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
POLICY:  
Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of formulary. The formulary is applied according to the formulary review process (see Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Part D Policy 143.0 D Geisinger Health Plan (GHP) and Geisinger Indemnity Insurance Company (GIIC) Formulary Development by the Pharmacy). The results of this process determine the development and application 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 all lines of business, unless a specific limitation or exception exists.

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

ADDITIONAL DEFINITIONS:
1. **Formulary** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. **Non-formulary products** – those medications that are not included in the Formulary.
3. **Healthcare provider** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
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 luliconazole may be made for members who meet the following criteria:

- Medical record documentation of a diagnosis or 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

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

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

Signed: ________________________________

Title: Director, Pharmacy Services

Date: March 1, 2020

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
POLICY: Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of formulary. The formulary is applied according to the formulary review process (see Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Part D Policy 143.0 D Geisinger Health Plan (GHP) and Geisinger Indemnity Insurance Company (GIIC) Formulary Development by the Pharmacy). The results of this process determine the development and application 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 all lines of business, unless a specific limitation or exception exists.

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).
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 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

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

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:
Uptravi®, bosentan®, treprostil 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: April 21, 2020

Revised: 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 Uptravi, 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 Uptravi 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
Applicable line of business:

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POLICY:

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of formulary. The formulary is applied according to the formulary review process (see Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Part D Policy 143.0 D Geisinger Health Plan (GHP) and Geisinger Indemnity Insurance Company (GIIC) Formulary Development by the Pharmacy). The results of this process determine the development and application 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 all lines of business, unless a specific limitation or exception exists.

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).
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 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*

**AUTHORIZATION DURATION:** Approval will be given for an initial duration of six (6) months. For continuation of coverage, medical record documentation of clinical or sustained improvement in the signs and symptoms of psoriatic arthritis on six (6) months of Otezla therapy will be required.

After the initial six (6) month approval, subsequent approvals will be for a duration of one (1) year requiring medical record documentation of clinical or sustained improvement in the signs and symptoms of psoriatic arthritis while on Otezla therapy.

**FORMULARY ALTERNATIVES:**
Cosentyx*, Humira*
*prior authorization required

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**
- 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*

**AUTHORIZATION DURATION:** Approval will be given for an initial duration of six (6) months. For continuation, medical record documentation of clinical improvement or lack of progression in signs and symptoms of psoriasis on six (6) months of Otezla therapy is required.

After the initial 6 month approval, subsequent approvals will be for a duration of 1 year, requiring medical record documentation of continued or sustained improvement in the signs and symptoms of psoriasis while on Otezla therapy.

**QUANTITY LIMIT:** Pharmacist note to CSR: *Authorization should be entered by HICL and only checking the Formulary PA required box (no QLs need to be entered within the authorization).*

- 2 tablets per day, 30 day supply per fill
For Bechet’s Disease
- Medical record documentation of age greater than or equal to 18 years \textbf{AND}
- Medical record documentation of oral ulcers associated with Bechet’s Disease

\textbf{NOTE:} The International Clinical Criteria for Bechet'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

\textbf{QUANTITY LIMIT:} Pharmacist note to CSR: \textit{Authorization should be entered by HICL and only checking the Formulary PA required box (no QLs need to be entered within the authorization).}
- 2 tablets per day, 30 day supply per fill

\textbf{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.

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

\textbf{THIS POLICY WILL BE REVISED AS NECESSARY AND REVIEWED NO LESS THAN ANNUALLY.}
Signed:_______________________________________________

Title: Director, Pharmacy Services

Date: March 1, 2020

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
POLICY NUMBER: 337.0

POLICY AND PROCEDURE
PHARMACY
MANUAL

SECTION: Commercial Drug
SUBJECT: Aveed

Applicable line of business:

<table>
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<tr>
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POLICY:

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of formulary. The formulary is applied according to the formulary review process (see Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Part D Policy 143.0 D Geisinger Health Plan (GHP) and Geisinger Indemnity Insurance Company (GIIC) Formulary Development by the Pharmacy). The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for Aveed for GHP members who have prescription drug benefits, including all lines of business, unless a specific limitation or exception exists.

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).
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 Aveed 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

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

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

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE STANDARDS 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: 337.0

SECTION: Commercial Drug
SUBJECT: Aveed

Signed: _____________________________________________

Title: Director, Pharmacy Services

Date: March 1, 2020

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
POLICY AND PROCEDURE
PHARMACY
MANUAL

POLICY NUMBER: 338.0
SECTION: Commercial Drug
SUBJECT: Myalept

Applicable line of business:

<table>
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POLICY:
Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of formulary. The formulary is applied according to the formulary review process (see Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Part D Policy 143.0 D Geisinger Health Plan (GHP) and Geisinger Indemnity Insurance Company (GIIC) Formulary Development by the Pharmacy). The results of this process determine the development and application 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 all lines of business, unless a specific limitation or exception exists.

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

*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

**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.**

Signed: __________________________________________

Title:  Director, Pharmacy Services

Date:  March 1, 2020
POLICY AND PROCEDURE  
PHARMACY  
MANUAL  

POLICY NUMBER: 339.0  
SECTION: Commercial Drug  
SUBJECT: Zontivity  

Applicable line of business:

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Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of formulary. The formulary is applied according to the formulary review process (see Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Part D Policy 143.0 D Geisinger Health Plan (GHP) and Geisinger Indemnity Insurance Company (GIIC) Formulary Development by the Pharmacy). The results of this process determine the development and application 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 all lines of business, unless a specific limitation or exception exists.

REQUIRED DEFINITIONS:

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

ADDITIONAL DEFINITIONS:

1. **Formulary** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. **Non-formulary products** – those medications that are not included in the Formulary.
3. **Healthcare provider** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
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 Zontivity may be made for members who meet **ALL** of the following criteria:

- 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

**OR**

- 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

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, 2020

Devised: 9/22/14
Reviewed: 3/1/15 – annual review
Reviewed: 3/1/16 – annual review, changed Aggrenox to aspirin/dipyridamole ER
Reviewed: 5/1/16 – updated format, logo, & procedure
Reviewed: 3/1/17 – annual review, removed Unicode characters
Reviewed: 3/1/18 – annual review, updated signature, updated Effient to generic, corrected typo
Reviewed: 3/1/19 – annual review, updated FA
Reviewed: 3/1/20 – annual review, added GHP Kids
Applicable line of business:

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<th>ACA</th>
<th>GHP Kids</th>
</tr>
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</table>

POLICY:

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of formulary. The formulary is applied according to the formulary review process (see Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Part D Policy 143.0 D Geisinger Health Plan (GHP) and Geisinger Indemnity Insurance Company (GIIC) Formulary Development by the Pharmacy). The results of this process determine the development and application 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 all lines of business, unless a specific limitation or exception exists.

REQUIRED DEFINITIONS:

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

ADDITIONAL DEFINITIONS:

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

**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, 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, 2020

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
POLICY:  
Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of formulary. The formulary is applied according to the formulary review process (see Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Part D Policy 143.0 D Geisinger Health Plan (GHP) and Geisinger Indemnity Insurance Company (GIIC) Formulary Development by the Pharmacy). The results of this process determine the development and application 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 all lines of business, unless a specific limitation or exception exists.

REQUIRED DEFINITIONS:
1. **Attachment** – a supporting document that is developed and maintained by the policy writer or 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).
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 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

**QUANTITY LIMIT:** 1 tablet per day, 30 day supply per fill should apply, 210 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, 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, 2020

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
Applicable line of business:

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**POLICY:**

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of formulary. The formulary is applied according to the formulary review process (see Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Part D Policy 143.0 D Geisinger Health Plan (GHP) and Geisinger Indemnity Insurance Company (GIIC) Formulary Development by the Pharmacy). The results of this process determine the development and application 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 all lines of business, unless a specific limitation or exception exists.

**REQUIRED DEFINITIONS:**

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

**ADDITIONAL DEFINITIONS:**

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

**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, 2020

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
Revised: 3/1/20 – annual review, added GHP Kids
POLICY:
Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of formulary. The formulary is applied according to the formulary review process (see Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Part D Policy 143.0 D Geisinger Health Plan (GHP) and Geisinger Indemnity Insurance Company (GIIIC) Formulary Development by the Pharmacy). The results of this process determine the development and application 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 all lines of business, unless a specific limitation or exception exists.

REQUIRED DEFINITIONS:
1. **Attachment** – a supporting document that is developed and maintained by the policy writer or 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).
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;
POLICY NUMBER: 343.0

POLICY AND PROCEDURE
PHARMACY
MANUAL

SECTION: Commercial Drug
SUBJECT: Zydelig

C. In accordance with current standards of medical practice;
D. Not primarily for the convenience of the Member, or the Member's Provider; and
E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to 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

**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.

**QUANTITY LIMIT:** Pharmacist note to CSR: *Authorization should be entered by HICL and only checking the Formulary PA required box (no QLs need to be entered within the authorization).*

• 2 tablets per day, 30 day supply per fill

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.**

Signed: ____________________________________________________________

Title: Director, Pharmacy Services

Date: March 1, 2020
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<th>Event</th>
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<tr>
<td>Reviewed</td>
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POLICY NUMBER: 344.0

POLICY AND PROCEDURE
PHARMACY
MANUAL

SECTION: Commercial Drug
SUBJECT: Controlled Substance DUR Denial

Applicable line of business:

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<th>Line of Business</th>
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POLICY:
Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of formulary. The formulary is applied according to the formulary review process (see Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Part D Policy 143.0 D Geisinger Health Plan (GHP) and Geisinger Indemnity Insurance Company (GIIC) Formulary Development by the Pharmacy). The results of this process determine the development and application 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 all lines of business, unless a specific limitation or exception exists.

REQUIRED DEFINITIONS:
1. **Attachment** – a supporting document that is developed and maintained by the policy writer or 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).
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 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

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
REVIEVED NO LESS THAN ANNUALLY.

Signed: __________________________________________________________________________

Title: Director, Pharmacy Services
POLICY: Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of formulary. The formulary is applied according to the formulary review process (see Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Part D Policy 143.0 D Geisinger Health Plan (GHP) and Geisinger Indemnity Insurance Company (GIIC) Formulary Development by the Pharmacy). The results of this process determine the development and application 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 all lines of business, unless a specific limitation or exception exists.

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

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

**QUANTITY LIMIT:** Pharmacist note to CSR: Authorization should be entered by HICL and only checking the Formulary PA required box (no QLs need to be entered within the authorization).
- 6 tablets

**AUTHORIZATION DURATION:** one-time, 6 day approval, RX count 1

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, ery e-succ/sulfisoxazole, 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: October 12, 2020

Devised: 12/1/14
Revised: 2/8/15 – added grade 2 infection or greater & revised inpatient criteria
Reviewed: 3/1/15 – annual review
Reviewed: 3/1/16 – annual review
Reviewed: 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
POLICY NUMBER: 349.0

SECTION: Commercial Drug

SUBJECT: Karbinal ER

Applicable line of business:

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<th>Medicaid</th>
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<th>ACA</th>
<th>GHP Kids</th>
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| Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of formulary. The formulary is applied according to the formulary review process (see Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Part D Policy 143.0 D Geisinger Health Plan (GHP) and Geisinger Indemnity Insurance Company (GIIC) Formulary Development by the Pharmacy). The results of this process determine the development and application 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 all lines of business, unless a specific limitation or exception exists.

REQUIRED DEFINITIONS:

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

ADDITIONAL DEFINITIONS:

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

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

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

THIS POLICY WILL BE REVISED AS NECESSARY AND REVIEWED NO LESS THAN ANNUALLY.
Signed: ____________________________________________________________

Title: Director, Pharmacy Services

Date: March 1, 2020

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
Applicable line of business:

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POLICY:
Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of formulary. The formulary is applied according to the formulary review process (see Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Part D Policy 143.0 D Geisinger Health Plan (GHP) and Geisinger Indemnity Insurance Company (GIIC) Formulary Development by the Pharmacy). The results of this process determine the development and application 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 all lines of business, unless a specific limitation or exception exists.

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

ADDITIONAL DEFINITIONS:
1. **Formulary** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. **Non-formulary products** – those medications that are not included in the Formulary.
3. **Healthcare provider** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
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 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
- Medical record documentation of a therapeutic failure on, intolerance to, or contraindication to Victoza AND either Ozempic or Rybelsus

QUANTITY LIMIT: Pharmacist note to CSR: Authorization should be entered by HICL and only checking the Step Therapy box (no QLs need to be entered within the authorization).

- 4 vials/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.

FORMULARY ALTERNATIVES:
Ozempic, Victoza, Rebelsus

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

THIS POLICY WILL BE REVISED AS NECESSARY AND REVIEWED NO LESS THAN ANNUALLY.
Signed:_______________________________________________

Title: Director, Pharmacy Services

Date: March 1, 2020

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: 01/28/20 – added failure of Rybelsus, updated FA
Revised: 3/1/20 – annual review, added GHP Kids
POLICY: Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of formulary. The formulary is applied according to the formulary review process (see Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Part D Policy 143.0 D Geisinger Health Plan (GHP) and Geisinger Indemnity Insurance Company (GIIC) Formulary Development by the Pharmacy). The results of this process determine the development and application 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 all lines of business, unless a specific limitation or exception exists.

REQUIRED DEFINITIONS:
1. **Attachment** – a supporting document that is developed and maintained by the policy writer or 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).
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 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

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.
Signed: ________________________________

Title: Director, Pharmacy Services

Date: March 1, 2020

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
Reviewed: 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
POLICY NUMBER: 352.0

Applicable line of business:

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POLICY:
Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of formulary. The formulary is applied according to the formulary review process (see Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Part D Policy 143.0 D Geisinger Health Plan (GHP) and Geisinger Indemnity Insurance Company (GIIC) Formulary Development by the Pharmacy). The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for Northera for GHP members who have prescription drug benefits, including all lines of business, unless a specific limitation or exception exists.

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

ADDITIONAL DEFINITIONS:
1. **Formulary** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. **Non-formulary products** – those medications that are not included in the Formulary.
3. **Healthcare provider** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
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 Northera may be made for members who meet the following criteria:

- Medical record documentation that Northera 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

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, Northera will be paid for under the member’s prescription drug benefit.

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

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, 2020

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
POLICY NUMBER: 353.0

POLICY AND PROCEDURE
PHARMACY
MANUAL

SECTION: Commercial Drug
SUBJECT: Evzio

Applicable line of business:

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POLICY:

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of formulary. The formulary is applied according to the formulary review process (see Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Part D Policy 143.0 D Geisinger Health Plan (GHP) and Geisinger Indemnity Insurance Company (GIIC) Formulary Development by the Pharmacy). The results of this process determine the development and application 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 all lines of business, unless a specific limitation or exception exists.

REQUIRED DEFINITIONS:

1. **Attachment** – a supporting document that is developed and maintained by the policy writer or 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.
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3. **Healthcare provider** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
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   A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
   B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
C. In accordance with current standards of medical practice;
D. Not primarily for the convenience of the Member, or the Member's Provider; and
E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services 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 patient 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

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 patient's 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)
- 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

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

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

Signed: [Signature]

Title: Director, Pharmacy Services

Date: March 1, 2020

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
Applicable line of business:

<table>
<thead>
<tr>
<th>Line of Business</th>
<th>X</th>
<th>Medicaid</th>
<th>ACA</th>
<th>X</th>
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<tr>
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POLICY:
Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of formulary. The formulary is applied according to the formulary review process (see Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Part D Policy 143.0 D Geisinger Health Plan (GHP) and Geisinger Indemnity Insurance Company (GIIC) Formulary Development by the Pharmacy). The results of this process determine the development and application 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 all lines of business, unless a specific limitation or exception exists.

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

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

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

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

Signed: ________________________________

Title: Director, Pharmacy Services

Date: March 1, 2020

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
POLICY: Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of formulary. The formulary is applied according to the formulary review process (see Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Part D Policy 143.0 D Geisinger Health Plan (GHP) and Geisinger Indemnity Insurance Company (GIIC) Formulary Development by the Pharmacy). The results of this process determine the development and application 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 all lines of business, unless a specific limitation or exception exists.

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).
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 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

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

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

Signed: ____________________________________________

Title: Director, Pharmacy Services

Date: March 1, 2020

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
POLICY:  
Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of formulary. The formulary is applied according to the formulary review process (see Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Part D Policy 143.0 D Geisinger Health Plan (GHP) and Geisinger Indemnity Insurance Company (GIIC) Formulary Development by the Pharmacy). The results of this process determine the development and application 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 all lines of business, unless a specific limitation or exception exists.

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).
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 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
- The prescribing physician is participating with the GHP or Behavioral Health network and has obtained the necessary waiver to be eligible to prescribe buprenorphine containing products. If the drug is prescribed by a Behavioral Health provider, that provider needs to have a signed agreement with one of the Behavioral Health-Managers Care Organizations (BH-MCOs). If the prescriber is not in the Geisinger Health Plan (GHP) or Behavior Health-Manager Care Organization (BH-MCO) network, Geisinger Health Plan will work with the member through the Special Needs Unit to ensure the member is redirected to an in-plan physician.
  - If the prescriber is in-network, they cannot bill the member for any services associated with the visit.
- For re-authorization, the member must be adherent to Bunavail therapy and must not be using opiates. This must be verified by urine drug screen (dated within 28 days of request date) for all controlled substances, including opiates, norbuprenorphine, and buprenorphine. The presence of controlled substances other than buprenorphine must be addressed 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 along with an attestation of attendance on the counselor’s/facility’s letterhead or rationale for non-participation 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
- Form and attestation must be completed by prescriber at each interval AND
- Medical record documentation of a reason why the patient cannot use buprenorphine/naloxone sublingually
QUANTITY LIMIT: Pharmacist note to CSR: Authorization should be entered by HICL and only checking the Formulary box (no QLs need to be entered within the authorization).

- 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

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:
Suboxone 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, 2020

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
POLICY NUMBER: 356.0

POLICY AND PROCEDURE
PHARMACY
MANUAL

SECTION: Commercial Drug
SUBJECT: Bunavail

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
POLICY NUMBER: 358.0

SECTION: Commercial Drug

SUBJECT: Ledipasvir/Sofosbuvir

Applicable line of business:

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POLICY:
Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is applied according to the formulary review process (see Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Part D Policy 143.0 D Geisinger Health Plan (GHP) and Geisinger Indemnity Insurance Company (GIIC) Formulary Development by the Pharmacy). The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for ledipasvir/sofosbuvir for GHP members who have prescription drug benefits, including all lines of business, unless a specific limitation or exception exists.

REQUIRED DEFINITIONS:
1. **Attachment** – a supporting document that is developed and maintained by the policy writer or 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).
5. **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 ledipasvir/sofosbuvir 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:
  o 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
  o 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
  o Genotype 5
    ▪ As monotherapy OR
  o 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 15mg/kg in pediatric patients < 47kg), 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 the following with the past 3 months:  
  o Hepatic function panel  
  o Complete blood count including differential  
  o Basic metabolic panel  
  o 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:  
  o Hepatitis B immunization series OR  
  o 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. St Luke's, AtlantiCare, 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

QUANTITY LIMIT: Pharmacist note to CSR: Authorization should be entered by HICL and only checking the Formulary box (no QLs need to be entered within the authorization):
  - 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, ledipasvir/sofosbuvir will be paid for under the member’s prescription drug benefit.
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: July 29, 2020

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, 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
POLICY NUMBER: 359.0

POLICY AND PROCEDURE
PHARMACY
MANUAL

SECTION: Commercial Drug
SUBJECT: Xigduo XR

Applicable line of business:

<table>
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POLICY:
Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of formulary. The formulary is applied according to the formulary review process (see Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Part D Policy 143.0 D Geisinger Health Plan (GHP) and Geisinger Indemnity Insurance Company (GIIC) Formulary Development by the Pharmacy). The results of this process determine the development and application 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 all lines of business, unless a specific limitation or exception exists.

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).
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 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

QUANTITY LIMIT: Pharmacist note to CSR: Authorization should be entered by HICL and only checking the Formulary box (no QLs need to be entered within the authorization).

- 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.

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, 2020

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
POLICY: 
Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of formulary. The formulary is applied according to the formulary review process (see Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Part D Policy 143.0 D Geisinger Health Plan (GHP) and Geisinger Indemnity Insurance Company (GIIC) Formulary Development by the Pharmacy). The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for Trulicity for GHP members who have prescription drug benefits, including all lines of business, unless a specific limitation or exception exists.

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

ADDITIONAL DEFINITIONS:
1. **Formulary** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. **Non-formulary products** – those medications that are not included in the Formulary.
3. **Healthcare provider** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
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 Trulicity 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
- Medical record documentation of therapeutic failure on, intolerance to, or contraindication to Victoza AND either Ozempic or Rybelsus

QUANTITY LIMIT: Pharmacist note to CSR: *Authorization should be entered by HICL and only checking the Step Therapy box (no QLs need to be entered within the authorization).*

- 0.072 mL per day

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

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

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

THIS POLICY WILL BE REVISED AS NECESSARY AND REVIEWED NO LESS THAN ANNUALLY.
Signed:_______________________________________________

Title:  Director, Pharmacy Services

Date:  March 1, 2020

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
Revised:  6/2/17 – removed diagnosis & age, changed from PA to ST, added QL
Revised:  1/17/18 – updated failure from Tanzeum to Ozempic, updated QL to daily limit, updated
FA, updated signature
Revised:  3/1/18 – annual review, updated FA
Revised:  3/1/19 – annual review, added QL approval note, added ST language, updated FA
Revised:  01/28/20 – added failure of Rybelsus, updated FA
Revised:  3/1/20 – annual review, added GHP Kids
POLICY: Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of formulary. The formulary is applied according to the formulary review process (see Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Part D Policy 143.0 D Geisinger Health Plan (GHP) and Geisinger Indemnity Insurance Company (GIIC) Formulary Development by the Pharmacy). The results of this process determine the development and application 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 all lines of business, unless a specific limitation or exception exists.

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E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to 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:

**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 epithelial ovarian, fallopian tube or primary peritoneal 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 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
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.

QUANTITY LIMIT: Pharmacist note to CSR: Authorization should be entered by HICL and only checking the Formulary PA required box (no QLs need to be entered within the authorization).

- 100 mg tablets: 4 tablets per day, 28 day supply per fill
- 150 mg tablets: 4 tablets per day, 28 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.

**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.**

Signed: __________________________

Title: Director, Pharmacy Services

Date: July 29, 2020
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<tr>
<th>Revised</th>
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<tr>
<td>3/1/17</td>
<td>annual review, defined abbreviations</td>
</tr>
<tr>
<td>3/24/17</td>
<td>increased authorization duration to 12 months</td>
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<tr>
<td>11/27/17</td>
<td>added tablets, updated format of age/prescriber for capsules, updated sig.</td>
</tr>
<tr>
<td>3/1/18</td>
<td>annual review, added grandfather language, updated prescriber criteria</td>
</tr>
<tr>
<td>4/6/18</td>
<td>added breast cancer indication to tablets</td>
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<tr>
<td>3/1/19</td>
<td>annual review, added QL approval note</td>
</tr>
<tr>
<td>3/28/19</td>
<td>removed capsules criteria, added first-line main. indication, updated auth duration</td>
</tr>
<tr>
<td>3/1/20</td>
<td>annual review, added GHP Kids</td>
</tr>
<tr>
<td>4/21/20</td>
<td>separated indications with headers, added pancreatic cancer indication</td>
</tr>
<tr>
<td>7/29/20</td>
<td>Restructured ovarian cancer criteria, added HRD ovarian cancer &amp; prostate cancer</td>
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</tbody>
</table>
POLICY: 
Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of formulary. The formulary is applied according to the formulary review process (see Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Part D Policy 143.0 D Geisinger Health Plan (GHP) and Geisinger Indemnity Insurance Company (GIIC) Formulary Development by the Pharmacy). The results of this process determine the development and application 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 all lines of business, unless a specific limitation or exception exists.

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

**QUANTITY LIMIT:** Pharmacist note to CSR: *Authorization should be entered by HICL and only checking the Formulary box (no QLs need to be entered within the authorization).*
- 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:
  o ≥ 10% fibrosis on a chest high resolution computer tomography AND
  o FVC ≥ 40% of predicted normal AND
  o DLCO (diffusion capacity of the lung for carbon monoxide) 30-89% of predicted normal

QUANTITY LIMIT: Pharmacist note to CSR: Authorization should be entered by HICL and only checking the Formulary box (no QLs need to be entered within the authorization).
• 2 capsules per day, 30 day supply per fill

Note: ACR/ELAR Diagnostic Criteria for Systemic Sclerosis

<table>
<thead>
<tr>
<th>Item</th>
<th>Sub-item(s)</th>
<th>Weight/score†</th>
</tr>
</thead>
<tbody>
<tr>
<td>Skin thickening of the fingers of both hands extending proximal to the metacarpophalangeal joints (sufficient criterion)</td>
<td></td>
<td>9</td>
</tr>
<tr>
<td>Skin thickening of the fingers (only count the higher score)</td>
<td>Puffy fingers</td>
<td>2</td>
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<td></td>
<td>Sclerosis of the fingers (distal to the metacarpophalangeal joints but proximal to the proximal interphalangeal joints)</td>
<td>4</td>
</tr>
<tr>
<td>Fingertip lesions (only count the higher score)</td>
<td>Digital tip ulcers</td>
<td>2</td>
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<tr>
<td></td>
<td>Fingertip pitting scars</td>
<td>3</td>
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<tr>
<td>Telangiectasia</td>
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<td>Abnormal nailfold capillaries</td>
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<tr>
<td>Pulmonary arterial hypertension and/or interstitial lung disease</td>
<td>Pulmonary arterial hypertension</td>
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<tr>
<td></td>
<td>Interstitial lung disease</td>
<td>2</td>
</tr>
<tr>
<td>Raynaud's phenomenon</td>
<td></td>
<td>3</td>
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<tr>
<td>SSc-related autoantibodies (anticientromere, anti-topoisomerase I, anti-RNA polymerase III) (maximum score is 3)</td>
<td>Anticientromere</td>
<td>3</td>
</tr>
<tr>
<td></td>
<td>Anti-topoisomerase I</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Anti–RNA polymerase III</td>
<td></td>
</tr>
</tbody>
</table>

* 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 fibrosing dermopathy, generalized morphea, eosinophilic fasciitis, scleredema diastematomyelia, 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:
  - ≥ 10% fibrosis on a chest high resolution computer tomography AND
  - FVC ≥ 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 ≥ 10% OR
  - FVC decline ≥ 5% to <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

QUANTITY LIMIT: Pharmacist note to CSR: Authorization should be entered by HICL and only checking the Formulary box (no QLs need to be entered within the authorization).
  - 2 capsules per day, 30 day supply per fill

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
REVIEWS NO LESS THAN ANNUALLY.

Signed: ________________________________

Title: Director, Pharmacy Services

Date: November 17, 2020

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
POLICY NUMBER: 366.0

POLICY AND PROCEDURE
PHARMACY
MANUAL

SECTION: Commercial Drug
SUBJECT: Esbriet

Applicable line of business:

<table>
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<tr>
<th>Applicable Line of Business</th>
<th>X</th>
<th>Medicaid</th>
<th>Medicare</th>
<th>ACA</th>
<th>GHP Kids</th>
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**REQUIRED DEFINITIONS:**

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

QUANTITY LIMIT: Pharmacist note to CSR: Authorization should be entered by HICL and only checking the Formulary box (no QLs need to be entered within the authorization).

- 9 capsules per day, 30 day supply per fill

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, 2020

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
POLICY:
Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of formulary. The formulary is applied according to the formulary review process (see Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Part D Policy 143.0 D Geisinger Health Plan (GHP) and Geisinger Indemnity Insurance Company (GIIC) Formulary Development by the Pharmacy). The results of this process determine the development and application 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 all lines of business, unless a specific limitation or exception exists.

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

ADDITIONAL DEFINITIONS:
1. **Formulary** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. **Non-formulary products** – those medications that are not included in the Formulary.
3. **Healthcare provider** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
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 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**
- **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.)
QUANTITY LIMIT: Pharmacist note to CSR: Authorization should be entered by HICL and only checking the Formulary PA required box (no QLs need to be entered within the authorization).
- 21 capsules per 28 days, 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 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, 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.

Signed: ________________________________
Title: Director, Pharmacy Services
Date: March 1, 2020

Devised: 4/13/15
Revised: 12/16/15 – Corrected quantity limit
Reviewed: 3/1/16 – annual review
POLICY NUMBER: 367.0

POLICY AND PROCEDURE
PHARMACY
MANUAL

SECTION: Commercial Drug
SUBJECT: Ibrance

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
Applicable line of business:

<table>
<thead>
<tr>
<th>Line of Business</th>
<th>Commercial</th>
<th>Medicaid</th>
<th>Medicare</th>
<th>ACA</th>
<th>GHP Kids</th>
</tr>
</thead>
</table>

POLICY:

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of formulary. The formulary is applied according to the formulary review process (see Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Part D Policy 143.0 D Geisinger Health Plan (GHP) and Geisinger Indemnity Insurance Company (GIIC) Formulary Development by the Pharmacy). The results of this process determine the development and application 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 all lines of business, unless a specific limitation or exception exists.

REQUIRED DEFINITIONS:

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

ADDITIONAL DEFINITIONS:

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

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

THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE STANDARDS 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: 371.0

POLICY AND PROCEDURE
PHARMACY
MANUAL

SECTION: Commercial Drug
SUBJECT: Belsomra

Applicable line of business:

<table>
<thead>
<tr>
<th>Line of Business</th>
<th>Commercial</th>
<th>Medicaid</th>
<th>Medicare</th>
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POLICY:
Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of formulary. The formulary is applied according to the formulary review process (see Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Part D Policy 143.0 D Geisinger Health Plan (GHP) and Geisinger Indemnity Insurance Company (GIIC) Formulary Development by the Pharmacy). The results of this process determine the development and application 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 all lines of business, unless a specific limitation or exception exists.

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

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

QUANTITY LIMIT: Pharmacist note to CSR: Authorization should be entered by HICL and only checking the Formulary box (no QLs need to be entered within the authorization).
- 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

THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE STANDARDS 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: 371.0

POLICY AND PROCEDURE
PHARMACY
MANUAL

SECTION: Commercial Drug
SUBJECT: Belsomra

Signed: ________________________________
Title: Director, Pharmacy Services
Date: March 1, 2020

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
POLICY AND PROCEDURE
PHARMACY
MANUAL

POLICY NUMBER: 372.0
SECTION: Commercial Drug
SUBJECT: Farydak

Applicable line of business:

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POLICY:
Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of formulary. The formulary is applied according to the formulary review process (see Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Part D Policy 143.0 D Geisinger Health Plan (GHP) and Geisinger Indemnity Insurance Company (GIIC) Formulary Development by the Pharmacy). The results of this process determine the development and application 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 all lines of business, unless a specific limitation or exception exists.

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

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

QUANTITY LIMIT: Pharmacist note to CSR: Authorization should be entered by HICL  
and only checking the Formulary PA required box (no QLs need to be entered within the  
authorization).  

- 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  
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, 2020

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
POLICY: 
Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of formulary. The formulary is applied according to the formulary review process (see Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Part D Policy 143.0 D Geisinger Health Plan (GHP) and Geisinger Indemnity Insurance Company (GIIC) Formulary Development by the Pharmacy). The results of this process determine the development and application 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 all lines of business, unless a specific limitation or exception exists.

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

ADDITIONAL DEFINITIONS:
1. Formulary – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. Non-formulary products – those medications that are not included in the Formulary.
3. Healthcare provider – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
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 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 use in combination with Afinitor (everolimus) 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, Sutent (sunitinib), Votrient (pazopanib), Inlyta (axitinib), Nexavar (sorafenib), Avastin (bevacizumab), Afinitor (everolimus), or Torisel (temsirolimus)

**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 appropriate dose of Lenvima is prescribed based on patient’s body weight (>60kg: Lenvima 12mg once daily, <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)

QUANTITY LIMIT: Pharmacist note to CSR: Authorization should be entered by HICL and only checking the Formulary PA required box (no QLs need to be entered within the authorization).
• 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

AUTHORIZATION DURATION: Initial approval will be for 12 months of 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.
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, 2020

Devised: 6/5/15
Reviewed: 3/1/16 – annual review
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
POLICY AND PROCEDURE
PHARMACY MANUAL

POLICY NUMBER: 375.0
SECTION: Commercial Drug
SUBJECT: Savaysa

Applicable line of business:

<table>
<thead>
<tr>
<th>Line of Business</th>
<th>Commercial</th>
<th>Medicaid</th>
<th>Medicare</th>
<th>ACA</th>
<th>GHP Kids</th>
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<td></td>
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</table>

POLICY:
Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of formulary. The formulary is applied according to the formulary review process (see Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Part D Policy 143.0 D Geisinger Health Plan (GHP) and Geisinger Indemnity Insurance Company (GIIC) Formulary Development by the Pharmacy). The results of this process determine the development and application 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 all lines of business, unless a specific limitation or exception exists.

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

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

QUANTITY LIMIT: 1 tablet per day

NOTE: If approved, requests for Savaysa should be approved by GPID.

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

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

Signed:_______________________________________________

Title: Director, Pharmacy Services

Date: March 1, 2020

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
Applicable line of business:

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**POLICY:**

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of formulary. The formulary is applied according to the formulary review process (see Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Part D Policy 143.0 D Geisinger Health Plan (GHP) and Geisinger Indemnity Insurance Company (GIIC) Formulary Development by the Pharmacy). The results of this process determine the development and application 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 all lines of business, unless a specific limitation or exception exists.

**REQUIRED DEFINITIONS:**

1. Attachment – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. Exhibit – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. Devised – the date the policy was implemented.
4. Revised – the date of every revision to the policy, including typographical and grammatical changes.
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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).
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 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
- Medical record documentation of hemoglobin (hgb) less than 10 g/dL for new starts
- 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
- Medical record documentation of hemoglobin (hgb) less than 12 g/dL for continuation of therapy
- 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

AUTHORIZATION DURATION: 3 months

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:**
Epogen*, Procrit*, Aranesp*

*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, 2020

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
POLICY NUMBER: 379.0

SECTION: Commercial Drug
SUBJECT: Cosentyx

Applicable line of business:

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

<table>
<thead>
<tr>
<th>If requesting a dose of:</th>
<th>Initial – One-time, one-week authorization</th>
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</thead>
<tbody>
<tr>
<td>150 mg every 4 weeks</td>
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<td>Quantity limit: 2 mL per 28 days Max quantity supply: 2 Min day supply: 28 Max day supply: 28</td>
</tr>
</tbody>
</table>

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 plaque psoriasis on six (6) months of Cosentyx therapy is required.

After the initial six (6) month approval, subsequent approvals will be for a duration of one (1) year, requiring medical record documentation of continued or sustained improvement in signs and symptoms of plaque psoriasis while on Cosentyx therapy.

FORMULARY ALTERNATIVES:
cyclosporine, methotrexate

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

Medium-potency topical corticosteroids: betamethasone valerate 0.1% cream (Valisone); flucinolone 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 18 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

**QUANTITY LIMIT/AUTHORIZATION PARAMETERS:** Authorization should be approved by NDC-11 for the requested dosage form (prefilled syringe: 00078-0639-98; sensoready pen: 00078-0639-41).

<table>
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</tr>
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</table>

**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 psoriatic arthritis on six (6) months of Cosentyx therapy is required.
After the initial six (6) month approval, subsequent approvals will be for a duration of one (1) year, requiring medical record documentation of continued or sustained improvement in signs and symptoms of psoriatic arthritis while on Cosentyx therapy.

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


<table>
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<td>Max quantity supply: 4</td>
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<td>Min day supply: 28</td>
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</table>

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 ankylosing spondylitis on six (6) months of Cosentyx therapy is required.

After the initial six (6) month approval, subsequent approvals will be for a duration of one (1) year, requiring medical record documentation of continued or sustained improvement in signs and symptoms of ankylosing spondylitis while on Cosentyx therapy.
FORMULARY ALTERNATIVES:
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, tolfetin
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)
- 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


<table>
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<tbody>
<tr>
<td>150 mg at week 0, 1, 2, 3, 4 followed by 150mg every 4 weeks</td>
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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 non-radiographic axial spondylarthritis on six (6) months of Cosentyx therapy is required.

After the initial six (6) month approval, subsequent approvals will be for a duration of one (1) year, requiring medical record documentation of continued or sustained improvement.
in signs and symptoms of non-radiographic axial spondylarthritis while on Cosentyx therapy.

FORMULARY ALTERNATIVES:
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
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: October 12, 2020

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: 380.0
SECTION: Commercial Drug
SUBJECT: Rytary

Applicable line of business:

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</table>

POLICY:
Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of formulary. The formulary is applied according to the formulary review process (see Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Part D Policy 143.0 D Geisinger Health Plan (GHP) and Geisinger Indemnity Insurance Company (GIIC) Formulary Development by the Pharmacy). The results of this process determine the development and application 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 all lines of business, unless a specific limitation or exception exists.

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

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

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, Azilect

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

THIS POLICY WILL BE REVISED AS NECESSARY AND REVIEWED NO LESS THAN ANNUALLY.
Signed: ________________________________

Title:  Director, Pharmacy Services

Date:  March 1, 2020

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
POLICY:  
Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of formulary. The formulary is applied according to the formulary review process (see Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Part D Policy 143.0 D Geisinger Health Plan (GHP) and Geisinger Indemnity Insurance Company (GIIC) Formulary Development by the Pharmacy). The results of this process determine the development and application 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 all lines of business, unless a specific limitation or exception exists.

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

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

QUANTITY LIMIT: Pharmacist note to CSR: Authorization should be entered by HICL and only checking the Formulary box (no QLs need to be entered within the authorization).

- 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

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

THIS POLICY WILL BE REVISED AS NECESSARY AND REVIEWED NO LESS THAN ANNUALLY.
Signed: ____________________________

Title: Director, Pharmacy Services

Date: March 1, 2020

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
Applicable line of business:

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<th>Line of Business</th>
<th>Commercial</th>
<th>Medicaid</th>
<th>Medicare</th>
<th>ACA</th>
<th>GHP Kids</th>
</tr>
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</table>

**POLICY:**

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of formulary. The formulary is applied according to the formulary review process (see Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Part D Policy 143.0 D Geisinger Health Plan (GHP) and Geisinger Indemnity Insurance Company (GIIC) Formulary Development by the Pharmacy). The results of this process determine the development and application 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 all lines of business, unless a specific limitation or exception exists.

**REQUIRED DEFINITIONS:**

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

**ADDITIONAL DEFINITIONS:**

1. **Formulary** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. **Non-formulary products** – those medications that are not included in the Formulary.
3. **Healthcare provider** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
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
QUANTITY LIMIT: Pharmacist note to CSR: Authorization should be entered by HICL and only checking the Formulary PA required box (no QLs need to be entered within the authorization).

- 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:____________________________________________

Title: Director, Pharmacy Services

Date: October 12, 2020

Devised: 7/22/15
Revised: 3/1/16 – annual review
POLICY NUMBER: 382.0

SECTION: Commercial Drug

SUBJECT: Corlanor

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
POLICY:
Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of formulary. The formulary is applied according to the formulary review process (see Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Part D Policy 143.0 D Geisinger Health Plan (GHP) and Geisinger Indemnity Insurance Company (GIIC) Formulary Development by the Pharmacy). The results of this process determine the development and application 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 all lines of business, unless a specific limitation or exception exists.

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

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

**QUANTITY LIMIT:** Pharmacist note to CSR: *Authorization should be entered by HICL and only checking the Formulary box (no QLs need to be entered within the authorization).*

- 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.

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

**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: John [Signature]

Title: Director, Pharmacy Services

Date: March 1, 2020

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
POLICY:
Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of formulary. The formulary is applied according to the formulary review process (see Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Part D Policy 143.0 D Geisinger Health Plan (GHP) and Geisinger Indemnity Insurance Company (GIIC) Formulary Development by the Pharmacy). The results of this process determine the development and application 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 all lines of business, unless a specific limitation or exception exists.

REQUIRED DEFINITIONS:
1. Attachment – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. Exhibit – a 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).
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 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\(^\text{®}\) **AND** amphetamine/dextroamphetamine SR combination

\(^\text{®}\) 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.”

**QUANTITY LIMIT:** 1 capsule per day

**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.
QUANTITY LIMIT: 1 capsule 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.

Signed:_______________________________________________
Title: Director, Pharmacy Services
Date: March 1, 2020

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
Applicable line of business:

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<th>Line of Business</th>
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<th>Medicaid</th>
<th>Medicare</th>
<th>ACA</th>
<th>GHP Kids</th>
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POLICY:
Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of formulary. The formulary is applied according to the formulary review process (see Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Part D Policy 143.0 D Geisinger Health Plan (GHP) and Geisinger Indemnity Insurance Company (GIIC) Formulary Development by the Pharmacy). The results of this process determine the development and application 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 all lines of business, unless a specific limitation or exception exists.

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

ADDITIONAL DEFINITIONS:
1. **Formulary** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. **Non-formulary products** – those medications that are not included in the Formulary.
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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 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
- Must be prescribed by a participating provider or a provider who participates in the plan's designated behavioral health benefit program AND
- Buprenorphine/naloxone must be used unless there is medical record documentation of intolerance to, contraindication to, or therapeutic failure on buprenorphine/naloxone (ex. use in pregnancy/breast feeding) 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 buprenorphine or buprenorphine/naloxone 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 therapeutic failure on, intolerance to, or contraindication to buprenorphine/naloxone SL tablets AND Suboxone Films

AUTHORIZATION DURATION: If approved, initial authorization duration will be 3 months. If approved, subsequent authorization duration will be 12 months.

QUANTITY LIMIT: 34 day supply per fill
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, Suboxone 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, 2020

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
POLICY NUMBER: 386.0

SECTION: Commercial Drug

SUBJECT: Cresemba Capsules

Applicable line of business:

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<th>Medicare</th>
<th>Medicaid</th>
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<td>GHP Kids</td>
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</tbody>
</table>

POLICY:

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of formulary. The formulary is applied according to the formulary review process (see Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Part D Policy 143.0 D Geisinger Health Plan (GHP) and Geisinger Indemnity Insurance Company (GIIC) Formulary Development by the Pharmacy). The results of this process determine the development and application 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 all lines of business, unless a specific limitation or exception exists.

REQUIRED DEFINITIONS:

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

ADDITIONAL DEFINITIONS:

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

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)

QUANTITY LIMIT: Pharmacist note to CSR: Authorization should be entered by HICL and only checking the Formulary box (no QLs need to be entered within the authorization).
- 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
POLICY NUMBER: 386.0

SECTION: Commercial Drug
SUBJECT: Cresemba 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, 2020

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
POLICY:
Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of formulary. The formulary is applied according to the formulary review process (see Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Part D Policy 143.0 D Geisinger Health Plan (GHP) and Geisinger Indemnity Insurance Company (GIIC) Formulary Development by the Pharmacy). The results of this process determine the development and application 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 all lines of business, unless a specific limitation or exception exists.

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

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

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, 2020

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
Revised: 3/1/19 – annual review, defined abbr.
Revised: 3/1/20 – annual review, added GHP Kids
POLICY:
Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of formulary. The formulary is applied according to the formulary review process (see Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Part D Policy 143.0 D Geisinger Health Plan (GHP) and Geisinger Indemnity Insurance Company (GIIC) Formulary Development by the Pharmacy). The results of this process determine the development and application 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 all lines of business, unless a specific limitation or exception exists.

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

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

- Medical record documentation of age greater than or equal to 18 years AND
- Medical record documentation of:
  - a diagnosis of schizophrenia OR
  - a diagnosis of major depressive disorder (MDD) AND medical record documentation that the patient is using Rexulti as adjunctive therapy AND
- For MDD:
  - 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 an 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) OR

- For schizophrenia
Medical record documentation of a therapeutic failure on, intolerance to, or contraindication to three generic, formulary atypical antipsychotics

**QUANTITY LIMIT**: Pharmacist note to CSR: *Authorization should be entered by HICL and only checking the Formulary box (no QLs need to be entered within the authorization).*

- 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
  - Bupropion
  - Tricyclic Antidepressants: amitriptyline, desipramine, doxepin, imipramine, nortriptyline
  - Mirtazapine
  - Augmentation Therapy: lithium, valproate, carbamazepine and lamotrigine

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE STANDARDS 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: 388.0

POLICY AND PROCEDURE
PHARMACY
MANUAL

SECTION: Commercial Drug
SUBJECT: Rexulti

Signed: ________________________________

Title: Director, Pharmacy Services

Date: March 1, 2020

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
POLICY: Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of formulary. The formulary is applied according to the formulary review process (see Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Part D Policy 143.0 D Geisinger Health Plan (GHP) and Geisinger Indemnity Insurance Company (GIIC) Formulary Development by the Pharmacy). The results of this process determine the development and application 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 all lines of business, unless a specific limitation or exception exists.

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

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

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
POLICY NUMBER: 390.0

POLICY AND PROCEDURE
PHARMACY
MANUAL

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, 2020

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

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Dev. 9/19/15
Rev. 3/1/20
POLICY NUMBER: 391.0

POLICY AND PROCEDURE
PHARMACY
MANUAL

SECTION: Commercial Drug
SUBJECT: Toujeo

Applicable line of business:

| Line of Business | 
|------------------|--------------------------------------------------|
| Commercial       | X                                                |
| Medicaid         |                                                  |
| Medicare         | ACA                                              |
| GHP Kids         | X                                                |

POLICY:
Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of formulary. The formulary is applied according to the formulary review process (see Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Part D Policy 143.0 D Geisinger Health Plan (GHP) and Geisinger Indemnity Insurance Company (GIIIC) Formulary Development by the Pharmacy). The results of this process determine the development and application 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 all lines of business, unless a specific limitation or exception exists.

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

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

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.

Signed: ____________________________________________
Title: Director, Pharmacy Services
Date: March 1, 2020
Applicable line of business:

POLICY:
Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is applied according to the formulary review process (see Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Part D Policy 143.0 D Geisinger Health Plan (GHP) and Geisinger Indemnity Insurance Company (GIIC) Formulary Development by the Pharmacy). The results of this process determine the development and application 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 all lines of business, unless a specific limitation or exception exists.

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

ADDITIONAL DEFINITIONS:
1. **Formulary** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. **Non-formulary products** – those medications that are not included in the Formulary.
3. **Healthcare provider** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
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
  - 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 European Society of Cardiology/European Atherosclerosis Society (ESC/EAS) guidelines and the World Health Organization AND
  - Medical record documentation that Praluent is prescribed by a cardiologist or lipidologist 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 patient has a diagnosis of heterozygous familial hypercholesterolemia (HeFH) and is using Praluent for primary prevention OR
- Low-density lipoprotein (LDL) greater than 70 if the patient has a diagnosis of atherosclerotic cardiovascular disease (ASCVD) or heterozygous familial hypercholesterolemia (HeFH) and 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, Juxtapid, or Kynamro

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).

**QUANTITY LIMIT:** Pharmacist note to CSR: *Authorization should be entered by HICL and only checking the Formulary PA required box (no QLs need to be entered within the authorization).*

- 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, Juxtapid, or Kynamro
Table 1. Diagnostic criteria for the clinical diagnosis of HeFH (WHO)

<table>
<thead>
<tr>
<th>Criteria</th>
<th>Score</th>
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<tr>
<td><strong>Family history</strong></td>
<td></td>
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<td>First-degree relative known 1</td>
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<tr>
<td>with premature CAD* and/or</td>
<td></td>
</tr>
<tr>
<td>first-degree relative with   2</td>
<td></td>
</tr>
<tr>
<td>LDL-C &gt; 95th percentile</td>
<td></td>
</tr>
<tr>
<td>First-degree relative with   2</td>
<td></td>
</tr>
<tr>
<td>Tx and/or children &lt; 18 with</td>
<td></td>
</tr>
<tr>
<td>LDL-C &gt; 95th centile</td>
<td></td>
</tr>
<tr>
<td><strong>Clinical history</strong></td>
<td></td>
</tr>
<tr>
<td>Patient has premature CAD*</td>
<td>2</td>
</tr>
<tr>
<td>Patient has premature</td>
<td>1</td>
</tr>
<tr>
<td>cerebral/peripheral vascular</td>
<td></td>
</tr>
<tr>
<td>disease</td>
<td></td>
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<tr>
<td><strong>Physical examination</strong></td>
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<tr>
<td>Tx</td>
<td>6</td>
</tr>
<tr>
<td>Arcus cornealis below the age</td>
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</tr>
<tr>
<td>of 45 years</td>
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</tr>
<tr>
<td><strong>LDL-C</strong></td>
<td></td>
</tr>
<tr>
<td>&gt; 8.5 mmol/L (more than ~330</td>
<td>8</td>
</tr>
<tr>
<td>mg/dL)</td>
<td></td>
</tr>
<tr>
<td>6.5-8.4 mmol/L (~250-329 mg/</td>
<td>5</td>
</tr>
<tr>
<td>dL)</td>
<td></td>
</tr>
<tr>
<td>5.0-6.4 mmol/L (~190-249 mg/</td>
<td>3</td>
</tr>
<tr>
<td>dL)</td>
<td></td>
</tr>
<tr>
<td>4.0-4.9 mmol/L (~155-189 mg/</td>
<td>1</td>
</tr>
<tr>
<td>dL)</td>
<td></td>
</tr>
<tr>
<td><strong>Definite FH</strong></td>
<td>Score &gt; 8</td>
</tr>
<tr>
<td><strong>Probable FH</strong></td>
<td>Score 6-8</td>
</tr>
<tr>
<td><strong>Possible FH</strong></td>
<td>Score 3-5</td>
</tr>
<tr>
<td><strong>No diagnosis</strong></td>
<td>Score &lt; 3</td>
</tr>
</tbody>
</table>

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, Welchol, 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.
POLICY NUMBER: 392.0

SECTION: Commercial Drug

SUBJECT: Praluent

Signed: ________________________________

Title: Director, Pharmacy Services

Date: October 1, 2019

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

Revised: 10/1/19 – extended initial auth duration to 12 months

Revised: 3/1/20 – annual review, added GHP Kids
POLICY:
Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of formulary. The formulary is applied according to the formulary review process (see Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Part D Policy 143.0 D Geisinger Health Plan (GHP) and Geisinger Indemnity Insurance Company (GIIC) Formulary Development by the Pharmacy). The results of this process determine the development and application 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 all lines of business, unless a specific limitation or exception exists.

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

ADDITIONAL DEFINITIONS:
1. **Formulary** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. **Non-formulary products** – those medications that are not included in the Formulary.
3. **Healthcare provider** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
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 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
  - 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 European Society of Cardiology/European Atherosclerosis Society (ESC/EAS) guidelines and the World Health Organization OR
  - Homozygous familial hypercholesterolemia (HoFH) AND either:
    - Genetic testing to confirm diagnosis showing at least one low-density lipoprotein (LDL) receptor-defective mutation 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 that Repatha is prescribed by a cardiologist or lipidologist 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 100 if the patient has a diagnosis of heterozygous familial hypercholesterolemia (HeFH) or homozygous familial hypercholesterolemia (HoFH) and is using Repatha 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) or homozygous familial hypercholesterolemia (HoFH) and 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 medical record documentation of age greater than or equal to 13 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, Juxtapid, or Kynamro AND
- If requesting Repatha Syringe or Repatha Sureclick 420 mg per 28 days (3 mL per 28 days), medical record documentation of therapeutic failure on, intolerance to, or contraindication to Repatha Pushtronex

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).

**QUANTITY LIMIT:** Pharmacist note to CSR: *Authorization should be entered by HICL and only checking the Formulary PA required box (no QLs need to be entered within the authorization).*
• 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**
- 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, Juxtapid, or Kynamro

Table 1. Diagnostic criteria for the clinical diagnosis of HeFH (WHO)

<table>
<thead>
<tr>
<th>Criteria</th>
<th>Score</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Family history</strong></td>
<td></td>
</tr>
<tr>
<td>First-degree relative known with premature CAD* and/or first-degree relative with LDL-C &gt;95th percentile</td>
<td>1</td>
</tr>
<tr>
<td>First-degree relative with Tx and/or children &lt;18 with LDL-C &gt;95th percentile</td>
<td>2</td>
</tr>
</tbody>
</table>

| **Clinical history**              |       |
| Patient has premature CAD*       | 2     |
| Patient has premature cerebral/vascular disease | 1     |

| **Physical examination**          |       |
| Tx                                | 6     |
| Arcus cornæs 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     |
| 4.0-4.0 mmol/L, (~155-189 mg/dL)   | 1     |

| **Definite FH Score**            |     |
| Score >8                         |     |
| **Probable FH Score**            |     |
| Score 6-8                        |     |
| **Possible FH Score**            |     |
| Score 3-5                        |     |
| **No diagnosis Score**           |     |
| 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, Welchol, 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: March 1, 2020

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
POLICY: Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of formulary. The formulary is applied according to the formulary review process (see Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Part D Policy 143.0 D Geisinger Health Plan (GHP) and Geisinger Indemnity Insurance Company (GIIC) Formulary Development by the Pharmacy). The results of this process determine the development and application 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 all lines of business, unless a specific limitation or exception exists.

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

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

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 20 mg/mL, Gilenya, Tecfidera, Betaseron, Plegridy, Extavia, Aubagio 14 mg, Avonex, Rebif

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

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

Title: Director, Pharmacy Services

Date: March 1, 2020

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
POLICY NUMBER: 395.0

POLICY AND PROCEDURE
PHARMACY
MANUAL

SECTION: Commercial Drug
SUBJECT: Orkambi

Applicable line of business:

<table>
<thead>
<tr>
<th>Line of Business</th>
<th>Commercial</th>
<th>Medicaid</th>
<th>Medicare</th>
<th>ACA</th>
<th>GHP Kids</th>
</tr>
</thead>
<tbody>
<tr>
<td>X</td>
<td></td>
<td></td>
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<tr>
<td></td>
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</tr>
</tbody>
</table>

POLICY:
Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of formulary. The formulary is applied according to the formulary review process (see Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Part D Policy 143.0 D Geisinger Health Plan (GHP) and Geisinger Indemnity Insurance Company (GIIC) Formulary Development by the Pharmacy). The results of this process determine the development and application 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 all lines of business, unless a specific limitation or exception exists.

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

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

QUANTITY LIMIT: Pharmacist note to CSR: Authorization should be entered by HICL and only checking the Formulary PA required box (no QLs need to be entered within the authorization).

- 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.

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, 2020

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
POLICY AND PROCEDURE
PHARMACY
MANUAL

POLICY NUMBER: 396.0
SECTION: Commercial Drug
SUBJECT: Lonsurf

Applicable line of business:

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<tr>
<th></th>
<th>Commercial</th>
<th>Medicaid</th>
<th>Medicare</th>
<th>ACA</th>
<th>GHP Kids</th>
</tr>
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<tbody>
<tr>
<td>X</td>
<td></td>
<td></td>
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POLICY:
Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of formulary. The formulary is applied according to the formulary review process (see Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Part D Policy 143.0 D Geisinger Health Plan (GHP) and Geisinger Indemnity Insurance Company (GIIC) Formulary Development by the Pharmacy). The results of this process determine the development and application 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 all lines of business, unless a specific limitation or exception exists.

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).
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 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
QUANTITY LIMIT: Pharmacist note to CSR: Authorization should be entered by HICL and only checking the Formulary PA required box (no QLs need to be entered within the authorization).

- 15 mg/6.14 mg tablet: 100 tablets per 28 days
- 20 mg/8.19 mg tablet: 80 tablets per 28 days

AUTHORIZATION DURATION: Initial approval will for 12 months of 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.

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.
POLICY NUMBER: 396.0

POLICY AND PROCEDURE
PHARMACY
MANUAL

SECTION: Commercial Drug
SUBJECT: Lonsurf

Signed: _______________________________________________________

Title: Director, Pharmacy Services

Date: March 1, 2020

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
POLICY NUMBER: 397.0

SECTION: Commercial Drug

SUBJECT: Odomzo

Applicable line of business:

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<td>GHP Kids</td>
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POLICY:
Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of formulary. The formulary is applied according to the formulary review process (see Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Part D Policy 143.0 D Geisinger Health Plan (GHP) and Geisinger Indemnity Insurance Company (GIIC) Formulary Development by the Pharmacy). The results of this process determine the development and application 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 all lines of business, unless a specific limitation or exception exists.

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

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

**QUANTITY LIMIT**: Pharmacist note to CSR: *Authorization should be entered by HICL and only checking the Formulary PA required box (no QLs need to be entered within the authorization).*

- 1 capsule per day, 30 day supply per fill

**AUTHORIZATION DURATION**: Initial approval will for 12 months of 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.
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: [Signature]

Title: Director, Pharmacy Services

Date: March 1, 2020

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

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
POLICY AND PROCEDURE
PHARMACY
MANUAL

POLICY NUMBER: 400.0
SECTION: Commercial Drug
SUBJECT: Daklinza

Applicable line of business:

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POLICY:
Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is applied according to the formulary review process (see Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Part D Policy 143.0 D Geisinger Health Plan (GHP) and Geisinger Indemnity Insurance Company (GIIC) Formulary Development by the Pharmacy). The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for Daklinza for GHP members who have prescription drug benefits, including all lines of business, unless a specific limitation or exception exists.

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

ADDITIONAL DEFINITIONS:
1. **Formulary** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. **Non-formulary products** – those medications that are not included in the Formulary.
3. **Healthcare provider** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
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. **HIV** – Human Immunodeficiency Virus
7. **HBV** – Hepatitis B Virus

**PROCEDURE:**
A formulary exception for coverage of Daklinza 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 a diagnosis of hepatitis C virus (HCV) genotype 3 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 3 and concurrent therapy with Sovaldi **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 **AND**
- Medical record documentation of appropriate duration of treatment **AND**
- Medical record documentation of previous treatment and treatment response (and does not include previous use of Harvoni or Daklinza) **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**
- 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 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 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. St Luke’s, AtlantiCare, Northern Light Health).

QUANTITY LIMIT: 1 tablet per day, 28 day supply per fill (unless additional tablets are needed for dose adjustments)
**AUTHORIZATION DURATION:** Daklinza will be approved for a time period of up to 12 weeks.

**CONTINUATION OF THERAPY CRITERIA:**
- Medical record documentation that the member is compliant with hepatitis C medications as evidenced by hepatitis C virus (HCV) RNA viral load and medication claims **AND**
- Medical record documentation of the member receiving a Food and Drug Administration (FDA) approved medication regimen and duration 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 Daklinza will be paid for under the member’s prescription drug benefit.

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: March 1, 2020

Devised:  11/20/15
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 – added continuation of therapy criteria
Revised:  11/22/16 – Added F2 fibrosis, referral to substance use treatment, failure of FA.
          Removed 6 months abstinence, substance use treatment compliance, UDS/fill
          history, GHP representative. Update FA, added if applicable.
Revised:  3/1/17 – annual review, removed Unicode characters, defined abbreviations
Revised:  3/27/17 – added regimen supported by compendia, removed peginterferon, added
          failure of Epclusa, updated FA
Revised:  6/2/17 – removed failure of FA, renal impair., fibrosis/liver manifest.; added METAVIR
Revised:  11/28/17 – added failure of Mavyret, removed Epclusa, updated FA, updated signature
Revised:  1/18/18 – 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.
Revised:  7/23/19 – added TPA COE exclusion
Revised:  3/1/20 – annual review, added GHP Kids
Applicable line of business:

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POLICY:
Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of formulary. The formulary is applied according to the formulary review process (see Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Part D Policy 143.0 D Geisinger Health Plan (GHP) and Geisinger Indemnity Insurance Company (GIIC) Formulary Development by the Pharmacy). The results of this process determine the development and application 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 all lines of business, unless a specific limitation or exception exists.

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

ADDITIONAL DEFINITIONS:
1. **Formulary** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. **Non-formulary products** – those medications that are not included in the Formulary.
3. **Healthcare provider** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
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 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 an FDA-approved test AND
- Medical record documentation of concomitant use with Zelboraf (vemurafenib)

QUANTITY LIMIT: Pharmacist note to CSR: Authorization should be entered by HICL and only checking the Formulary PA required box (no QLs need to be entered within the authorization).
- 3 tablets 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. 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 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, 2020

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 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
POLICY:
Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of formulary. The formulary is applied according to the formulary review process (see Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Part D Policy 143.0 D Geisinger Health Plan (GHP) and Geisinger Indemnity Insurance Company (GIIC) Formulary Development by the Pharmacy). The results of this process determine the development and application 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 all lines of business, unless a specific limitation or exception exists.

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

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

**QUANTITY LIMIT:** Pharmacist note to CSR: Authorization should be entered by HiCL and only checking the Formulary box (no QLs need to be entered within the authorization).

- 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.

**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, 2020

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
POLICY NUMBER: 403.0

SECTION: Commercial Drug
SUBJECT: Ninlaro

Applicable line of business:

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POLICY:
Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of formulary. The formulary is applied according to the formulary review process (see Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Part D Policy 143.0 D Geisinger Health Plan (GHP) and Geisinger Indemnity Insurance Company (GIIC) Formulary Development by the Pharmacy). The results of this process determine the development and application 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 all lines of business, unless a specific limitation or exception exists.

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

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

QUANTITY LIMIT: Pharmacist note to CSR: Authorization should be entered by HICL and only checking the Formulary PA required box (no QLs need to be entered within the authorization).
- 3 capsules 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 the member experiences unacceptable toxicity or worsening of disease.

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, 2020
Applicable line of business:

<table>
<thead>
<tr>
<th>Line of Business</th>
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<th>Medicaid</th>
<th>Medicare</th>
<th>ACA</th>
<th>GHP Kids</th>
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POLICY:
Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of formulary. The formulary is applied according to the formulary review process (see Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Part D Policy 143.0 D Geisinger Health Plan (GHP) and Geisinger Indemnity Insurance Company (GIIC) Formulary Development by the Pharmacy). The results of this process determine the development and application 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 all lines of business, unless a specific limitation or exception exists.

REQUIRED DEFINITIONS:
1. Attachment – a supporting document that is developed and maintained by the policy writer or 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).
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   A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
   B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
C. In accordance with current standards of medical practice;
D. Not primarily for the convenience of the Member, or the Member’s Provider; and
E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to 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:

- 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)

**QUANTITY LIMIT:** Pharmacist note to CSR: *Authorization should be entered by HICL and only checking the Formulary PA required box (no QLs need to be entered within the authorization)*.

- 1 tablet 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. 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 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.

**FORMULARY ALTERNATIVES:**
EGFR T790 mutation: Gilotrif*, Iressa*, Tarceva*

*prior authorization required*
POLICY:
Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of formulary. The formulary is applied according to the formulary review process (see Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Part D Policy 143.0 D Geisinger Health Plan (GHP) and Geisinger Indemnity Insurance Company (GIIC) Formulary Development by the Pharmacy). The results of this process determine the development and application 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 all lines of business, unless a specific limitation or exception exists.

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

QUANTITY LIMIT: Pharmacist note to CSR: Authorization should be entered by HICL and only checking the Formulary PA required box (no QLs need to be entered within the authorization).

- 8 capsules per day, 30 day supply per fill

AUTHORIZATION DURATION: Initial approval will be for twelve (12) months or less if the reviewing provider feels it is medically appropriate. Subsequent approvals will be for an additional twelve (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 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, 2020

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
POLICY: Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of formulary. The formulary is applied according to the formulary review process (see Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Part D Policy 143.0 D Geisinger Health Plan (GHP) and Geisinger Indemnity Insurance Company (GIIC) Formulary Development by the Pharmacy). The results of this process determine the development and application 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 all lines of business, unless a specific limitation or exception exists.

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).
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C. In accordance with current standards of medical practice;
D. Not primarily for the convenience of the Member, or the Member’s Provider; and
E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to 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

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.

Signed:_______________________________________________
Title: Director, Pharmacy Services
Date: March 1, 2020

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
Reviewed: 7/20/18 – added failure of Incruse Ellipta
Reviewed: 3/1/19 – annual review
Revised: 3/1/20 – annual review, added GHP Kids
Applicable line of business:

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POLICY:
Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of formulary. The formulary is applied according to the formulary review process (see Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Part D Policy 143.0 D Geisinger Health Plan (GHP) and Geisinger Indemnity Insurance Company (GIIC) Formulary Development by the Pharmacy). The results of this process determine the development and application 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 all lines of business, unless a specific limitation or exception exists.

REQUIRED DEFINITIONS:
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D. Not primarily for the convenience of the Member, or the Member's Provider; and
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**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

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.**

Signed: _________________________________
Title: Director, Pharmacy Services
Date: March 1, 2020

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
POLICY AND PROCEDURE
PHARMACY
MANUAL

POLICY NUMBER: 411.0
SECTION: Commercial Drug
SUBJECT: Viberzi

Applicable line of business:

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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).
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D. Not primarily for the convenience of the Member, or the Member's Provider; and
E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to 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

QUANTITY LIMIT: Pharmacist note to CSR: Authorization should be entered by HICL and only checking the Formulary PA required box (no QLs need to be entered within the authorization).

- 2 tablets per day

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

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, 2020

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
Reviewed: 3/1/19 – annual review, added QL approval note
Revised: 3/1/20 – annual review, added GHP Kids
Applicable line of business:

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**POLICY:**

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of formulary. The formulary is applied according to the formulary review process (see Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Part D Policy 143.0 D Geisinger Health Plan (GHP) and Geisinger Indemnity Insurance Company (GIIC) Formulary Development by the Pharmacy). The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for Strepsiq for GHP members who have prescription drug benefits, including all lines of business, unless a specific limitation or exception exists.

**REQUIRED DEFINITIONS:**

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**ADDITIONAL DEFINITIONS:**

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3. **Healthcare provider** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
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   B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
C. In accordance with current standards of medical practice;
D. Not primarily for the convenience of the Member, or the Member’s Provider; and
E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to 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 \textbf{AND}
- Medical record documentation of a diagnosis of perinatal/infantile- or juvenile-onset hypophosphatasia (HPP) \textbf{AND}
- Medical record documentation of low total serum alkaline phosphatase activity (see chart below for typical lowest normal reference values) \textbf{AND}
- Medical record documentation that member will receive a weight and diagnosis appropriate dosing regimen

\begin{table}[h]
\centering
\begin{tabular}{|c|c|c|}
\hline
\textbf{Age} & \textbf{Lowest Normal Total Serum or Plasma Alkaline Phosphatase Activity (U/L)} & \textbf{Male} & \textbf{Female} \\
\hline
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 & \\
\hline
\end{tabular}
\caption{Typical Lowest Normal Reference Values for Serum Alkaline Phosphatase Activity in North America}
\end{table}

\textbf{QUANTITY LIMIT}: 30 day supply per fill

\textbf{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.

Signed: [Signature]
Title: Director, Pharmacy Services
Date: March 1, 2020
Applicable line of business:

<table>
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<tr>
<th>Line of Business</th>
<th></th>
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POLICY:

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of formulary. The formulary is applied according to the formulary review process (see Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Part D Policy 143.0 D Geisinger Health Plan (GHP) and Geisinger Indemnity Insurance Company (GIIC) Formulary Development by the Pharmacy). The results of this process determine the development and application 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 all lines of business, unless a specific limitation or exception exists.

REQUIRED DEFINITIONS:

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

ADDITIONAL DEFINITIONS:

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

QUANTITY LIMIT: Pharmacist note to CSR: Authorization should be entered by HICL and only checking the Formulary PA required box (no QLs need to be entered within the authorization).

- 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.

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, 2020

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
POLICY:
Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of formulary. The formulary is applied according to the formulary review process (see Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Part D Policy 143.0 D Geisinger Health Plan (GHP) and Geisinger Indemnity Insurance Company (GIIC) Formulary Development by the Pharmacy). The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for Vivlodex for GHP members who have prescription drug benefits, including all lines of business, unless a specific limitation or exception exists.

REQUIRED DEFINITIONS:
1. **Attachment** – a supporting document that is developed and maintained by the policy writer or 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).
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 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

**QUANTITY LIMIT:** Pharmacist note to CSR: *Authorization should be entered by HICL and only checking the Formulary box (no QLs need to be entered within the authorization).*

- 1 capsule per day

If a formulary exception is approved 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, meclofenamate, meloxicam, nabumetone, naproxen, naproxen sodium, naproxen EC, oxaprozin, piroxicam, salsalate, sulindac, tolmetin
POLICY NUMBER: 415.0

POLICY AND PROCEDURE
PHARMACY
MANUAL

SECTION: Commercial Drug
SUBJECT: Vivlodex

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

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

Signed: ____________________________________________

Title: Director, Pharmacy Services

Date: March 1, 2020

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
Applicable line of business:

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POLICY:

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of formulary. The formulary is applied according to the formulary review process (see Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Part D Policy 143.0 D Geisinger Health Plan (GHP) and Geisinger Indemnity Insurance Company (GIIC) Formulary Development by the Pharmacy). The results of this process determine the development and application 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 all lines of business, unless a specific limitation or exception exists.

REQUIRED DEFINITIONS:

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

ADDITIONAL DEFINITIONS:

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

**QUANTITY LIMIT:** Pharmacist note to CSR: Authorization should be entered by HICL and only checking the Formulary PA required box (no QLs need to be entered within the authorization).
- 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, 2020

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: 
Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of formulary. The formulary is applied according to the formulary review process (see Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Part D Policy 143.0 D Geisinger Health Plan (GHP) and Geisinger Indemnity Insurance Company (GIIC) Formulary Development by the Pharmacy). The results of this process determine the development and application 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 all lines of business, unless a specific limitation or exception exists.

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).
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 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
QUANTITY LIMIT: Pharmacist note to CSR: Authorization should be entered by HICL and only checking the Formulary PA required box (no QLs need to be entered within the authorization).
- 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

AUTHORIZATION DURATION: Initial approval will be for twelve (12) months or less if the reviewing provider feels it is medically appropriate. Subsequent approvals will be for an additional twelve (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 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 Section: Commercial Drug Pharmacy
Subject: Venclexta

Signed: ________________________________________________
Signed: John Miller
Title: Director, Pharmacy Services
Date: March 1, 2020

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
Applicable line of business:

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POLICY:
Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of formulary. The formulary is applied according to the formulary review process (see Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Part D Policy 143.0 D Geisinger Health Plan (GHP) and Geisinger Indemnity Insurance Company (GIIC) Formulary Development by the Pharmacy). The results of this process determine the development and application 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 all lines of business, unless a specific limitation or exception exists.

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).
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   B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
C. In accordance with current standards of medical practice;
D. Not primarily for the convenience of the Member, or the Member’s Provider; and
E. The most appropriate source or level of service that can safely be provided to the
Member. When applied to hospitalization, this further means that the Member
requires acute care as an inpatient due to 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, function 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])

QUANTITY LIMIT: Pharmacist note to CSR: Authorization should be entered by HICL
and only checking the Formulary PA required box (no QLs need to be entered within the
authorization).

- 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:
  ambrisentan*, tadalafl*, 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, 2020

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
Reviewed: 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
POLICY NUMBER: 419.0

SECTION: Commercial Drug
SUBJECT: Zepatier

Applicable line of business:

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POLICY:
Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is applied according to the formulary review process (see Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Part D Policy 143.0 D Geisinger Health Plan (GHP) and Geisinger Indemnity Insurance Company (GIIC) Formulary Development by the Pharmacy). The results of this process determine the development and application 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 all lines of business, unless a specific limitation or exception exists.

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

ADDITIONAL DEFINITIONS:
1. Formulary – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. Non-formulary products – those medications that are not included in the Formulary.
3. Healthcare provider – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
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 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 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:
  o Hepatic function panel
  o Complete blood count including differential
  o Basic metabolic panel
  o 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:
  o Hepatitis B immunization series **OR**
  o 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:
  o Is being treated for human immunodeficiency virus (HIV) **OR**
  o 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. St Luke’s, AtlantiCare, Northern Light Health).

**QUANTITY LIMIT:** 1 tablet per day, 28 day supply per fill

**AUTHORIZATION DURATION:**
- Genotype 1a
  - Zepatier will be approved for a time period of 12 weeks if NS5A- **OR**
  - Zepatier will be approved for a time period of 16 weeks if NS5A+ **OR**
- Genotype 1b
  - Zepatier will be approved for a time period of 12 weeks **OR**
- Genotype 4
  - Zepatier will be approved for a time period of 12 weeks **OR**
Zepatier will be approved for a time period of 16 weeks if peginterferon and ribavirin treatment experienced.

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: March 1, 2020

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.
Revised: 7/23/19 – added TPA COE exclusion
Revised: 3/1/20 – annual review, added GHP Kids
POLICY

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of formulary. The formulary is applied according to the formulary review process (see Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Part D Policy 143.0 D Geisinger Health Plan (GHP) and Geisinger Indemnity Insurance Company (GIIC) Formulary Development by the Pharmacy). The results of this process determine the development and application 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 all lines of business, unless a specific limitation or exception exists.

REQUIRED DEFINITIONS:
1. **Attachment** – a supporting document that is developed and maintained by the policy writer or 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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C. In accordance with current standards of medical practice;
D. Not primarily for the convenience of the Member, or the Member’s Provider; and
E. The most appropriate source or level of service that can safely be provided to the
Member. When applied to hospitalization, this further means that the Member
requires acute care as an inpatient due to 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 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
QUANTITY LIMIT: Pharmacist note to CSR: Authorization should be entered by HICL and only checking the Formulary PA required box (no QLs need to be entered within the authorization).

- 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

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.

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.

FORMULARY ALTERNATIVES:
- Renal Cell Carcinoma: Afinitor\textsuperscript{®}, Inlyta\textsuperscript{®}, Lenvima\textsuperscript{®}, Nexavar\textsuperscript{®}, Sutent\textsuperscript{®}, Votrient\textsuperscript{®}
- Hepatocellular Carcinoma: Nexavar\textsuperscript{®}
- \textsuperscript{®}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: 420.0

POLICY AND PROCEDURE
PHARMACY
MANUAL

SECTION: Commercial Drug
SUBJECT: Cabometyx

---

Title: Director, Pharmacy Services
Date: March 1, 2020

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

Signed: ____________________________

Title: Director, Pharmacy Services
Date: March 1, 2020
Applicable line of business:

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POLICY:

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REQUIRED DEFINITIONS:

1. **Attachment** – a supporting document that is developed and maintained by the policy writer or 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. **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 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)

QUANTITY LIMIT: Pharmacist note to CSR: Authorization should be entered by HICL and only checking the Formulary PA required box (no QLs need to be entered within the authorization).

- 10 mg tablets and 34 mg capsules: 1 per day, 30 day supply per fill
- 17 mg tablets: 2 tablets 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, 2020

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
Revised: 3/1/20 – annual review, added GHP Kids
Applicable line of business:

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**POLICY:**
Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of formulary. The formulary is applied according to the formulary review process (see Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Part D Policy 143.0 D Geisinger Health Plan (GHP) and Geisinger Indemnity Insurance Company (GIIC) Formulary Development by the Pharmacy). The results of this process determine the development and application 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 all lines of business, unless a specific limitation or exception exists.

**REQUIRED DEFINITIONS:**
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   B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
C. In accordance with current standards of medical practice;
D. Not primarily for the convenience of the Member, or the Member’s Provider; and
E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to 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 4 years **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

**QUANTITY LIMIT:** Pharmacist note to CSR: *Authorization should be entered by HICL and only checking the Formulary box (no QLs need to be entered within the authorization).*

- 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.

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 > 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+), Gabitril (12+), lamotrigine ER (13+),
  - felbamate (14+), and zonisamide (16+)

*prior authorization required

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

Signed: [Signature]
Title: Director, Pharmacy Services
Date: March 1, 2020

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
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
POLICY NUMBER: 423.0

POLICY AND PROCEDURE
PHARMACY
MANUAL

SECTION: Commercial Drug
SUBJECT: Adzenys XR-ODT

Applicable line of business:

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   B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
C. In accordance with current standards of medical practice;
D. Not primarily for the convenience of the Member, or the Member’s Provider; and
E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to 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 dextroamphetamine/dextroamphetamine SR combination

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.

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, 2020

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
Applicable line of business:

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POLICY:
Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of formulary. The formulary is applied according to the formulary review process (see Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Part D Policy 143.0 D Geisinger Health Plan (GHP) and Geisinger Indemnity Insurance Company (GIIC) Formulary Development by the Pharmacy). The results of this process determine the development and application 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 all lines of business, unless a specific limitation or exception exists.

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

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

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.

**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, 2020

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
POLICY: Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of formulary. The formulary is applied according to the formulary review process (see Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Part D Policy 143.0 D Geisinger Health Plan (GHP) and Geisinger Indemnity Insurance Company (GIIC) Formulary Development by the Pharmacy). The results of this process determine the development and application 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 all lines of business, unless a specific limitation or exception exists.

REQUIRED DEFINITIONS:
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ADDITIONAL DEFINITIONS:
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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)**
- 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: dexamphetamine immediate release, dextroamphetamine immediate release, dextroamphetamine/amphetamine immediate release, or methylphenidate immediate release **AND**
- **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**
- Medical record documentation of a diagnosis of narcolepsy **AND**
- Medical record documentation of age greater than or equal to 12 years **AND**
- Medical record documentation of a therapeutic failure on, intolerance to, or contraindication to dextroamphetamine immediate release, dextroamphetamine/amphetamine immediate release **AND** methylphenidate immediate release
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

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

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

Signed:__________________________________________
Title: Director, Pharmacy Services
Date: March 1, 2020
Applicable line of business:

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Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of formulary. The formulary is applied according to the formulary review process (see Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Part D Policy 143.0 D Geisinger Health Plan (GHP) and Geisinger Indemnity Insurance Company (GIIC) Formulary Development by the Pharmacy). The results of this process determine the development and application 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 all lines of business, unless a specific limitation or exception exists.

**REQUIRED DEFINITIONS:**

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

**ADDITIONAL DEFINITIONS:**

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

- 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.

QUANTITY LIMIT: Pharmacist note to CSR: *Authorization should be entered by HICL  
and only checking the Formulary PA required box (no QLs need to be entered within the  
authorization).*

- 4 packets per day

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

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

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, 2020

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
POLICY NUMBER: 428.0

SECTION: Commercial Drug

SUBJECT: Bosentan

Applicable line of business:

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POLICY:
Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of formulary. The formulary is applied according to the formulary review process (see Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Part D Policy 143.0 D Geisinger Health Plan (GHP) and Geisinger Indemnity Insurance Company (GIIC) Formulary Development by the Pharmacy). The results of this process determine the development and application 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 for GHP members who have prescription drug benefits, including all lines of business, unless a specific limitation or exception exists.

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

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

**QUANTITY LIMIT:** Pharmacist note to CSR: *Authorization should be entered by HICL and only checking the Formulary PA required box (no QLs need to be entered within the authorization).*

- 2 tablets per day, 30 day supply per fill

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

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*, 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, 2020

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
Applicable line of business:

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POLICY:

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of formulary. The formulary is applied according to the formulary review process (see Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Part D Policy 143.0 D Geisinger Health Plan (GHP) and Geisinger Indemnity Insurance Company (GIIC) Formulary Development by the Pharmacy). The results of this process determine the development and application 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 all lines of business, unless a specific limitation or exception exists.

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).
5. **Medically Necessary or Medical Necessity** – covered services rendered by a provider that the Health Plan determines are:
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C. In accordance with current standards of medical practice;
D. Not primarily for the convenience of the Member, or the Member's Provider; and
E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to 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

QUANTITY LIMIT: 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

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, 2020

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
Applicable line of business:

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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:
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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

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 psoriasis on six (6) months of Taltz therapy is required.

After the initial six (6) month approval, subsequent approvals will be for a duration of one (1) year, requiring medical record documentation of continued or sustained improvement in signs and symptoms of psoriasis while on Taltz therapy.
QUANTITY LIMIT:
• At time of initial authorization (loading dose):
  o Three (3) month authorization for a maximum total quantity of 8 mL
  o Remainder of six (6) month authorization duration: 1 mL per 28 days
• For ongoing or reauthorization: 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

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 psoriasis on six (6) months of Taltz therapy is required.

After the initial six (6) month approval, subsequent approvals will be for a duration of one (1) year, requiring medical record documentation of continued or sustained improvement in signs and symptoms of psoriasis while on Taltz therapy.

QUANTITY LIMIT:
- At time of initial authorization (loading dose):
  - One-time, one-week authorization of 3 mL per 28 days
  - Remainder of six (6) month authorization duration: 1 mL per 28 days
- For ongoing or reauthorization: 1 mL per 28 days

FORMULARY ALTERNATIVES:
Low-potency topical corticosteroids: alclometasone dipropionate 0.5% cream and ointment (Aclovate); fluorocinolone acetonide 0.01% soln. (Synalar); hydrocortisone 2.5% cream, ointment, and lotion (Hytone)
Medium-potency topical corticosteroids: betamethasone valerate 0.1% cream (Valisone); fluorocinolone 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 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

**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 psoriatic arthritis on six (6) months of Taltz therapy is required.

After the initial six (6) month approval, subsequent approvals will be for a duration of one (1) year, requiring medical record documentation of continued or sustained improvement in signs and symptoms of psoriatic arthritis while on Taltz therapy.

**QUANTITY LIMIT:**
- At time of initial authorization (loading dose):
  - One-time, one-week authorization of 3 mL per 28 days
  - Remainder of six (6) month authorization duration: 1 mL per 28 days
- For ongoing or reauthorization: 1 mL per 28 days

**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.

**FORMULARY ALTERNATIVES:**
- methotrexate, cyclosporine, azathioprine, acitretin*, Humira**^**, Cosentyx**^**

*prior authorization required, ^quantity limits apply
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 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

**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 ankylosing spondylitis on six (6) months of Taltz therapy is required.

After the initial six (6) month approval, subsequent approvals will be for a duration of one (1) year, requiring medical record documentation of continued or sustained improvement in signs and symptoms of ankylosing spondylitis while on Taltz therapy.

**QUANTITY LIMIT:**

- At time of initial authorization (loading dose):
  - One-time, one-week authorization of 3 mL per 28 days
  - Remainder of six (6) month authorization duration: 1 mL per 28 days
- For ongoing or reauthorization: 1 mL per 28 days

**FORMULARY ALTERNATIVES:**

Humira*, Cosentyx*

* prior authorization required, ^quantity limits apply
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

**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 non-radiographic axial spondylarthritis on six (6) months of Taltz therapy is required.

After the initial six (6) month approval, subsequent approvals will be for a duration of one (1) year, requiring medical record documentation of continued or sustained improvement in signs and symptoms of non-radiographic axial spondylarthritis while on Taltz therapy.

**QUANTITY LIMIT:** 1 mL per 28 days

**FORMULARY ALTERNATIVES:**
- Cosentyx*^

  *prior authorization required, ^quantity limits apply
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: October 12, 2020

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
POLICY NUMBER: 432.0

POLICY AND PROCEDURE
PHARMACY
MANUAL

SECTION: Commercial Drug
SUBJECT: Zembrace Symtouch

POLICY:
Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of formulary. The formulary is applied according to the formulary review process (see Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Part D Policy 143.0 D Geisinger Health Plan (GHP) and Geisinger Indemnity Insurance Company (GIIC) Formulary Development by the Pharmacy). The results of this process determine the development and application 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 all lines of business, unless a specific limitation or exception exists.

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

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

QUANTITY LIMIT: 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.

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, 2020

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, updated 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
Applicable line of business:

<table>
<thead>
<tr>
<th>Line of Business</th>
<th>Commercial</th>
<th>Medicaid</th>
<th>Medicare</th>
<th>ACA</th>
<th>GHP Kids</th>
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POLICY:
Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of formulary. The formulary is applied according to the formulary review process (see Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Part D Policy 143.0 D Geisinger Health Plan (GHP) and Geisinger Indemnity Insurance Company (GIIC) Formulary Development by the Pharmacy). The results of this process determine the development and application 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 all lines of business, unless a specific limitation or exception exists.

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

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

QUANTITY LIMIT: Pharmacist note to CSR: Authorization should be entered by HICL and only checking the Formulary box (no QLs need to be entered within the authorization).

- 1ml (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.

FORMULARY ALTERNATIVES:
Aubagio 14mg, Avonex, Betaseron, Copaxone, Extavia, Gilenya, Plegridy, Rebif, Tecfidera

^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, 2020

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
POLICY AND PROCEDURE
PHARMACY
MANUAL

POLICY NUMBER: 434.0

SECTION: Commercial Drug
SUBJECT: Sofosbuvir/Velpatasvir

Applicable line of business:

<table>
<thead>
<tr>
<th>Applicable line of business</th>
<th>Commercial</th>
<th>Medicaid</th>
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POLICY:
Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is applied according to the formulary review process (see Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Part D Policy 143.0 D Geisinger Health Plan (GHP) and Geisinger Indemnity Insurance Company (GIIC) Formulary Development by the Pharmacy). The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for sofosbuvir/velpatasvir for GHP members who have prescription drug benefits, including all lines of business, unless a specific limitation or exception exists.

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

ADDITIONAL DEFINITIONS:
1. Formulary – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. Non-formulary products – those medications that are not included in the Formulary.
3. Healthcare provider – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
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 sofosbuvir/velpatasvir may be made for members who meet the following criteria:

- Medical record documentation of age greater than or equal to 6 years or weight 17 kg or more **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
• 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. St Luke’s, AtlantiCare, Northern Light Health).

QUANTITY LIMIT: one (1) tablet 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 sofosbuvir/velpatasvir will be paid for under the member’s prescription drug benefit.

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.
POLICY NUMBER: 434.0

SECTION: Commercial Drug
SUBJECT: Sofosbuvir/Velpatasvir

Signed: ____________________________________________

Title: Director, Pharmacy Services

Date: July 29, 2020

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
POLICY AND PROCEDURE
PHARMACY
MANUAL

POLICY NUMBER: 435.0
SECTION: Commercial Drug
SUBJECT: Bevespi Aerosphere

Applicable line of business:

<table>
<thead>
<tr>
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POLICY:
Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of formulary. The formulary is applied according to the formulary review process (see Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Part D Policy 143.0 D Geisinger Health Plan (GHP) and Geisinger Indemnity Insurance Company (GIIC) Formulary Development by the Pharmacy). The results of this process determine the development and application 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 all lines of business, unless a specific limitation or exception exists.

REQUIRED DEFINITIONS:
1. **Attachment** – a supporting document that is developed and maintained by the policy writer or 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).
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 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

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, Advair Diskus, 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.
Signed: _________________________________

Title: Director, Pharmacy Services

Date: March 1, 2020

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
POLICY:
Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of formulary. The formulary is applied according to the formulary review process (see Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Part D Policy 143.0 D Geisinger Health Plan (GHP) and Geisinger Indemnity Insurance Company (GIIC) Formulary Development by the Pharmacy). The results of this process determine the development and application 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 all lines of business, unless a specific limitation or exception exists.

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

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

QUANTITY LIMIT: Pharmacist note to CSR: Authorization should be entered by HICL and only checking the Formulary box (no QLs need to be entered within the authorization).

- 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:
Amitiza, 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, 2020

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
POLICY:
Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of formulary. The formulary is applied according to the formulary review process (see Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Part D Policy 143.0 D Geisinger Health Plan (GHP) and Geisinger Indemnity Insurance Company (GIIC) Formulary Development by the Pharmacy). The results of this process determine the development and application 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 all lines of business, unless a specific limitation or exception exists.

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

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

QUANTITY LIMIT: Pharmacist note to CSR: *Authorization should be entered by HICL and only checking the Formulary box (no QLs need to be entered within the authorization).*
- 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, 2020
POLICY AND PROCEDURE
PHARMACY
MANUAL

POLICY NUMBER: 438.0
SECTION: Commercial Drug
SUBJECT: Zurampic

Applicable line of business:

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<th>GHP Kids</th>
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POLICY:
Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of formulary. The formulary is applied according to the formulary review process (see Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Part D Policy 143.0 D Geisinger Health Plan (GHP) and Geisinger Indemnity Insurance Company (GIIC) Formulary Development by the Pharmacy). The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for Zurampic for GHP members who have prescription drug benefits, including all lines of business, unless a specific limitation or exception exists.

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

ADDITIONAL DEFINITIONS:
1. Formulary – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. Non-formulary products – those medications that are not included in the Formulary.
3. Healthcare provider – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
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 Zurampic 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) OR febuxostat and did not achieve target serum uric acid levels AND
- Medical record documentation that Zurampic will be co-administered with a xanthine oxidase inhibitor (allopurinol or febuxostat) AND
- Medical record documentation of an estimated creatinine clearance greater than or equal to 45 mL/min AND
- Medical record documentation that Zurampic 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

QUANTITY LIMIT: Pharmacist note to CSR: Authorization should be entered by HICL and only checking the Formulary box (no QLs need to be entered within the authorization).

- one (1) tablet per day

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

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, Uloric*

*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
REVIEWS NO LESS THAN ANNUALLY.

Signed:_______________________________________________

Title:  Director, Pharmacy Services

Date:  March 1, 2020

Devised:  1/25/17
Reviewed:  3/1/17 – annual review
Revised:  3/1/18 – annual review, updated signature
Revised:  3/1/19 – annual review, added QL approval note
POLICY: 
Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of formulary. The formulary is applied according to the formulary review process (see Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Part D Policy 143.0 D Geisinger Health Plan (GHP) and Geisinger Indemnity Insurance Company (GIIC) Formulary Development by the Pharmacy). The results of this process determine the development and application 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 all lines of business, unless a specific limitation or exception exists.

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

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

THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE STANDARDS 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: 439.0

POLICY AND PROCEDURE
PHARMACY
MANUAL

SECTION: Commercial Drug
SUBJECT: Emverm

Signed:_______________________________________________

Title: Director, Pharmacy Services

Date: March 1, 2020

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
Applicable line of business:

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POLICY:

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of formulary. The formulary is applied according to the formulary review process (see Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Part D Policy 143.0 D Geisinger Health Plan (GHP) and Geisinger Indemnity Insurance Company (GIIC) Formulary Development by the Pharmacy). The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for Yosprala for GHP members who have prescription drug benefits, including all lines of business, unless a specific limitation or exception exists.

REQUIRED DEFINITIONS:

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

ADDITIONAL DEFINITIONS:

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

- Medical record documentation of aspirin, component of Yosprala, 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

QUANTITY LIMIT: Pharmacist note to CSR: Authorization should be entered by HICL and only checking the Formulary box (no QLs need to be entered within the authorization).

- one (1) tablet per day

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

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, 2020

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
POLICY:
Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of formulary. The formulary is applied according to the formulary review process (see Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Part D Policy 143.0 D Geisinger Health Plan (GHP) and Geisinger Indemnity Insurance Company (GIIC) Formulary Development by the Pharmacy). The results of this process determine the development and application 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 all lines of business, unless a specific limitation or exception exists.

REQUIRED DEFINITIONS:
1. **Attachment** – a supporting document that is developed and maintained by the policy writer or 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).
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 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

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.

Signed: ____________________________________________

Title: Director, Pharmacy Services

Date: March 1, 2020
Applicable line of business:

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<th>Line of Business</th>
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POLICY:
Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of formulary. The formulary is applied according to the formulary review process (see Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Part D Policy 143.0 D Geisinger Health Plan (GHP) and Geisinger Indemnity Insurance Company (GIIC) Formulary Development by the Pharmacy). The results of this process determine the development and application 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 all lines of business, unless a specific limitation or exception exists.

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

ADDITIONAL DEFINITIONS:
1. **Formulary** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. **Non-formulary products** – those medications that are not included in the Formulary.
3. **Healthcare provider** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
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
QUANTITY LIMIT: Pharmacist note to CSR: Authorization should be entered by HICL and only checking the Formulary PA required box (no QLs need to be entered within the authorization).
  - 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)

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.

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

THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE STANDARDS 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: 442.0

SECTION: Commercial Drug

SUBJECT: Rubraca

Signed: ________________________________

Title: Director, Pharmacy Services

Date: July 29, 2020

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
POLICY:
Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of formulary. The formulary is applied according to the formulary review process (see Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Part D Policy 143.0 D Geisinger Health Plan (GHP) and Geisinger Indemnity Insurance Company (GIIC) Formulary Development by the Pharmacy). The results of this process determine the development and application 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 all lines of business, unless a specific limitation or exception exists.

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

ADDITIONAL DEFINITIONS:
1. **Formulary** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. **Non-formulary products** – those medications that are not included in the Formulary.
3. **Healthcare provider** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
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 Nuedexta may be made for members who meet the following criteria:

- Medical record documentation of a diagnosis of pseudobulbar affect (PBA)

**QUANTITY LIMIT:** Pharmacist note to CSR: *Authorization should be entered by HICL and only checking the Formulary box (no QLs need to be entered within the authorization).*

- 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.**
Signed: ________________________________

Title: Director, Pharmacy Services

Date: March 1, 2020

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
Applicable line of business:

<table>
<thead>
<tr>
<th>Commercial</th>
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</thead>
<tbody>
<tr>
<td>X</td>
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</tr>
<tr>
<td>Medicare</td>
<td>ACA</td>
</tr>
<tr>
<td>GHP Kids</td>
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POLICY:
Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of formulary. The formulary is applied according to the formulary review process (see Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Part D Policy 143.0 D Geisinger Health Plan (GHP) and Geisinger Indemnity Insurance Company (GIIC) Formulary Development by the Pharmacy). The results of this process determine the development and application 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 Respliclick GHP members who have prescription drug benefits, including all lines of business, unless a specific limitation or exception exists.

REQUIRED DEFINITIONS:
1. Attachment – a supporting document that is developed and maintained by the policy writer or 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).
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;
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

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.

Signed: ________________________________
Title: Director, Pharmacy Services
Date: October 12, 2020

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 formulary)
POLICY NUMBER: 445.0

SECTION: Commercial Drug

SUBJECT: Diabetic Testing Supplies

Applicable line of business:

<table>
<thead>
<tr>
<th>Line of Business</th>
<th>Medicaid</th>
<th>Medicare</th>
<th>ACA</th>
<th>GHP Kids</th>
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<td>GHP Kids</td>
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POLICY:
Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of formulary. The formulary is applied according to the formulary review process (see Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Part D Policy 143.0 D Geisinger Health Plan (GHP) and Geisinger Indemnity Insurance Company (GIIC) Formulary Development by the Pharmacy). The results of this process determine the development and application 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 diabetic testing supplies for GHP members who have prescription drug benefits, including all lines of business, unless a specific limitation or exception exists.

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

ADDITIONAL DEFINITIONS:
1. **Formulary** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. **Non-formulary products** – those medications that are not included in the Formulary.
3. **Healthcare provider** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
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;
POLICY AND PROCEDURE
PHARMACY
MANUAL

POLICY NUMBER: 445.0
SECTION: Commercial Drug
SUBJECT: Diabetic Testing Supplies

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

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

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

THIS POLICY WILL BE REVISED AS NECESSARY AND REVIEWED NO LESS THAN ANNUALLY.
Signed: ____________________________

Title: Director, Pharmacy Services

Date: March 1, 2020

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
POLICY AND PROCEDURE
PHARMACY
MANUAL

POLICY NUMBER: 446.0
SECTION: Commercial Drug
SUBJECT: Emflaza

Applicable line of business:

<table>
<thead>
<tr>
<th></th>
<th>Commercial</th>
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<th>ACA</th>
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POLICY:

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of formulary. The formulary is applied according to the formulary review process (see Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Part D Policy 143.0 D Geisinger Health Plan (GHP) and Geisinger Indemnity Insurance Company (GIIC) Formulary Development by the Pharmacy). The results of this process determine the development and application 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 all lines of business, unless a specific limitation or exception exists.

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).
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 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

QUANTITY LIMIT: Pharmacist note to CSR: Authorization should be entered by HICL and only checking the Formulary box (no QLs need to be entered within the authorization).

- 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.

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, 2020

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
POLICY:
Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of formulary. The formulary is applied according to the formulary review process (see Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Part D Policy 143.0 D Geisinger Health Plan (GHP) and Geisinger Indemnity Insurance Company (GIIC) Formulary Development by the Pharmacy). The results of this process determine the development and application 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 all lines of business, unless a specific limitation or exception exists.

REQUIRED DEFINITIONS:
1. Attachment – a supporting document that is developed and maintained by the policy writer or 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).
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:
- 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 AND that member will be treated with ovarian ablation or suppression 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
- 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 ovarian ablation or suppression with a luteinizing hormone-releasing hormone (LHRH) agonist

**QUANTITY LIMIT:** Pharmacist note to CSR: *Authorization should be entered by HICL, including 44151 and 44246, and only checking the Formulary PA required box (no QLs need to be entered within the authorization).*

- 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

**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.

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.

**FORMULARY ALTERNATIVES:**

Ibrance*

*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, 2020

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
Applicable line of business:

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<th>ACA</th>
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POLICY:
Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of formulary. The formulary is applied according to the formulary review process (see Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Part D Policy 143.0 D Geisinger Health Plan (GHP) and Geisinger Indemnity Insurance Company (GIICC) Formulary Development by the Pharmacy). The results of this process determine the development and application 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 all lines of business, unless a specific limitation or exception exists.

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.
3. Healthcare provider – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
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 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

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: [Signature]
Title: Director, Pharmacy Services
Date: March 1, 2020

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
POLICY:  
Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of formulary. The formulary is applied according to the formulary review process (see Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Part D Policy 143.0 D Geisinger Health Plan (GHP) and Geisinger Indemnity Insurance Company (GIIC) Formulary Development by the Pharmacy). The results of this process determine the development and application 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 all lines of business, unless a specific limitation or exception exists.

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

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

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

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

THIS POLICY WILL BE REVISED AS NECESSARY AND REVIEWED NO LESS THAN ANNUALLY.
Signed: ________________________________
Title: Director, Pharmacy Services
Date: March 1, 2020

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
Applicable line of business:

<table>
<thead>
<tr>
<th>Line of Business</th>
<th>Commercial</th>
<th>Medicaid</th>
<th>Medicare</th>
<th>ACA</th>
<th>GHP Kids</th>
</tr>
</thead>
</table>

POLICY:
Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of formulary. The formulary is applied according to the formulary review process (see Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Part D Policy 143.0 D Geisinger Health Plan (GHP) and Geisinger Indemnity Insurance Company (GIIC) Formulary Development by the Pharmacy). The results of this process determine the development and application 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 all lines of business, unless a specific limitation or exception exists.

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

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

QUANTITY LIMIT: 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

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

THIS POLICY WILL BE REVISED AS NECESSARY AND REVIEWED NO LESS THAN ANNUALLY.
Signed:_______________________________________________

Title:  Director, Pharmacy Services

Date:  March 1, 2020

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
POLICY:  
Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of formulary. The formulary is applied according to the formulary review process (see Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Part D Policy 143.0 D Geisinger Health Plan (GHP) and Geisinger Indemnity Insurance Company (GIIC) Formulary Development by the Pharmacy). The results of this process determine the development and application 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 all lines of business, unless a specific limitation or exception exists.

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

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

QUANTITY LIMIT: Pharmacist note to CSR: Authorization should be entered by HICL and only checking the Formulary box (no QLs need to be entered within the authorization).

- 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:
Ozempic, Victoza, Rybelsus

THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE STANDARDS 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: 451.0

POLICY AND PROCEDURE
PHARMACY
MANUAL

SECTION: Commercial Drug
SUBJECT: Adlyxin

Signed:_______________________________________________

Title: Director, Pharmacy Services

Date: March 1, 2020

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: 01/28/20 – added failure of Rybelsus, updated FA
Revised: 3/1/20 – annual review, added GHP Kids
POLICY:
Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of formulary. The formulary is applied according to the formulary review process (see Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Part D Policy 143.0 D Geisinger Health Plan (GHP) and Geisinger Indemnity Insurance Company (GIIC) Formulary Development by the Pharmacy). The results of this process determine the development and application 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 all lines of business, unless a specific limitation or exception exists.

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

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

QUANTITY LIMIT:
Pharmacist note to CSR: Authorization should be entered by HICL and only checking the Step Therapy box (no QLs need to be entered within the authorization).

- 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, 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.

Signed: _______________________________________________

Title: Director, Pharmacy Services

Date: March 1, 2020

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
POLICY NUMBER: 453.0

SECTION: Commercial Drug

POLICY AND PROCEDURE
PHARMACY
MANUAL

SUBJECT: Alunbrig

POLICY:

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of formulary. The formulary is applied according to the formulary review process (see Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Part D Policy 143.0 D Geisinger Health Plan (GHP) and Geisinger Indemnity Insurance Company (GIIC) Formulary Development by the Pharmacy). The results of this process determine the development and application 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 all lines of business, unless a specific limitation or exception exists.

REQUIRED DEFINITIONS:

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

ADDITIONAL DEFINITIONS:

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

QUANTITY LIMIT: Pharmacist note to CSR: Authorization should be entered by HICL and only checking the Formulary PA required box (no QLs need to be entered within the authorization).
- 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

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.

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: October 12, 2020

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
POLICY:
Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of formulary. The formulary is applied according to the formulary review process (see Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Part D Policy 143.0 D Geisinger Health Plan (GHP) and Geisinger Indemnity Insurance Company (GIIC) Formulary Development by the Pharmacy). The results of this process determine the development and application 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 all lines of business, unless a specific limitation or exception exists.

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

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

**QUANTITY LIMIT:**
AML: 56 capsules per 21 days
ASM / SM-AHN / MCL: 224 capsules 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 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 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

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

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

Signed:_______________________________________________
Title: Director, Pharmacy Services
Date: March 1, 2020

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
POLICY AND PROCEDURE
PHARMACY
MANUAL

POLICY NUMBER: 455.0
SECTION: Commercial Drug
SUBJECT: Zejula

Applicable line of business:

<table>
<thead>
<tr>
<th>Line of Business</th>
<th>Commercial</th>
<th>Medicaid</th>
<th>Medicare</th>
<th>ACA</th>
<th>GHP Kids</th>
</tr>
</thead>
</table>

POLICY:
Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of formulary. The formulary is applied according to the formulary review process (see Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Part D Policy 143.0 D Geisinger Health Plan (GHP) and Geisinger Indemnity Insurance Company (GIIC) Formulary Development by the Pharmacy). The results of this process determine the development and application 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 all lines of business, unless a specific limitation or exception exists.

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

ADDITIONAL DEFINITIONS:
1. **Formulary** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. **Non-formulary products** – those medications that are not included in the Formulary.
3. **Healthcare provider** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
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 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 consistence 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/µL, 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/µL, the recommended dose is 300 mg (three 100-mg capsules) taken orally once daily.

**QUANTITY LIMIT:** Pharmacist note to CSR: *Authorization should be entered by HICL and only checking the Formulary PA required box (no QLs need to be entered within the authorization).*

- 3 tablets 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. 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 a formulary exception is approved Zejula will be paid for under the member’s prescription drug benefit.
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: July 29, 2020

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: 01/28/20 – 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
POLICY AND PROCEDURE
PHARMACY
MANUAL

POLICY NUMBER: 456.0
SECTION: Commercial Drug
SUBJECT: Eucrisa

Applicable line of business:

<table>
<thead>
<tr>
<th>Line of Business</th>
<th>Medicaid</th>
<th>ACA</th>
<th>GHP Kids</th>
</tr>
</thead>
<tbody>
<tr>
<td>Commercial</td>
<td>X</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Medicare</td>
<td></td>
<td>ACA</td>
<td>X</td>
</tr>
<tr>
<td>GHP Kids</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

POLICY:
Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of formulary. The formulary is applied according to the formulary review process (see Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Part D Policy 143.0 D Geisinger Health Plan (GHP) and Geisinger Indemnity Insurance Company (GIIC) Formulary Development by the Pharmacy). The results of this process determine the development and application 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 all lines of business, unless a specific limitation or exception exists.

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

ADDITIONAL DEFINITIONS:
1. **Formulary** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. **Non-formulary products** – those medications that are not included in the Formulary.
3. **Healthcare provider** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
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   B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
C. In accordance with current standards of medical practice;
D. Not primarily for the convenience of the Member, or the Member's Provider; and
E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to 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

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.

FORMULARY ALTERNATIVES:
tacrolimus ointment

**Low-potency topical corticosteroids:** alcometasone 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)
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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: October 12, 2020

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
POLICY AND PROCEDURE
PHARMACY
MANUAL

POLICY NUMBER: 457.0
SECTION: Commercial Drug
SUBJECT: Dupixent

Applicable line of business:

<table>
<thead>
<tr>
<th>Line of Business</th>
<th>Medicaid</th>
<th>Medicare</th>
<th>ACA</th>
<th>GHP Kids</th>
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<tbody>
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<td></td>
<td></td>
<td></td>
</tr>
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<td>ACA</td>
<td>X</td>
<td></td>
</tr>
<tr>
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<td></td>
<td></td>
<td></td>
</tr>
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   B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
C. In accordance with current standards of medical practice;
D. Not primarily for the convenience of the Member, or the Member's Provider; and
E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to 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 one of the following:
  - If request is for Dupixent pre-filled pen: documentation of age greater than or equal to 12 years **OR**
  - If request for Dupixent pre-filled syringe: 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 contraindication to, intolerance to, or therapeutic failure* on an adequate trial of at least one medium potency** 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 between 2 and 15 years of age **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 Eucrisa* **AND**
- Medical record documentation of contraindication to, intolerance to, or therapeutic failure on an adequate trial of phototherapy (UVA/UVB treatment)

*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 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 Parameters:**

<table>
<thead>
<tr>
<th>If requesting a dose of:</th>
<th>Initial – One-time, one-week authorization</th>
<th>Remainder/Subsequent</th>
</tr>
</thead>
<tbody>
<tr>
<td>300 mg every other week</td>
<td>Quantity limit: 8 mL per 42 days</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Max quantity supply: 8</td>
<td>Max quantity supply: 4</td>
</tr>
<tr>
<td></td>
<td>Min day supply: 42</td>
<td>Min day supply: 28</td>
</tr>
<tr>
<td></td>
<td>Max day supply: 42</td>
<td>Max day supply: 28</td>
</tr>
</tbody>
</table>

**Topical Corticosteroid Potency Chart:**

<table>
<thead>
<tr>
<th>Potency Group</th>
<th>Corticosteroid</th>
<th>Vehicle/Form</th>
<th>Strength</th>
</tr>
</thead>
<tbody>
<tr>
<td>Super-high Potency</td>
<td>Betamethasone dipropionate, augmented</td>
<td>Ointment, Lotion, Gel</td>
<td>0.05%</td>
</tr>
<tr>
<td></td>
<td>Clobetasol propionate</td>
<td>Ointment, Cream, Gel, Lotion Foam, Shampoo, Solution, Spray</td>
<td>0.05%</td>
</tr>
<tr>
<td></td>
<td>Fluocinonide</td>
<td>Cream</td>
<td>0.1%</td>
</tr>
<tr>
<td></td>
<td>Halobetasol propionate</td>
<td>Ointment, Cream, Lotion</td>
<td>0.05%</td>
</tr>
<tr>
<td>High Potency</td>
<td>Aminiconide</td>
<td>Ointment</td>
<td>0.1%</td>
</tr>
<tr>
<td></td>
<td>Betamethasone dipropionate</td>
<td>Ointment, Cream</td>
<td>0.05%</td>
</tr>
<tr>
<td></td>
<td>Desoximetasone</td>
<td>Cream</td>
<td>0.05%</td>
</tr>
<tr>
<td></td>
<td>Diflornasone diacetate</td>
<td>Cream</td>
<td>0.05%</td>
</tr>
<tr>
<td></td>
<td>Fluocinonide</td>
<td>Cream</td>
<td>0.05%</td>
</tr>
<tr>
<td></td>
<td>Fluticasone propionate</td>
<td>Ointment</td>
<td>0.005%</td>
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<tr>
<td></td>
<td>Mometasone furoate</td>
<td>Ointment</td>
<td>0.1%</td>
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<tr>
<td></td>
<td>Triamcinolone acetonide</td>
<td>Ointment, Cream</td>
<td>0.5%</td>
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<tr>
<td>Medium Potency</td>
<td>Betamethasone dipropionate</td>
<td>Spray</td>
<td>0.05%</td>
</tr>
<tr>
<td></td>
<td>Clocortolone pivalate</td>
<td>Cream</td>
<td>0.1%</td>
</tr>
<tr>
<td></td>
<td>Fluocinolone acetonide</td>
<td>Ointment</td>
<td>0.025%</td>
</tr>
<tr>
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<td>Flurandrenolide</td>
<td>Ointment</td>
<td>0.05%</td>
</tr>
<tr>
<td></td>
<td>Hydrocortisone valerate</td>
<td>Ointment</td>
<td>0.2%</td>
</tr>
<tr>
<td></td>
<td>Mometasone furoate</td>
<td>Cream, Lotion, Solution</td>
<td>0.1%</td>
</tr>
<tr>
<td></td>
<td>Triamcinolone acetonide</td>
<td>Cream, Ointment</td>
<td>0.1%</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Aerosol Spray</td>
<td>0.2%</td>
</tr>
<tr>
<td>Lower-mid Potency</td>
<td>Betamethasone dipropionate</td>
<td>Lotion</td>
<td>0.05%</td>
</tr>
<tr>
<td></td>
<td>Betamethasone valerate</td>
<td>Cream</td>
<td>0.1%</td>
</tr>
<tr>
<td></td>
<td>Desonide</td>
<td>Ointment, Gel</td>
<td>0.05%</td>
</tr>
<tr>
<td></td>
<td>Fluocinolone acetonide</td>
<td>Cream</td>
<td>0.025%</td>
</tr>
<tr>
<td></td>
<td>Flurandrenolide</td>
<td>Cream, Lotion</td>
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<td></td>
<td>Fluticasone propionate</td>
<td>Cream, Lotion</td>
<td>0.05%</td>
</tr>
<tr>
<td></td>
<td>Hydrocortisone butyrate</td>
<td>Ointment, Cream, Lotion, Solution</td>
<td>0.1%</td>
</tr>
<tr>
<td></td>
<td>Hydrocortisone probutate</td>
<td>Cream</td>
<td>0.1%</td>
</tr>
<tr>
<td></td>
<td>Hydrocortisone valerate</td>
<td>Cream</td>
<td>0.2%</td>
</tr>
<tr>
<td></td>
<td>Prednicarbate</td>
<td>Cream, Ointment</td>
<td>0.1%</td>
</tr>
<tr>
<td></td>
<td>Triamcinolone acetonide</td>
<td>Lotion</td>
<td>0.1%</td>
</tr>
<tr>
<td>Low Potency</td>
<td>Alclometasone dipropionate</td>
<td>Ointment, Cream</td>
<td>0.05%</td>
</tr>
</tbody>
</table>
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:**
tacrolimus ointment, Elidel*, 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)
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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 12 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 Xolair, Fasenra, Nucala, or CinQair

**Measures of Disease Severity**

<table>
<thead>
<tr>
<th>Measure</th>
<th>Not Well Controlled</th>
<th>Very Poorly Controlled</th>
</tr>
</thead>
<tbody>
<tr>
<td>Symptoms</td>
<td>&gt; 2 days per week</td>
<td>Throughout the day</td>
</tr>
<tr>
<td>Nighttime awakenings</td>
<td>1-3x/week</td>
<td>&gt; 4x/week</td>
</tr>
<tr>
<td>Interference with normal activity</td>
<td>Some limitation</td>
<td>Extremely limited</td>
</tr>
<tr>
<td>SABA use for symptom control (not to prevent exercise-induced bronchospasm)</td>
<td>&gt; 2 days/week</td>
<td>Several times per day</td>
</tr>
<tr>
<td>FEV1 (% predicted) or peak flow (% personal best)</td>
<td>60-80%</td>
<td>&lt; 60%</td>
</tr>
<tr>
<td>Asthma Control Test (ACT) Score</td>
<td>16-19</td>
<td>&lt; 15</td>
</tr>
</tbody>
</table>

**AUTHORIZATION PARAMETERS:**

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<tr>
<td></td>
<td>Max day supply: 42</td>
<td>Max day supply: 28</td>
</tr>
<tr>
<td>200 mg every other week</td>
<td>Quantity limit: 4.56 mL per 42 days</td>
<td>Quantity Limit: 2.28 mL per 28 days</td>
</tr>
<tr>
<td></td>
<td>Max quantity supply: 4.56</td>
<td>Max quantity supply: 2.28</td>
</tr>
<tr>
<td></td>
<td>Min day supply: 42</td>
<td>Min day supply: 28</td>
</tr>
<tr>
<td></td>
<td>Max day supply: 42</td>
<td>Max day supply: 28</td>
</tr>
</tbody>
</table>
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 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.

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 otolaryngologist **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

**AUTHORIZATION PARAMETERS:**

| If requesting a dose of: | Quantity limit: 4 mL per 28 days  
|                          | Max quantity supply: 4  
|                          | Min day supply: 28  
|                          | Max day supply: 28 |

**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 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.

**FORMULARY ALTERNATIVES:**
fluticasone propionate, triamcinolone acetonide, mometasone furoate

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: November 17, 2020

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
Applicable line of business:

<table>
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<tr>
<th>Line of Business</th>
<th>Commercial</th>
<th>Medicaid</th>
<th>Medicare</th>
<th>ACA</th>
<th>GHP Kids</th>
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POLICY:
Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of formulary. The formulary is applied according to the formulary review process (see Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Part D Policy 143.0 D Geisinger Health Plan (GHP) and Geisinger Indemnity Insurance Company (GIIC) Formulary Development by the Pharmacy). The results of this process determine the development and application 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 all lines of business, unless a specific limitation or exception exists.

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

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

**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

**QUANTITY LIMIT:** Pharmacist note to CSR: *Authorization should be entered by HICL and only checking the Formulary box (no QLs need to be entered within the authorization).*
- 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.

**FORMULARY ALTERNATIVES:**
- Chronic Idiopathic Constipation: Amitiza, 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: November 18, 2020

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
POLICY:
Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of formulary. The formulary is applied according to the formulary review process (see Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Part D Policy 143.0 D Geisinger Health Plan (GHP) and Geisinger Indemnity Insurance Company (GIIC) Formulary Development by the Pharmacy). The results of this process determine the development and application 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 all lines of business, unless a specific limitation or exception exists.

REQUIRED DEFINITIONS:
1. **Attachment** – a supporting document that is developed and maintained by the policy writer or 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).
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 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.

QUANTITY LIMIT: Pharmacist note to CSR:
Authorization should be entered by HICL and only checking the Formulary PA required box (no QLs need to be entered within the authorization).
- 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.

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, 2020

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
POLICY NUMBER: 460.0

SECTION: Commercial Drug

SUBJECT: Vosevi

Applicable line of business:

<table>
<thead>
<tr>
<th>Line of Business</th>
<th>X</th>
<th>Medicaid</th>
<th>Medicare</th>
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**POLICY:**

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is applied according to the formulary review process (see Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Part D Policy 143.0 D Geisinger Health Plan (GHP) and Geisinger Indemnity Insurance Company (GIIC) Formulary Development by the Pharmacy). The results of this process determine the development and application 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 all lines of business, unless a specific limitation or exception exists.

**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).
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 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**

- 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. St Luke’s, AtlantiCare, Northern Light Health).

QUANTITY LIMIT: 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

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

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

Signed:_______________________________________________
Title: Director, Pharmacy Services
Date: March 1, 2020

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
POLICY NUMBER: 461.0

POLICY AND PROCEDURE
PHARMACY
MANUAL

SECTION: Commercial Drug
SUBJECT: Mavyret

Applicable line of business:

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<tr>
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POLICY:
Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of formulary. The formulary is applied according to the formulary review process (see Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Part D Policy 143.0 D Geisinger Health Plan (GHP) and Geisinger Indemnity Insurance Company (GIIC) Formulary Development by the Pharmacy). The results of this process determine the development and application 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 all lines of business, unless a specific limitation or exception exists.

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).
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 Mavyret may be made for members who meet the following criteria:

- Medical record documentation of age greater than or equal to 12 years **OR** weight greater than 45 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, 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 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

OR

• 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. St Luke’s, AtlantiCare, Northern Light Health).
QUANTITY LIMIT: Pharmacist note to CSR: Authorization should be entered by HICL and only checking the Formulary PA required box (no QLs need to be entered within the authorization).
  - three (3) tablets 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 except for genotype 1-infected patients who are NS5A inhibitor-experienced without prior treatment with an NS3/4A PI and genotype 3-infected patients who are prior treatment experienced with regimens containing (peg) interferon, ribavirin, and/or sofosbuvir, but no prior treatment experience with an HCV NS3/4A PI or NS5A inhibitor. Treatment duration is 16 weeks in these 2 cases.

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 NUMBER: 461.0

POLICY AND PROCEDURE
PHARMACY
MANUAL

SECTION: Commercial Drug
SUBJECT: Mavyret

Signed:_______________________________________________

Title: Director, Pharmacy Services

Date: March 1, 2020

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
Applicable line of business:

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<th>Medicaid</th>
<th>Medicare</th>
<th>ACA</th>
<th>GHP Kids</th>
</tr>
</thead>
</table>

**POLICY:**

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of formulary. The formulary is applied according to the formulary review process (see Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Part D Policy 143.0 D Geisinger Health Plan (GHP) and Geisinger Indemnity Insurance Company (GIIC) Formulary Development by the Pharmacy). The results of this process determine the development and application 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 all lines of business, unless a specific limitation or exception exists.

**REQUIRED DEFINITIONS:**

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

**ADDITIONAL DEFINITIONS:**

1. **Formulary** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. **Non-formulary products** – those medications that are not included in the Formulary.
3. **Healthcare provider** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
5. **Medically Necessary or Medical Necessity** – covered services rendered by a provider that the Health Plan determines are:
   - Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
   - Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
C. In accordance with current standards of medical practice;
D. Not primarily for the convenience of the Member, or the Member’s Provider; and
E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to 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

QUANTITY LIMIT: PHARMacist note to CSR: Authorization should be entered by HICL and only checking the Formulary PA required box (no QLs need to be entered within the authorization).
- 1 tablet 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. 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 test is Abbott RealTime™ IDH2 assay.
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, 2020

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
POLICY AND PROCEDURE
PHARMACY
MANUAL

POLICY NUMBER: 463.0
SECTION: Commercial Drug
SUBJECT: Nerlynx

Applicable line of business:

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<td>X</td>
</tr>
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</table>

POLICY:
Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of formulary. The formulary is applied according to the formulary review process (see Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Part D Policy 143.0 D Geisinger Health Plan (GHP) and Geisinger Indemnity Insurance Company (GIIC) Formulary Development by the Pharmacy). The results of this process determine the development and application 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 all lines of business, unless a specific limitation or exception exists.

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

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

QUANTITY LIMIT:
- 6 tablets per day, up to a 30 day supply per fill

Pharmacist note to CSR: Authorization should be entered by HICL and only checking the Formulary PA required box (no QLs need to be entered within the authorization).
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:
  Tykerb*

*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 4, 2020
POLICY NUMBER: 463.0

SECTION: Commercial Drug

SUBJECT: Nerlynx

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
POLICY:
Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of formulary. The formulary is applied according to the formulary review process (see Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Part D Policy 143.0 D Geisinger Health Plan (GHP) and Geisinger Indemnity Insurance Company (GIIC) Formulary Development by the Pharmacy). The results of this process determine the development and application 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 all lines of business, unless a specific limitation or exception exists.

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

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

QUANTITY LIMIT: Pharmacist note to CSR: Authorization should be entered by HICL and only checking the Formulary box (no QLs need to be entered within the authorization).
  • 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

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, 2020

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
POLICY:
Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of formulary. The formulary is applied according to the formulary review process (see Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Part D Policy 143.0 D Geisinger Health Plan (GHP) and Geisinger Indemnity Insurance Company (GIIC) Formulary Development by the Pharmacy). The results of this process determine the development and application 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 all lines of business, unless a specific limitation or exception exists.

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

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

QUANTITY LIMIT: Pharmacist note to CSR: Authorization should be entered by HICL and only checking the Formulary box (no QLs need to be entered within the authorization).
- 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, 2020

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
POLICY NUMBER: 466.0

SECTION: Commercial Drug

SUBJECT: Tetrabenazine

Applicable line of business:

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POLICY:

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of formulary. The formulary is applied according to the formulary review process (see Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Part D Policy 143.0 D Geisinger Health Plan (GHP) and Geisinger Indemnity Insurance Company (GIIC) Formulary Development by the Pharmacy). The results of this process determine the development and application 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 all lines of business, unless a specific limitation or exception exists.

REQUIRED DEFINITIONS:

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

ADDITIONAL DEFINITIONS:

1. Formulary – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. Non-formulary products – those medications that are not included in the Formulary.
3. Healthcare provider – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
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 tetrabenazine may be made for members who meet the following criteria:

- Medical record documentation of a diagnosis of chorea associated with Huntington’s Disease

QUANTITY LIMIT: Pharmacist note to CSR: Authorization should be entered by HICL and only checking the Formulary PA required box (no QLs need to be entered within the authorization).

- 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

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

THIS POLICY WILL BE REVISED AS NECESSARY AND REVIEWED NO LESS THAN ANNUALLY.
Signed: ________________________________
Title: Director, Pharmacy Services
Date: March 1, 2020

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
Applicable line of business:

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POLICY:
Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of formulary. The formulary is applied according to the formulary review process (see Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Part D Policy 143.0 D Geisinger Health Plan (GHP) and Geisinger Indemnity Insurance Company (GIIC) Formulary Development by the Pharmacy). The results of this process determine the development and application 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 all lines of business, unless a specific limitation or exception exists.

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. **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)

QUANTITY LIMIT: Pharmacist note to CSR: Authorization should be entered by HICL and only checking the Formulary PA required box (no QLs need to be entered within the authorization).
- 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)

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, 2020
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<thead>
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POLICY NUMBER: 468.0

POLICY AND PROCEDURE
PHARMACY
MANUAL

SECTION: Commercial Drug
SUBJECT: Siliq

Applicable line of business:

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POLICY:
Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of formulary. The formulary is applied according to the formulary review process (see Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Part D Policy 143.0 D Geisinger Health Plan (GHP) and Geisinger Indemnity Insurance Company (GIIC) Formulary Development by the Pharmacy). The results of this process determine the development and application 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 all lines of business, unless a specific limitation or exception exists.

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

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

QUANTITY LIMIT: One-week authorization: 6 mL per 28 days; Remainder of 4 month authorization duration: 3 mL per 28 days

AUTHORIZATION DURATION: Approval will be given for an initial duration of four (4) months. For continuation of coverage, medical record documentation of clinical improvement or lack of progression in the signs and symptoms of plaque psoriasis on four (4) months of brodalumab therapy is required.
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 continued or sustained improvement in the signs and symptoms of plaque psoriasis while on brodalumab therapy.

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, 2020
Applicable line of business:

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<th>Line of Business</th>
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<td>Application</td>
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POLICY:
Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of formulary. The formulary is applied according to the formulary review process (see Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Part D Policy 143.0 D Geisinger Health Plan (GHP) and Geisinger Indemnity Insurance Company (GIIC) Formulary Development by the Pharmacy). The results of this process determine the development and application 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 all lines of business, unless a specific limitation or exception exists.

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

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

NOTE: Approved quantity limit exceptions should be entered by GPID and the approved maximum daily dosage should be indicated. Authorizations will require a forced restriction edit.

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 10 mg: 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

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

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

Signed:_______________________________________________
Title: Director, Pharmacy Services
Date: March 1, 2020

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
POLICY NUMBER: 470.0

POLICY AND PROCEDURE
PHARMACY
MANUAL

SECTION: Commercial Drug
SUBJECT: Xadago

Applicable line of business:

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<tr>
<td>Medicare</td>
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<tr>
<td>GHP Kids</td>
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POLICY:
Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of formulary. The formulary is applied according to the formulary review process (see Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Part D Policy 143.0 D Geisinger Health Plan (GHP) and Geisinger Indemnity Insurance Company (GIIC) Formulary Development by the Pharmacy). The results of this process determine the development and application 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 all lines of business, unless a specific limitation or exception exists.

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

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

QUANTITY LIMIT: Pharmacist note to CSR: Authorization should be entered by HICL and only checking the Formulary box (no QLs need to be entered within the authorization).

- 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.

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, 2020

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
Applicable line of business:

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**POLICY:**

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of formulary. The formulary is applied according to the formulary review process (see Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Part D Policy 143.0 D Geisinger Health Plan (GHP) and Geisinger Indemnity Insurance Company (GIIC) Formulary Development by the Pharmacy). The results of this process determine the development and application 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 all lines of business, unless a specific limitation or exception exists.

**REQUIRED DEFINITIONS:**

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

**ADDITIONAL DEFINITIONS:**

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

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, Firazyr*

*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, 2020

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
POLICY NUMBER: 472.0

POLICY AND PROCEDURE
PHARMACY
MANUAL

SECTION: Commercial Drug
SUBJECT: Kevzara

Applicable line of business:

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POLICY:
Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of formulary. The formulary is applied according to the formulary review process (see Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Part D Policy 143.0 D Geisinger Health Plan (GHP) and Geisinger Indemnity Insurance Company (GIIC) Formulary Development by the Pharmacy). The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for Kevzara for GHP members who have prescription drug benefits, including all lines of business, unless a specific limitation or exception exists.

REQUIRED DEFINITIONS:
1. Attachment – a supporting document that is developed and maintained by the policy writer or 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:
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3. Healthcare provider – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
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 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

QUANTITY LIMIT: Pharmacist note to CSR: Authorization should be entered by HICL and only checking the Formulary PA required box (no QLs need to be entered within the authorization).
- 2.28 mL per 28 days

AUTHORIZATION DURATION: Approval will be given for an initial duration of six (6) months. For continuation, medical record documentation of clinical improvement or lack of progression in signs and symptoms of rheumatoid arthritis on six (6) months of Kevzara is required.

After the initial six (6) month approval, subsequent approval will be for a duration of one (1) year. Reevaluation will be every one (1) year requiring medical record documentation
of continued or sustained improvement in signs and symptoms of rheumatoid arthritis while on Kevzara therapy.

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, 2020

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: 01/28/20 – updated RA FA and added failure of Rinvoq and Xeljanz
Revised: 3/1/20 – annual review, added GHP Kids
POLICY NUMBER: 473.0

POLICY AND PROCEDURE
PHARMACY
MANUAL

SECTION: Commercial Drug
SUBJECT: Verzenio

Applicable line of business:

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<td>GHP Kids</td>
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POLICY:
Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is applied according to the formulary review process (see Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Part D Policy 143.0 D Geisinger Health Plan (GHP) and Geisinger Indemnity Insurance Company (GIIC) Formulary Development by the Pharmacy). The results of this process determine the development and application 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 all lines of business, unless a specific limitation or exception exists.

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

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

**QUANTITY LIMIT:** Pharmacist note to CSR: *Authorization should be entered by HICL and only checking the Formulary PA required box (no QLs need to be entered within the authorization).*
- 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 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:**
*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.

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: [Signature]

Title: Director, Pharmacy Services

Date: March 1, 2020

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
Applicable line of business:

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POLICY:
Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of formulary. The formulary is applied according to the formulary review process (see Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Part D Policy 143.0 D Geisinger Health Plan (GHP) and Geisinger Indemnity Insurance Company (GIIC) Formulary Development by the Pharmacy). The results of this process determine the development and application 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 all lines of business, unless a specific limitation or exception exists.

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

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

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
REVIELED NO LESS THAN ANNUALLY.

Signed: _____________________________________________

Title: Director, Pharmacy Services

Date: March 1, 2020
POLICY NUMBER: 474.0

SECTION: Commercial Drug

SUBJECT: Basaglar

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
Applicable line of business:

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**POLICY:**

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of formulary. The formulary is applied according to the formulary review process (see Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Part D Policy 143.0 D Geisinger Health Plan (GHP) and Geisinger Indemnity Insurance Company (GIIC) Formulary Development by the Pharmacy). The results of this process determine the development and application 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 SC for GHP members who have prescription drug benefits, including all lines of business, unless a specific limitation or exception exists.

**REQUIRED DEFINITIONS:**

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

**ADDITIONAL DEFINITIONS:**

1. **Formulary** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. **Non-formulary products** – those medications that are not included in the Formulary.
3. **Healthcare provider** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
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 Benlysta 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 a diagnosis of active systemic lupus erythematosus AND
- Medical record documentation that Benlytsa SC is prescribed by a rheumatologist AND
- Medical record documentation of a positive ANA/anti-sDNA 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 active severe nephritis or central nervous system (CNS) involvement

QUANTITY LIMIT: Pharmacist note to CSR: Authorization should be entered by HICL and only checking the Formulary PA required box (no QLs need to be entered within the authorization).
- 4 mL per 28 days

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
- Decrease in the number of exacerbations since the start of Benlysta
- Decrease in the daily required dose of oral corticosteroids such as prednisone
If a formulary exception is approved Benlysta 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.

**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, 2020
POLICY NUMBER: 476.0

POLICY AND PROCEDURE
PHARMACY
MANUAL

SECTION: Commercial Drug
SUBJECT: Non-Preferred Acne Medications

Applicable line of business:

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POLICY:
Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of formulary. The formulary is applied according to the formulary review process (see Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Part D Policy 143.0 D Geisinger Health Plan (GHP) and Geisinger Indemnity Insurance Company (GIIIC) Formulary Development by the Pharmacy). The results of this process determine the development and application 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 all lines of business, unless a specific limitation or exception exists.

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

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

Title: Director, Pharmacy Services

Date: March 1, 2020

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
Applicable line of business:

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POLICY:
Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of formulary. The formulary is applied according to the formulary review process (see Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Part D Policy 143.0 D Geisinger Health Plan (GHP) and Geisinger Indemnity Insurance Company (GIIC) Formulary Development by the Pharmacy). The results of this process determine the development and application 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 all lines of business, unless a specific limitation or exception exists.

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

**QUANTITY LIMIT:** Pharmacist note to CSR: *Authorization should be entered by HICL and only checking the Formulary box (no QLs need to be entered within the authorization).*

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

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

Signed:_______________________________________________

Title:  Director, Pharmacy Services

Date:  March 1, 2020

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
POLICY: Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of formulary. The formulary is applied according to the formulary review process (see Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Part D Policy 143.0 D Geisinger Health Plan (GHP) and Geisinger Indemnity Insurance Company (GIIC) Formulary Development by the Pharmacy). The results of this process determine the development and application 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 all lines of business, unless a specific limitation or exception exists.

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

ADDITIONAL DEFINITIONS:
1. **Formulary** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. **Non-formulary products** – those medications that are not included in the Formulary.
3. **Healthcare provider** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician’s assistant, certified registered nurse practitioner).
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 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, enalaprilat, fosphenytoin, lumacaftor, mitotane, phenytoin, rifampin, St. John’s Wort

QUANTITY LIMIT: Pharmacist note to CSR: Authorization should be entered by HICL and only checking the Formulary PA required box (no QLs need to be entered within the authorization).
- 2 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.

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.

Signed:_______________________________________________
Title: Director, Pharmacy Services
Date: March 1, 2020
Devised: 1/17/18
Applicable line of business:

<table>
<thead>
<tr>
<th>Line of Business</th>
<th>X</th>
<th>Medicaid</th>
<th>X</th>
<th>ACA</th>
<th>X</th>
</tr>
</thead>
<tbody>
<tr>
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<tr>
<td>GHP Kids</td>
<td></td>
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</tr>
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POLICY:
Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of formulary. The formulary is applied according to the formulary review process (see Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Part D Policy 143.0 D Geisinger Health Plan (GHP) and Geisinger Indemnity Insurance Company (GIIC) Formulary Development by the Pharmacy). The results of this process determine the development and application 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 all lines of business, unless a specific limitation or exception exists.

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

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

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.

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, 2020

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
POLICY NUMBER: 482.0

SECTION: Commercial Drug

SUBJECT: Orfadin

Applicable line of business:

| Line of Business | X | \n|------------------|---|--- |
| Commercial       | X | Medicaid              |
| Medicare         |   | ACA                   |
| GHP Kids         |   | X                     |

POLICY:
Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of formulary. The formulary is applied according to the formulary review process (see Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Part D Policy 143.0 D Geisinger Health Plan (GHP) and Geisinger Indemnity Insurance Company (GIIC) Formulary Development by the Pharmacy). The results of this process determine the development and application 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 all lines of business, unless a specific limitation or exception exists.

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).
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 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

**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.

**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: John Miller
Title: Director, Pharmacy Services
Date: March 1, 2020

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
POLICY AND PROCEDURE
PHARMACY
MANUAL

Applicable line of business:

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REQUIRED DEFINITIONS:
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   B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
C. In accordance with current standards of medical practice;
D. Not primarily for the convenience of the Member, or the Member's Provider; and
E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to 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

QUANTITY LIMIT: Pharmacist note to CSR: Authorization should be entered by HICL and only checking the Formulary box (no QLs need to be entered within the authorization).

- 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.

FORMULARY ALTERNATIVES:
allopurinol, probenecid, Uloric*
*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, 2020

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
POLICY AND PROCEDURE
PHARMACY
MANUAL

POLICY NUMBER: 484.0

SECTION: Commercial Drug
SUBJECT: Tremfya

Applicable line of business:

<p>| | | |</p>
<table>
<thead>
<tr>
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<tbody>
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POLICY:
Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of formulary. The formulary is applied according to the formulary review process (see Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Part D Policy 143.0 D Geisinger Health Plan (GHP) and Geisinger Indemnity Insurance Company (GIIC) Formulary Development by the Pharmacy). The results of this process determine the development and application 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 all lines of business, unless a specific limitation or exception exists.

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).
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

QUANTITY LIMIT/AUTHORIZATION PARAMETERS:

<table>
<thead>
<tr>
<th>Initial – One-time, two-week authorization</th>
<th>Remainder/Subsequent</th>
</tr>
</thead>
<tbody>
<tr>
<td>Quantity limit: 1 mL per 28 days</td>
<td>QL: 1 mL per 56 days</td>
</tr>
<tr>
<td>Max quantity supply: 1</td>
<td>Max quantity supply: 1</td>
</tr>
<tr>
<td>Min day supply: 28</td>
<td>Min day supply: 56</td>
</tr>
<tr>
<td>Max day supply: 28</td>
<td>Max day supply: 56</td>
</tr>
</tbody>
</table>

AUTHORIZATION DURATION: Approval will be given for an initial duration of six (6) months. For continuation, medical record documentation of clinical improvement or lack of progression in signs and symptoms of plaque psoriasis on six (6) months of Tremfya is required.
After the initial six (6) month approval, subsequent approval will be for a duration of one (1) year. Reevaluation will be every one (1) year requiring medical record documentation of continued or sustained improvement in signs and symptoms of plaque psoriasis while on Tremfya therapy.
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 included 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*

QUANTITY LIMIT/AUTHORIZATION PARAMETERS:

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AUTHORIZATION DURATION: Approval will be given for an initial duration of six (6) months. For continuation, medical record documentation of clinical improvement or lack of progression in signs and symptoms of psoriatic arthritis on six (6) months of Tremfya is required.

After the initial six (6) month approval, subsequent approval will be for a duration of one (1) year. Reevaluation will be every one (1) year requiring medical record documentation of continued or sustained improvement in signs and symptoms of psoriatic arthritis while on Tremfya therapy.

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
POLICY NUMBER: 484.0

SECTION: Commercial Drug

SUBJECT: Tremfya

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

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

Signed: [Signature]

Title: Director, Pharmacy Services

Date: November 18, 2020

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 PsO
Applicable line of business:

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**POLICY:**

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of formulary. The formulary is applied according to the formulary review process (see Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Part D Policy 143.0 D Geisinger Health Plan (GHP) and Geisinger Indemnity Insurance Company (GIIC) Formulary Development by the Pharmacy). The results of this process determine the development and application 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 all lines of business, unless a specific limitation or exception exists.

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

**QUANTITY LIMIT:** Pharmacist note to CSR: *Authorization should be entered by HICL and only checking the Formulary PA required box (no QLs need to be entered within the authorization).*

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

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

Signed: _____________________________________________

Title:  Director, Pharmacy Services

Date:  March 1, 2020

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
POLICY: Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of formulary. The formulary is applied according to the formulary review process (see Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Part D Policy 143.0 D Geisinger Health Plan (GHP) and Geisinger Indemnity Insurance Company (GIIC) Formulary Development by the Pharmacy). The results of this process determine the development and application 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 all lines of business, unless a specific limitation or exception exists.

REQUIRED DEFINITIONS:
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B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
C. In accordance with current standards of medical practice;
D. Not primarily for the convenience of the Member, or the Member's Provider; and
E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to 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

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

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

Signed:______________________________

Title: Director, Pharmacy Services

Date: March 1, 2020

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
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 |

POLICY:
Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of formulary. The formulary is applied according to the formulary review process (see Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Part D Policy 143.0 D Geisinger Health Plan (GHP) and Geisinger Indemnity Insurance Company (GIIC) Formulary Development by the Pharmacy). The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for Cumulative MED POS Edit for GHP members who have prescription drug benefits, including all lines of business, unless a specific limitation or exception exists.

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

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

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 or 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**
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
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)

NOTE: Authorizations will be entered by GPID for each drug meeting the above criteria

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
Reference Table: Abuse-Deterrent Opioids and Routes of Abuse Each is Intended to Deter Drug Abuse

<table>
<thead>
<tr>
<th>Drug</th>
<th>Drug Deters Abuse Via These Routes</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>IV/injection</td>
</tr>
<tr>
<td>Arymo ER</td>
<td>X</td>
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<tr>
<td>Embeda</td>
<td>X</td>
</tr>
<tr>
<td>Hysingla ER</td>
<td>X</td>
</tr>
<tr>
<td>MorphaBond ER</td>
<td>X</td>
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<tr>
<td>OxyContin (oxycodone ER)</td>
<td>X</td>
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<tr>
<td>Troxyca ER</td>
<td>X</td>
</tr>
<tr>
<td>Xtampza ER</td>
<td>X</td>
</tr>
<tr>
<td>RoxyBond</td>
<td>X</td>
</tr>
</tbody>
</table>

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^, meclofenamate, meloxicam, nabumetone, naproxen, naproxen sodium, naproxen ec, oxaprazin, 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
THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE STANDARDS OF NCQA AND ANY OTHER APPLICABLE 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 9, 2020

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
POLICY NUMBER: 489.0

POLICY AND PROCEDURE
PHARMACY
MANUAL

SECTION: Commercial Drug
SUBJECT: Auryxia

Applicable line of business:

<table>
<thead>
<tr>
<th>Line of Business</th>
<th>Commercial</th>
<th>Medicaid</th>
<th>Medicare</th>
<th>ACA</th>
<th>GHP Kids</th>
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POLICY:
Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of formulary. The formulary is applied according to the formulary review process (see Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Part D Policy 143.0 D Geisinger Health Plan (GHP) and Geisinger Indemnity Insurance Company (GIIC) Formulary Development by the Pharmacy). The results of this process determine the development and application 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 all lines of business, unless a specific limitation or exception exists.

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).
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

**QUANTITY LIMIT:** Pharmacist note to CSR: *Authorization should be entered by HICL and only checking the Formulary PA required box (no QLs need to be entered within the authorization).*
- 12 tablets per day

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, 2020

Devised: 4/5/18
Revised: 3/1/19 – annual review, added QL approval note
Revised: 3/1/20 – annual review, added GHP Kids
Applicable line of business:

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**POLICY:**

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of formulary. The formulary is applied according to the formulary review process (see Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Part D Policy 143.0 D Geisinger Health Plan (GHP) and Geisinger Indemnity Insurance Company (GIIC) Formulary Development by the Pharmacy). The results of this process determine the development and application 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 all lines of business, unless a specific limitation or exception exists.

**REQUIRED DEFINITIONS:**

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1. **Formulary** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
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   - Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
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C. In accordance with current standards of medical practice;
D. Not primarily for the convenience of the Member, or the Member's Provider; and
E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to 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

**QUANTITY LIMIT:** Pharmacist note to CSR: Authorization should be entered by HICL and only checking the Formulary box (noQLs need to be entered within the authorization).

- 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, 2020

Devised: 4/5/18
Revised: 3/1/19 – annual review, added QL approval note
Revised: 3/1/20 – annual review, added GHP Kids
POLICY: Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of formulary. The formulary is applied according to the formulary review process (see Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Part D Policy 143.0 D Geisinger Health Plan (GHP) and Geisinger Indemnity Insurance Company (GIIC) Formulary Development by the Pharmacy). The results of this process determine the development and application 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 all lines of business, unless a specific limitation or exception exists.

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E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to 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

QUANTITY LIMIT: Pharmacist note to CSR: Authorization should be entered by HICL and only checking the Formulary box (no QLs need to be entered within the authorization).

- 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.

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, 2020

Devised: 4/6/18
Revised: 3/1/19 – annual review, added QL approval note
Revised: 3/1/20 – annual review, added GHP Kids
Applicable line of business:

<table>
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<tr>
<th>Line of Business</th>
<th>Commercial</th>
<th>Medicaid</th>
<th>Medicare</th>
<th>ACA</th>
<th>GHP Kids</th>
</tr>
</thead>
</table>

POLICY:
Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of formulary. The formulary is applied according to the formulary review process (see Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Part D Policy 143.0 D Geisinger Health Plan (GHP) and Geisinger Indemnity Insurance Company (GIIC) Formulary Development by the Pharmacy). The results of this process determine the development and application 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 all lines of business, unless a specific limitation or exception exists.

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

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

QUANTITY LIMIT: Pharmacist note to CSR: Authorization should be entered by HICL and only checking the Formulary box (no QLs need to be entered within the authorization).
- 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.

FORMULARY ALTERNATIVES:
Amitiza, 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, 2020

Devised:  4/6/18
Revised:  3/1/19 – annual review, added QL approval note
Revised:  3/1/20 – annual review, added GHP Kids
POLICY AND PROCEDURE
PHARMACY
MANUAL

POLICY NUMBER: 493.0
SECTION: Commercial Drug
SUBJECT: Benznidazole

Applicable line of business:

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<td>Medicaid</td>
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<td>Medicare</td>
<td>ACA</td>
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<tr>
<td>GHP Kids</td>
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</table>

POLICY:
Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of formulary. The formulary is applied according to the formulary review process (see Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Part D Policy 143.0 D Geisinger Health Plan (GHP) and Geisinger Indemnity Insurance Company (GIIC) Formulary Development by the Pharmacy). The results of this process determine the development and application 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 all lines of business, unless a specific limitation or exception exists.

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

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

**QUANTITY LIMIT:** Pharmacist note to CSR: **Authorization should be entered by HICL
and only checking the Formulary box (no QLs need to be entered within the
authorization).**

- 100 mg tablets: 4 tablets per day
- 12.5 mg tablets: 2 tablets per day

**AUTHORIZATION DURATION:** 60 days (enter as RX count of 2, max 30 days supply
per fill)

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, 2020

Devised: 4/6/18
Revised: 3/1/19 – annual review, added QL approval note
Revised: 3/1/20 – annual review, added GHP Kids
POLICY AND PROCEDURE
PHARMACY
MANUAL

POLICY NUMBER: 494.0
SECTION: Commercial Drug
SUBJECT: Baxdela Tablets

Applicable line of business:

| Line of Business | Commercial | X | Medicaid | X | Medicare | ACA | X | GHP Kids | X |

POLICY:
Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of formulary. The formulary is applied according to the formulary review process (see Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Part D Policy 143.0 D Geisinger Health Plan (GHP) and Geisinger Indemnity Insurance Company (GIIC) Formulary Development by the Pharmacy). The results of this process determine the development and application 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 all lines of business, unless a specific limitation or exception exists.

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

ADDITIONAL DEFINITIONS:
1. *Formulary* – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. *Non-formulary products* – those medications that are not included in the Formulary.
3. *Healthcare provider* – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
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
QUANTITY LIMIT: Pharmacist note to CSR: 
Authorization should be entered by HICL and only checking the Formulary PA required box (no QLs need to be entered within the authorization).

- 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: April 21, 2020
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
POLICY: Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of formulary. The formulary is applied according to the formulary review process (see Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Part D Policy 143.0 D Geisinger Health Plan (GHP) and Geisinger Indemnity Insurance Company (GIIC) Formulary Development by the Pharmacy). The results of this process determine the development and application 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 all lines of business, unless a specific limitation or exception exists.

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

QUANTITY LIMIT: Pharmacist note to CSR: Authorization should be entered by HICL and only checking the Formulary box (no QLs need to be entered within the authorization).

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

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

Signed:_______________________________________________

Title: Director, Pharmacy Services

Date: March 1, 2020

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
Applicable line of business:

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<th>Line of Business</th>
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POLICY:

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of formulary. The formulary is applied according to the formulary review process (see Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Part D Policy 143.0 D Geisinger Health Plan (GHP) and Geisinger Indemnity Insurance Company (GIIC) Formulary Development by the Pharmacy). The results of this process determine the development and application 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 all lines of business, unless a specific limitation or exception exists.

REQUIRED DEFINITIONS:

1. **Attachment** – a supporting document that is developed and maintained by the policy writer or 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).
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 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.

QUANTITY LIMIT: Pharmacist note to CSR: *Authorization should be entered by HICL and only checking the Formulary PA required box (no QLs need to be entered within the authorization).*

- 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.

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
REVIEWS NO LESS THAN ANNUALLY.

 Signed: John Miller

Title: Director, Pharmacy Services

Date: March 1, 2020

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
POLICY AND PROCEDURE
PHARMACY
MANUAL

POLICY NUMBER: 498.0
SECTION: Commercial Drug
SUBJECT: Erleada

Applicable line of business:

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<th>Line of Business</th>
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<td>X</td>
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POLICY:
Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of formulary. The formulary is applied according to the formulary review process (see Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Part D Policy 143.0 D Geisinger Health Plan (GHP) and Geisinger Indemnity Insurance Company (GIIC) Formulary Development by the Pharmacy). The results of this process determine the development and application 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 all lines of business, unless a specific limitation or exception exists.

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).
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;
POLICY NUMBER: 498.0

SECTION: Commercial Drug

SUBJECT: Erleada

C. In accordance with current standards of medical practice;

D. Not primarily for the convenience of the Member, or the Member’s Provider; and

E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to 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:
  o Medical record documentation of a diagnosis of prostate cancer with evidence of metastatic castration-sensitive disease OR
  o 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

QUANTITY LIMIT: Pharmacist note to CSR: Authorization should be entered by HICL and only checking the Formulary PA required box (no QLs need to be entered within the authorization).

• 4 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. Erleada will no longer be covered if there is medical record documentation of disease progression.

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, 2020

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
Applicable line of business:

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POLICY:

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of formulary. The formulary is applied according to the formulary review process (see Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Part D Policy 143.0 D Geisinger Health Plan (GHP) and Geisinger Indemnity Insurance Company (GIIC) Formulary Development by the Pharmacy). The results of this process determine the development and application 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 all lines of business, unless a specific limitation or exception exists.

REQUIRED DEFINITIONS:

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

ADDITIONAL DEFINITIONS:

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

- 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

QUANTITY LIMIT: Pharmacist note to CSR: Authorization should be entered by HICL and only checking the Formulary box (no QLs need to be entered within the authorization).

- 68.5 mg capsule: 1 capsule per day
- 137 mg capsule: 2 capsules per day

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

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

Signed: ________________________________

Title: Director, Pharmacy Services

Date: March 1, 2020

Devised: 5/29/18
Revised: 3/1/19 – annual review, added QL approval note
Revised: 3/1/20 – annual review, added GHP Kids
Applicable line of business:

<table>
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<tr>
<th>Line of Business</th>
<th>Commercial</th>
<th>Medicaid</th>
<th>Medicare</th>
<th>ACA</th>
<th>GHP Kids</th>
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POLICY:
Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of formulary. The formulary is applied according to the formulary review process (see Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Part D Policy 143.0 D Geisinger Health Plan (GHP) and Geisinger Indemnity Insurance Company (GIIC) Formulary Development by the Pharmacy). The results of this process determine the development and application 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 all lines of business, unless a specific limitation or exception exists.

REQUIRED DEFINITIONS:
1. **Attachment** – a supporting document that is developed and maintained by the policy writer or 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).
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 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 fainae or Dermatophagoides 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

QUANTITY LIMIT: Pharmacist note to CSR: Authorization should be entered by HICL and only checking the Formulary box (no QLs need to be entered within the authorization).

- 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, 2020

Devised: 5/29/18
Revised: 3/1/19 – annual review, added QL approval note
Revised: 3/1/20 – annual review, added GHP Kids
POLICY:
Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of formulary. The formulary is applied according to the formulary review process (see Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Part D Policy 143.0 D Geisinger Health Plan (GHP) and Geisinger Indemnity Insurance Company (GIIC) Formulary Development by the Pharmacy). The results of this process determine the development and application 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 all lines of business, unless a specific limitation or exception exists.

REQUIRED DEFINITIONS:
1. **Attachment** – a supporting document that is developed and maintained by the policy writer or 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).
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 Solosec may be made for members who meet the following criteria:

- 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

**QUANTITY LIMIT:** Pharmacist note to CSR: *Authorization should be entered by HICL and only checking the Formulary box (no QLs need to be entered within the authorization).*

- 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.

**FORMULARY ALTERNATIVES:**
- clindamycin 2% vaginal cream, Clindesse 2% extended release vaginal cream, Cleocin 100 mg vaginal suppository, metronidazole 0.75% vaginal gel, 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, 2020

Devised: 5/30/18
Revised: 3/1/19 – annual review, added QL approval note
Revised: 3/1/20 – annual review, added GHP Kids
POLICY:
Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of formulary. The formulary is applied according to the formulary review process (see Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Part D Policy 143.0 D Geisinger Health Plan (GHP) and Geisinger Indemnity Insurance Company (GIIC) Formulary Development by the Pharmacy). The results of this process determine the development and application 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 all lines of business, unless a specific limitation or exception exists.

REQUIRED DEFINITIONS:
1. **Attachment** – a supporting document that is developed and maintained by the policy writer or 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).
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 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

**QUANTITY LIMIT:** Pharmacist note to CSR: *Authorization should be entered by HICL and only checking the Formulary box (no QLs need to be entered within the authorization).*

- 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

**THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE STANDARDS 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: 502.0

POLICY AND PROCEDURE
PHARMACY
MANUAL

SECTION: Commercial Drug
SUBJECT: Steglatro

Signed: ____________________________________________

Title: Director, Pharmacy Services

Date: March 1, 2020

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
POLICY AND PROCEDURE
PHARMACY
MANUAL

POLICY NUMBER: 503.0
SECTION: Commercial Drug
SUBJECT: Steglujan

Applicable line of business:

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POLICY:
Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of formulary. The formulary is applied according to the formulary review process (see Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Part D Policy 143.0 D Geisinger Health Plan (GHP) and Geisinger Indemnity Insurance Company (GIIC) Formulary Development by the Pharmacy). The results of this process determine the development and application 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 all lines of business, unless a specific limitation or exception exists.

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

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

QUANTITY LIMIT: Pharmacist note to CSR: Authorization should be entered by HICL and only checking the Formulary box (no QLs need to be entered within the authorization).
- 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
THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND FEDERAL REGULATORY ENTITIES.

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

Signed: ________________________________

Title: Director, Pharmacy Services

Date: March 1, 2020

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
POLICY:
Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of formulary. The formulary is applied according to the formulary review process (see Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Part D Policy 143.0 D Geisinger Health Plan (GHP) and Geisinger Indemnity Insurance Company (GIIC) Formulary Development by the Pharmacy). The results of this process determine the development and application 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 all lines of business, unless a specific limitation or exception exists.

REQUIRED DEFINITIONS:
1. **Attachment** – a supporting document that is developed and maintained by the policy writer or 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).
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 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

QUANTITY LIMIT: Pharmacist note to CSR: Authorization should be entered by HICL
and only checking the Formulary box (no QLs need to be entered within the
authorization).
- 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
THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND FEDERAL REGULATORY ENTITIES.

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

Signed:_______________________________________________

Title: Director, Pharmacy Services

Date: March 1, 2020

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
POLICY NUMBER: 505.0

SECTION: Commercial Drug

SUBJECT: Prevymis

Applicable line of business:

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POLICY:
Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of formulary. The formulary is applied according to the formulary review process (see Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Part D Policy 143.0 D Geisinger Health Plan (GHP) and Geisinger Indemnity Insurance Company (GIIC) Formulary Development by the Pharmacy). The results of this process determine the development and application 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 all lines of business, unless a specific limitation or exception exists.

REQUIRED DEFINITIONS:
1. **Attachment** – a supporting document that is developed and maintained by the policy writer or 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.
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5. **Medically Necessary or Medical Necessity** – covered services rendered by a provider that the Health Plan determines are:
   - Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
   - Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
C. In accordance with current standards of medical practice;
D. Not primarily for the convenience of the Member, or the Member's Provider; and
E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to 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 Prevymis may be made for members who meet the following criteria:

- Medical record documentation that Prevymis 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 Prevymis is being used for cytomegalovirus (CMV) prophylaxis AND
- Medical record documentation that Prevymis is being initiated between Day 0 and Day 28 post-transplantation AND
- Medical record documentation that Prevymis is not being used in combination with pimozide, ergot alkaloids (ergotamine and dihydroergotamine), and/or pitavastatin and simvastatin (if co-administered with cyclosporine)

QUANTITY LIMIT: Pharmacist note to CSR: Authorization should be entered by HICL and only checking the Formulary PA required box (no QLs need to be entered within the authorization).

- 1 tablet per day

AUTHORIZATION DURATION: 100 days

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, 2020

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
POLICY NUMBER: 506.0

SECTION: Commercial Drug
SUBJECT: Vyzulta

Applicable line of business:

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POLICY:
Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of formulary. The formulary is applied according to the formulary review process (see Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Part D Policy 143.0 D Geisinger Health Plan (GHP) and Geisinger Indemnity Insurance Company (GIIC) Formulary Development by the Pharmacy). The results of this process determine the development and application 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 all lines of business, unless a specific limitation or exception exists.

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

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

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), Travatan Z, 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.**
Signed: ______________________________

Title: Director, Pharmacy Services

Date: March 1, 2020

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
POLICY:  
Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of formulary. The formulary is applied according to the formulary review process (see Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Part D Policy 143.0 D Geisinger Health Plan (GHP) and Geisinger Indemnity Insurance Company (GIIC) Formulary Development by the Pharmacy). The results of this process determine the development and application 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 all lines of business, unless a specific limitation or exception exists.

REQUIRED DEFINITIONS:
1. **Attachment** – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. **Exhibit** – a 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).
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 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
- 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
- Medical record documentation of therapeutic failure on, intolerance to, or contraindication to at least two (2) anti-epileptic drug (AED) regimens

**AUTHORIZATION DURATION (SEGA ONLY):** Each treatment period will be defined as 12 months. Re-review will occur every 12 months. Afinitor will no longer be covered if there is medical record documentation of disease progression.

**QUANTITY LIMIT (ALL INDICATIONS):** Pharmacist note to CSR: *Authorization should be entered by HICL and only checking the Formulary PA required box (no QLs need to be entered within the authorization).*
- 1 tablet per day, 28 day supply per fill
If a formulary exception is approved, 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:**

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, oxcarbazepine, phenobarbital, phenytoin, tiagabine, topiramate immediate release

- **Age 13 and older:** carbamazepine, divalproex, gabapentin, lamotrigine extended release, lamotrigine immediate release, levetiracetam extended release, oxcarbazepine, phenobarbital, phenytoin, tiagabine, topiramate immediate release

- **Age 14 and older:** carbamazepine, divalproex, felbamate, gabapentin, lamotrigine extended release, lamotrigine 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, 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, 2020

Devised: 5/30/18
Revised: 3/1/19 – annual review, added QL approval note
Revised: 3/1/20 – annual review, added GHP Kids
POLICY NUMBER: 508.0

POLICY AND PROCEDURE
PHARMACY
MANUAL

SECTION: Commercial Drug
SUBJECT: Auvi-Q 0.1 mg

Applicable line of business:

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POLICY:
Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of formulary. The formulary is applied according to the formulary review process (see Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Part D Policy 143.0 D Geisinger Health Plan (GHP) and Geisinger Indemnity Insurance Company (GIIC) Formulary Development by the Pharmacy). The results of this process determine the development and application 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 all lines of business, unless a specific limitation or exception exists.

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

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

QUANTITY LIMIT: Pharmacist note to CSR: Authorization should be entered by HICL and only checking the Formulary PA required box (no QLs need to be entered within the authorization).
- 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

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

THIS POLICY WILL BE REVISED AS NECESSARY AND REVIEWED NO LESS THAN ANNUALLY.
Signed: _________________________________________________  

Title: Director, Pharmacy Services  

Date: March 1, 2020  

Devised: 5/30/18  
Revised: 3/1/19 – annual review, added QL approval note  
Revised: 3/1/20 – annual review, added GHP Kids
Applicable line of business:

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**POLICY:**

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of formulary. The formulary is applied according to the formulary review process (see Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Part D Policy 143.0 D Geisinger Health Plan (GHP) and Geisinger Indemnity Insurance Company (GIIC) Formulary Development by the Pharmacy). The results of this process determine the development and application 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 all lines of business, unless a specific limitation or exception exists.

**REQUIRED DEFINITIONS:**

1. **Attachment** – a supporting document that is developed and maintained by the policy writer or 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).
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 Fiasp may be made for members who meet the following criteria:

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

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

THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE STANDARDS OF NCQA AND ANY OTHER APPLICABLE 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 4, 2020
POLICY NUMBER: 510.0

POLICY AND PROCEDURE
PHARMACY MANUAL

SECTION: Commercial Drug
SUBJECT: Admelog

Applicable line of business:

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POLICY:
Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of formulary. The formulary is applied according to the formulary review process (see Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Part D Policy 143.0 D Geisinger Health Plan (GHP) and Geisinger Indemnity Insurance Company (GIIC) Formulary Development by the Pharmacy). The results of this process determine the development and application 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 all lines of business, unless a specific limitation or exception exists.

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

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

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

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

Signed:__________________________
Title: Director, Pharmacy Services

Date: March 1, 2020
Applicable line of business:

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POLICY:
Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is applied according to the formulary review process (see Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Part D Policy 143.0 D Geisinger Health Plan (GHP) and Geisinger Indemnity Insurance Company (GIIC) Formulary Development by the Pharmacy). The results of this process determine the development and application 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 all lines of business, unless a specific limitation or exception exists.

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

ADDITIONAL DEFINITIONS:
1. Formulary – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. Non-formulary products – those medications that are not included in the Formulary.
3. Healthcare provider – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
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   A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;

C. In accordance with current standards of medical practice;

D. Not primarily for the convenience of the Member, or the Member's Provider; and

E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services 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., Ajovy, 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

QUANTITY LIMIT: Pharmacist note to CSR: Authorization should be entered by HICL and only checking the Formulary PA required box (no QLs need to be entered within the authorization).

- QL: 1 mL per 30 days

<table>
<thead>
<tr>
<th>Migraine without Aura:</th>
<th>Migraine with Aura:</th>
</tr>
</thead>
<tbody>
<tr>
<td>A) At least five (5) attacks fulfilling criteria B through D below:</td>
<td>A) At least two (2) attacks fulfilling criteria B through C below:</td>
</tr>
<tr>
<td>B) Headache lasting 4 to 72 hours (untreated or unsuccessfully treated)</td>
<td>B) One (1) or more of the following fully reversible aura symptoms:</td>
</tr>
<tr>
<td>C) Headache with at least two (2) of the following characteristics:</td>
<td>C) At least three (3) of the following:</td>
</tr>
<tr>
<td>o unilateral location</td>
<td>o at least one (1) aura symptom spreads over 5 or more minutes</td>
</tr>
<tr>
<td>o pulsating quality</td>
<td>o two (2) or more aura symptoms occur in succession</td>
</tr>
<tr>
<td>o moderate to severe pain intensity</td>
<td></td>
</tr>
</tbody>
</table>

ICHD-III Diagnostic Criteria 3

HPRX02
\geisinger.edu\dfs\0004\0142\142006\COMMERCIAL\Commercial 2020-2021\Policy 511.0 Aimovig.docx
Dev. 7/20/18
Revised:10/5/20
### POLICY AND PROCEDURE

**PHARMACY MANU**

**SECTION:** Commercial Drug

**SUBJECT:** Aimovig

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| **A)** Aggravation by or causing avoidance of routine physical activity (e.g. walking or climbing stairs) |
| **B)** Each individual aura symptom lasts 5 to 60 minutes¹ |
| **C)** At least one (1) aura symptom is unilateral² |
| **D)** At least one (1) aura symptom is positive³ |
| **E)** The aura is accompanied, or followed within 60 minutes, by a headache |

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- **D)** At least one of the following during the headache:
  - Nausea and/or vomiting
  - Photophobia and phonophobia

- **E)** Not better accounted for by another ICHD-3 diagnosis

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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

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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

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

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

---

Signed: [Signature]

Title: Director, Pharmacy Services

Date: October 5, 2020

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Devised: 7/20/18

HPRX02

\geisinger.edu\dfs\0004\0142\142006\COMMERCIAL\Commercial 2020-2021\Policy 511.0 Aimovig.docx

Dev. 7/20/18

Revised: 10/5/20
POLICY NUMBER: 511.0

POLICY AND PROCEDURE
PHARMACY
MANUAL

SECTION: Commercial Drug
SUBJECT: Aimovig

Revised: 12/28/18 – updated prescriber to include by/in consultation with headache specialist, updated QL
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
POLICY AND PROCEDURE
PHARMACY
MANUAL

POLICY NUMBER: 512.0
SECTION: Commercial Drug
SUBJECT: Lonhala Magnair

Applicable line of business:
<table>
<thead>
<tr>
<th>Business</th>
<th>Commercial</th>
<th>Medicaid</th>
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<td>GHP Kids</td>
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POLICY:
Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of formulary. The formulary is applied according to the formulary review process (see Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Part D Policy 143.0 D Geisinger Health Plan (GHP) and Geisinger Indemnity Insurance Company (GIIC) Formulary Development by the Pharmacy). The results of this process determine the development and application 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 all lines of business, unless a specific limitation or exception exists.

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

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

**QUANTITY LIMIT:** Pharmacist note to CSR: Authorization should be entered by HICL and only checking the Formulary box (no QLs need to be entered within the authorization).

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

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

Signed: _____________________________________________

Title: Director, Pharmacy Services

Date: March 1, 2020

Devised: 7/20/18
Revised: 3/1/19 – annual review, added QL approval note
Revised: 3/1/20 – annual review, added GHP Kids
POLICY:
Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of formulary. The formulary is applied according to the formulary review process (see Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Part D Policy 143.0 D Geisinger Health Plan (GHP) and Geisinger Indemnity Insurance Company (GIIC) Formulary Development by the Pharmacy). The results of this process determine the development and application 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 all lines of business, unless a specific limitation or exception exists.

REQUIRED DEFINITIONS:
1. **Attachment** – a supporting document that is developed and maintained by the policy writer or 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).
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 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

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 FEDERAL REGULATORY ENTITIES.

THIS POLICY WILL BE REVISED AS NECESSARY AND REVIEWED NO LESS THAN ANNUALLY.
Signed:_______________________________________________

Title:  Director, Pharmacy Services

Date:  March 1, 2020

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
### Applicable line of business:

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<tr>
<th>Line of Business</th>
<th>GHP</th>
<th>Medicaid</th>
<th>ACA</th>
<th>X</th>
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</tr>
<tr>
<td>GHP Kid</td>
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</tr>
</tbody>
</table>

### POLICY:

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of formulary. The formulary is applied according to the formulary review process (see Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Part D Policy 143.0 D Geisinger Health Plan (GHP) and Geisinger Indemnity Insurance Company (GIIC) Formulary Development by the Pharmacy). The results of this process determine the development and application 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 all lines of business, unless a specific limitation or exception exists.

### 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).
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

<table>
<thead>
<tr>
<th>Antihemophilic Agents</th>
<th>Routine Prophylaxis</th>
<th>On-Demand/ Perioperative</th>
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</thead>
<tbody>
<tr>
<td>Advate</td>
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<td>Jivi</td>
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<tr>
<td>Xyntha/Xyntha Solofuse</td>
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<td></td>
</tr>
</tbody>
</table>

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: [Signature]

Title: Director, Pharmacy Services

Date: May 29, 2020

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 NUMBER: 515.0

POLICY AND PROCEDURE
PHARMACY
MANUAL

SECTION: Commercial Drug
SUBJECT: Novoseven

Applicable line of business:

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<thead>
<tr>
<th>Line of Business</th>
<th>Commercial</th>
<th>Medicaid</th>
<th>Medicare</th>
<th>ACA</th>
<th>GHP Kids</th>
</tr>
</thead>
</table>

POLICY:
Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of formulary. The formulary is applied according to the formulary review process (see Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Part D Policy 143.0 D Geisinger Health Plan (GHP) and Geisinger Indemnity Insurance Company (GIIC) Formulary Development by the Pharmacy). The results of this process determine the development and application 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 all lines of business, unless a specific limitation or exception exists.

REQUIRED DEFINITIONS:
1. **Attachment** – a supporting document that is developed and maintained by the policy writer or 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.
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3. **Healthcare provider** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician’s assistant, certified registered nurse practitioner).
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 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

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.

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, 2020

Devised:  7/20/18
Reviewed:  3/1/19 – annual review
Revised:  3/1/20 – annual review, added GHP Kids
POLICY: Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of formulary. The formulary is applied according to the formulary review process (see Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Part D Policy 143.0 D Geisinger Health Plan (GHP) and Geisinger Indemnity Insurance Company (GIIC) Formulary Development by the Pharmacy). The results of this process determine the development and application 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 all lines of business, unless a specific limitation or exception exists.

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.
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3. **Healthcare provider** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
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 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

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

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

THIS POLICY WILL BE REVISED AS NECESSARY AND REVIEWED NO LESS THAN ANNUALLY.
Signed:_______________________________________________

Title: Director, Pharmacy Services

Date: March 1, 2020

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
POLICY AND PROCEDURE
PHARMACY
MANUAL

Applicable line of business:

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POLICY:
Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of formulary. The formulary is applied according to the formulary review process (see Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Part D Policy 143.0 D Geisinger Health Plan (GHP) and Geisinger Indemnity Insurance Company (GIIC) Formulary Development by the Pharmacy). The results of this process determine the development and application 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 all lines of business, unless a specific limitation or exception exists.

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

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

NOCTIVA QUANTITY LIMIT: Pharmacist note to CSR: Authorization should be entered by HICL and only checking the Formulary box (no QLs need to be entered within the authorization).
- 3.8 grams per 30 days

NOCDURNA QUANTITY LIMIT (enter by GPID): 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

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

THIS POLICY WILL BE REVISED AS NECESSARY AND REVIEWED NO LESS THAN ANNUALLY.
Signed: ____________________________________________

Title:  Director, Pharmacy Services

Date:  March 1, 2020

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
Applicable line of business:

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POLICY:
Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of formulary. The formulary is applied according to the formulary review process (see Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Part D Policy 143.0 D Geisinger Health Plan (GHP) and Geisinger Indemnity Insurance Company (GIIC) Formulary Development by the Pharmacy). The results of this process determine the development and application 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 all lines of business, unless a specific limitation or exception exists.

REQUIRED DEFINITIONS:
1. **Attachment** – a supporting document that is developed and maintained by the policy writer or 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).
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:

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<tr>
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QUANTITY LIMIT: Pharmacist note to CSR: Authorization should be entered by HICL and only checking the Formulary PA required box (no QLs need to be entered within the authorization).

- 2 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.
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, 2020

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
POLICY NUMBER: 519.0

POLICY AND PROCEDURE
PHARMACY
MANUAL

SECTION: Commercial Drug

SUBJECT: Yonsa

Applicable line of business:

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POLICY:
Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of formulary. The formulary is applied according to the formulary review process (see Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Part D Policy 143.0 D Geisinger Health Plan (GHP) and Geisinger Indemnity Insurance Company (GIIIC) Formulary Development by the Pharmacy). The results of this process determine the development and application 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 all lines of business, unless a specific limitation or exception exists.

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

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

QUANTITY LIMIT: Pharmacist note to CSR: Authorization should be entered by HICL and only checking the Formulary PA required box (no QLs need to be entered within the authorization).

- 4 tablets per day, 30 day supply per fill

AUTHORIZATION DURATION: Each treatment period will be defined as twelve (12) months. Re-review will occur every twelve (12) months. Yonsa will no longer be covered if there is medical record documentation of disease progression.

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, 2020

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
POLICY NUMBER: 520.0

SECTION: Commercial Drug
SUBJECT: Lucemyra

Applicable line of business:

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POLICY:
Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of formulary. The formulary is applied according to the formulary review process (see Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Part D Policy 143.0 D Geisinger Health Plan (GHP) and Geisinger Indemnity Insurance Company (GIIC) Formulary Development by the Pharmacy). The results of this process determine the development and application 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 all lines of business, unless a specific limitation or exception exists.

REQUIRED DEFINITIONS:

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

ADDITIONAL DEFINITIONS:

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

QUANTITY LIMIT: Pharmacist note to CSR: Authorization should be entered by HICL and only checking the Formulary PA required box (no QLs need to be entered within the authorization).
- 16 tablets per day, 7 day supply per fill

AUTHORIZATION DURATION: 14 days (approve with RX count = 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.

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, 2020

Devised: 10/1/18
Revised: 3/1/19 – annual review, added QL approval note
Revised: 3/1/20 – annual review, added GHP Kids
POLICY:
Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of formulary. The formulary is applied according to the formulary review process (see Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Part D Policy 143.0 D Geisinger Health Plan (GHP) and Geisinger Indemnity Insurance Company (GIIC) Formulary Development by the Pharmacy). The results of this process determine the development and application 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 all lines of business, unless a specific limitation or exception exists.

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

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

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

THIS POLICY WILL BE REVISED AS NECESSARY AND REVIEWED NO LESS THAN ANNUALLY.
Signed: __________________________
Title: Director, Pharmacy Services
Date: March 1, 2020

Devised: 10/1/18
Reviewed: 3/1/19 – annual review
Revised: 3/1/20 – annual review, added GHP Kids
Applicable line of business:

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POLICY:

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of formulary. The formulary is applied according to the formulary review process (see Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Part D Policy 143.0 D Geisinger Health Plan (GHP) and Geisinger Indemnity Insurance Company (GIIC) Formulary Development by the Pharmacy). The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for Zypitamag for GHP members who have prescription drug benefits, including all lines of business, unless a specific limitation or exception exists.

REQUIRED DEFINITIONS:

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

ADDITIONAL DEFINITIONS:

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

QUANTITY LIMIT: Pharmacist note to CSR: Authorization should be entered by HICL and only checking the Formulary PA required box (no QLs need to be entered within the authorization).

- 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

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

THIS POLICY WILL BE REVISED AS NECESSARY AND REVIEWED NO LESS THAN ANNUALLY.
Signed: ______________________________________________

Title:    Director, Pharmacy Services

Date:    March 1, 2020

Devised:  10/1/18
Revised:  3/1/19 – annual review, added QL approval note
Revised:  3/1/20 – annual review, added GHP Kids
POLICY:
Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of formulary. The formulary is applied according to the formulary review process (see Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Part D Policy 143.0 D Geisinger Health Plan (GHP) and Geisinger Indemnity Insurance Company (GIIC) Formulary Development by the Pharmacy). The results of this process determine the development and application 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 all lines of business, unless a specific limitation or exception exists.

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

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

QUANTITY LIMIT: Pharmacist note to CSR: Authorization should be entered by HICL and only checking the Formulary box (no QLs need to be entered within the authorization).
- 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:

*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.

Signed:_______________________________________________

Title: Director, Pharmacy Services

Date: March 1, 2020

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
POLICY:
Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of formulary. The formulary is applied according to the formulary review process (see Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Part D Policy 143.0 D Geisinger Health Plan (GHP) and Geisinger Indemnity Insurance Company (GIIC) Formulary Development by the Pharmacy). The results of this process determine the development and application 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 all lines of business, unless a specific limitation or exception exists.

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

ADDITIONAL DEFINITIONS:
1. **Formulary** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. **Non-formulary products** – those medications that are not included in the Formulary.
3. **Healthcare provider** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
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 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 **OR** a platelet count of less than 20,000/microL and an increased risk of bleeding **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)
  - Rituxan*
  - Splenectomy
  - Promacta*/Nplate*

**QUANTITY LIMIT:** Pharmacist note to CSR: *Authorization should be entered by HICL and only checking the Formulary PA required box (no QLs need to be entered within the authorization).*

- 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. 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*

*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, 2020

Devised: 10/1/18
Revised: 3/1/19 – annual review, added QL approval note
Revised: 3/1/20 – annual review, added GHP Kids
POLICY NUMBER: 525.0

SECTION: Commercial Drug

SUBJECT: Braftovi

Applicable line of business:

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POLICY:

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of formulary. The formulary is applied according to the formulary review process (see Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Part D Policy 143.0 D Geisinger Health Plan (GHP) and Geisinger Indemnity Insurance Company (GIIC) Formulary Development by the Pharmacy). The results of this process determine the development and application 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 all lines of business, unless a specific limitation or exception exists.

REQUIRED DEFINITIONS:

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

ADDITIONAL DEFINITIONS:

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

**QUANTITY LIMIT:**
- Melanoma – 75 mg: 6 tablets per day, 30 day supply per fill
  50 mg: 4 tablets per day, 30 day supply per fill
- Colorectal Cancer – 75 mg: 4 tablets 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. 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 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
POLICY AND PROCEDURE
PHARMACY
MANUAL

POLICY NUMBER: 525.0

SECTION: Commercial Drug
SUBJECT: Braftovi

Signed: ________________________________

Title: Director, Pharmacy Services

Date: June 4, 2020

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
Applicable line of business:

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POLICY:
Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of formulary. The formulary is applied according to the formulary review process (see Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Part D Policy 143.0 D Geisinger Health Plan (GHP) and Geisinger Indemnity Insurance Company (GIIC) Formulary Development by the Pharmacy). The results of this process determine the development and application 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 all lines of business, unless a specific limitation or exception exists.

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

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

QUANTITY LIMIT: Pharmacist note to CSR: Authorization should be entered by HICL and only checking the Formulary PA required box (no QLs need to be entered within the authorization).

• 6 tablets 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. 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 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*, Cotelic*
*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, 2020

Devised: 10/1/18
Revised: 3/1/19 – annual review, added QL approval note
Revised: 3/1/20 – annual review, added GHP Kids
POLICY:
Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is applied according to the formulary review process (see Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Part D Policy 143.0 D Geisinger Health Plan (GHP) and Geisinger Indemnity Insurance Company (GIIC) Formulary Development by the Pharmacy). The results of this process determine the development and application 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 all lines of business, unless a specific limitation or exception exists.

REQUIRED DEFINITIONS:
1. **Attachment** – a supporting document that is developed and maintained by the policy writer or 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.
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5. **Medically Necessary or Medical Necessity** – covered services rendered by a provider that the Health Plan determines are:
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   B. Provided for the diagnosis, or the direct care and treatment of the Member’s condition, illness, disease or injury;
C. In accordance with current standards of medical practice;  
D. Not primarily for the convenience of the Member, or the Member’s Provider; and  
E. The most appropriate source or level of service that can safely be provided to the  
Member. When applied to hospitalization, this further means that the Member  
requires acute care as an inpatient due to the nature of the services 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:  
  o Mayo classification class 1C, 1D, or 1E  
  o Total Kidney Volume greater than 750 mL  
  o PROPKD score greater than 6  
  o 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

QUANTITY LIMIT: Pharmacist note to CSR: Authorization should be entered by HICL  
and only checking the Formulary PA required box (no QLs need to be entered within the  
authorization).  
- 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, 2020

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 NUMBER: 528.0

SECTION: Commercial Drug

SUBJECT: Tibsovo

POLICY AND PROCEDURE
PHARMACY
MANUAL

Applicable line of business:

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POLICY:
Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of formulary. The formulary is applied according to the formulary review process (see Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Part D Policy 143.0 D Geisinger Health Plan (GHP) and Geisinger Indemnity Insurance Company (GIIC) Formulary Development by the Pharmacy). The results of this process determine the development and application 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 all lines of business, unless a specific limitation or exception exists.

REQUIRED DEFINITIONS:

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

ADDITIONAL DEFINITIONS:

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

**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 X ULN, or creatinine clearance < 45 mL/min. The FDA approved test for IDH1 is the Abbott RealTime IDH1 Assay.

QUANTITY LIMIT: Pharmacist note to CSR: Authorization should be entered by HICL and only checking the Formulary PA required box (no QLs need to be entered within the authorization).

- 2 tablets 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. 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 a formulary exception is approved, Tibsovo will be paid for under the member’s prescription drug benefit.

Reviewers 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, 2020

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
POLICY:  
Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is applied according to the formulary review process (see Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Part D Policy 143.0 D Geisinger Health Plan (GHP) and Geisinger Indemnity Insurance Company (GIIC) Formulary Development by the Pharmacy). The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for Lyrica CR for GHP members who have prescription drug benefits, including all lines of business, unless a specific limitation or exception exists.

REQUIRED DEFINITIONS:
1. **Attachment** – a supporting document that is developed and maintained by the policy writer or 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).
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 Lyrica CR 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** Lyrica

**Postherpetic Neuralgia**
- Medical record documentation of postherpetic neuralgia **AND**
- Medical record documentation of therapeutic failure on, intolerance to, or contraindication to gabapentin **AND** Lyrica

**QUANTITY LIMIT:** Pharmacist note to CSR: *Authorization should be entered by HICL and only checking the Formulary box (no QLs need to be entered within the authorization).*
- 82.5 and 165 mg tablets: 3 tablets per day
- 330 mg tablets: 2 tablets per day

If a formulary exception is approved, Lyrica CR will be paid for under the member’s prescription drug benefit.

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

**FORMULARY ALTERNATIVES:**
- Diabetic Peripheral Neuropathy: duloxetine, Lyrica
- Postherpetic Neuralgia: gabapentin, Lyrica
THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND FEDERAL REGULATORY ENTITIES.

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

Signed:_______________________________________________

Title: Director, Pharmacy Services

Date: March 1, 2020

Devised: 11/26/18
Revised: 3/1/19 – annual review, updated QL approval note
Revised: 3/1/20 – annual review, added GHP Kids
POLICY:
Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of formulary. The formulary is applied according to the formulary review process (see Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Part D Policy 143.0 D Geisinger Health Plan (GHP) and Geisinger Indemnity Insurance Company (GIIC) Formulary Development by the Pharmacy). The results of this process determine the development and application 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 all lines of business, unless a specific limitation or exception exists.

REQUIRED DEFINITIONS:
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   B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
C. In accordance with current standards of medical practice;
D. Not primarily for the convenience of the Member, or the Member's Provider; and
E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due 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

**QUANTITY LIMIT:** Pharmacist note to CSR: *Authorization should be entered by HICL and only checking the Formulary PA required box (no QLs need to be entered within the authorization).*
- 1 tablet per day, 30 day supply per fill

**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 rheumatoid arthritis on six (6) months of Olumiant 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 continued or sustained improvement in signs and symptoms of rheumatoid arthritis while on Olumiant.

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

Date: March 1, 2020

Devised: 11/26/18
Revised: 3/1/19 – annual review, added QL approval note
Revised: 01/28/20 – updated RA FA and added failure of Rinvoq and Xeljanz
Revised: 3/1/20 – annual review, added GHP Kids
Applicable line of business:

<table>
<thead>
<tr>
<th>Line of Business</th>
<th>Commercial</th>
<th>Medicaid</th>
<th>Medicare</th>
<th>ACA</th>
<th>GHP Kids</th>
</tr>
</thead>
</table>

POLICY:
Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of formulary. The formulary is applied according to the formulary review process (see Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Part D Policy 143.0 D Geisinger Health Plan (GHP) and Geisinger Indemnity Insurance Company (GIIC) Formulary Development by the Pharmacy). The results of this process determine the development and application 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 all lines of business, unless a specific limitation or exception exists.

REQUIRED DEFINITIONS:
1. **Attachment** – a supporting document that is developed and maintained by the policy writer or 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.
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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).
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 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

**QUANTITY LIMIT:** Pharmacist note to CSR: *Authorization should be entered by HICL and only checking the Formulary PA required box (no QLs need to be entered within the authorization).*

- 2 tablets 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. 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 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, 2020

Devised: 11/26/18
Revised: 3/1/19 – annual review, added QL approval note
Revised: 3/1/20 – annual review, added GHP Kids
POLICY: Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of formulary. The formulary is applied according to the formulary review process (see Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Part D Policy 143.0 D Geisinger Health Plan (GHP) and Geisinger Indemnity Insurance Company (GIIC) Formulary Development by the Pharmacy). The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for Ajovy for GHP members who have prescription drug benefits, including all lines of business, unless a specific limitation or exception exists.

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

ADDITIONAL DEFINITIONS:
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3. **Healthcare provider** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
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 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**
- One of the following:
  - 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

QUANTITY LIMIT: Pharmacist note to CSR: **Authorization should be entered by HICL and only checking the Formulary PA required box (no QLs need to be entered within the authorization).**

- 4.5 mL per 90 days

### ICHD-III Diagnostic Criteria

<table>
<thead>
<tr>
<th>Migraine without Aura:</th>
<th>Migraine with Aura:</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>A)</strong> At least five (5) attacks fulfilling criteria B through D below:</td>
<td><strong>A)</strong> At least two (2) attacks fulfilling criteria B through C below:</td>
</tr>
<tr>
<td><strong>B)</strong> Headache lasting 4 to 72 hours (untreated or unsuccessfully treated)</td>
<td><strong>B)</strong> One (1) or more of the following fully reversible aura symptoms:</td>
</tr>
<tr>
<td><strong>C)</strong> Headache with at least two (2) of the following characteristics:</td>
<td>• at least one (1) aura symptom spreads over 5 or more minutes</td>
</tr>
<tr>
<td>o unilateral location</td>
<td>o two (2) or more aura symptoms occur in succession</td>
</tr>
<tr>
<td>o pulsating quality</td>
<td>o moderate to severe pain intensity</td>
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<tr>
<td>o moderate to severe pain intensity</td>
<td>o Visual</td>
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<td></td>
<td>o Sensory</td>
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<td></td>
<td>o Speech and/or language</td>
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<td></td>
<td>o Motor</td>
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<tr>
<td></td>
<td>o Brainstem</td>
</tr>
<tr>
<td></td>
<td>o Retinal</td>
</tr>
</tbody>
</table>
POLICY AND PROCEDURE
PHARMACY
MANUAL

POLICY NUMBER: 532.0
SECTION: Commercial Drug
SUBJECT: Ajovy

O aggravation by or causing avoidance of routine physical activity (e.g. walking or climbing stairs)
O each individual aura symptom lasts 5 to 60 minutes
O at least one (1) aura symptom is unilateral
O at least one (1) aura symptom is positive
O the aura is accompanied, or followed within 60 minutes, by a headache

D) At least one of the following during the headache:
O nausea and/or vomiting
O photophobia and phonophobia

E) Not better accounted for by another ICHD-3 diagnosis

D) 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, 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.
Signed: __________________________________________________________________________________________

Title: Director, Pharmacy Services

Date: October 5, 2020

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
POLICY:  
Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of formulary. The formulary is applied according to the formulary review process (see Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Part D Policy 143.0 D Geisinger Health Plan (GHP) and Geisinger Indemnity Insurance Company (GIIC) Formulary Development by the Pharmacy). The results of this process determine the development and application 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 all lines of business, unless a specific limitation or exception exists.

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3. **Healthcare provider** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
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 a 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

QUANTITY LIMIT/AUTHORIZATION PARAMETERS:

<table>
<thead>
<tr>
<th>Initial – One-time, one-week authorization</th>
<th>Remainder/Subsequent</th>
</tr>
</thead>
<tbody>
<tr>
<td>Quantity limit: 2 mL per 30 days</td>
<td>QL: 1 mL per 30 days</td>
</tr>
<tr>
<td>Max quantity supply: 2</td>
<td>Pharmacist note to CSR: Authorization should be entered by HICL and only checking the Formulary PA required box (no QLs need to be entered within the authorization).</td>
</tr>
<tr>
<td>Min day supply: 30</td>
<td></td>
</tr>
<tr>
<td>Max day supply: 30</td>
<td></td>
</tr>
</tbody>
</table>

ICHD-III Diagnostic Criteria

<table>
<thead>
<tr>
<th>Migraine without Aura:</th>
<th>Migraine with Aura:</th>
</tr>
</thead>
<tbody>
<tr>
<td>A) At least five (5) attacks fulfilling criteria B through D below:</td>
<td>A) At least two (2) attacks fulfilling criteria B through C below:</td>
</tr>
<tr>
<td>B) Headache lasting 4 to 72 hours (untreated or unsuccessfully treated)</td>
<td>B) One (1) or more of the following fully reversible aura symptoms:</td>
</tr>
<tr>
<td>o Visual</td>
<td>o Visual</td>
</tr>
<tr>
<td>o Sensory</td>
<td>o Sensory</td>
</tr>
<tr>
<td>o Speech and/or language</td>
<td>o Speech and/or language</td>
</tr>
<tr>
<td>o Motor</td>
<td>o Motor</td>
</tr>
<tr>
<td>o Brainstem</td>
<td>o Brainstem</td>
</tr>
</tbody>
</table>
C) Headache with at least two (2) of the following characteristics:
   - unilateral location
   - pulsating quality
   - moderate to severe pain intensity
   - aggravation by or causing avoidance of routine physical activity (e.g. walking or climbing stairs)

D) At least one of the following during the headache:
   - nausea and/or vomiting
   - photophobia and phonophobia

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

C) At least three (3) of the following:
   - at least one (1) aura symptom spreads over 5 or more minutes
   - two (2) or more aura symptoms occur in succession
   - each individual aura symptom lasts 5 to 60 minutes
   - at least one (1) aura symptom is unilateral
   - at least one (1) aura symptom is positive
   - the aura is accompanied, or followed within 60 minutes, by a headache

D) Not better accounted for by another ICHD-3 diagnosis
**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

**QUANTITY LIMIT/AUTHORIZATION PARAMETERS:** Pharmacist note to CSR:

*Authorization should be entered by HICL and only checking the Formulary PA required box (no QLs need to be entered within the authorization).*

- Quantity limit: 3 mL per 30 days
- Max quantity supply: 3
- Min day supply: 30
- Max day supply: 30

<table>
<thead>
<tr>
<th>ICHD-III Diagnostic Criteria</th>
<th>Diagnosis of Cluster Headache</th>
<th>Diagnosis of Episodic Cluster Headache</th>
</tr>
</thead>
<tbody>
<tr>
<td>At least 5 attacks fulfilling the following criteria:</td>
<td>Diagnosis of Cluster Headache fulfilling occurring in bouts (cluster periods) the following criteria:</td>
<td>At least two cluster periods lasting from 7 days to 1 year (when untreated) and separated by pain-free remission periods of ≥ 3 months.</td>
</tr>
<tr>
<td>Severe or very severe unilateral orbital, supraorbital and/or temporal pain lasting 15-180 minutes (when untreated) During part (but less than half) of the active time-course attacks may be less severe and/or of shorter or longer duration.</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
One or both of the following:

- At least one of the following symptoms or signs, ipsilateral to the headache:
  - 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 During part (but less than half) of the active time-course attacks may be less frequent

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.

Signed: ________________________________
Title: Director, Pharmacy Services
Date: October 5, 2020
POLICY NUMBER: 533.0

SECTION: Commercial Drug
SUBJECT: Emgality

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
POLICY

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of formulary. The formulary is applied according to the formulary review process (see Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Part D Policy 143.0 D Geisinger Health Plan (GHP) and Geisinger Indemnity Insurance Company (GIIC) Formulary Development by the Pharmacy). The results of this process determine the development and application 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 all lines of business, unless a specific limitation or exception exists.

REQUIRED DEFINITIONS:

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

ADDITIONAL DEFINITIONS:

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

QUANTITY LIMIT: Pharmacist note to CSR: Authorization should be entered by HICL and only checking the Formulary PA required box (no QLs need to be entered within the authorization).

- 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: 56 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: [Signature]

Title: Director, Pharmacy Services

Date: March 1, 2020

Devised: 11/26/18
Reviewed: 3/1/19 – annual review
Revised: 3/1/20 – annual review, added GHP Kids
Applicable line of business:

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<tr>
<th>Line of Business</th>
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**POLICY:**

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is applied according to the formulary review process (see Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Part D Policy 143.0 D Geisinger Health Plan (GHP) and Geisinger Indemnity Insurance Company (GIIC) Formulary Development by the Pharmacy). The results of this process determine the development and application 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 all lines of business, unless a specific limitation or exception exists.

**REQUIRED DEFINITIONS:**

1. **Attachment** – a supporting document that is developed and maintained by the policy writer or 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).
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 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)


QUANTITY LIMIT: Pharmacist note to CSR: Authorization should be entered by HICL and only checking the Formulary PA required box (no QLs need to be entered within the authorization).

- 150 mg tablet: 30 tablets per 30 days
- 200 mg tablet: 60 tablets per 30 days

AUTHORIZATION DURATION: Initial approval will be for 6 months (or less, if there is medical record documentation of a previous incomplete course of therapy with Orilissa) for either the 150 mg or the 200 mg tablets. One subsequent approval for Orilissa 150 mg for a period of 18 months (or less, if there is medical record documentation of a previous incomplete course of therapy with Orilissa) may be approved if the criteria below to be met. No subsequent approvals for the 200 mg strength will be allowed.
REAUTHORIZATION:

- Medical record documentation that the correct FDA approved strength/dosing is being prescribed (150 mg once daily) AND
- 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, tolfenin

- Extended Cycle Contraceptives: Amethia, Amethia Lo, Amethyst, Ashlyna, Camrese, Camrese Lo, Daysee, Fayosim, Introvale, Jaimiess, Jolessa, LoSeasonique, Quasense, Quartette, Rivelasa, Seasonique, Simpessse, 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.
Signed: 

Title: Director, Pharmacy Services

Date: March 1, 2020

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
Policy Number: 536.0

Policy and Procedure Section: Commercial Drug Pharmacy

Subject: Doptelet

Applicable line of business:

<table>
<thead>
<tr>
<th>Line of Business</th>
<th>Commercial</th>
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Policy:

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is applied according to the formulary review process (see Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Part D Policy 143.0 D Geisinger Health Plan (GHP) and Geisinger Indemnity Insurance Company (GIIC) Formulary Development by the Pharmacy). The results of this process determine the development and application 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 all lines of business, unless a specific limitation or exception exists.

Required Definitions:

1. Attachment – a supporting document that is developed and maintained by the policy writer or 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).
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)

**QUANTITY LIMIT:** Pharmacist note to CSR: *Authorization should be entered by HICL and only checking the Formulary PA required box (no QLs need to be entered within the authorization).*
- 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 x 10^9/L OR a platelet count of less than 20 x 10^9/L and an increased risk of bleeding 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 treatment, including, but not limited to:
  - Corticosteroids
  - IVIG*
  - Rhogam (if RhD-positive and spleen intact)
  - Rituximab*
  - Splenectomy
  - Promacta*/Nplate*

QUANTITY LIMIT: Pharmacist note to CSR: Authorization should be entered by HICL and only checking the Formulary PA required box (no QLs need to be entered within the authorization).

- 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 50x 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 x 10^9/L OR
  - If the platelet count does exceed 400 x 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

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: March 1, 2020

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
Applicable line of business:

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<tr>
<th>Line of Business</th>
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POLICY:
Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is applied according to the formulary review process (see Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Part D Policy 143.0 D Geisinger Health Plan (GHP) and Geisinger Indemnity Insurance Company (GIIC) Formulary Development by the Pharmacy). The results of this process determine the development and application 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 all lines of business, unless a specific limitation or exception exists.

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

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

QUANTITY LIMIT: Pharmacist note to CSR: Authorization should be entered by HICL and only checking the Formulary PA required box (no QLs need to be entered within the authorization).

- 1 tablet 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. 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 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*, Tarceva*

*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, 2020

Devised: 11/28/18
Reviewed: 3/1/19 – annual review
Revised: 3/1/20 – annual review, added GHP Kids
POLICY:  
Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of formulary. The formulary is applied according to the formulary review process (see Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Part D Policy 143.0 Geisinger Health Plan (GHP) and Geisinger Indemnity Insurance Company (GIIC) Formulary Development by the Pharmacy). The results of this process determine the development and application 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 all lines of business, unless a specific limitation or exception exists.

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).
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 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

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.

FORMULARY ALTERNATIVES:
For patients > 2 years of age: clonazepam, felbamate, lamotrigine, topiramate, topiramate ER*, Banzel*, Onfi*

*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: October 12, 2020

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
POLICY NUMBER: 539.0

POLICY AND PROCEDURE
PHARMACY
MANUAL

SECTION: Commercial Drug
SUBJECT: Lorbrena

Applicable line of business:

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<th>ACA</th>
<th>GHP Kids</th>
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POLICY:
Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is applied according to the formulary review process (see Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Part D Policy 143.0 D Geisinger Health Plan (GHP) and Geisinger Indemnity Insurance Company (GIIC) Formulary Development by the Pharmacy). The results of this process determine the development and application 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 all lines of business, unless a specific limitation or exception exists.

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).
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 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) AND
- Medical record documentation of disease progression on one of the following:
  o Crizotinib (Xalkori) and at least one other anaplastic lymphoma kinase (ALK) inhibitor for metastatic disease; OR
  o Alectinib (Alecensa) as the first anaplastic lymphoma kinase (ALK) inhibitor therapy for metastatic disease; OR
  o Ceritinib (Zykadia) as the first anaplastic lymphoma kinase (ALK) inhibitor therapy for metastatic disease

QUANTITY LIMIT: Pharmacist note to CSR: Authorization should be entered by HICL and only checking the Formulary PA required box (no QLs need to be entered within the authorization).
- 25 mg tablet: 3 tablets per day, 30 day supply per fill
- 100 mg tablet: 1 tablet 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. 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 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, 2020

Devised: 2/5/19
Revised: 3/1/19 – annual review, defined ALK
Revised: 3/1/20 – annual review, added GHP Kids
POLICY:
Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of formulary. The formulary is applied according to the formulary review process (see Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Part D Policy 143.0 D Geisinger Health Plan (GHP) and Geisinger Indemnity Insurance Company (GIIC) Formulary Development by the Pharmacy). The results of this process determine the development and application 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 all lines of business, unless a specific limitation or exception exists.

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).
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 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

QUANTITY LIMIT: Pharmacist note to CSR: Authorization should be entered by HICL and only checking the Formulary PA required box (no QLs need to be entered within the authorization).

- 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.

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, 2020

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
POLICY:
Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is applied according to the formulary review process (see Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Part D Policy 143.0 D Geisinger Health Plan (GHP) and Geisinger Indemnity Insurance Company (GIIC) Formulary Development by the Pharmacy). The results of this process determine the development and application 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 all lines of business, unless a specific limitation or exception exists.

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).
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 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 x 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

QUANTITY LIMIT: Pharmacist note to CSR: Authorization should be entered by HICL and only checking the Formulary PA required box (no QLs need to be entered within the authorization).

- 7 tablets per fill

AUTHORIZATION DURATION: 30 days, RX count 1

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, 2020

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
Applicable line of business:

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POLICY:
Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is applied according to the formulary review process (see Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Part D Policy 143.0 D Geisinger Health Plan (GHP) and Geisinger Indemnity Insurance Company (GIIC) Formulary Development by the Pharmacy). The results of this process determine the development and application 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 all lines of business, unless a specific limitation or exception exists.

REQUIRED DEFINITIONS:
1. **Attachment** – a supporting document that is developed and maintained by the policy writer or 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).
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 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)

QUANTITY LIMIT: Pharmacist note to CSR: Authorization should be entered by HICL and only checking the Formulary PA required box (no QLs need to be entered within the authorization).
- 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

Date: March 1, 2020

Devised: 2/5/19
Reviewed: 3/1/19 – annual review
Revised: 3/1/20 – annual review, added GHP Kids
Applicable line of business:

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</table>

**POLICY:**

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is applied according to the formulary review process (see Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Part D Policy 143.0 D Geisinger Health Plan (GHP) and Geisinger Indemnity Insurance Company (GIIC) Formulary Development by the Pharmacy). The results of this process determine the development and application 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 all lines of business, unless a specific limitation or exception exists.

**REQUIRED DEFINITIONS:**

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

**ADDITIONAL DEFINITIONS:**

1. **Formulary** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. **Non-formulary products** – those medications that are not included in the Formulary.
3. **Healthcare provider** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
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 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
- Medical record documentation of therapeutic failure on, intolerance to, or contraindication to danazol
QUANTITY LIMIT: Pharmacist note to CSR: Authorization should be entered by HICL and only checking the Formulary PA required box (no QLs need to be entered within the authorization).

- 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.

Signed: ____________________________
Title: Director, Pharmacy Services
Date: March 1, 2020
POLICY NUMBER: 544.0

POLICY AND PROCEDURE
PHARMACY
MANUAL

SECTION: Commercial Drug
SUBJECT: Talzenna

Applicable line of business:

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POLICY:
Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is applied according to the formulary review process (see Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Part D Policy 143.0 Geisinger Health Plan (GHP) and Geisinger Indemnity Insurance Company (GIIC) Formulary Development by the Pharmacy). The results of this process determine the development and application 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 all lines of business, unless a specific limitation or exception exists.

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

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

QUANTITY LIMIT: Pharmacist note to CSR: Authorization should be entered by HICL and only checking the Formulary PA required box (no QLs need to be entered within the authorization).

- 0.25 mg capsule: 3 capsules per day, 30 day supply per fill
- 1 mg capsule: 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

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.
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:  March 1, 2020

Devised:  2/6/19
Reviewed:  3/1/19 – annual review
Revised:  3/1/20 – annual review, added GHP Kids
POLICY NUMBER:  545.0

POLICY AND PROCEDURE
PHARMACY
MANUAL

SECTION:  Commercial Drug
SUBJECT:  Qbrexza

Applicable line of business:

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POLICY:
Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is applied according to the formulary review process (see Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Part D Policy 143.0 D Geisinger Health Plan (GHP) and Geisinger Indemnity Insurance Company (GIIC) Formulary Development by the Pharmacy). The results of this process determine the development and application 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 all lines of business, unless a specific limitation or exception exists.

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

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

QUANTITY LIMIT: Pharmacist note to CSR: Authorization should be entered by HICL and only checking the Formulary PA required box (no QLs need to be entered within the authorization).
- 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

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

THIS POLICY WILL BE REVISED AS NECESSARY AND REVIEWED NO LESS THAN ANNUALLY.
Signed: ________________________________________________

Title: Director, Pharmacy Services

Date: March 1, 2020

Devised: 2/6/19
Reviewed: 3/1/19 – annual review
Revised: 3/1/20 – annual review, added GHP Kids
POLICY:

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is applied according to the formulary review process (see Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Part D Policy 143.0 D Geisinger Health Plan (GHP) and Geisinger Indemnity Insurance Company (GIIC) Formulary Development by the Pharmacy). The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for Nuvessa for GHP members who have prescription drug benefits, including all lines of business, unless a specific limitation or exception exists.

REQUIRED DEFINITIONS:

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

ADDITIONAL DEFINITIONS:

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

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

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

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

THIS POLICY WILL BE REVISED AS NECESSARY AND REVIEWED NO LESS THAN ANNUALLY.
Signed: ______________________________________________________________________________________

Title: Director, Pharmacy Services

Date: March 1, 2020

Devised: 2/6/19
Reviewed: 3/1/19 – annual review
Revised: 3/1/20 – annual review, added GHP Kids
POLICY:
Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is applied according to the formulary review process (see Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Part D Policy 143.0 D Geisinger Health Plan (GHP) and Geisinger Indemnity Insurance Company (GIIC) Formulary Development by the Pharmacy). The results of this process determine the development and application 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 or ArmonAir for GHP members who have prescription drug benefits, including all lines of business, unless a specific limitation or exception exists.

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

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

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

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

THIS POLICY WILL BE REVISED AS NECESSARY AND REVIEWED NO LESS THAN ANNUALLY.
Signed: ________________________________
Title: Director, Pharmacy Services
Date: March 1, 2020

Devised: 2/6/19
Reviewed: 3/1/19 – annual review
Revised: 3/1/20 – annual review, added GHP Kids
POLICY NUMBER: 548.0

POLICY AND PROCEDURE
PHARMACY
MANUAL

SECTION: Commercial Drug
SUBJECT: Daurismo

Applicable line of business:

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POLICY:
Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is applied according to the formulary review process (see Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Part D Policy 143.0 D Geisinger Health Plan (GHP) and Geisinger Indemnity Insurance Company (GIIC) Formulary Development by the Pharmacy). The results of this process determine the development and application 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 all lines of business, unless a specific limitation or exception exists.

REQUIRED DEFINITIONS:
1. **Attachment** – a supporting document that is developed and maintained by the policy writer or 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).
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

QUANTITY LIMIT: Pharmacist note to CSR: Authorization should be entered by HICL and only checking the Formulary PA required box (no QLs need to be entered within the authorization).
- 100 mg tablet: 1 tablet per day, 30 day supply per fill
- 25 mg tablet: 2 tablets per day, 30 day supply per fill

AUTHORIZATION DURATION: Initial approval will be for twelve (12) months or less if the reviewing provider feels it is medically appropriate. Subsequent approvals will be for an additional twelve (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 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, 2020

Devised: 3/21/19
Revised: 3/1/20 – annual review, added GHP Kids
POLICY AND PROCEDURE
PHARMACY
MANUAL

POLICY NUMBER: 549.0
SECTION: Commercial Drug
SUBJECT: Vitrakvi

Applicable line of business:

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POLICY:
Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is applied according to the formulary review process (see Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Part D Policy 143.0 D Geisinger Health Plan (GHP) and Geisinger Indemnity Insurance Company (GIIC) Formulary Development by the Pharmacy). The results of this process determine the development and application 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 all lines of business, unless a specific limitation or exception exists.

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

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

QUANTITY LIMIT: Pharmacist note to CSR: Authorization should be entered by HICL and only checking the Formulary PA required box (no QLs need to be entered within the authorization).
- 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

AUTHORIZATION DURATION: Initial approval will be for 12 months. Subsequent approvals will be for an additional 12 months 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 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, 2020

Devised: 3/21/19
Revised: 3/1/20 – annual review, added GHP Kids
POLICY AND PROCEDURE
PHARMACY
MANUAL

POLICY NUMBER: 550.0

SECTION: Commercial Drug
SUBJECT: Xospata

Applicable line of business:

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POLICY:

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is applied according to the formulary review process (see Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Part D Policy 143.0 D Geisinger Health Plan (GHP) and Geisinger Indemnity Insurance Company (GIIC) Formulary Development by the Pharmacy). The results of this process determine the development and application 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 all lines of business, unless a specific limitation or exception exists.

REQUIRED DEFINITIONS:

1. **Attachment** – a supporting document that is developed and maintained by the policy writer or 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).
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

**AUTHORIZATION DURATION:** Initial approval will be for twelve (12) months or less if
the reviewing provider feels it is medically appropriate. Subsequent approvals will be for
an additional twelve (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 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, 2020

Devised: 3/21/19
Revised: 3/1/20 – annual review, added GHP Kids
Applicable line of business:

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**POLICY:**
Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is applied according to the formulary review process (see Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Part D Policy 143.0 D Geisinger Health Plan (GHP) and Geisinger Indemnity Insurance Company (GIIC) Formulary Development by the Pharmacy). The results of this process determine the development and application 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 all lines of business, unless a specific limitation or exception exists.

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

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

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:
ataovaquone/proguanil, chloroquine, doxycycline, mefloquine

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

THIS POLICY WILL BE REVISED AS NECESSARY AND REVIEWED NO LESS THAN ANNUALLY.
Signed:_______________________________________________

Title: Director, Pharmacy Services

Date: March 1, 2020

Devised: 3/21/19
Revised: 3/1/20 – annual review, added GHP Kids
POLICY:
Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is applied according to the formulary review process (see Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Part D Policy 143.0 D Geisinger Health Plan (GHP) and Geisinger Indemnity Insurance Company (GIIC) Formulary Development by the Pharmacy). The results of this process determine the development and application 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 all lines of business, unless a specific limitation or exception exists.

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:
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E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services 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

**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

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

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

Title:  Director, Pharmacy Services

Date:  March 1, 2020

Devised:  3/21/19
Revised:  3/1/20 – annual review, added GHP Kids
Applicable line of business:

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REQUIRED DEFINITIONS:
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ADDITIONAL DEFINITIONS:
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C. In accordance with current standards of medical practice;
D. Not primarily for the convenience of the Member, or the Member's Provider; and
E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services 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:
  o Biopsy of tissue/organ to confirm amyloid presence OR
  o 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

QUANTITY LIMIT: Pharmacist note to CSR: Authorization should be entered by HICL and only checking the Formulary PA required box (no QLs need to be entered within the authorization).
- 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-unimpaired 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

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

THIS POLICY WILL BE REVISED AS NECESSARY AND REVIEWED NO LESS THAN ANNUALLY.
Signed: ____________________________________________

Title: Director, Pharmacy Services

Date: March 1, 2020

Devised: 3/28/19
Revised: 3/1/20 – annual review, added GHP Kids
Applicable line of business:

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C. In accordance with current standards of medical practice;
D. Not primarily for the convenience of the Member, or the Member’s Provider; and
E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services 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

QUANTITY LIMIT: Pharmacist note to CSR: Authorization should be entered by HICL and only checking the Formulary PA required box (no QLs need to be entered within the authorization).

- 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
- 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, 2020

Devised: 5/24/19
Revised: 3/1/20 – annual review, added GHP Kids
Applicable line of business:

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POLICY:
Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is applied according to the formulary review process (see Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Part D Policy 143.0 D Geisinger Health Plan (GHP) and Geisinger Indemnity Insurance Company (GIIC) Formulary Development by the Pharmacy). The results of this process determine the development and application 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 all lines of business, unless a specific limitation or exception exists.

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

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

QUANTITY LIMIT: Pharmacist note to CSR: Authorization should be entered by HICL and only checking the Formulary PA required box (no QLs need to be entered within the authorization).
- 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

THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE STANDARDS OF NCQA AND ANY OTHER APPLICABLE 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 24, 2019

Devised: 5/24/19
Revised: 3/1/20 – annual review, added GHP Kids
POLICY NUMBER: 556.0

SECTION: Commercial Drug

SUBJECT: Tiglutik

Applicable line of business:

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<tr>
<th>Line of Business</th>
<th>Commercial</th>
<th>Medicaid</th>
<th>Medicare</th>
<th>ACA</th>
<th>GHP Kids</th>
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POLICY:
Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is applied according to the formulary review process (see Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Part D Policy 143.0 D Geisinger Health Plan (GHP) and Geisinger Indemnity Insurance Company (GIIC) Formulary Development by the Pharmacy). The results of this process determine the development and application 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 all lines of business, unless a specific limitation or exception exists.

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

QUANTITY LIMIT: Pharmacist note to CSR: Authorization should be entered by HICL and only checking the Formulary PA required box (no QLs need to be entered within the authorization).

- 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.

FORMULARY ALTERNATIVES:
riluzole tablets
POLICY NUMBER: 556.0

SECTION: Commercial Drug

SUBJECT: Tiglutik

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

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

Signed: ______________________________________________

Title: Director, Pharmacy Services

Date: March 1, 2020

Devised: 5/24/19
Revised: 3/1/20 – annual review, added GHP Kids
POLICY NUMBER: 557.0

POLICY AND PROCEDURE
PHARMACY
MANUAL

SECTION: Commercial Drug
SUBJECT: Oxtellar XR

Applicable line of business:

POLICY:
Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is applied according to the formulary review process (see Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Part D Policy 143.0 D Geisinger Health Plan (GHP) and Geisinger Indemnity Insurance Company (GIIC) Formulary Development by the Pharmacy). The results of this process determine the development and application 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 all lines of business, unless a specific limitation or exception exists.

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).
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 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

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

THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE STANDARDS 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: Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is applied according to the formulary review process (see Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Part D Policy 143.0 D Geisinger Health Plan (GHP) and Geisinger Indemnity Insurance Company (GIIC) Formulary Development by the Pharmacy). The results of this process determine the development and application 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 all lines of business, unless a specific limitation or exception exists.

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

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

QUANTITY LIMIT: 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

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

THIS POLICY WILL BE REVISED AS NECESSARY AND REVIEWED NO LESS THAN ANNUALLY.
Signed: ____________________________________________

Title:  Director, Pharmacy Services

Date:  March 1, 2020

Devised:  5/24/19
Revised:  3/1/20 – annual review, added GHP Kids
POLICY:
Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is applied according to the formulary review process (see Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Part D Policy 143.0 D Geisinger Health Plan (GHP) and Geisinger Indemnity Insurance Company (GIIC) Formulary Development by the Pharmacy). The results of this process determine the development and application 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 all lines of business, unless a specific limitation or exception exists.

REQUIRED DEFINITIONS:
1. Attachment – a supporting document that is developed and maintained by the policy writer or 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).
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C. In accordance with current standards of medical practice;
D. Not primarily for the convenience of the Member, or the Member’s Provider; and
E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services 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

QUANTITY LIMIT: Pharmacist note to CSR: *Authorization should be entered by HICL and only checking the Formulary box (no QLs need to be entered within the authorization).*

- 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:
Aubagio 14 mg, Avonex, Betaseron, glatiramer acetate, Extavia, Gilenya, Plegridy, Rebif, Tecfidera

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

THIS POLICY WILL BE REVISED AS NECESSARY AND REVIEWED NO LESS THAN ANNUALLY.
Signed: John Miller

Title: Director, Pharmacy Services

Date: March 1, 2020

Devised: 5/24/19
Revised: 3/1/20 – annual review, added GHP Kids
Applicable line of business:

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**POLICY:**

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of formulary. The formulary is applied according to the formulary review process (see Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Part D Policy 143.0 D Geisinger Health Plan (GHP) and Geisinger Indemnity Insurance Company (GIIC) Formulary Development by the Pharmacy). The results of this process determine the development and application 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 all lines of business, unless a specific limitation or exception exists.

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

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.

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, 2020

Devised: 5/24/19
Revised: 3/1/20 – annual review, added GHP Kids
POLICY AND PROCEDURE
PHARMACY
MANUAL

POLICY NUMBER: 561.0
SECTION: Commercial Drug
SUBJECT: Daraprim

Applicable line of business:

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POLICY:
Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is applied according to the formulary review process (see Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Part D Policy 143.0 D Geisinger Health Plan (GHP) and Geisinger Indemnity Insurance Company (GIIC) Formulary Development by the Pharmacy). The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for Daraprim for GHP members who have prescription drug benefits, including all lines of business, unless a specific limitation or exception exists.

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

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

Treatment of Toxoplasmosis
- Medical record documentation that Daraprim is prescribed by or in consultation with
an infectious disease specialist AND
- Medical record documentation of diagnosis of toxoplasmosis AND
- Medical record documentation that Daraprim will be used in combination with
leucovorin and a sulfonamide OR therapeutic failure on, intolerance to, or
contra indication 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 Daraprim 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
contra indication to trimethoprim-sulfamethoxazole
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 Daraprim 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 Daraprim 200 mg loading dose followed by 50 mg daily (<60 kg) or 75 mg daily (≥60 kg). The recommended chronic maintenance dose of Daraprim 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 Daraprim 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 Daraprim 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, Daraprim will be paid for under the member’s prescription drug benefit.

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, 2020

Devised: 5/29/19
Revised: 3/1/20 – annual review, added GHP Kids
POLICY NUMBER: 562.0

SECTION: Commercial Drug

SUBJECT: Cablivi

Applicable line of business:

<table>
<thead>
<tr>
<th>Line of Business</th>
<th>Medicaid</th>
<th>Medicare</th>
<th>ACA</th>
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POLICY:
Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is applied according to the formulary review process (see Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Part D Policy 143.0 D Geisinger Health Plan (GHP) and Geisinger Indemnity Insurance Company (GIIC) Formulary Development by the Pharmacy). The results of this process determine the development and application 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 all lines of business, unless a specific limitation or exception exists.

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

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

QUANTITY LIMIT: 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
- 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, 2020

Devised: 7/23/19
Revised: 3/1/20 – annual review, added GHP Kids
POLICY NUMBER: 563.0

POLICY AND PROCEDURE
PHARMACY
MANUAL

SECTION: Commercial Drug
SUBJECT: Balversa

Applicable line of business:

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<tr>
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POLICY:
Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is applied according to the formulary review process (see Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Part D Policy 143.0 D Geisinger Health Plan (GHP) and Geisinger Indemnity Insurance Company (GIIC) Formulary Development by the Pharmacy). The results of this process determine the development and application 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 all lines of business, unless a specific limitation or exception exists.

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

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

QUANTITY LIMIT: Pharmacist note to CSR: Authorization should be entered by HICL and only checking the Formulary PA required box (no QLs need to be entered within the authorization).

- 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

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.
NOTE: The FDA-approved test is the *therascreen*® FGFR RGQ RT-PCR Kit.

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, 2020

Devised: 7/23/19

Revised: 3/1/20 – annual review, added GHP Kids
POLICY NUMBER: 564.0

POLICY AND PROCEDURE
PHARMACY
MANUAL

SECTION: Commercial Drug
SUBJECT: Symjepi

Applicable line of business:

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POLICY:
Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is applied according to the formulary review process (see Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Part D Policy 143.0 D Geisinger Health Plan (GHP) and Geisinger Indemnity Insurance Company (GIIC) Formulary Development by the Pharmacy). The results of this process determine the development and application 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 all lines of business, unless a specific limitation or exception exists.

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

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

QUANTITY LIMIT: Pharmacist note to CSR: Authorization should be entered by HICL and only checking the Formulary PA required box (no QLs need to be entered within the authorization).

• 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)

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

THIS POLICY WILL BE REVISED AS NECESSARY AND REVIEWED NO LESS THAN ANNUALLY.
Signed: ________________________________

Title: Director, Pharmacy Services

Date: March 1, 2020

Devised: 7/23/19
Revised: 3/1/20 – annual review, added GHP Kids
POLICY:  
Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is applied according to the formulary review process (see Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Part D Policy 143.0 D Geisinger Health Plan (GHP) and Geisinger Indemnity Insurance Company (GIIC) Formulary Development by the Pharmacy). The results of this process determine the development and application 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 all lines of business, unless a specific limitation or exception exists.

REQUIRED DEFINITIONS:
1. Attachment – a supporting document that is developed and maintained by the policy writer or 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).
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 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

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

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

Signed:_______________________________________________

Title: Director, Pharmacy Services

Date: March 1, 2020

Devised: 7/23/19
Revised: 3/1/20 – annual review, added GHP Kids
POLICY:
Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is applied according to the formulary review process (see Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Part D Policy 143.0 D Geisinger Health Plan (GHP) and Geisinger Indemnity Insurance Company (GIIC) Formulary Development by the Pharmacy). The results of this process determine the development and application 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 all lines of business, unless a specific limitation or exception exists.

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).
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 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

NOTE: The FDA-approved test is the therascreen® PIK3CA RGQ PCR Kit.

Examples of endocrine therapy include: exemestane, letrozole, anastrozole, tamoxifen, and toremifene.

QUANTITY LIMIT: Pharmacist note to CSR: Authorization should be entered by HICL and only checking the Formulary PA required box (no QLs need to be entered within the authorization).

- 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
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.

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, 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.

Signed: [Signature]
Title: Director, Pharmacy Services
Date: March 1, 2020

Devised: 7/23/19
Revised: 3/1/20 – annual review, added GHP Kids
POLICY:
Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is applied according to the formulary review process (see Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Part D Policy 143.0 D Geisinger Health Plan (GHP) and Geisinger Indemnity Insurance Company (GIIC) Formulary Development by the Pharmacy). The results of this process determine the development and application 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, Lotemax Gel, and Lotemax SM for GHP members who have prescription drug benefits, including all lines of business, unless a specific limitation or exception exists.

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

If a formulary exception is approved, Inveltys, loteprednol, Lotemax Gel, or Lotemax SM will be paid for under the member's prescription drug benefit.

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, 2020

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
POLICY NUMBER: 568.0

POLICY AND PROCEDURE
PHARMACY
MANUAL

SECTION: Commercial Drug
SUBJECT: Motegrity

Applicable line of business:

<table>
<thead>
<tr>
<th>Line of Business</th>
<th>Commercial</th>
<th>Medicaid</th>
<th>Medicare</th>
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POLICY:
Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is applied according to the formulary review process (see Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Part D Policy 143.0 D Geisinger Health Plan (GHP) and Geisinger Indemnity Insurance Company (GIIC) Formulary Development by the Pharmacy). The results of this process determine the development and application 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 all lines of business, unless a specific limitation or exception exists.

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

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

QUANTITY LIMIT: Pharmacist note to CSR: Authorization should be entered by HICL and only checking the Formulary box (no QLs need to be entered within the authorization).

- 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:
Amitiza, 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.
POLICY AND PROCEDURE
PHARMACY
MANUAL

Signed: ________________________________

Title: Director, Pharmacy Services

Date: March 1, 2020

Devised: 7/23/19
Revised: 3/1/20 – annual review, added GHP Kids
POLICY:
Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is applied according to the formulary review process (see Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Part D Policy 143.0 D Geisinger Health Plan (GHP) and Geisinger Indemnity Insurance Company (GIIC) Formulary Development by the Pharmacy). The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for Monurol for GHP members who have prescription drug benefits, including all lines of business, unless a specific limitation or exception exists.

REQUIRED DEFINITIONS:
1. Attachment – a supporting document that is developed and maintained by the policy writer or 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).
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 Monurol 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

**QUANTITY LIMIT:** 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

**QUANTITY LIMIT:** 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, Monurol will be paid for under the member’s prescription drug benefit.

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, 2020

Devised: 7/23/19
Revised: 3/1/20 – annual review, added GHP Kids
POLICY NUMBER: 570.0

POLICY AND PROCEDURE
PHARMACY
MANUAL

SECTION: Commercial Drug
SUBJECT: Follistim AQ

Applicable line of business:

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POLICY:
Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of formulary. The formulary is applied according to the formulary review process (see Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Part D Policy 143.0 D Geisinger Health Plan (GHP) and Geisinger Indemnity Insurance Company (GIIC) Formulary Development by the Pharmacy). The results of this process determine the development and application 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 all lines of business, unless a specific limitation or exception exists.

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

ADDITIONAL DEFINITIONS:
1. **Formulary** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. **Non-formulary products** – those medications that are not included in the Formulary.
3. **Healthcare provider** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
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 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:
o Uncorrected prolactin levels, greater than 25 ng/mL, after 6 months of therapy on bromocriptine or cabergoline OR
o 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

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

Date: March 1, 2020

Devised: 9/20/19
Revised: 3/1/20 – annual review, added GHP Kids
POLICY:  
Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of formulary. The formulary is applied according to the formulary review process (see Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Part D Policy 143.0 D Geisinger Health Plan (GHP) and Geisinger Indemnity Insurance Company (GIIC) Formulary Development by the Pharmacy). The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for Menopur for GHP members who have prescription drug benefits, including all lines of business, unless a specific limitation or exception exists.

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

ADDITIONAL DEFINITIONS:
1. Formulary – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. Non-formulary products – those medications that are not included in the Formulary.
3. Healthcare provider – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
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 Menopur may be made for members who meet the following
criteria:

**For Females:**
- Medical record documentation that Menopur 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**
  - Menopur is being used with donor eggs **OR**
  - In Vitro Fertilization **AND**

**OR**

- Medical record documentation that Menopur 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 Menopur 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

OR

- Medical record documentation that Menopur 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 a diagnosis of hypothalamic amenorrhea

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

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
Date: March 1, 2020
Devised: 9/23/19
Revised: 01/28/20 – Removed failure of Gonal f for patients with poor/diminished ovarian reserve, tubal
factor infertility, when used with donor eggs, or IVF
Revised: 3/1/20 – annual review, added GHP Kids
POLICY NUMBER: 572.0

POLICY AND PROCEDURE
PHARMACY
MANUAL

SECTION: Commercial Drug
SUBJECT: Human Chorionic Gonadotropin (hCG)

Applicable line of business:

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<tr>
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POLICY:
Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of formulary. The formulary is applied according to the formulary review process (see Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Part D Policy 143.0 D Geisinger Health Plan (GHP) and Geisinger Indemnity Insurance Company (GIIC) Formulary Development by the Pharmacy). The results of this process determine the development and application 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 all lines of business, unless a specific limitation or exception exists.

REQUIRED DEFINITIONS:
1. Attachment – a supporting document that is developed and maintained by the policy writer or 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).
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   A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
B. Provided for the diagnosis, or the direct care and treatment of the Member’s condition, illness, disease or injury;
C. In accordance with current standards of medical practice;
D. Not primarily for the convenience of the Member, or the Member’s Provider; and
E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services 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

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.

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, 2020

Devised:  9/23/19
Revised:  3/1/20 – annual review, added GHP Kids
POLICY:  
Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of formulary. The formulary is applied according to the formulary review process (see Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Part D Policy 143.0 D Geisinger Health Plan (GHP) and Geisinger Indemnity Insurance Company (GIIC) Formulary Development by the Pharmacy). The results of this process determine the development and application 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 all lines of business, unless a specific limitation or exception exists.

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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3. Healthcare provider – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
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 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

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.

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, 2020

Devised: 9/23/19
Revised: 3/1/20 – annual review, added GHP Kids
Applicable line of business:

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<th>ACA</th>
<th>GHP Kids</th>
</tr>
</thead>
</table>

POLICY:

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of formulary. The formulary is applied according to the formulary review process (see Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Part D Policy 143.0 D Geisinger Health Plan (GHP) and Geisinger Indemnity Insurance Company (GIIIC) Formulary Development by the Pharmacy). The results of this process determine the development and application 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 all lines of business, unless a specific limitation or exception exists.

REQUIRED DEFINITIONS:

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

ADDITIONAL DEFINITIONS:

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

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

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

THIS POLICY WILL BE REVISED AS NECESSARY AND REVIEWED NO LESS THAN ANNUALLY.
Signed:______________________________

Title: Director, Pharmacy Services

Date: March 1, 2020

Devised: 9/23/19
Revised: 3/1/20 – annual review, added GHP Kids
POLICY NUMBER: 575.0

POLICY AND PROCEDURE
PHARMACY
MANUAL

SECTION: Commercial Drug
SUBJECT: Durezol

Applicable line of business:

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<thead>
<tr>
<th>Line of Business</th>
<th>Medicaid</th>
<th>ACA</th>
<th>GHP Kids</th>
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</tr>
<tr>
<td>GHP Kids</td>
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<td></td>
<td>X</td>
</tr>
</tbody>
</table>

POLICY:
Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is applied according to the formulary review process (see Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Part D Policy 143.0 D Geisinger Health Plan (GHP) and Geisinger Indemnity Insurance Company (GIIC) Formulary Development by the Pharmacy). The results of this process determine the development and application 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 all lines of business, unless a specific limitation or exception exists.

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

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

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%, 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, 2020

Devised: 09/25/2019
Revised: 3/1/20 – annual review, added GHP Kids
POLICY:  
Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is applied according to the formulary review process (see Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Part D Policy 143.0 D Geisinger Health Plan (GHP) and Geisinger Indemnity Insurance Company (GIIC) Formulary Development by the Pharmacy). The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for Alrex for GHP members who have prescription drug benefits, including all lines of business, unless a specific limitation or exception exists.

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

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

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%

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

THIS POLICY WILL BE REVISED AS NECESSARY AND REVIEWED NO LESS THAN ANNUALLY.
Signed:_______________________________________________

Title: Director, Pharmacy Services

Date: March 1, 2020

Devised: 09/25/2019
Revised: 3/1/20 – annual review, added GHP Kids
POLICY: Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is applied according to the formulary review process (see Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Part D Policy 143.0 D Geisinger Health Plan (GHP) and Geisinger Indemnity Insurance Company (GIIIC) Formulary Development by the Pharmacy). The results of this process determine the development and application 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 all lines of business, unless a specific limitation or exception exists.

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

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

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.

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, 2020

Devised: 09/25/2019
Revised: 3/1/20 – annual review, added GHP Kids
POLICY: Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is applied according to the formulary review process (see Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Part D Policy 143.0 D Geisinger Health Plan (GHP) and Geisinger Indemnity Insurance Company (GIIC) Formulary Development by the Pharmacy). The results of this process determine the development and application 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, Illevo, Nevanac, and Prolensa for GHP members who have prescription drug benefits, including all lines of business, unless a specific limitation or exception exists.

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).
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 Acuvail, BromSite, Illevro, 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

If a formulary exception is approved, Acuvail, BromSite, Illevro, Nevanac, and 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.

THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE STANDARDS 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: 578.0

POLICY AND PROCEDURE
PHARMACY
MANUAL

SECTION: Commercial Drug
SUBJECT: Acuvail, BromSite, Ilevro, Nevanac, & Prolensa

Signed: ________________________________

Title: Director, Pharmacy Services

Date: March 1, 2020

Devised: 09/25/2019
Revised: 3/1/20 – annual review, added GHP Kids
Applicable line of business:

<table>
<thead>
<tr>
<th>Line of Business</th>
<th>Commercial</th>
<th>Medicaid</th>
<th>Medicare</th>
<th>ACA</th>
<th>GHP Kids</th>
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</tbody>
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**POLICY:**

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is applied according to the formulary review process (see Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Part D Policy 143.0 D Geisinger Health Plan (GHP) and Geisinger Indemnity Insurance Company (GIIC) Formulary Development by the Pharmacy). The results of this process determine the development and application 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 all lines of business, unless a specific limitation or exception exists.

**REQUIRED DEFINITIONS:**

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

**ADDITIONAL DEFINITIONS:**

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

NOTE: Cumulative use of Mavenclad for more than two years (4 cycles) of treatment during a member’s lifetime has not been evaluated.

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<thead>
<tr>
<th>Weight Range (kg)</th>
<th>First Cycle</th>
<th>Second Cycle</th>
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<tbody>
<tr>
<td>40” to less than 50</td>
<td>40 mg (4 tablets)</td>
<td>40 mg (4 tablets)</td>
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<tr>
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<td>60 to less than 70</td>
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<tr>
<td>80 to less than 90</td>
<td>80 mg (8 tablets)</td>
<td>70 mg (7 tablets)</td>
</tr>
<tr>
<td>90 to less than 100</td>
<td>90 mg (9 tablets)</td>
<td>80 mg (8 tablets)</td>
</tr>
</tbody>
</table>
POLICY NUMBER: 579.0

SECTION: Commercial Drug

SUBJECT: Mavenclad

| QUANTITY LIMIT: Pharmacist note to CSR: Authorization should be entered by HICL and only checking the Formulary PA required box (no QLs need to be entered within the authorization). |
|---|---|---|
| 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:**

**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, 2020

Devised:  9/25/19
Revised:  3/1/20 – annual review, added GHP Kids
POLICY:  
Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of formulary. The formulary is applied according to the formulary review process (see Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Part D Policy 143.0 D Geisinger Health Plan (GHP) and Geisinger Indemnity Insurance Company (GIIC) Formulary Development by the Pharmacy). The results of this process determine the development and application 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 all lines of business, unless a specific limitation or exception exists.

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

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

QUANTITY LIMIT/AUTHORIZATION PARAMETERS:

<table>
<thead>
<tr>
<th>Initial – One-time, one-week authorization</th>
<th>Remainder/Subsequent</th>
</tr>
</thead>
<tbody>
<tr>
<td>Quantity limit: 1 kit per 28 days</td>
<td>QL: 1 mL per 84 days</td>
</tr>
<tr>
<td>Max quantity supply: 1</td>
<td>Max quantity supply: 1</td>
</tr>
<tr>
<td>Min day supply: 28</td>
<td>Min day supply: 84</td>
</tr>
<tr>
<td>Max day supply: 28</td>
<td>Max day supply: 84</td>
</tr>
</tbody>
</table>
AUTHORIZATION DURATION: Approval will be given for an initial duration of six (6) months. For continuation, medical record documentation of clinical improvement or lack of progression in signs and symptoms of plaque psoriasis on six (6) months of Skyrizi is required.

After the initial six (6) month approval, subsequent approval will be for a duration of one (1) year. Reevaluation will be every one (1) year requiring medical record documentation of continued or sustained improvement in signs and symptoms of plaque psoriasis while on Skyrizi therapy.

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: March 1, 2020
Devised: 9/25/19
Revised: 11/5/19 – corrected typo, adjusted QL
Revised: 3/1/20 – annual review, added GHP Kids
Applicable line of business:

<table>
<thead>
<tr>
<th>Line of Business</th>
<th>Medicaid</th>
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</table>

POLICY:

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of formulary. The formulary is applied according to the formulary review process (see Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Part D Policy 143.0 D Geisinger Health Plan (GHP) and Geisinger Indemnity Insurance Company (GIIC) Formulary Development by the Pharmacy). The results of this process determine the development and application 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 all lines of business, unless a specific limitation or exception exists.

REQUIRED DEFINITIONS:

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

ADDITIONAL DEFINITIONS:

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

QUANTITY LIMIT: Pharmacist note to CSR: *Authorization should be entered by HICL and only checking the Formulary box (no QLs need to be entered within the authorization).*
- 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:

*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.

Signed: ________________________________
Title:  Director, Pharmacy Services
Date: March 1, 2020

Devised:  9/25/19
Revised:  3/1/20 – annual review, added GHP Kids
Applicable line of business:

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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).
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
- Medical record documentation that the patient has New York Heart Association (NYHA) Class I, II, or III heart failure

QUANTITY LIMIT: Pharmacist note to CSR: Authorization should be entered by HICL and only checking the Formulary PA required box (no QLs need to be entered within the authorization).
- 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, 2020

Devised: 9/25/19
Revised: 3/1/20 – annual review, added GHP Kids
Applicable line of business:

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POLICY:

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is applied according to the formulary review process (see Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Part D Policy 143.0 D Geisinger Health Plan (GHP) and Geisinger Indemnity Insurance Company (GIIC) Formulary Development by the Pharmacy). The results of this process determine the development and application 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 all lines of business, unless a specific limitation or exception exists.

REQUIRED DEFINITIONS:

1. **Attachment** – a supporting document that is developed and maintained by the policy writer or 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).
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 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

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: John Miller
Title: Director, Pharmacy Services
Date: March 1, 2020

Devised: 09/25/2019
Revised: 3/1/20 – annual review, added GHP Kids
POLICY AND PROCEDURE
PHARMACY
MANUAL

POLICY NUMBER: 584.0
SECTION: Commercial Drug
SUBJECT: Xpovio

Applicable line of business:

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<th>ACA</th>
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POLICY:
Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is applied according to the formulary review process (see Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Part D Policy 143.0 D Geisinger Health Plan (GHP) and Geisinger Indemnity Insurance Company (GIIC) Formulary Development by the Pharmacy). The results of this process determine the development and application 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 all lines of business, unless a specific limitation or exception exists.

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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3. **Devised** – the date the policy was implemented.
4. **Revised** – the date of every revision to the policy, including typographical and grammatical changes.
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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).
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 Xpovio may be made for members who meet the following criteria:

**Relapsed or Refractory 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 that Xpovio will be used in combination with dexamethasone **AND**
- 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

**NOTE:** Currently approved agents for the treatment of multiple myeloma

<table>
<thead>
<tr>
<th>Class</th>
<th>Single-agent (+/- steroids)</th>
<th>Combination therapy</th>
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</thead>
<tbody>
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<td>Immunomodulatory agents (IMid)</td>
<td>Revlimid (lenalidomide)</td>
<td>Ninlaro (ixazomib)</td>
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<tr>
<td></td>
<td>Pomalyst (pomalidomide)</td>
<td>(with lenalidomide)</td>
</tr>
<tr>
<td>Proteasome inhibitors (PI)</td>
<td>Velcade (bortezomib)</td>
<td>Ninlaro (ixazomib)</td>
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<td>Kyprolis (carfilzomib)</td>
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<td>anti-CD38</td>
<td>Darzalex (daratumumab)</td>
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<tr>
<td>Anti-SLAM F7</td>
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<td>Empliciti (elotuzumab) (with IMid)</td>
</tr>
<tr>
<td>Histone deacetylase inhibitor (HDAC)</td>
<td>--</td>
<td>Farydak (panobinostat) (with bortezomib)</td>
</tr>
</tbody>
</table>
Relapsed or Refractory Diffuse Large B-cell Lymphoma (DLBCL)

- 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 a diagnosis of relapsed or refractory diffuse B-cell lymphoma (DLBCL), not otherwise specified, including DLBCL arising from follicular lymphoma AND
- Medical record documentation of treatment with at least two (2) prior lines of therapy

QUANTITY LIMIT: Pharmacist note to CSR: Authorization should be entered by HICL and only checking the Formulary PA required box (no QLs need to be entered within the authorization).

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<tr>
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<td>80 mg twice daily</td>
<td>32 tablets per 28 days</td>
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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 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 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.

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: October 12, 2020

Devised: 9/25/19
Revised: 3/1/20 – annual review, added GHP Kids
Revised: 10/12/20 – added B-cell lymphoma indication, updated QL
Applicable line of business:

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**POLICY:**

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**REQUIRED DEFINITIONS:**

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1. **Formulary** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. **Non-formulary products** – those medications that are not included in the Formulary.
3. **Healthcare provider** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
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   A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
   B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
C. In accordance with current standards of medical practice;
D. Not primarily for the convenience of the Member, or the Member's Provider; and
E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to 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

QUANTITY LIMIT: Pharmacist note to CSR: Authorization should be entered by HICL and only checking the Formulary PA required box (no QLs need to be entered within the authorization).

- 4 tablets 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. 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 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, 2020

Devised:  9/27/19
Revised:  3/1/20 – annual review, added GHP Kids
Applicable line of business:

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POLICY:
Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is applied according to the formulary review process (see Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Part D Policy 143.0 D Geisinger Health Plan (GHP) and Geisinger Indemnity Insurance Company (GIIC) Formulary Development by the Pharmacy). The results of this process determine the development and application 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 all lines of business, unless a specific limitation or exception exists.

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

ADDITIONAL DEFINITIONS:
1. Formulary – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. Non-formulary products – those medications that are not included in the Formulary.
3. Healthcare provider – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
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 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:
  o Associated with functional limitations or severe morbidity AND
  o Not amenable to improvement with surgery

QUANTITY LIMIT: Pharmacist note to CSR: Authorization should be entered by HICL and only checking the Formulary PA required box (no QLs need to be entered within the authorization).

- 4 capsules 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. 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 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, 2020

Devised: 9/27/19
Revised: 3/1/20 – annual review, added GHP Kids
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REQUIRED DEFINITIONS:
1. **Attachment** – a supporting document that is developed and maintained by the policy writer or 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).
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 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*

**QUANTITY LIMIT:** Pharmacist note to CSR: *Authorization should be entered by HICL and only checking the Formulary PA required box (no QLs need to be entered within the authorization).*
- 1 tablet per day

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*

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, 2020

Devised: 11/20/19
Revised: 3/1/20 – annual review, added GHP Kids
POLICY NUMBER: 588.0

POLICY AND PROCEDURE
PHARMACY
MANUAL

SECTION: Commercial Drug
SUBJECT: Rozlytrek

Applicable line of business:

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POLICY:
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REQUIRED DEFINITIONS:
1. **Attachment** – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. **Exhibit** – a 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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ADDITIONAL DEFINITIONS:
1. **Formulary** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. **Non-formulary products** – those medications that are not included in the Formulary.
3. **Healthcare provider** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician’s assistant, certified registered nurse practitioner).
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

**QUANTITY LIMIT:** Pharmacist note to CSR: *Authorization should be entered by HICL and only checking the Formulary PA required box (no QLs need to be entered within the authorization)*.
- 100 mg capsules: 1 capsule per day, 30 day supply per fill
• 200 mg capsules: 3 capsules 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. 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 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.**

Signed: ____________________________________________
Title: Director, Pharmacy Services
Date: March 1, 2020

Devised: 11/20/19
Revised: 3/1/20 – annual review, added GHP Kids
POLICY:  
Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is applied according to the formulary review process (see Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Part D Policy 143.0 D Geisinger Health Plan (GHP) and Geisinger Indemnity Insurance Company (GIIC) Formulary Development by the Pharmacy). The results of this process determine the development and application 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 all lines of business, unless a specific limitation or exception exists.

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).
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 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 thrombocytemia myelofibrosis **AND**
- Medical record documentation of platelet count greater than or equal to 50 x 10⁹/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 allogenic
  hematopoietic cell transplantation

**QUANTITY LIMIT:** Pharmacist note to CSR: *Authorization should be entered by HICL
and only checking the Formulary PA required box (no QLs need to be entered within the
authorization)*.

- 4 capsules per day, 30 day supply per fill
AUTHORIZATION DURATION: Each treatment period will be defined as six (6) months. Re-review will 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 x 10^9/L
- Hemoglobin < 10 g/dL
- Blood Blasts ≥ 1%
- Presence of Constitutional Symptoms (weight loss, fever, excessive sweats, etc.)
- Transfusion dependency
- Platelets less than 100 X 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
THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND FEDERAL REGULATORY ENTITIES.

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

Signed:_______________________________________________

Title:  Director, Pharmacy Services

Date:  March 1, 2020

Devised:  11/20/19
Revised:  3/1/20 – annual review, added GHP Kids
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POLICY:

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is applied according to the formulary review process (see Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Part D Policy 143.0 D Geisinger Health Plan (GHP) and Geisinger Indemnity Insurance Company (GIIC) Formulary Development by the Pharmacy). The results of this process determine the development and application 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 all lines of business, unless a specific limitation or exception exists.

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

QUANTITY LIMIT: Pharmacist note to CSR: Authorization should be entered by HICL and only checking the Formulary PA required box (no QLs need to be entered within the authorization).

- 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, 2020

Devised: 11/20/19
Revised: 3/1/20 – annual review, added GHP Kids
POLICY NUMBER: 591.0

POLICY AND PROCEDURE
PHARMACY
MANUAL

SECTION: Commercial Drug
SUBJECT: Nayzilam

Applicable line of business:

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POLICY:
Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is applied according to the formulary review process (see Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Part D Policy 143.0 D Geisinger Health Plan (GHP) and Geisinger Indemnity Insurance Company (GIIC) Formulary Development by the Pharmacy). The results of this process determine the development and application 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 all lines of business, unless a specific limitation or exception exists.

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

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

QUANTITY LIMIT: Pharmacist note to CSR: Authorization should be entered by HICL and only checking the Formulary PA required box (no QLs need to be entered within the authorization).
- 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
THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND FEDERAL REGULATORY ENTITIES.

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

Signed:_______________________________________________

Title: Director, Pharmacy Services

Date: March 1, 2020

Devised: 11/20/19
Revised: 3/1/20 – annual review, added GHP Kids
Applicable line of business:

<table>
<thead>
<tr>
<th>Applicable Line of Business</th>
<th>Commercial</th>
<th>Medicaid</th>
<th>Medicare</th>
<th>ACA</th>
<th>GHP Kids</th>
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</table>

**POLICY:**
Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is applied according to the formulary review process (see Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Part D Policy 143.0 D Geisinger Health Plan (GHP) and Geisinger Indemnity Insurance Company (GIIC) Formulary Development by the Pharmacy). The results of this process determine the development and application 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 all lines of business, unless a specific limitation or exception exists.

**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).
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;
POLICY NUMBER:  592.0
SECTION:  Commercial Drug
SUBJECT:  Nucala for Self-Administration

B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
C. In accordance with current standards of medical practice;
D. Not primarily for the convenience of the Member, or the Member's Provider; and
E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services 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 is not being used in combination with Fasenra (benralizumab), Cinqair (reslizumab), or Xolair (omalizumab).
*Measures of disease severity

<table>
<thead>
<tr>
<th>Measure</th>
<th>Not Well Controlled</th>
<th>Very Poorly Controlled</th>
</tr>
</thead>
<tbody>
<tr>
<td>Symptoms</td>
<td>&gt; 2 days per week</td>
<td>Throughout the day</td>
</tr>
<tr>
<td>Nighttime awakenings</td>
<td>1-3x/week</td>
<td>&gt; 4x/week</td>
</tr>
<tr>
<td>Interference with normal activity</td>
<td>Some limitation</td>
<td>Extremely limited</td>
</tr>
<tr>
<td>SABA use for symptom control (not to prevent exercise-induced bronchospasm)</td>
<td>&gt; 2 days/week</td>
<td>Several times per day</td>
</tr>
<tr>
<td>FEV1 (% predicted) or peak flow (% personal best)</td>
<td>60-80%</td>
<td>&lt; 60%</td>
</tr>
<tr>
<td>Asthma Control Test (ACT) Score</td>
<td>16-19</td>
<td>&lt; 15</td>
</tr>
</tbody>
</table>

**QUANTITY LIMIT:** 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 $\geq 1500$ 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)

**QUANTITY LIMIT:** 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.

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.
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

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

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

Signed:_______________________________________________
Title: Director, Pharmacy Services
Date: March 1, 2020

Devised: 11/20/19
Revised: 3/1/20 – annual review, added GHP Kids
POLICY:
Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is applied according to the formulary review process (see Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Part D Policy 143.0 D Geisinger Health Plan (GHP) and Geisinger Indemnity Insurance Company (GIIC) Formulary Development by the Pharmacy). The results of this process determine the development and application 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 all lines of business, unless a specific limitation or exception exists.

REQUIRED DEFINITIONS:
1. **Attachment** – a supporting document that is developed and maintained by the policy writer or 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).
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 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 is not being used in combination with Nucala (mepolizumab), Cinqair (reslizumab), or Xolair (omalizumab)
### Measures of disease severity

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<tr>
<th>Measure</th>
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</table>

### QUANTITY LIMIT:

<table>
<thead>
<tr>
<th>Initial – 3-month authorization</th>
<th>Remainder/Subsequent</th>
</tr>
</thead>
<tbody>
<tr>
<td>Quantity limit: 1 mL per 28 days</td>
<td>Quantity limit: 1 mL per 56 days</td>
</tr>
<tr>
<td>Max quantity supply: 1</td>
<td>Max quantity supply: 1</td>
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<tr>
<td>Min day supply: 28</td>
<td>Min day supply: 56</td>
</tr>
<tr>
<td>Max day supply: 28</td>
<td>Max day supply: 56</td>
</tr>
</tbody>
</table>

### 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
  - 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: March 1, 2020

Devised: 11/20/19
Revised: 3/1/20 – annual review, added GHP Kids
POLICY:  
Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is applied according to the formulary review process (see Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Part D Policy 143.0 D Geisinger Health Plan (GHP) and Geisinger Indemnity Insurance Company (GIIC) Formulary Development by the Pharmacy). The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for Freestyle Libre for self-administration for GHP members who have prescription drug benefits, including all lines of business, unless a specific limitation or exception exists.

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

PROCEDURE:
An exception for coverage of Freestyle Libre may be made for members who meet the following criteria:

- Medical record documentation of type 1 or 2 diabetes mellitus AND
- Medical record documentation of member age greater than or equal to 18 years AND
- One of the following:
  - Medical record documentation of current insulin therapy use OR
  - Medical record documentation of functional barriers to finger stick blood glucose monitoring OR
  - Medical record documentation of history of recurrent hypoglycemia episodes OR
  - Medical record documentation of HgA1c greater than 9

QUANTITY LIMIT: Pharmacist note to CSR: Authorization should be entered by HICL and only checking the Formulary PA required box (no QLs need to be entered within the authorization). Authorizations must be placed for both the reader and sensors.

- Freestyle Libre 10 or 14 day reader: 1 reader every 2 years
- Freestyle Libre 10 day sensors: 3 sensors per 30 days
- Freestyle Libre 14 day sensors: 2 sensors per 28 days

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

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

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

Signed: ________________________________
Title: Director, Pharmacy Services
Date: March 1, 2020

Devised: 11/20/19
Revised: 3/1/20 – annual review, added GHP Kids
POLICY AND PROCEDURE
PHARMACY
MANUAL

POLICY NUMBER:  595.0
SECTION:  Commercial Drug
SUBJECT:  Bijuva

Applicable line of business:

<table>
<thead>
<tr>
<th>Line of Business</th>
<th></th>
<th></th>
</tr>
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<tbody>
<tr>
<td>Commercial</td>
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<tr>
<td>Medicaid</td>
<td></td>
<td>ACA</td>
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<tr>
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<td></td>
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POLICY:
Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of formulary. The formulary is applied according to the formulary review process (see Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Part D Policy 143.0 D Geisinger Health Plan (GHP) and Geisinger Indemnity Insurance Company (GIIC) Formulary Development by the Pharmacy). The results of this process determine the development and application 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 all lines of business, unless a specific limitation or exception exists.

REQUIRED DEFINITIONS:
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E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services 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.

QUANTITY LIMIT: 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, northe thindrone/ethinyl estradiol, progesterone, Combi patch, Premarin, Prempro, Premphase

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

THIS POLICY WILL BE REVISED AS NECESSARY AND REVIEWED NO LESS THAN ANNUALLY.
Signed: ____________________________

Title: Director, Pharmacy Services

Date: March 1, 2020

Devised: 01/16/2020
Revised: 3/1/20 – annual review, added GHP Kids
POLICY NUMBER: 596.0

POLICY AND PROCEDURE
PHARMACY
MANUAL

SECTION: Commercial Drug
SUBJECT: Cequa

Applicable line of business:

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POLICY:
Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is applied according to the formulary review process (see Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Part D Policy 143.0 D Geisinger Health Plan (GHP) and Geisinger Indemnity Insurance Company (GIIC) Formulary Development by the Pharmacy). The results of this process determine the development and application 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 all lines of business, unless a specific limitation or exception exists.

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

QUANTITY LIMIT: 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:
Restasis, 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.
POLICY NUMBER: 597.0

POLICY AND PROCEDURE
PHARMACY
MANUAL

SECTION: Commercial Drug
SUBJECT: Drizalma

Applicable line of business:

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POLICY:
Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of formulary. The formulary is applied according to the formulary review process (see Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Part D Policy 143.0 D Geisinger Health Plan (GHP) and Geisinger Indemnity Insurance Company (GIIC) Formulary Development by the Pharmacy). The results of this process determine the development and application 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 all lines of business, unless a specific limitation or exception exists.

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

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

QUANTITY LIMIT: 2 capsules per day

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:
duloxetine capsules, citalopram solution, doxepin solution, escitalopram solution, fluoxetine solution, nortriptyline solution, sertraline solution, pregabalin solution

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

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

Signed: ____________________________________________

Title:  Director, Pharmacy Services

Date:  March 1, 2020

Devised:  01/17/2020
Revised:  3/1/20 – annual review, added GHP Kids
POLICY NUMBER: 598.0

POLICY AND PROCEDURE
PHARMACY
MANUAL

SECTION: Commercial Drug
SUBJECT: Ezallor

Applicable line of business:

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<td>GHP Kids</td>
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POLICY:
Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of formulary. The formulary is applied according to the formulary review process (see Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Part D Policy 143.0 D Geisinger Health Plan (GHP) and Geisinger Indemnity Insurance Company (GIIC) Formulary Development by the Pharmacy). The results of this process determine the development and application 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 all lines of business, unless a specific limitation or exception exists.

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

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

QUANTITY LIMIT: 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

THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE STANDARDS 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: 599.0
SECTION: Commercial Drug
SUBJECT: Kapspargo

Applicable line of business:

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POLICY:
Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of formulary. The formulary is applied according to the formulary review process (see Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Part D Policy 143.0 D Geisinger Health Plan (GHP) and Geisinger Indemnity Insurance Company (GIIC) Formulary Development by the Pharmacy). The results of this process determine the development and application of criteria for non-formulary products or prior authorization criteria for certain formulary medications. This specific policy explains how coverage decisions are determined for Kapspargo for GHP members who have prescription drug benefits, including all lines of business, unless a specific limitation or exception exists.

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).
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 Kapspargo 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.

QUANTITY LIMIT: 25 mg, 50 mg, 100 mg capsule: 1 capsule/day
200 mg capsule: 2 capsules/day

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

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-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, 2020

Devised: 01/17/20
Revised: 3/1/20 – annual review, added GHP Kids
POLICY:"Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of formulary. The formulary is applied according to the formulary review process (see Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Part D Policy 143.0 D Geisinger Health Plan (GHP) and Geisinger Indemnity Insurance Company (GIIC) Formulary Development by the Pharmacy). The results of this process determine the development and application 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 all lines of business, unless a specific limitation or exception exists.

REQUIRED DEFINITIONS:

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

ADDITIONAL DEFINITIONS:

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

QUANTITY LIMIT: 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.

FORMULARY ALTERNATIVES:
celecoxib, choline salicylate/magnesium salicylate, diclofenac, diclofenac-misoprostol, diflunisal, etodolac, fenoprofen, flurbiprofen, ibuprofen, indomethacin,
ketoconazole, ketoconazole, ketoprofen, meclofenamate 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: John Miller
Title: Director, Pharmacy Services
Date: March 1, 2020

Devised: 01/17/20
Revised: 3/1/20 – annual review, added GHP Kids
Applicable line of business:

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POLICY:
Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of formulary. The formulary is applied according to the formulary review process (see Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Part D Policy 143.0 D Geisinger Health Plan (GHP) and Geisinger Indemnity Insurance Company (GIIC) Formulary Development by the Pharmacy). The results of this process determine the development and application 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 all lines of business, unless a specific limitation or exception exists.

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).
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 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).

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.

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, 2020

Devised: 01/17/20
Revised: 3/1/20 – annual review, added GHP Kids
POLICY:  
Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of formulary. The formulary is applied according to the formulary review process (see Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Part D Policy 143.0 D Geisinger Health Plan (GHP) and Geisinger Indemnity Insurance Company (GIIC) Formulary Development by the Pharmacy). The results of this process determine the development and application 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 all lines of business, unless a specific limitation or exception exists.

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

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

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), Travatan Z

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

THIS POLICY WILL BE REVISED AS NECESSARY AND
REVIEWED NO LESS THAN ANNUALLY.
Signed:_______________________________________________

Title: Director, Pharmacy Services

Date: March 1, 2020

Devised: 01/17/20
Revised: 3/1/20 – annual review, added GHP Kids
POLICY AND PROCEDURE
PHARMACY
MANUAL

POLICY NUMBER: 603.0
SECTION: Commercial Drug
SUBJECT: Zioptan

Applicable line of business:

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POLICY:
Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of formulary. The formulary is applied according to the formulary review process (see Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Part D Policy 143.0 D Geisinger Health Plan (GHP) and Geisinger Indemnity Insurance Company (GIIC) Formulary Development by the Pharmacy). The results of this process determine the development and application 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 all lines of business, unless a specific limitation or exception exists.

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

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

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), Travatan Z, 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, 2020
POLICY NUMBER: 603.0

SECTION: Commercial Drug

SUBJECT: Zioptan
POLICY: Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of formulary. The formulary is applied according to the formulary review process (see Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Part D Policy 143.0 D Geisinger Health Plan (GHP) and Geisinger Indemnity Insurance Company (GIIC) Formulary Development by the Pharmacy). The results of this process determine the development and application 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 all lines of business, unless a specific limitation or exception exists.

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

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

**QUANTITY LIMIT:** Pharmacist note to CSR: *Authorization should be entered by HICL and only checking the Formulary PA required box (no QLs need to be entered within the authorization).*

- 2 films per day

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, 2020
Devised: 01/17/20
Revised: 3/1/20 – annual review, added GHP Kids
POLICY NUMBER: 605.0

POLICY AND PROCEDURE
PHARMACY
MANUAL

SECTION: Commercial Drug
SUBJECT: Rinvoq

Applicable line of business:

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POLICY:
Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of formulary. The formulary is applied according to the formulary review process (see Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Part D Policy 143.0 D Geisinger Health Plan (GHP) and Geisinger Indemnity Insurance Company (GIIC) Formulary Development by the Pharmacy). The results of this process determine the development and application 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 all lines of business, unless a specific limitation or exception exists.

REQUIRED DEFINITIONS:

1. **Attachment** – a supporting document that is developed and maintained by the policy writer or 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).
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 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  

**QUANTITY LIMIT:** 1 tablet 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 signs and symptoms of rheumatoid arthritis on six  
(6) months of Rinvoq therapy 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 continued or sustained improvement in the signs and  
symptoms of rheumatoid arthritis while on Rinvoq therapy.
FORMULARY ALTERNATIVES:
    azathioprine, cyclosporine, hydroxychloroquine, methotrexate, sulfasalazine, leflunomide, Depen, Ridaura

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.

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

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

Signed: ___________________________________________

Title: Director, Pharmacy Services

Date: March 1, 2020

Devised: 01/27/20
Revised: 3/1/20 – annual review, added GHP Kids
POLICY NUMBER: 606.0

POLICY AND PROCEDURE
PHARMACY
MANUAL

SECTION: Commercial Drug
SUBJECT: Trikafta

Applicable line of business:

<table>
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<tr>
<th>Line of Business</th>
<th>Commercial</th>
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POLICY:
Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of formulary. The formulary is applied according to the formulary review process (see Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Part D Policy 143.0 D Geisinger Health Plan (GHP) and Geisinger Indemnity Insurance Company (GIIC) Formulary Development by the Pharmacy). The results of this process determine the development and application 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 all lines of business, unless a specific limitation or exception exists.

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

ADDITIONAL DEFINITIONS:
1. **Formulary** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. **Non-formulary products** – those medications that are not included in the Formulary.
3. **Healthcare provider** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
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 Trikafta 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 cystic fibrosis AND
- Medical record documentation that the patient has at least one F508del mutation in the cystic fibrosis transmembrane conductance regulator (CFTR) gene as determined by an FDA-cleared cystic fibrosis mutation test 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.

QUANTITY LIMIT: 3 tablets per day, 34 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 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
THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE STANDARDS OF NCQA AND ANY OTHER APPLICABLE STATE AND FEDERAL REGULATORY ENTITIES.

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

Signed:_______________________________________________

Title:  Director, Pharmacy Services

Date:  March 1, 2020

Devised:  01/28/20
Revised:  3/1/20 – annual review, added GHP Kids
POLICY:
Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is applied according to the formulary review process (see Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Part D Policy 143.0 D Geisinger Health Plan (GHP) and Geisinger Indemnity Insurance Company (GIIC) Formulary Development by the Pharmacy). The results of this process determine the development and application 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 all lines of business, unless a specific limitation or exception exists.

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

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

**QUANTITY LIMIT:** 10 tablets per 5 days

**AUTHORIZATION DURATION:** 5 days

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: [Signature]
Title: Director, Pharmacy Services
Date: March 1, 2020

Devised: 01/28/20
Revised: 3/1/20 – annual review, added GHP Kids
POLICY:  
Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is applied according to the formulary review process (see Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Part D Policy 143.0 D Geisinger Health Plan (GHP) and Geisinger Indemnity Insurance Company (GIIC) Formulary Development by the Pharmacy). The results of this process determine the development and application 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 all lines of business, unless a specific limitation or exception exists.

REQUIRED DEFINITIONS:
1. Attachment – a supporting document that is developed and maintained by the policy writer or 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).
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

QUANTITY LIMIT: 4 capsules per day

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.

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, 2020

Devised: 01/28/20
Revised: 3/1/20 – annual review, added GHP Kids
POLICY AND PROCEDURE
PHARMACY
MANUAL

POLICY NUMBER: 609.0
SECTION: Commercial Drug
SUBJECT: Enstilar

Applicable line of business:

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POLICY:
Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is applied according to the formulary review process (see Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Part D Policy 143.0 D Geisinger Health Plan (GHP) and Geisinger Indemnity Insurance Company (GIIC) Formulary Development by the Pharmacy). The results of this process determine the development and application 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 all lines of business, unless a specific limitation or exception exists.

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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2. Non-formulary products – those medications that are not included in the Formulary.
3. Healthcare provider – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
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 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.

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**: 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 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) (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

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

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

Signed:_______________________________________________

Title:  Director, Pharmacy Services

Date:  March 1, 2020

Devised: 09/25/2019
Revised: 3/1/20 – annual review, added GHP Kids
Applicable line of business:

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**POLICY:**

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of formulary. The formulary is applied according to the formulary review process (see Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Part D Policy 143.0 D Geisinger Health Plan (GHP) and Geisinger Indemnity Insurance Company (GIIC) Formulary Development by the Pharmacy). The results of this process determine the development and application 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 all lines of business, unless a specific limitation or exception exists.

**REQUIRED DEFINITIONS:**

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

**ADDITIONAL DEFINITIONS:**

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

QUANTITY LIMITS:
Vascepa 0.5 grams: 8 capsules per day
Vascepa 1 gram: 4 capsules per day

*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, 2020

Devised:  01/29/20
Revised:  3/1/20 – annual review, added GHP Kids
POLICY:
Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is applied according to the formulary review process (see Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Part D Policy 143.0 D Geisinger Health Plan (GHP) and Geisinger Indemnity Insurance Company (GIIC) Formulary Development by the Pharmacy). The results of this process determine the development and application 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 all lines of business, unless a specific limitation or exception exists.

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).
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:

- 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

QUANTITY LIMIT: Pharmacist note to CSR: *Authorization should be entered by HICL
and only checking the Formulary PA required box (no QLs need to be entered within
the authorization).*
- 1 tablet 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. 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, 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:**
- imatinib*, Sprycel*, Stivarga*, Sutent*

* 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 9, 2020

Devised:  4/9/20
POLICY NUMBER: 612.0

POLICY AND PROCEDURE
PHARMACY
MANUAL

SECTION: Commercial Drug
SUBJECT: Wakix

Applicable line of business:

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POLICY:

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of formulary. The formulary is applied according to the formulary review process (see Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Part D Policy 143.0 D Geisinger Health Plan (GHP) and Geisinger Indemnity Insurance Company (GIIC) Formulary Development by the Pharmacy). The results of this process determine the development and application 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 all lines of business, unless a specific limitation or exception exists.

REQUIRED DEFINITIONS:

1. **Attachment** – a supporting document that is developed and maintained by the policy writer or 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).
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 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 a 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

QUANTITY LIMIT: 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.

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

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
REVIEWS NO LESS THAN ANNUALLY.

Signed:_______________________________________________

Title: Director, Pharmacy Services
Date: November 18, 2020

Devised: 4/9/20
Revised: 11/18/20 – added authorization duration
Applicable line of business:

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**POLICY:**
Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is applied according to the formulary review process (see Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Part D Policy 143.0 D Geisinger Health Plan (GHP) and Geisinger Indemnity Insurance Company (GIIC) Formulary Development by the Pharmacy). The results of this process determine the development and application 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 all lines of business, unless a specific limitation or exception exists.

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

**ADDITIONAL DEFINITIONS:**
1. **Formulary** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. **Non-formulary products** – those medications that are not included in the Formulary.
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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

*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.

**QUANTITY LIMIT:** Pharmacist note to CSR: *Authorization should be entered by HICL and only checking the Formulary PA required box (no QLs need to be entered within the authorization).*

- 8 tablets 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. 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, 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

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THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE STANDARDS 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: 613.0

SECTION: Commercial Drug

SUBJECT: Tazverik

Signed: ________________________________________________

Title: Director, Pharmacy Services

Date: October 12, 2020

Devised: 4/21/20
Revised: 10/12/20 – added follicular lymphoma indication and note
POLICY NUMBER: 614.0

SECTION: Commercial Drug
SUBJECT: Nourianz

Applicable line of business:

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POLICY:
Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is applied according to the formulary review process (see Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Part D Policy 143.0 D Geisinger Health Plan (GHP) and Geisinger Indemnity Insurance Company (GIIC) Formulary Development by the Pharmacy). The results of this process determine the development and application 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 all lines of business, unless a specific limitation or exception exists.

REQUIRED DEFINITIONS:
1. **Attachment** – a supporting document that is developed and maintained by the policy writer or 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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   A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
   B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
C. In accordance with current standards of medical practice;
D. Not primarily for the convenience of the Member, or the Member’s Provider; and
E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services 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

QUANTITY LIMIT: Pharmacist note to CSR: Authorization should be entered by HICL and only checking the Formulary PA required box (no QLs need to be entered within the authorization).
- 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.

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: April 21, 2020

Devised: 4/21/20
POLICY:
Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is applied according to the formulary review process (see Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Part D Policy 143.0 D Geisinger Health Plan (GHP) and Geisinger Indemnity Insurance Company (GIIC) Formulary Development by the Pharmacy). The results of this process determine the development and application 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 all lines of business, unless a specific limitation or exception exists.

REQUIRED DEFINITIONS:
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D. Not primarily for the convenience of the Member, or the Member’s Provider; and
E. The most appropriate source or level of service that can safely be provided to the
   Member. When applied to hospitalization, this further means that the Member
   requires acute care as an inpatient due to the nature of the services 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 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 entacapone or carbidopa/levodopa/entacapone

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, 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
REVIEWS NO LESS THAN ANNUALLY.
POLICY AND PROCEDURE
PHARMACY
MANUAL

POLICY NUMBER: 616.0
SECTION: Commercial Drug
SUBJECT: Pretomanid

Applicable line of business:

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POLICY:
Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is applied according to the formulary review process (see Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Part D Policy 143.0 D Geisinger Health Plan (GHP) and Geisinger Indemnity Insurance Company (GIIC) Formulary Development by the Pharmacy). The results of this process determine the development and application 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 all lines of business, unless a specific limitation or exception exists.

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

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

QUANTITY LIMIT: Pharmacist note to CSR: *Authorization should be entered by HICL and only checking the Formulary PA required box (no QLs need to be entered within the authorization).*
- 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.

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: April 21, 2020

Devised: 4/21/20
POLICY:  
Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is applied according to the formulary review process (see Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Part D Policy 143.0 D Geisinger Health Plan (GHP) and Geisinger Indemnity Insurance Company (GIIC) Formulary Development by the Pharmacy). The results of this process determine the development and application 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 all lines of business, unless a specific limitation or exception exists.

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

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

QUANTITY LIMIT: Pharmacist note to CSR: Authorization should be entered by HICL and only checking the Formulary PA required box (no QLs need to be entered within the authorization).

- 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.

FORMULARY ALTERNATIVES:
- diazepam rectal gel, Nayzilam<sup>^</sup>, Diastat Acudial

<sup>^</sup>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: April 21, 2020

Devised: 4/21/20
Applicable line of business:

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POLICY:
Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is applied according to the formulary review process (see Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Part D Policy 143.0 D Geisinger Health Plan (GHP) and Geisinger Indemnity Insurance Company (GIIC) Formulary Development by the Pharmacy). The results of this process determine the development and application 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 all lines of business, unless a specific limitation or exception exists.

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).
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;
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D. Not primarily for the convenience of the Member, or the Member’s Provider; and
E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to 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:

- 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

QUANTITY LIMIT: Pharmacist note to CSR: Authorization should be entered by HICL and only checking the Formulary PA required box (no QLs need to be entered within the authorization).

- 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:
arianiprazole, 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.

Signed: John Miller
Title: Director, Pharmacy Services
Date: April 21, 2020
Devised: 4/21/20
Applicable line of business:

| Line of Business | X | Medicaid | ACA | X |

POLICY:
Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is applied according to the formulary review process (see Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Part D Policy 143.0 D Geisinger Health Plan (GHP) and Geisinger Indemnity Insurance Company (GIIC) Formulary Development by the Pharmacy). The results of this process determine the development and application 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 all lines of business, unless a specific limitation or exception exists.

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).
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 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
  - For major depressive disorder (MDD)
    - Medical record documentation of reason why aripiprazole oral tablets cannot be used
QUANTITY LIMIT: Pharmacist note to CSR: Authorization should be entered by HICL and only checking the Formulary PA required box (no QLs need to be entered within the authorization).
- 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.
POLICY AND PROCEDURE
PHARMACY
MANUAL

POLICY NUMBER: 619.0

SECTION: Commercial Drug
SUBJECT: Abilify Mycite

Signed: ________________________________
Title: Director, Pharmacy Services
Date: July 29, 2020

Devised: 5/29/20
Revised: 7/29/20 – added alternative criteria to reauthorization
Applicable line of business:

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POLICY:

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is applied according to the formulary review process (see Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Part D Policy 143.0 D Geisinger Health Plan (GHP) and Geisinger Indemnity Insurance Company (GIIC) Formulary Development by the Pharmacy). The results of this process determine the development and application 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 all lines of business, unless a specific limitation or exception exists.

REQUIRED DEFINITIONS:

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

ADDITIONAL DEFINITIONS:

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

**QUANTITY LIMIT:** Pharmacist note to CSR: *Authorization should be entered by HICL and only checking the Formulary PA required box (no QLs need to be entered within the authorization).*

- 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.

**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:  May 29, 2020

Devised:  5/29/20
Applicable line of business:

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POLICY:

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is applied according to the formulary review process (see Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Part D Policy 143.0 D Geisinger Health Plan (GHP) and Geisinger Indemnity Insurance Company (GIIC) Formulary Development by the Pharmacy). The results of this process determine the development and application 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 all lines of business, unless a specific limitation or exception exists.

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.
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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:
  o Pediatric oncologist
  o Pediatric neurologist
  o 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:
  o Diagnosis of schizophrenia OR
  o 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)
  o Freckling in axillary or inguinal regions
  o Two or more neurofibromas of any type, or one plexiform neurofibroma
  o A tumor of the nerve to the eye called optic glioma
  o Two or more Lisch nodules (iris hamartomas)
  o A distinctive osseous lesion (sphenoid dysplasia or tibial pseudarthrosis)
  o A first degree relative with NF1

AND
- Medical record documentation of symptomatic, inoperable* plexiform neurofibromas (PN)
QUANTITY LIMIT: Pharmacist note to CSR: Authorization should be entered by HICL and only checking the Formulary PA required box (no QLs need to be entered within the authorization).
  - 10 mg capsules: 8 capsules per day, 30 day supply per fill
  - 25 mg capsules: 4 capsules 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. 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: 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.
Signed:  

Title:  Director, Pharmacy Services

Date:  May 29, 2020

Devised:  5/29/20
POLICY AND PROCEDURE
PHARMACY
MANUAL

Applicable line of business:

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POLICY:
Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is applied according to the formulary review process (see Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Part D Policy 143.0 D Geisinger Health Plan (GHP) and Geisinger Indemnity Insurance Company (GIIC) Formulary Development by the Pharmacy). The results of this process determine the development and application 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 all lines of business, unless a specific limitation or exception exists.

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

ADDITIONAL DEFINITIONS:
1. **Formulary** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. **Non-formulary products** – those medications that are not included in the Formulary.
3. **Healthcare provider** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
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 12 years **AND**
- Medical record documentation of a diagnosis of sickle cell disease **AND**
- Medical record documentation of baseline hemoglobin **AND**
- Medical record documentation of therapeutic failure on, intolerance to, or contraindication to a minimum three (3) month trial of generic hydroxyurea **AND**
- Medical record documentation of therapeutic failure on, intolerance to, or contraindication to Endari **AND**
- If the requested dose is 2,500 mg daily: 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, enfalumide, mitotane, phenobarbital, phenytoin, primidone, rifampin, St. John’s Wort

**QUANTITY LIMIT:** Pharmacist note to CSR: *Authorization should be entered by HICL and only checking the Formulary PA required box (no QLs need to be entered within the authorization).*
- 3 tablets per day, 30 day supply per fill

**AUTHORIZATION DURATION:** Each treatment period will be defined as 12 months. 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 vasoocclusive crisis related emergencies) **AND**
- If the requested dose is 2,500 mg daily: 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

Date:  May 29, 2020

Devised:  5/29/20
Policymaker: Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is applied according to the formulary review process (see Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Part D Policy 143.0 D Geisinger Health Plan (GHP) and Geisinger Indemnity Insurance Company (GIIC) Formulary Development by the Pharmacy). The results of this process determine the development and application 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 all lines of business, unless a specific limitation or exception exists.

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

ADDITIONAL DEFINITIONS:
1. **Formulary** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. **Non-formulary products** – those medications that are not included in the Formulary.
3. **Healthcare provider** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
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 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:
  o Superficial keratopathy
  o Persistent epithelial defects
  o 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

QUANTITY LIMIT: Pharmacist note to CSR: Authorization should be entered by HICL and only checking the Formulary PA required box (no QLs need to be entered within the authorization).
- 56 vials per 28 days

AUTHORIZATION DURATION: 8 weeks
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:
Restasis, Xiidra

*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 29, 2020
Devised: 5/29/20
POLICY:
Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is applied according to the formulary review process (see Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Part D Policy 143.0 D Geisinger Health Plan (GHP) and Geisinger Indemnity Insurance Company (GIIC) Formulary Development by the Pharmacy). The results of this process determine the development and application 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 all lines of business, unless a specific limitation or exception exists.

REQUIRED DEFINITIONS:
1. **Attachment** – a supporting document that is developed and maintained by the policy writer or 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).
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 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

QUANTITY LIMIT: Pharmacist note to CSR: Authorization should be entered by HICL and only checking the Formulary PA required box (no QLs need to be entered within the authorization).

- 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.

FORMULARY ALTERNATIVES:
- Saphris*, 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: June 4, 2020

Devised: 6/4/20
POLICY AND PROCEDURE
PHARMACY
MANUAL

POLICY NUMBER: 625.0
SECTION: Commercial Drug
SUBJECT: Talicia

Applicable line of business:

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POLICY:
Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is applied according to the formulary review process (see Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Part D Policy 143.0 D Geisinger Health Plan (GHP) and Geisinger Indemnity Insurance Company (GIIC) Formulary Development by the Pharmacy). The results of this process determine the development and application 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 all lines of business, unless a specific limitation or exception exists.

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

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

QUANTITY LIMIT: Pharmacist note to CSR: Authorization should be entered by HICL and only checking the Formulary PA required box (no QLs need to be entered within the authorization).

• 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

THIS POLICY WILL BE MAINTAINED IN COMPLIANCE WITH THE STANDARDS OF NCQA AND ANY OTHER APPLICABLE 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 4, 2020
Devised:  6/4/20
POLICY AND PROCEDURE
PHARMACY
MANUAL

POLICY NUMBER: 626.0
SECTION: Commercial Drug
SUBJECT: Ubrelvy

Applicable line of business:

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POLICY:
Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is applied according to the formulary review process (see Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Part D Policy 143.0 D Geisinger Health Plan (GHP) and Geisinger Indemnity Insurance Company (GIIC) Formulary Development by the Pharmacy). The results of this process determine the development and application 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 all lines of business, unless a specific limitation or exception exists.

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).
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 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 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 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)

QUANTITY LIMIT: Pharmacist note to CSR: Authorization should be entered by HICL and only checking the Formulary PA required box (no QLs need to be entered within the authorization).
- 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.
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: July 28, 2020

Devised: 6/4/20
Revised: 7/28/20 – added concomitant CGRP criterion
POLICY NUMBER: 627.0

SECTION: Commercial Drug

SUBJECT: Pemazyre

POLICY AND PROCEDURE
PHARMACY
MANUAL

Applicable line of business:

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POLICY:
Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is applied according to the formulary review process (see Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Part D Policy 143.0 D Geisinger Health Plan (GHP) and Geisinger Indemnity Insurance Company (GIIC) Formulary Development by the Pharmacy). The results of this process determine the development and application 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 all lines of business, unless a specific limitation or exception exists.

REQUIRED DEFINITIONS:
1. Attachment – a supporting document that is developed and maintained by the policy writer or 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).
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;
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 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.

QUANTITY LIMIT: Pharmacist note to CSR: Authorization should be entered by HICL and only checking the Formulary PA required box (no QLs need to be entered within the authorization).

- 14 tablets per 21 days

AUTHORIZATION DURATION: Initial approval will be for 12 months. Subsequent approvals will be for an additional 12 months and will require medical record documentation of continued disease improvement or lack of disease progression.
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:  July 28, 2020

Devised:  7/28/20
REQUIRED DEFINITIONS:
1. **Attachment** – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. **Exhibit** – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. **Devised** – the date the policy was implemented.
4. **Revised** – the date of every revision to the policy, including typographical and grammatical changes.
5. **Reviewed** – the date documenting the annual review if the policy has no revisions necessary.

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

QUANTITY LIMIT: Pharmacist note to CSR: Authorization should be entered by HICL and only checking the Formulary PA required box (no QLs need to be entered within the authorization).

- 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

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, Gabitril, 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: July 28, 2020

Devised: 7/28/20
POLICY:
Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is applied according to the formulary review process (see Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Part D Policy 143.0 DGeisinger Health Plan (GHP) and Geisinger Indemnity Insurance Company (GIIC) Formulary Development by the Pharmacy). The results of this process determine the development and application 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 all lines of business, unless a specific limitation or exception exists.

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:
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3. **Healthcare provider** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
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;
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C. In accordance with current standards of medical practice;
D. Not primarily for the convenience of the Member, or the Member’s Provider; and
E. The most appropriate source or level of service that can safely be provided to the
Member. When applied to hospitalization, this further means that the Member
requires acute care as an inpatient due to the nature of the services 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:

- 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 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 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)

QUANTITY LIMIT: Pharmacist note to CSR: Authorization should be entered by HICL
and only checking the Formulary PA required box (no QLs need to be entered within the
authorization).
- 15 tablets per 30 days

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:
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: July 28, 2020

Devised: 7/28/20
POLICY NUMBER: 630.0

SECTION: Commercial Drug

SUBJECT: Palforzia

Applicable line of business:

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<thead>
<tr>
<th>Line of Business</th>
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<th>Medicaid</th>
<th>ACA</th>
<th>X</th>
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POLICY:
Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is applied according to the formulary review process (see Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Part D Policy 143.0 D Geisinger Health Plan (GHP) and Geisinger Indemnity Insurance Company (GIIC) Formulary Development by the Pharmacy). The results of this process determine the development and application 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 all lines of business, unless a specific limitation or exception exists.

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.
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3. **Healthcare provider** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
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D. Not primarily for the convenience of the Member, or the Member's Provider; and
E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services 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
QUANTITY LIMIT: Pharmacist note to CSR: Authorization should be entered by HICL and only checking the Formulary PA required box (no QLs need to be entered within the authorization).

<table>
<thead>
<tr>
<th>Packaging Presentation</th>
<th>Quantity Limits</th>
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<tbody>
<tr>
<td><strong>Initial Dose Escalation</strong></td>
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<tr>
<td>0.5 mg to 6 mg capsules</td>
<td>13 capsules / 1 day</td>
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<tr>
<td><strong>Up-Dosing</strong></td>
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<tr>
<td>3 mg (Level 1)</td>
<td>3 capsules / day, 30 day supply per fill</td>
</tr>
<tr>
<td>6 mg (Level 2)</td>
<td>6 capsules / day, 30 day supply per fill</td>
</tr>
<tr>
<td>12 mg (Level 3)</td>
<td>3 capsules / day, 30 day supply per fill</td>
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<tr>
<td>20 mg (Level 4)</td>
<td>1 capsule / day, 30 day supply per fill</td>
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<tr>
<td>40 mg (Level 5)</td>
<td>2 capsules / day, 30 day supply per fill</td>
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<tr>
<td>80 mg (Level 6)</td>
<td>4 capsules / day, 30 day supply per fill</td>
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<tr>
<td>120 mg (Level 7)</td>
<td>2 capsules / day, 30 day supply per fill</td>
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<tr>
<td>160 mg (Level 8)</td>
<td>4 capsules / day, 30 day supply per fill</td>
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<tr>
<td>200 mg (Level 9)</td>
<td>2 capsules / day, 30 day supply per fill</td>
</tr>
<tr>
<td>240 mg (Level 10)</td>
<td>4 capsules / day, 30 day supply per fill</td>
</tr>
<tr>
<td>300 mg (Level 11)</td>
<td>1 packet / day, 30 day supply per fill</td>
</tr>
<tr>
<td><strong>Maintenance</strong></td>
<td></td>
</tr>
<tr>
<td>300 mg (Level 11)</td>
<td>1 packet / day, 30 day supply per fill</td>
</tr>
</tbody>
</table>

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.
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: October 13, 2020

Devised: 7/28/20
Revised: 10/13/20 – removed Pemazyre criteria
Applicable line of business:

<table>
<thead>
<tr>
<th>Line of Business</th>
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POLICY:
Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is applied according to the formulary review process (see Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Part D Policy 143.0 D Geisinger Health Plan (GHP) and Geisinger Indemnity Insurance Company (GIIC) Formulary Development by the Pharmacy). The results of this process determine the development and application 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 all lines of business, unless a specific limitation or exception exists.

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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3. **Healthcare provider** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
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 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

QUANTITY LIMIT: Pharmacist note to CSR: Authorization should be entered by HICL and only checking the Formulary PA required box (no QLs need to be entered within the authorization).
  • 90 tablets per 30 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 the member experiences unacceptable toxicity or worsening of disease.

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*, Sutent*, 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: July 28, 2020

Devised: 7/28/20
Applicable line of business:

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POLICY:
Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is applied according to the formulary review process (see Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Part D Policy 143.0 D Geisinger Health Plan (GHP) and Geisinger Indemnity Insurance Company (GIIC) Formulary Development by the Pharmacy). The results of this process determine the development and application 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 all lines of business, unless a specific limitation or exception exists.

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:
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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 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:
  o Documentation that systemic therapy is required **AND**
  o Documentation that member is radioactive-iodine refractory when radioactive iodine is appropriate
QUANTITY LIMIT: Pharmacist note to CSR: Authorization should be entered by HICL and only checking the Formulary PA required box (no QLs need to be entered within the authorization).

- 40 mg capsules: 2 capsules per day, 30 day supply per fill
- 80 mg capsules: 4 capsules 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 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 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
Date:  July 28, 2020
Devised:  7/28/20
Applicable line of business:

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C. In accordance with current standards of medical practice;
D. Not primarily for the convenience of the Member, or the Member's Provider; and
E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services 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

QUANTITY LIMIT: Pharmacist note to CSR: Authorization should be entered by HICL and only checking the Formulary PA required box (no QLs need to be entered within the authorization).

- 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.

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
POLICY AND PROCEDURE
PHARMACY
MANUAL

POLICY NUMBER: 633.0

SECTION: Commercial Drug
SUBJECT: Reyvow

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

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

Signed:_______________________________________________

Title:  Director, Pharmacy Services

Date:  July 28, 2020

Devised:  7/28/20
POLICY NUMBER: 634.0

POLICY AND PROCEDURE
PHARMACY
MANUAL

SECTION: Commercial Drug
SUBJECT: Tabrecta

Applicable line of business:

<table>
<thead>
<tr>
<th>Line of Business</th>
<th>Commercial</th>
<th>Medicaid</th>
<th>Medicare</th>
<th>ACA</th>
<th>GHP Kids</th>
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</table>

POLICY:
Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is applied according to the formulary review process (see Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Part D Policy 143.0 D Geisinger Health Plan (GHP) and Geisinger Indemnity Insurance Company (GIIC) Formulary Development by the Pharmacy). The results of this process determine the development and application 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 all lines of business, unless a specific limitation or exception exists.

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

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

QUANTITY LIMIT: Pharmacist note to CSR: Authorization should be entered by HICL and only checking the Formulary PA required box (no QLs need to be entered within the authorization).
- 4 tablets 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. 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 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: July 28, 2020

Devised: 7/28/20
POLICY:  
Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is applied according to the formulary review process (see Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Part D Policy 143.0 D Geisinger Health Plan (GHP) and Geisinger Indemnity Insurance Company (GIIC) Formulary Development by the Pharmacy). The results of this process determine the development and application 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 all lines of business, unless a specific limitation or exception exists.

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

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

QUANTITY LIMIT: Pharmacist note to CSR: Authorization should be entered by HICL and only checking the Formulary PA required box (no QLs need to be entered within the authorization).
- 4 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 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 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:  July 28, 2020

Devised:  7/28/20
POLICY:
Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is applied according to the formulary review process (see Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Part D Policy 143.0 D Geisinger Health Plan (GHP) and Geisinger Indemnity Insurance Company (GIIC) Formulary Development by the Pharmacy). The results of this process determine the development and application 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 all lines of business, unless a specific limitation or exception exists.

REQUIRED DEFINITIONS:
1. **Attachment** – a supporting document that is developed and maintained by the policy writer or 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).
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

QUANTITY LIMIT: Pharmacist note to CSR: Authorization should be entered by HICL and only checking the Formulary PA required box (no QLs need to be entered within the authorization).

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

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

Signed: ______________________________________________________
Title: Director, Pharmacy Services
Date: October 5, 2020
Devised: 10/5/20
POLICY AND PROCEDURE
PHARMACY
MANUAL

POLICY NUMBER: 637.0
SECTION: Commercial Drug
SUBJECT: Fintepla

Applicable line of business:

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<th>GHP Kids</th>
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</table>

POLICY:
Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is applied according to the formulary review process (see Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Part D Policy 143.0 D Geisinger Health Plan (GHP) and Geisinger Indemnity Insurance Company (GIIC) Formulary Development by the Pharmacy). The results of this process determine the development and application 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 all lines of business, unless a specific limitation or exception exists.

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

ADDITIONAL DEFINITIONS:
1. **Formulary** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. **Non-formulary products** – those medications that are not included in the Formulary.
3. **Healthcare provider** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
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 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 Dravet Syndrome AND
- Medical record documentation of therapeutic failure on, intolerance to, or contraindication to two (2) formulary alternatives

QUANTITY LIMIT: Pharmacist note to CSR: Authorization should be entered by HICL and only checking the Formulary PA required box (no QLs need to be entered within the authorization).

- 12 mL per day

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

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+), Gabitril (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:  October 5, 2020

Devised:  10/5/20
POLICY:
Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is applied according to the formulary review process (see Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Part D Policy 143.0 D Geisinger Health Plan (GHP) and Geisinger Indemnity Insurance Company (GIIC) Formulary Development by the Pharmacy). The results of this process determine the development and application 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 all lines of business, unless a specific limitation or exception exists.

REQUIRED DEFINITIONS:
1. **Attachment** – a supporting document that is developed and maintained by the policy writer or 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).
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 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

QUANTITY LIMIT: Pharmacist note to CSR: Authorization should be entered by HICL and only checking the Formulary PA required box (no QLs need to be entered within the authorization).

- 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.

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:    October 5, 2020

Devised:    10/5/20
POLICY: Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is applied according to the formulary review process (see Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Part D Policy 143.0 D Geisinger Health Plan (GHP) and Geisinger Indemnity Insurance Company (GIIC) Formulary Development by the Pharmacy). The results of this process determine the development and application 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 all lines of business, unless a specific limitation or exception exists.

REQUIRED DEFINITIONS:
1. **Attachment** – a supporting document that is developed and maintained by the policy writer or 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).
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 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

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.

Signed:____________________________________
Title: Director, Pharmacy Services
Date: October 12, 2020
POLICY AND PROCEDURE
PHARMACY
MANUAL

POLICY NUMBER: 640.0
SECTION: Commercial Drug
SUBJECT: Nexletol

Applicable line of business:

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<th>Commercial</th>
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<th>Medicare</th>
<th>ACA</th>
<th>GHP Kids</th>
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POLICY:
Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is applied according to the formulary review process (see Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Part D Policy 143.0 D Geisinger Health Plan (GHP) and Geisinger Indemnity Insurance Company (GIIC) Formulary Development by the Pharmacy). The results of this process determine the development and application 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 all lines of business, unless a specific limitation or exception exists.

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

ADDITIONAL DEFINITIONS:
1. **Formulary** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. **Non-formulary products** – those medications that are not included in the Formulary.
3. **Healthcare provider** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
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 European Society of Cardiology/European Atherosclerosis Society (ESC/EAS) guidelines and the World Health Organization 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
  - 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

**QUANTITY LIMIT:** Pharmacist note to CSR: *Authorization should be entered by HICL and only checking the Formulary PA required box (no QLs need to be entered within the authorization).*

  • 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.**

Signed: __________________________

Title: Director, Pharmacy Services

Date: November 17, 2020

Devised: 11/17/20
POLICY AND PROCEDURE
PHARMACY
MANUAL

POLICY NUMBER: 641.0

SECTION: Commercial Drug
SUBJECT: Nexlizet

Applicable line of business:
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<th>Medicare</th>
<th>ACA</th>
<th>GHP Kids</th>
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POLICY:
Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is applied according to the formulary review process (see Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Part D Policy 143.0 D Geisinger Health Plan (GHP) and Geisinger Indemnity Insurance Company (GIIC) Formulary Development by the Pharmacy). The results of this process determine the development and application 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 all lines of business, unless a specific limitation or exception exists.

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

ADDITIONAL DEFINITIONS:
1. **Formulary** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. **Non-formulary products** – those medications that are not included in the Formulary.
3. **Healthcare provider** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
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 European Society of Cardiology/European Atherosclerosis Society (ESC/EAS) guidelines and the World Health Organization 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
- 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

QUANTITY LIMIT: Pharmacist note to CSR: Authorization should be entered by HICL and only checking the Formulary PA required box (no QLs need to be entered within the authorization).
  • 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.
POLICY AND PROCEDURE
PHARMACY
MANUAL

POLICY NUMBER: 642.0
SECTION: Commercial Drug
SUBJECT: Santyl

Applicable line of business:

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POLICY:
Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is applied according to the formulary review process (see Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Part D Policy 143.0 D Geisinger Health Plan (GHP) and Geisinger Indemnity Insurance Company (GIIC) Formulary Development by the Pharmacy). The results of this process determine the development and application 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 all lines of business, unless a specific limitation or exception exists.

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

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

AUTHORIZATION DURATION: Initial approval will be for 3 months. Subsequent
approval will be for 3 months. Reauthorization will require medication record
documentation that continued use of Santyl ointment is medically necessary because
debridement of necrotic tissue is incomplete and granulation of tissue is not well
established.

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
POLICY NUMBER: 642.0

SECTION: Commercial Drug

SUBJECT: Santyl

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

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

Signed: ____________________________________________

Title: Director, Pharmacy Services

Date: November 18, 2020

Devised: 11/18/20
Applicable line of business:

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POLICY:

Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is applied according to the formulary review process (see Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Part D Policy 143.0 Geisinger Health Plan (GHP) and Geisinger Indemnity Insurance Company (GIIC) Formulary Development by the Pharmacy). The results of this process determine the development and application 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 all lines of business, unless a specific limitation or exception exists.

REQUIRED DEFINITIONS:

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

ADDITIONAL DEFINITIONS:

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

QUANTITY LIMIT: Pharmacist note to CSR: Authorization should be entered by HICL and only checking the Formulary PA required box (no QLs need to be entered within the authorization).
- 5 tablets 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 the member experiences unacceptable toxicity or worsening of disease.
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: November 17, 2020

Devised: 11/17/20
POLICY: 
Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is applied according to the formulary review process (see Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Part D Policy 143.0 D Geisinger Health Plan (GHP) and Geisinger Indemnity Insurance Company (GIIC) Formulary Development by the Pharmacy). The results of this process determine the development and application 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 all lines of business, unless a specific limitation or exception exists.

REQUIRED DEFINITIONS:
1. **Attachment** – a supporting document that is developed and maintained by the policy writer or 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).
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 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

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.

*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: November 18, 2020

Devised: 11/18/20
POLICY AND PROCEDURE
PHARMACY
MANUAL

POLICY NUMBER: 645.0
SECTION: Commercial Drug
SUBJECT: Gavreto

Applicable line of business:

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POLICY:
Geisinger Health Plan (GHP) administers a pharmacy benefit through the use of a formulary. The formulary is applied according to the formulary review process (see Pharmacy Policy 2.0 Geisinger Health Plan (GHP) Formulary Application and Recalls, Pharmacy Policy 3.0 Geisinger Health Plan (GHP) Formulary Exception, and Pharmacy Part D Policy 143.0 D Geisinger Health Plan (GHP) and Geisinger Indemnity Insurance Company (GIIC) Formulary Development by the Pharmacy). The results of this process determine the development and application 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 all lines of business, unless a specific limitation or exception exists.

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

- 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*

*NOTE: The FDA approved companion diagnostic test for Gavreto to determine the presence of a RET gene fusion is the Oncomine Dx Target Test.

QUANTITY LIMIT: Pharmacist note to CSR: Authorization should be entered by HICL and only checking the Formulary PA required box (no QLs need to be entered within the authorization).
- 4 capsules 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 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 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

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

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

Signed: ________________________________
Title: Director, Pharmacy Services
Date: November 18, 2020
Devised: 11/18/20
POLICY AND PROCEDURE
PHARMACY
MANUAL

POLICY NUMBER: 646.0
SECTION: Commercial Drug
SUBJECT: Onureg

Applicable line of business:

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POLICY:
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REQUIRED DEFINITIONS:
1. Attachment – a supporting document that is developed and maintained by the policy writer or 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).
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 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

QUANTITY LIMIT: Pharmacist note to CSR: Authorization should be entered by HICL and only checking the Formulary PA required box (no QLs need to be entered within the authorization).
- 14 tablets per 28 days

AUTHORIZATION DURATION: Initial approval will be for 12 months. Subsequent approvals will be for an additional 12 months 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 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: [Signature]

Title: Director, Pharmacy Services

Date: November 18, 2020

Devised: 11/18/20