<table>
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<td>UBRELVY</td>
</tr>
<tr>
<td>1527.0F</td>
<td>OXERVATE</td>
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</table>
PROCEDURE:

Coverage of **linezolid oral suspension** will be restricted to those who meet one of the following criteria:

1. Medical record documentation of Vancomycin-Resistant Enterococcus (VRE) faecium infection which has been diagnosed and documented with Infectious Disease consultation.
2. 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.
3. 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.
4. Medical record documentation of a diagnosis of uncomplicated skin and skin structure infections caused by *Staphylococcus aureus* (MSSA only) or *Streptococcus pyogenes* which has been diagnosed and documented with Infectious Disease consultation.
5. Medical record documentation of a diagnosis of Community-acquired pneumonia caused by *Streptococcus pneumoniae* or *Staphylococcus aureus* (MSSA only) which has been diagnosed and documented with Infectious Disease consultation AND

6. **For all indications** – 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 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 tablets:**

1. QL of 2 tablets per day, 28 day supply per fill, maximum of 56 day supply within a 180 window.
2. For quantity limit exception requests beyond 8 weeks of therapy in 180 days: Medical record documentation of an infectious disease consultation documenting continued need of linezolid therapy. Authorization duration will be for 28 days. Authorization for a duration longer than 28 days would be based on indication.

**Formulary alternatives:** Sivextro*

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

Reviewer should refer to the process and procedure in GHP Family Policy 4.0F Geisinger Health Plan (GHP) Formulary Exception/Prior Authorization for additional information.

This policy will be maintained in compliance with the standards of any applicable state and federal regulatory entities.
PROCEDURE:
Prior authorization of Pulmozyme** will be made for members who meet all of the following criteria:

1. There is medical record documentation of a diagnosis of cystic fibrosis (CF).
2. There is medical record documentation that Pulmozyme** is being prescribed by a pulmonologist.

**Quantity Limit: 30 units per 30 days (75 mL per 30 days)

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 GHP Family Policy 4.0F Geisinger Health Plan (GHP) Formulary Exception/Prior Authorization for additional information.

This policy will be maintained in compliance with the standards of any applicable state and federal regulatory entities.
PROCEDURE:
Prior authorization of Kuvan will be made for members who meet the following criteria:

Medical record documentation of the following criteria:

1. Prescription is written by a metabolic specialist AND
2. A diagnosis of hyperphenylalaninemia (baseline blood Phe level ≥ 360 μmol/L)) AND
3. A baseline Phe level AND
4. The patient 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.

FORMULARY ALTERNATIVES: none

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 GHP Family Policy 4.0F Geisinger Health Plan (GHP) Formulary Exception/Prior Authorization for additional information.

This policy will be maintained in compliance with the standards of any applicable state and federal regulatory entities.
PROCEDURE:
Prior authorization of Kalydeco will be made for members who meet the following criteria:
Medical record documentation of:
1. Prescription written by a pulmonologist or Cystic Fibrosis Specialist AND
2. Age greater than or equal to 6 months AND
3. Medical record documentation of one mutation in the CFTR gene that is responsive to ivacaftor potentiation per product labeling as evidenced by an FDA cleared CF mutation test AND
4. Medical record documentation that the patient is not homozygous for the F508del mutation in the CFTR gene

Note to reviewer: List of CFTR gene mutations that are responsive to Kalydeco:

<table>
<thead>
<tr>
<th>Mutation</th>
<th>D110H</th>
<th>F1052V</th>
<th>G551S</th>
<th>R117H</th>
<th>S549R</th>
</tr>
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<tbody>
<tr>
<td>2789+5G→A</td>
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<tr>
<td>3272-26A→G</td>
<td>D1152H</td>
<td>F1074L</td>
<td>K1060T</td>
<td>R347H</td>
<td>S945L</td>
</tr>
<tr>
<td>3849+10kbC→T</td>
<td>D1270N</td>
<td>G1069R</td>
<td>L206W</td>
<td>R352Q</td>
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<td>711+3A→G</td>
<td>D579G</td>
<td>G1244E</td>
<td>P67L</td>
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<td>E831X</td>
<td>G551D</td>
<td>R117C</td>
<td>S549N</td>
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</table>

**QUANTITY LIMITS:** 68 tablets/packets per 34 days

**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 or, based on the prescriber’s assessment, the member continues to benefit from Kalydeco.

**FORMULARY ALTERNATIVES –** None

Distribution limited to specialty pharmacy.

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 GHP Family Policy 4.0F Geisinger Health Plan (GHP) Formulary Exception/Prior Authorization for additional information.

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

GRANDFATHER PROVISION – Members already established on therapy are eligible for approval as long as there is medical record documentation that the safety and effectiveness of use for the prescribed indication is supported by Food and Drug Administration (FDA) approval or adequate medical and scientific evidence in the medical literature.

Prior authorization of Sylatron will be made for members who meet the following criteria:

1. Prescription written by an oncologist or dermatologist AND
2. 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.

Quantity Limit: 4 syringes per 28 days for each strength

FORMULARY ALTERNATIVES: Intron A

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 GHP Family Policy 4.0F Geisinger Health Plan (GHP) Formulary Exception/Prior Authorization for additional information.

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

Prior authorization of Sucraid will be made for members who meet all of the following criteria:

1. Order is written by a Gastroenterologist, Endocrinologist or Genetic Specialist
2. Member has medical documentation of a diagnosis of congenital sucrase-isomaltase deficiency characterized by stool pH less than 6 **AND**
3. Has an increase in breath hydrogen of greater than 10ppm when challenged with sucrose after fasting **AND**
4. Has a negative lactose breath test **OR**
5. Has a diagnosis of congenital sucrase-isomaltase deficiency characterized by low sucrose activity on duodenal biopsy **AND**
6. Other disaccharidases normal on same duodenal biopsy.

Quantity Limit: one box (containing 2 bottles) per fill

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

Reviewer should refer to the process and procedure in GHP Family Policy 4.0F Geisinger Health Plan (GHP) Formulary Exception/Prior Authorization for additional information.

This policy will be maintained in compliance with the standards any applicable state and federal regulatory entities.
PROCEDURE:

GRANDFATHER PROVISION – Members already established on therapy are eligible for approval as long as there is medical record documentation that the safety and effectiveness of use for the prescribed indication is supported by Food and Drug Administration (FDA) approval or adequate medical and scientific evidence in the medical literature.

Prior authorization of Bexarotene will be made for members who meet all of the following criteria:

1. Prescription is written by an Oncologist or Dermatologist AND
2. There is medical documentation of a diagnosis of Cutaneous T-cell Lymphoma (CTCL) AND
3. There is medical documentation of failure on, intolerance to, or contraindication to one prior systemic therapy for Bexarotene Capsules OR one prior therapy for Targretin Gel

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

Reviewer should refer to the process and procedure in GHP Family Policy 4.0F Geisinger Health Plan (GHP) Formulary Exception/Prior Authorization for additional information.

This policy will be maintained in compliance with the standards any applicable state and federal regulatory entities.
PROCEDURE:
Prior authorization is required for compounded prescriptions that contain any nonformulary drugs or cost $200.00 or greater (for up to a one month supply). Prior authorization of compounded prescriptions will be given if the following criteria are met:

1. The compounded medication does not contain any items precluded from coverage (i.e. items for a cosmetic purpose or erectile dysfunction) AND
2. The compounded medication contains at least one medication that is an OTC agent, a legend drug, or a bulk chemical in therapeutic quantities AND
3. The safety and effectiveness of use for the prescribed indication is supported by FDA-approval or adequate medical and scientific evidence in the medical literature or compendia listings AND
4. Medical record documentation of therapeutic failure on, contraindication to, or intolerance to formulary alternatives if available

**A prescription is required for dispensing. **

**Compounds of products for a diagnosis for which there is no FDA approved treatment indication or the indication is not recognized in a national compendium are excluded from coverage (i.e., natural hormones). **

Claims for compounded prescriptions must be submitted at the point of service through the electronic claims processing system and will be paid at the usual and customary fee charged by the compounding pharmacist.

Reviewer should refer to the process and procedure in GHP Family Policy 4.0F Geisinger Health Plan (GHP) Formulary Exception/Prior Authorization for additional information.

This policy will be maintained in compliance with the standards of any applicable state and federal regulatory entities.
PROCEDURE:
Prior authorization of Riluzole will be made for members who meet the following criteria:

1. There is medical record documentation of a diagnosis of amyotrophic lateral sclerosis (ALS; Lou Gehrig’s disease).

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

Reviewer should refer to the process and procedure in GHP Family Policy 4.0F Geisinger Health Plan (GHP) Formulary Exception/Prior Authorization for additional information.

This policy will be maintained in compliance with the standards of any applicable state and federal regulatory entities.
PROCEDURE:
Prior authorization of Elmiron will be made for members who meet all of the following criteria:

1. There is medical record documentation of a diagnosis of interstitial cystitis.
2. The prescription is written by or in consultation with 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 GHP Family Policy 4.0F Geisinger Health Plan (GHP) Formulary Exception/Prior Authorization for additional information.

This policy will be maintained in compliance with the standards of any applicable state and federal regulatory entities.
PROCEDURE:
Prior authorization of Actimmune will be made for members who meet the following criterion:

The member has a medical record documentation of a diagnosis of one of the following:
   A. chronic granulomatous disease
   B. osteoporosis

FORMULARY ALTERNATIVES: none

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 GHP Family Policy 4.0F Geisinger Health Plan (GHP) Formulary Exception/Prior Authorization for additional information.

This policy will be maintained in compliance with the standards of any applicable state and federal regulatory entities.
PROCEDURE:
Prior authorization of Somavert will be made for members who meet ALL of the following criteria:

1. Prescription must be written by an endocrinologist.
2. There is medical record documentation of a diagnosis of acromegaly.
3. The member is ≥ 18 years of age.
4. There is medical record documentation of failure, intolerance to or contraindication with Somatuline Depot*

FORMULARY ALTERNATIVES: Bromocriptine, Somatuline Depot* (*Requires prior authorization)

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 GHP Family Policy 4.0F Geisinger Health Plan (GHP) Formulary Exception/Prior Authorization for additional information.

This policy will be maintained in compliance with the standards of any applicable state and federal regulatory entities.
PROCEDURE:
Prior authorization of Gelclair will be made for members who meet the following criteria:

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

FORMULARY ALTERNATIVES: sucralfate tablets or Maalox + viscous lidocaine + (otc) benadryl liquid = Magic Mouthwash Compound

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 GHP Family Policy 4.0F Geisinger Health Plan (GHP) Formulary Exception/Prior Authorization for additional information.

This policy will be maintained in compliance with the standards of any applicable state and federal regulatory entities.
PROCEDURE:
Prior authorization of Moviprep or Suprep will be made for members who meet the following criteria:

1. Medical record documentation that the member is scheduled for a gastroenterological procedure.
2. Medical record documentation of a therapeutic failure on, intolerance to, or contraindication to PEG + electrolytes.


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

Reviewer should refer to the process and procedure in GHP Family Policy 4.0F Geisinger Health Plan (GHP) Formulary Exception/Prior Authorization for additional information.

This policy will be maintained in compliance with the standards of any applicable state and federal regulatory entities.
PROCEDURE:
Prior authorization of Veregen will be made for members who meet the following criteria:

Medical record documentation of both of the following criteria:

1. Member is 18 years old or older and is immunocompetent
2. Therapeutic failure on, intolerance to, or contraindication to podofilox solution and imiquimod (generic Aldara)

FORMULARY ALTERNATIVES: Podofilox solution, 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 GHP Family Policy 4.0F Geisinger Health Plan (GHP) Formulary Exception/Prior Authorization for additional information.

This policy will be maintained in compliance with the standards of any applicable state and federal regulatory entities.
PROCEDURE:
Prior authorization of Xyrem will be made for members who meet the following criteria:
Medical record documentation of the following criteria:
1. Diagnosis of an FDA approved indication AND
2. For cataplexy with narcolepsy, medical record documentation of failure on, intolerance to or contraindication to venlafaxine XR or fluoxetine OR
3. For excessive daytime sleepiness with narcolepsy:
   a. For patients 18 years and older, medical record documentation of failure on, intolerance to or contraindication to any of the following: modafinil* AND methylphenidate IR or amphetamine/dextroamphetamine IR OR
   b. For patients 7-17 years, medical record documentation of failure on, intolerance to methylphenidate IR or amphetamine/dextroamphetamine IR

QUANTITY LIMITS: 18ml/day, max 30 days supply per fill

FORMULARY ALTERNATIVES: Dextroamphetamine, dextroamphetamine/amphetamine combination, methylphenidate, modafinil*, venlafaxine ER, fluoxetine (*Requires prior authorization)

Please note: all formulary alternatives, except venlafaxine ER and fluoxetine, quantity limits

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 GHP Family Policy 4.0F Geisinger Health Plan (GHP) Formulary Exception/Prior Authorization for additional information.

This policy will be maintained in compliance with the standards of any applicable state and federal regulatory entities.
PROCEDURE:
Prior authorization of Spacer or Mask for an MDI will be made for members who meet the following criteria:

- Medical record documentation of therapeutic failure on Optichamber

The member will be limited to 1 unit per fill, 2 spacers/masks per calendar year

FORMULARY ALTERNATIVES: Optichamber

If an exception is made, a Spacer or Mask for an MDI will be paid for under the member’s prescription drug benefit.

Reviewer should refer to the process and procedure in GHP Family Policy 4.0F Geisinger Health Plan (GHP) Formulary Exception/Prior Authorization for additional information.

This policy will be maintained in compliance with the standards of any applicable state and federal regulatory entities.
PROCEDURE:
Prior authorization of Cycloset will be made for members who meet the following criteria:

1. Medical record documentation of therapeutics failure on, intolerance to, or contraindication to 3 oral formulary alternatives

FORMULARY ALTERNATIVES: see Statewide PDL https://papdl.com/preferred-drug-list

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 GHP Family Policy 4.0F Geisinger Health Plan (GHP) Formulary Exception/Prior Authorization for additional information.

This policy will be maintained in compliance with the standards of any applicable state and federal regulatory entities.
PROCEDURE:
Prior authorization of Korlym** will be made for members who meet the following criteria:

Medical record documentation of:

1. Prescription written by an endocrinologist AND
2. Medical record documentation of a negative pregnancy test within 14 days of initiating Korlym therapy in women of reproductive potential AND
3. Medical record documentation of a diagnosis of endogenous Cushing’s syndrome AND
4. Medical record documentation of failed surgical treatment for Cushing’s syndrome or that the patient is not a candidate for surgery AND
5. Medical record documentation of therapeutic failure or, contraindication to, or intolerance to insulin AND a sulfonylurea AND a TZD AND either a DPP-4 inhibitor OR aGLP-1 receptor agonist

**QUANTITY LIMITS: 4 tablets per day

FORMULARY ALTERNATIVES: None

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 GHP Family Policy 4.0F Geisinger Health Plan (GHP) Formulary Exception/Prior Authorization for additional information.

This policy will be maintained in compliance with the standards of any applicable state and federal regulatory entities.
PROCEDURE:
Prior authorization of Picato** will be made for members who meet the following criteria:

- Medical record documentation that the prescription is written by a dermatologist AND
- Medical record documentation of greater than or equal to 4 lesions within a contiguous 25 cm² area AND
- Medical record documentation of a therapeutic failure on, intolerance to, or contraindication to topical fluorouracil

**QUANTITY LIMITS: 1 package (2 or 3 tubes depending on strength) per dispensing

FORMULARY ALTERNATIVES: topical fluorouracil

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 GHP Family Policy 4.0F Geisinger Health Plan (GHP) Formulary Exception/Prior Authorization for additional information.

This policy will be maintained in compliance with the standards of any applicable state and federal regulatory entities.
PROCEDURE:
Prior authorization of a non-Statewide Preferred Drug List branded medication, for which there is an AB-rated generic, will be made for members who meet the following criterion:

The member has:
- medical record documentation of a therapeutic failure on, or intolerance to the generic formulary agent(s) OR
- an intolerance to or contraindication to the inactive ingredients of the generic formulary agent(s) AND
- medical record documentation of a therapeutic failure on, or intolerance to or contraindication to up to three formulary alternatives if available

OR

- The medication is considered to have a narrow therapeutic index and the patient is currently stable on the requested narrow therapeutic index medication.

FORMULARY ALTERNATIVES: formulary class alternatives

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 GHP Family Policy 4.0F Geisinger Health Plan (GHP) Formulary Exception/Prior Authorization for additional information.

This policy will be maintained in compliance with the standards any applicable state and federal regulatory entities.
PROCEDURE:
Prior authorization of Albendazole will be made for members who meet the following criteria:

1. Medical record documentation of use for an FDA approved indication (Hydatid Disease or Neurocysticercosis) OR
2. Medical record documentation of use to treat *Enterobius vermicularis* (pinworm) infection*

*Quantity Limit: 4 tablets per 30 days

FORMULARY ALTERNATIVES: None

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 GHP Family Policy 4.0F Geisinger Health Plan (GHP) Formulary Exception/Prior Authorization for additional information.

This policy will be maintained in compliance with the standards of any applicable state and federal regulatory entities.
PROCEDURE:
Prior authorization of Albenza will be made for members who meet the following criteria:

1. Medical record documentation of use for an FDA approved indication (Hydatid Disease or Neurocysticercosis) OR
2. Medical record documentation of use to treat Enterobius vermicularis (pinworm) infection*

*Quantity Limit: 4 tablets per 30 days

FORMULARY ALTERNATIVES: None

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

Reviewer should refer to the process and procedure in GHP Family Policy 4.0F Geisinger Health Plan (GHP) Formulary Exception/Prior Authorization for additional information.

This policy will be maintained in compliance with the standards of any applicable state and federal regulatory entities.
PROCEDURE:
Prior authorization of H.P. Acthar Gel will be made for members who meet one of the following criteria:

1) For acute exacerbations of MS:
   A) Prescribed by a neurologist AND
   B) Documentation of non-response to steroids or clearly identifiable reason a steroid cannot be used. Must try three different steroids (i.e. Medrol, prednisone, and Decadron) or two courses of two different steroids

2) For infantile myoclonic seizures (infantile spasms):
   A) Documentation that the member is < 2 years of age AND
   B) Must be prescribed by neurologist AND
   C) Documentation of diagnosis confirmed by EEG

   OR

3) Rheumatic Disorders:
   A) Prescribed by a rheumatologist or documentation of rheumatology consult AND
   B) Documented diagnosis of a medically accepted indication: adjunctive therapy for short-term administration (to tide the patient over an acute episode or exacerbation) in: psoriatic arthritis, rheumatoid arthritis, including juvenile rheumatoid arthritis (selected cases may require low-dose maintenance therapy), ankylosing spondylitis AND
   C) Use of H.P. Acthar Gel for treatment of corticosteroid-responsive conditions will require documentation of non-response to steroids or clearly identifiable reason a steroid cannot be used. Must try two different steroids (i.e. Medrol and Decadron) or two courses of same steroid

   OR

4) Collagen Diseases:
   A) Prescribed by a rheumatologist/dermatologist or documentation of rheumatology/dermatology consult AND
   B) Documented diagnosis of a medically accepted indication: During an exacerbation or as maintenance therapy in selected cases of: systemic lupus erythematosus, systemic dermatomyositis (polymyositis) AND
C) Use of H.P. Acthar Gel for treatment of corticosteroid-responsive conditions will require
documentation of non-response to steroids or clearly identifiable reason a steroid cannot be
used. Must try two different steroids (i.e. Medrol and Decadron) or two courses of same
steroid

OR

5) Dermatologic Diseases

A) Prescribed by a dermatologist or documentation of dermatology consult AND
B) Documented diagnosis of a medically accepted indication: Severe erythema multiforme, Stevens-
Johnson syndrome AND
C) Use of H.P. Acthar Gel for treatment of corticosteroid-responsive conditions will require
documentation of non-response to steroids or clearly identifiable reason a steroid cannot be used.
Must try two different steroids (i.e. Medrol and Decadron) or two courses of same steroid

OR

6) Allergic States

A) Prescribed by an allergist or documentation of allergist consult AND
B) Documented diagnosis of a medically accepted indication: Serum sickness AND
C) Use of H.P. Acthar Gel for treatment of corticosteroid-responsive conditions will require
documentation of non-response to steroids or clearly identifiable reason a steroid cannot be used.
Must try two different steroids (i.e. Medrol and Decadron) or two courses of same steroid

OR

7) Ophthalmic Diseases

A) Prescribed by an ophthalmologist or documentation of ophthalmology consult AND
B) Documented diagnosis of a medically accepted indication: Severe acute and chronic allergic and
inflammatory processes involving the eye and its adnexa such as: keratitis, iritis, iridocyclitis,
diffuse posterior uveitis and choroiditis, optic neuritis, chorioretinitis, anterior segment inflammation
AND
C) Use of H.P. Acthar Gel for treatment of corticosteroid-responsive conditions will require
documentation of non-response to steroids or clearly identifiable reason a steroid cannot be used.
Must try two different steroids or two courses of same steroid

OR

8) Respiratory Diseases
A) Prescribed by a pulmonologist or documentation of pulmonology consult AND
B) Documented diagnosis of a medically accepted indication: Symptomatic sarcoidosis AND
C) Use of H.P. Acthar Gel for treatment of corticosteroid-responsive conditions will require documentation of non-response to steroids or clearly identifiable reason a steroid cannot be used. Must try two different steroids (i.e. Medrol and Decadron) or two courses of same steroid

OR

9) Edematous State

A) Prescribed by a nephrologist or documentation of nephrology consult AND
B) Documented diagnosis of a medically accepted indication: To induce a remission of proteinuria in the nephrotic syndrome AND
C) Use of H.P. Acthar Gel in nephrotic syndrome will require medical record documentation demonstrating failure to respond or contraindication to current standard of care therapy as defined in UptoDate

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

Note: Use of H.P. Acthar Gel for treatment of glucocorticoid-responsive conditions will require documentation of medical contraindication or intolerance (i.e. severe anaphylaxis) to corticosteroids that are not also expected to occur with H.P. Acthar Gel

All other uses of H.P. Acthar Gel will not be covered without a case review by a medical director

If an exception is made, H.P. Acthar Gel will be paid for under the member's prescription drug benefit.

Reviewer should refer to the process and procedure in GHP Family Policy 4.0F Geisinger Health Plan (GHP) Formulary Exception/Prior Authorization for additional information.

This policy will be maintained in compliance with the standards of any applicable state and federal regulatory entities.
PROCEDURE:
Prior authorization of Gattex will be made for members who meet the following criteria:

- Prescription is written by a gastroenterologist AND
- Member is ≥1 year of age AND
- Medical record documentation of a diagnosis of short bowel syndrome AND

If age 1 to 17 years of age:
- Medical record documentation that the member is dependent on parenteral nutrition/intravenous support

If age ≥ 18 years of age:
- 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

If approved, authorization will be for an initial duration of six (6) months. For continuation, medical record documentation of a decrease of at least 20% volume of parenteral nutrition/intravenous support from baseline, enteral autonomy, or reduction in parenteral support infusion of ≥ 1 day per week is required.

After the initial six (6) month approval, subsequent approvals will be for the duration of one (1) year. Reevaluation will be every (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, enteral autonomy, or continued reduction in parenteral support infusion of ≥ 1 day per week.

Distribution will be limited to specialty pharmacy and a quantity limit of one vial per day and a 34 day supply limit per fill will be applied.

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 GHP Family Policy 4.0F Geisinger Health Plan (GHP) Formulary Exception/Prior Authorization for additional information.

This policy will be maintained in compliance with the standards of any applicable state and federal regulatory entities.
PROCEDURE:
Prior authorization of Mytesi will be made for members who meet the following criteria:

Medical record documentation of:
- Medical record documentation of HIV or AIDS AND
- Medical record documentation of ART therapy for at least four weeks duration AND
- Medical record documentation of contraindication to, therapeutic failure on or intolerance to loperamide AND diphenoxylate-atropine

Formulary alternatives: loperamide, 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 GHP Family Policy 4.0F Geisinger Health Plan (GHP) Formulary Exception/Prior Authorization for additional information.

This policy will be maintained in compliance with the standards of any applicable state and federal regulatory entities.
PROCEDURE:
Prior authorization of Signifor will be made for members who meet the following criteria:

- Must be prescribed by an endocrinologist **AND**
- Medical record documentation 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, contraindication to, or intolerance to ketoconazole and metyrapone* (*Requires prior authorization)

Authorization duration: 6 months. Re-authorization requires medical record documentation that urinary free cortisol levels are within normal limits
Quantity Limit: 60 ampules per month for each strength

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 GHP Family Policy 4.0F Geisinger Health Plan (GHP) Formulary Exception/Prior Authorization for additional information.

This policy will be maintained in compliance with the standards of any applicable state and federal regulatory entities.
PROCEDURE:
Prior authorization of Sirturo will be made for members who meet the following criteria:

- Prescription is written 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 12 years, weighing at least 30 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

Approval will be given for a total duration of 24 weeks. A 28-day supply limit per fill will apply. A quantity limit of 56 tablets will be applied to the first fill. Subsequent fills will be for a quantity of 24 tablets.

**FORMULARY ALTERNATIVES:** Amoxicillin-clavulanic acid, clarithromycin, ethambutol, isoniazid, levofloxacin, pyrazinamide, rifampin, linezolid

If an exception is made, Sirturo will be paid for under the member’s prescription drug benefit. Quantity limits apply.

Reviewer should refer to the process and procedure in GHP Family Policy 4.0F Geisinger Health Plan (GHP) Formulary Exception/Prior Authorization for additional information.

This policy will be maintained in compliance with the standards of any applicable state and federal regulatory entities.
PROCEDURE:
Prior authorization of Procysbi will be made for members who meet the following criteria:

- Medical record of a diagnosis of nephropathic cystinosis AND
- Medical record documentation of age greater than or equal to 1 year AND
- Prescription is written by a nephrologist AND
- There is medical record documentation of therapeutic failure on, intolerance to, or contraindication to Cystagon

Formulary Alternative: Cystagon

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 GHP Family Policy 4.0F Geisinger Health Plan (GHP) Formulary Exception/Prior Authorization for additional information.

This policy will be maintained in compliance with the standards any applicable state and federal regulatory entities.
Prior authorization of Mirvaso will be made for members who meet the following criteria:

- Medical record documentation of a diagnosis of rosacea **AND**
- Medical record documentation of age \( \geq 18 \) **AND**
- Medical record documentation of therapeutic failure on, intolerance to, or contraindication to topical metronidazole

**QUANTITY LIMIT:** 1 (30 g) tube per fill

**FORMULARY ALTERNATIVES:** metronidazole 0.75% cream, lotion gel, metronidazole 1% gel

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 **GHP Family Policy 4.0F Geisinger Health Plan (GHP) Formulary Exception/Prior Authorization** for additional information.

This policy will be maintained in compliance with the standards any applicable state and federal regulatory entities.
PROCEDURE:

GRANDFATHER PROVISION – Members already established on therapy are eligible for approval as long as there is medical record documentation that the safety and effectiveness of use for the prescribed indication is supported by Food and Drug Administration (FDA) approval or adequate medical and scientific evidence in the medical literature.

Prior authorization of Valchlor will be made for members who meet the following criteria:

- Prescription is written by a dermatologist or oncologist AND
- Medical record documentation of a diagnosis of Stage IA or IB mycosis fungoides-type cutaneous T-cell lymphoma 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 one of the following skin-directed therapies: topical corticosteroid, topical retinoid, topical nitrogen mustard, phototherapy, imiquimod, local radiation.

Each authorization will be for 12 months. Re-review will occur every 12 months. Valchlor will no longer be considered medically necessary if there is medication record documentation of disease progression.

FORMULARY ALTERNATIVES: see Statewide PDL https://papdl.com/preferred-drug-list

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 GHP Family Policy 4.0F Geisinger Health Plan (GHP) Formulary Exception/Prior Authorization for additional information.

This policy will be maintained in compliance with the standards any applicable state and federal regulatory entities.
PROCEDURE:
Prior authorization of Controlled Substances when used concurrently with an Oral Buprenorphine Agent will be made for members who meet the following criteria:

- The prescription for the oral buprenorphine agent and the other controlled substance(s) are written by the same prescriber and the other controlled substance(s) are medically necessary OR
- There is medical record documentation that, if the oral buprenorphine agent and other controlled substance(s) are written by different prescribers, that all prescribers are aware of the other prescription(s) and the other controlled substance(s) are medically necessary.

NOTE: if concurrent use is addressed in the Statewide PDL guidelines, the Statewide PDL policy will be applied.

If an exception is made, Controlled Substances when used concurrently with an Oral Buprenorphine Agent will be paid for under the member’s prescription drug benefit.

Reviewer should refer to the process and procedure in GHP Family Policy 4.0F Geisinger Health Plan (GHP) Formulary Exception/Prior Authorization for additional information.

This policy will be maintained in compliance with the standards any applicable state and federal regulatory entities.
PROCEDURE:
Prior authorization of Myalept will be made for members who meet the following criteria:

- Prescription written 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 lipodystrophy AND
- No medical record documentation of 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 HbA1c value) AND failure (defined by HbA1c ≥ 7% 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 > 300mg/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 is managed by a cardiologist

AUTHORIZATION DURATION: Initial authorization will be for 6 months. For continuation, medical record documentation of improvement in objective measures associated with the complications related to congenital or acquired generalized lipodystrophy (i.e.: 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 GHP Family Policy 4.0F Geisinger Health Plan (GHP) Formulary Exception/Prior Authorization for additional information.

This policy will be maintained in compliance with the standards of any applicable state and federal regulatory entities.
PHARMACY POLICY & PROCEDURE MANUAL

POLICY NUMBER: 1267.0F
SECTION: Pharmacy – GHP Family Drug Policies
SUBJECT: Grastek

PROCEDURE:
Prior authorization of Grastek will be made for members who meet the following criteria:
• Prescription is written by an allergist, immunologist, or a prescriber qualified to prescribe 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 epinephrine auto-injector AND
• Medical record documentation that the member does not have severe, unstable, or uncontrolled asthma AND
• Medical record documentation that member will no longer be receiving injectable allergy shots AND
• Medical record documentation that Grastek will not be used in combination with sublingual immunotherapy (e.g Odactra, Oralair, and Ragwitek) AND
• Medical record documentation of therapeutic failure on, intolerance to, or contraindication to three (3) formulary alternatives, one of which must be an intranasal glucocorticoid.

Formulary alternatives:
Antihistamines: loratadine, cetirizine, fexofenadine, levocetirizine
Intranasal glucocorticoids: fluticasone propionate, triamcinolone acetonide, flunisolide

Quantity Limit: 1 tablet per day for 34 days and 180 tablets per 365 days
Note: Grastek may be taken daily for 3 consecutive years (including intervals between grass pollen seasons).

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 GHP Family Policy 4.0F Geisinger Health Plan (GHP) Formulary Exception/Prior Authorization for additional information.

This policy will be maintained in compliance with the standards of any applicable state and federal regulatory entities.
PROCEDURE:
Prior authorization of Oralair will be made for members who meet the following criteria:
• Prescription is written by an allergist, immunologist, or a prescriber qualified to prescribe 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 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 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. Odactra, Grastek, 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.

Formulary alternatives:
Antihistamines: loratadine, cetirizine, fexofenadine, levocetirizine
Intranasal glucocorticoids: fluticasone propionate, triamcinolone acetonide, flunisolide

Quantity Limit: 1 tablet per day for 34 days and 210 tablets per 365 days

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 GHP Family Policy 4.0F Geisinger Health Plan (GHP) Formulary Exception/Prior Authorization for additional information.

This policy will be maintained in compliance with the standards of any applicable state and federal regulatory entities.
PROCEDURE:
Prior authorization of Ragwitek will be made for members who meet the following criteria:

- Prescription is written by an allergist, immunologist, or a prescriber qualified to prescribe 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 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, Oralair, and Odactra) 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.

Formulary alternatives:
**Antihistamines:** loratadine, cetirizine, fexofenadine, levocetirizine
**Intranasal glucocorticoids:** fluticasone propionate, triamcinolone acetonide, flunisolide

**Quantity Limit:** 1 tablet per day for 34 days and 180 tablets per 365 days

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 [GHP Family Policy 4.0F Geisinger Health Plan (GHP) Formulary Exception/Prior Authorization](#) for additional information.

This policy will be maintained in compliance with the standards of any applicable state and federal regulatory entities.
PROCEDURE:
Prior authorization of Sivextro Oral will be made for members who meet the following criteria:

- Documentation of that patient is ≥ 18 years of age AND
- Medical record documentation of a diagnosis of an acute bacterial skin and skin structure infection (including cellulitis/erysipelas, wound infection, and major cutaneous abscess) caused by: *Staphylococcus aureus* (including methicillin-susceptible and methicillin-resistant strains), *Streptococcus pyogenes*, *Streptococcus agalactiae*, *Streptococcus anginosus*, *Streptococcus intermedius*, *Streptococcus constellatus*, or *Enterococcus faecalis* which has been diagnosed and documented with Infectious Disease consultation 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 other antibiotics shown to be susceptible on the culture and sensitivity OR
- If initiated during an inpatient stay: 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 other antibiotics shown to be susceptible on the culture and sensitivity

**Quantity Limit:** one-time fill of 6 tablets for a 6-day supply

**Formulary Alternatives:** clindamycin, cefaclor, cefadroxil, cefdinir, cefpodoxime, cefuroxime, cephalaxin, azithromycin, clarithromycin, erythromycin, amoxicillin, amoxicillin/clav, dicloxacillin, penicillin, ciprofloxacin, levofloxacin, ofloxacin, sulfamethoxazole/trimethoprim, doxycycline, minocycline, Zyvox*  
*requires prior authorization

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

Reviewer should refer to the process and procedure in GHP Family Policy 4.0F Geisinger Health Plan (GHP) Formulary Exception/Prior Authorization for additional information.

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

, 10/09/17—updated signature
PROCEDURE:
Prior authorization of Karbinal ER will be made for members who meet the following criteria:

- Documentation of that patient is ≥ 2 years of age AND
- Medical record documentation that Karbinal ER is being used for an FDA-approved indication AND
- Medical record documentation of a therapeutic failure on, intolerance to or contraindication to OTC loratadine, OTC cetirizine, OTC fexofenadine, levocetirizine, immediate-release carbinoxamine, diphenhydramine AND chlorpheniramine

Formulary Alternatives: OTC loratadine, OTC cetirizine, OTC fexofenadine, levocetirizine, immediate-release carbinoxamine, diphenhydramine, 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 GHP Family Policy 4.0F Geisinger Health Plan (GHP) Formulary Exception/Prior Authorization for additional information.

This policy will be maintained in compliance with the standards of any applicable state and federal regulatory entities.
PROCEDURE:
Prior authorization of Northera will be made for members who meet the following criteria:
- Prescription is written by a cardiologist or neurologist AND
- Medical record documentation that patient is ≥ 18 years of age 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 AND
- Medical record documentation of a therapeutic failure on, intolerance to, or contraindication to midodrine and fludrocortisone

QUANTITY LIMITS:
- 100 and 200 mg capsules: 3 capsules per day
- 300 mg capsules: 6 capsules per day

AUTHORIZATION DURATION: Approval will be given for an initial duration of four weeks. Subsequent approvals will be for an additional 3 months each, requiring medical record documentation of continued or sustained improvement in the symptoms of NOH.

Formulary Alternatives: midodrine, fludrocortisone

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 GHP Family Policy 4.0F Geisinger Health Plan (GHP) Formulary Exception/Prior Authorization for additional information.

This policy will be maintained in compliance with the standards of any applicable state and federal regulatory entities.
PROCEDURE:
Prior authorization of Corlanor will be made for members who meet the following criteria:

- Medical record documentation of stable, symptomatic heart failure with a left ventricular ejection fraction ≤35% AND
- Must be prescribed by a cardiologist AND
- Medical record documentation of being in sinus rhythm with resting heart rate ≥70 beats per minute AND
- Medical record documentation of hospitalization for worsening heart failure within the previous 12 months 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.

QUANTITY LIMIT: 2 tablets daily

FORMULARY ALTERNATIVES: carvedilol, metoprolol succinate, bisoprolol

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 GHP Family Policy 4.0F Geisinger Health Plan (GHP) Formulary Exception/Prior Authorization for additional information.

This policy will be maintained in compliance with the standards of any applicable state and federal regulatory entities.
PROCEDURE:
Prior authorization of Natpara will be made for members who meet the following criteria:
- Medical record documentation of a diagnosis of hypocalcemia secondary to hypoparathyroidism AND
- Medication 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 treating hypocalcemia AND
- Medical record documentation that medication is going to be used concurrently with a calcium supplement

Authorization will be for a duration 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).

Quantity Limit: 2 cartridges (1 pack) per 28 days

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 GHP Family Policy 4.0F Geisinger Health Plan (GHP) Formulary Exception/Prior Authorization for additional information.

This policy will be maintained in compliance with the standards of any applicable state and federal regulatory entities.
PROCEDURE:
Prior authorization of Orkambi will be made for members who meet the following criteria:
- Must be prescribed by a pulmonologist or cystic fibrosis specialist AND
- Medical record documentation of the patient being ≥ 2 years of age AND
- Medical record documentation of a diagnosis of cystic fibrosis AND
- Medical record documentation of that member is homozygous for the F508del CFTR mutation as documented by an FDA-cleared CF mutation test

Quantity limit: 4 tablets per day, 28-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 or, based on the prescriber’s assessment, the member continues to benefit from Orkambi.

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

Reviewer should refer to the process and procedure in GHP Family Policy 4.0F Geisinger Health Plan (GHP) Formulary Exception/Prior Authorization for additional information.

This policy will be maintained in compliance with the standards of any applicable state and federal regulatory entities.
PROCEDURE:
Prior authorization of Keveyis will 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
- Documentation that the patient is ≥ 18 years of age AND
- Medical record documentation that the patient’s condition was diagnosed by a neurologist with neuromuscular expertise AND
- Medical record documentation of a therapeutic failure on, intolerance to, or contraindication to acetazolamide AND
- For hypokalemic periodic paralysis only: Medical record documentation of a therapeutic failure on, intolerance to, or contraindication to spironolactone.

Quantity Limit: 4 tablets per day

Authorization Duration: Initial authorization will be for 2 months. Reauthorization will require documentation that the patient has had a reduction in the number of paralytic attacks. Subsequent authorizations will be for 6 months each requiring documentation that the patient is stable and has had a reduction in the number of paralytic paralysis attacks as compared to baseline

Formulary alternatives: acetazolamide

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

Reviewer should refer to the process and procedure in GHP Family Policy 4.0F Geisinger Health Plan (GHP) Formulary Exception/Prior Authorization for additional information.

This policy will be maintained in compliance with the standards of any applicable state and federal regulatory entities.
PROCEDURE:
Prior authorization of Quantity Limits will 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 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 an exception is made, Quantity Limits will be paid for under the member’s prescription drug benefit.

Reviewer should refer to the process and procedure in GHP Family Policy 4.0F Geisinger Health Plan (GHP) Formulary Exception/Prior Authorization for additional information.

This policy will be maintained in compliance with the standards of any applicable state and federal regulatory entities.
PROCEDURE:
Prior authorization of Strensiq will be made for members who meet the following criteria:

- Must be prescribed by an endocrinologist or metabolic specialist AND
- Medical record documentation of a diagnosis of perinatal/infantile- or juvenile-onset hypophosphatasia (HPP) AND
- Medical record documentation of low total serum alkaline phosphatase activity (see chart below for typical lowest normal reference values) AND
- Medical record documentation that member will receive a weight and diagnosis appropriate dosing regimen

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.

Quantity Limit: A maximum of 30 day supply per fill will be approved.

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.

If an exception is made, Strensiq will be paid for under the member's prescription drug benefit.
Reviewer should refer to the process and procedure in GHP Family Policy 4.0F Geisinger Health Plan (GHP) Formulary Exception/Prior Authorization for additional information.

This policy will be maintained in compliance with the standards of any applicable state and federal regulatory entities.
PROCEDURE:
Prior authorization of Xuriden will 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
- Medical record documentation of an appropriate dose for the patient’s weight* AND
- Prescription written is made by a metabolic specialist, medical geneticist, or other physician with experience in the diagnosis and treatment of inborn errors of metabolism

*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: 4 packets per day, 30 day supply per fill

Formulary alternatives: none

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

Reviewer should refer to the process and procedure in GHP Family Policy 4.0F Geisinger Health Plan (GHP) Formulary Exception/Prior Authorization for additional information.

This policy will be maintained in compliance with the standards of any applicable state and federal regulatory entities.
PROCEDURE:
Prior authorization of Remodulin will be made for members who meet the following criteria:

- Prescription is written by a pulmonologist or cardiologist **AND**
- Medical record documentation that Remodulin is being administered subcutaneously **AND**
- Medical record documentation of a diagnosis of functional class II, III, or IV pulmonary arterial hypertension **AND**
- Medical record documentation of use in combination with, or failure on, intolerance to, contraindication to, or use in combination with sildenafil* **AND** an appropriate second line agent (an endothelin receptor antagonist or Uptravi) used with sildenafil

Formulary alternatives: sildenafil*, Letairis*, Tracleer* (* requires prior authorization)

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

Reviewer should refer to the process and procedure in **GHP Family Policy 4.0F Geisinger Health Plan (GHP) Formulary Exception/Prior Authorization** for additional information.

This policy will be maintained in compliance with the standards of any applicable state and federal regulatory entities.
PROCEDURE:
Prior authorization of Impavido will be made for members who meet the following criteria:
- Medical record documentation that the patient is at least 12 years of age AND
- Medical record documentation that the patient weighs at least 30 kg AND
- Prescription is written by a board certified infectious disease specialist AND
- Medical record documentation of one of the following:
  - 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

A QL of a one-time fill for 84 capsules (BW ≥ 45 kg) or 56 capsules (BW 30 – 44 kg) per 28 days and authorization duration of 1 month will apply.

Formulary alternatives: fluconazole, ketoconazole, itraconazole* (*requires prior authorization)

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

Reviewer should refer to the process and procedure in GHP Family Policy 4.0F Geisinger Health Plan (GHP) Formulary Exception/Prior Authorization for additional information.

This policy will be maintained in compliance with the standards of any applicable state and federal regulatory entities.
PROCEDURE:
Prior authorization of Nuedexta will be made for members who meet the following criteria:
• Medical record documentation of a diagnosis of pseudobulbar affect (PBA)

QUANTITY LIMITS: two capsules per day

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

Reviewer should refer to the process and procedure in GHP Family Policy 4.0F Geisinger Health Plan (GHP) Formulary Exception/Prior Authorization for additional information.

This policy will be maintained in compliance with the standards of any applicable state and federal regulatory entities.
PROCEDURE:
Prior authorization of Emverm will be made for members who meet the following criteria:

- Medical record documentation of 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:**

For *Enterobius vermicularis* (pinworm): 1 tablet, max of 2 fills
For all other FDA-approved indications: *Ancylostoma duodenale* or *Necator americanus* (hookworms), *Ascaris lumbricoides* (roundworms), and *Trichuris trichiura* (whipworms): 6 tablets (2 tablets per day for 3 days), max of 2 fills

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

Reviewer should refer to the process and procedure in GHP Family Policy 4.0F Geisinger Health Plan (GHP) Formulary Exception/Prior Authorization for additional information.

This policy will be maintained in compliance with the standards of any applicable state and federal regulatory entities.
PROCEDURE:
Prior authorization of Oral Dietary Supplements will be made for members who meet the following criteria:

- Medical record documentation that the requested product is not meant to increase or replace caloric intake (i.e. Ensure, Enfamil [covered as a DME benefit]) AND
- Medical record documentation of a description of the member’s clinical condition that clearly outlines why the nutritional needs cannot be met through dietary modification AND
- The product must be labeled and used for the dietary management of a specific medical disorder, disease, or condition for which there are distinctive nutritional requirements to avert the development of serious physical or mental disabilities or to promote normal development or function AND
- For supplements that are outside the parameters of use approved by the FDA or accepted standards of care or current nationally recognized guidelines the provider must provide documentation as recognized in a national compendium AND
- Medical record documentation of a therapeutic failure on, intolerance to or contraindication to up to three formulary alternatives if available

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

Reviewer should refer to the process and procedure in GHP Family Policy 4.0F Geisinger Health Plan (GHP) Formulary Exception/Prior Authorization for additional information.

This policy will be maintained in compliance with the standards of any applicable state and federal regulatory entities.
PROCEDURE:
Prior authorization of Xermelo will 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.

Authorization Duration: Each treatment period will be defined as 12 months. Re-review will occur every 12 months. The following criteria is recommended for reauthorization:
- Medical record documentation that Xermelo will continue to be used in combination with a somatostatin analog (i.e. octreotide, Sandostatin LAR Depot, Somatuline Depot) AND
- Medical record documentation of sustained reduction in bowel movement frequency from baseline

Quantity Limit: three tablets daily

Formulary Alternative: octreotide

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

Reviewer should refer to the process and procedure in GHP Family Policy 4.0F Geisinger Health Plan (GHP) Formulary Exception/Prior Authorization for additional information.

This policy will be maintained in compliance with the standards of any applicable state and federal regulatory entities.
PROCEDURE:
Prior authorization of Benlysta SQ will be made for members who meet the following criteria:
- Medical record documentation of age ≥ 18 years
- Medical record documentation of active systemic lupus erythematosus AND
- Positive ANA and/or anti-dsDNA antibody AND
- Concurrently receiving a stable treatment regimen with prednisone, NSAID, anti-malarial, or immunosuppressant AND
- No active severe nephritis or CNS involvement AND
- Prescribed by a rheumatologist

Note: Benlysta has not been studied in combination with other biologics or intravenous cyclophosphamide. Use of Benlysta is not recommended in these situations

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

Formulary Alternative: none

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

Reviewer should refer to the process and procedure in GHP Family Policy 4.0F Geisinger Health Plan (GHP) Formulary Exception/Prior Authorization for additional information.

This policy will be maintained in compliance with the standards of any applicable state and federal regulatory entities.
PROCEDURE:
Prior authorization of Norpace CR will be made for members who meet the following criteria:

- Medical record documentation that Norpace CR is being used for an FDA-approved indication (ventricular arrhythmia considered life-threatening) **AND**
- Medical record documentation of therapeutic failure on or intolerance to disopyramide IR **OR**
  - Medical record documentation that Norpace CR is being used to treat hypertrophic obstructive cardiomyopathy **AND**
  - Medical record documentation of therapeutic failure on a beta-blocker **AND** verapamil

**Quantity Limit:**
- 100 mg capsules: 8 capsules/day
- 150 mg capsules: 5 capsules/day

**Formulary Alternative:** disopyramide, verapamil, atenolol, bisoprolol, metoprolol, propranolol

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

Reviewer should refer to the process and procedure in GHP Family Policy 4.0F Geisinger Health Plan (GHP) Formulary Exception/Prior Authorization for additional information.

This policy will be maintained in compliance with the standards of any applicable state and federal regulatory entities.
PROCEDURE:
Prior authorization of Nityr will be made for members who meet the following criteria:
  - Prescription is written by or in consultation with a specialist in medical genetics or metabolic diseases AND
  - Medication is being used in combination with dietary restriction of tyrosine and phenylalanine AND
  - Medical record documentation of hereditary tyrosinemia type 1 (HT-1) diagnosis established and supported by documentation of elevated plasma or urine succinylacetone (SA) levels

Quantity Limit: none

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.

Formulary Alternative: none

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

Reviewer should refer to the process and procedure in GHP Family Policy 4.0F Geisinger Health Plan (GHP) Formulary Exception/Prior Authorization for additional information.

This policy will be maintained in compliance with the standards of any applicable state and federal regulatory entities.
PROCEDURE:
Prior authorization of Orfadin will be made for members who meet the following criteria:

- Prescription is written by or in consultation with a specialist in medical genetics or metabolic diseases AND
- Medication is being used in combination with dietary restriction of tyrosine and phenylalanine AND
- Medical record documentation of hereditary tyrosinemia type 1 (HT-1) diagnosis established and supported by documentation of elevated plasma or urine succinylacetone (SA) levels AND
- Medical record documentation of therapeutic failure on, intolerance to, or contraindication to Nityr tablets

Quantity Limit: none

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.

Formulary Alternative: Nityr

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

Reviewer should refer to the process and procedure in GHP Family Policy 4.0F Geisinger Health Plan (GHP) Formulary Exception/Prior Authorization for additional information.

This policy will be maintained in compliance with the standards of any applicable state and federal regulatory entities.
PROCEDURE:
Prior authorization of Bevyxxa will be made for members who meet the following criteria:
- Member is at least 18 years of age **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 has received Bevyxxa during hospitalization and will be continuing therapy following discharge from the hospital

**Quantity Limit:** 1 tablet per day

**Authorization Duration:** 42 days (*will need to authorize a one-time fill of up to 42 tablets for GHP Family)

**Formulary Alternative:** enoxaparin, fondaparinux, heparin, Xarelto, Eliquis, Pradaxa* (* requires prior authorization)

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

Reviewer should refer to the process and procedure in **GHP Family Policy 4.0F Geisinger Health Plan (GHP) Formulary Exception/Prior Authorization** for additional information.

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

Prior authorization of Cinacalcet will be made for members who meet the following criteria:

- Medical record documentation that patient is ≥ 18 years of age AND
- Medical record documentation of one of the following:
  - Medical record documentation of a diagnosis of secondary hyperparathyroidism (SHPT) in patients with chronic kidney disease (CKD) AND
  - Medical record documentation that the patient is on dialysis AND
  - Medical record documentation of failure on, intolerance to, or contraindication to calcitriol AND paricalcitol

  OR

  - Medical record documentation of hypercalcemia in patients with parathyroid carcinoma

  OR

  - Medical record documentation of hypercalcemia in patients with primary hyperparathyroidism for whom parathyroidectomy would be indicated on the basis of serum calcium levels, but who are unable to undergo parathyroidectomy

Quantity Limit: none

Authorization Duration: none

Formulary Alternative: calcitriol, paricalcitol

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

Reviewer should refer to the process and procedure in GHP Family Policy 4.0F Geisinger Health Plan (GHP) Formulary Exception/Prior Authorization for additional information.

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

Prior authorization of Benznidazole will be made for members who meet the following criteria:

Treatment of Chagas Disease in pediatric patients:
- Prescribed by or in consultation with an infectious disease specialist AND
- Medical record documentation that the member is between the ages of 2 to ≤ 12 years old AND
- Medical record documentation of a diagnosis of Chagas disease confirmed by one (1) of the following diagnostic tests:
  - Detection of circulating *T. cruzi* trypomastigotes on microscopy OR
  - Detection of *T. cruzi* DNA by polymerase chain reaction assay OR
  - Two positive diagnostic serologic tests* using different techniques (ex. enzyme-linked immunoassay (ELISA), indirect fluorescent antibody (IFA)) and antigens (ex. whole-parasite lysate, recombinant antigens) showing IgG antibodies to *T. cruzi*;

Quantity Limit: 100 mg tablets: 4 tablets per day 12.5 mg tablets:2 tablets per day (Note: must enter as two authorizations)

Authorization Duration: Rx count of 2, 30-day supply for each fill

Formulary Alternative: none

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

Reviewer should refer to the process and procedure in GHP Family Policy 4.0F Geisinger Health Plan (GHP) Formulary Exception/Prior Authorization for additional information.

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

Prior authorization of Endari will be made for members who meet the following criteria:

- Prescription written by or in consultation with a hematologist AND
- Medical record documentation of the member being ≥ 5 years AND
- Medical record documentation of diagnosis of sickle cell disease AND
- Medical record documentation of Endari being used to reduce the acute complications of sickle cell disease* AND
- Medical record documentation of therapeutic failure on#, intolerance to, or contraindication to a 3 month trial of generic hydroxyurea.

*Note to reviewer: In the clinical trials, patients were included if they had two or more painful crises within the previous 12 months.

Quantity Limit: 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 recommended 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)

Formulary Alternative: hydroxyurea

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

Reviewer should refer to the process and procedure in GHP Family Policy 4.0F Geisinger Health Plan (GHP) Formulary Exception/Prior Authorization for additional information.

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

Prior authorization of Odactra will 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 Dermatophagoides farinae 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 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: One (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.

Reauthorization Info:

- Medical record documentation of sustained improvement in allergic rhinitis symptoms AND
- Medical record documentation that the patient is tolerating Odactra

Formulary Alternative:

Antihistamines: loratadine, cetirizine, fexofenadine, levocetirizine

Intranasal glucocorticoids: fluticasone propionate, triamcinolone acetonide, flunisolide

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

Reviewer should refer to the process and procedure in GHP Family Policy 4.0F Geisinger Health Plan (GHP) Formulary Exception/Prior Authorization for additional information.

This policy will be maintained in compliance with the standards of any applicable state and federal regulatory entities.
PROCEDURE:
Prior authorization of Nocdurna or Noctiva will 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 patient is waking at least 2 times per night to void AND
- Medical record documentation that the patient is not currently hyponatremic (serum sodium < 135 meq/L) and does not have a history of hyponatremia AND
- Medical record documentation of an eGFR >50 ml/min/1.73m² AND
- Medical record documentation that the patient 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 Nocdurna 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 authorizations will be for a period of 6 months.

**Reauthorization:** Reauthorizations will also be for 6 months and will require the following:
- Medical record documentation the individual is experiencing clinical benefit from the use of Nocdurna or Noctiva AND
- Medical record documentation that the patient is not currently hyponatremic (serum sodium < 135 meq/L) and does not have a history of hyponatremia AND
- Medical record documentation of an eGFR >50 ml/min/1.73m² AND
- Medical record documentation that the patient 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 Nocdurna or Noctiva 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
Formulary Alternatives: None

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

Reviewer should refer to the process and procedure in GHP Family Policy 4.0F Geisinger Health Plan (GHP) Formulary Exception/Prior Authorization for additional information.

This policy will be maintained in compliance with the standards of any applicable state and federal regulatory entities.
PROCEDURE:
Prior authorization of Symdeko will 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 patient age greater than or equal to 6 years AND
- Medical record documentation of a diagnosis of cystic fibrosis (CF) AND
- One of the following, as detected by an FDA cleared 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 to reviewer: List of CFTR gene mutations that are responsive to Symdeko:

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<td>E56K</td>
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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 or, based on the prescriber's assessment, the member continues to benefit from Symdeko.

Quantity Limit: 2 tablets per day, 28 day supply per fill

Formulary Alternatives: None

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

Reviewer should refer to the process and procedure in GHP Family Policy 4.0F Geisinger Health Plan (GHP) Formulary Exception/Prior Authorization for additional information.

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

Prior authorization of Jynarque will be made for members who meet the following criteria:

- Prescription written by a nephrologist **AND**
- Medical record documentation of the member being ≥ 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 a GFR ≥ 25 mL/min **AND**
- Medical record documentation the member is at risk for rapidly progressing ADPKD as documented by one of the following:
  - Mayo classification class 1C, 1D, or 1E
  - Total Kidney Volume greater than or equal to 750 mL based on the inclusion criteria of the TEMPO 3:4 Trial
  - PROPKD score > 6
  - Kidney length > 16.5 cm as measured by ultrasound (if CT and MRI contraindicated)
  - Or other indicators of rapid disease progression supported by medical literature

*Note to reviewer: 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.

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).

Quantity Limit: 56 tablets per 28 days

Formulary Alternatives: not applicable

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

Reviewer should refer to the process and procedure in GHP Family Policy 4.0F Geisinger Health Plan (GHP) Formulary Exception/Prior Authorization for additional information.

This policy will be maintained in compliance with the standards of any applicable state and federal regulatory entities.
PROCEDURE:
Prior authorization of Palynziq will 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 diagnosis of phenylketonuria (PKU) AND
- Medical record documentation of the member being ≥ 18 years 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*

Authorization Duration: Initial approval will be for twelve (12) months and subsequent approvals will be for twelve (12) months.

Reauthorization Criteria:
- Medical record documentation of a 20% reduction in Phe concentration from baseline or a blood Phe concentration ≤ 600 micromol/L OR
- Medical record documentation of improvement in neuropsychiatric symptoms or an increase in Phe tolerance.

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/0.5 mL syringe: 0.15 mL per day
- 10 mg/0.5 mL syringe: 0.5 mL per day
- 20 mg/mL syringe: 2 mL per day

Formulary Alternatives: Kuvan*  
(*requires prior authorization)

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

Reviewer should refer to the process and procedure in GHP Family Policy 4.0F Geisinger Health Plan (GHP) Formulary Exception/Prior Authorization for additional information.

This policy will be maintained in compliance with the standards of any applicable state and federal regulatory entities.
PROCEDURE:
Prior authorization of Galafold will be made for members who meet the following criteria:

- **Patient is 18 years of age or older AND**
- **Prescription written by or in consultation with a geneticist, metabolic specialist, nephrologist, cardiologist, or a physician who specializes in the treatment of Fabry disease 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 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).**

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)

Quantity Limit: 14 capsules per 28 days

Formulary Alternatives: not applicable

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

Reviewer should refer to the process and procedure in GHP Family Policy 4.0F Geisinger Health Plan (GHP) Formulary Exception/Prior Authorization for additional information.

This policy will be maintained in compliance with the standards of any applicable state and federal regulatory entities.
POLICY NUMBER: 1481.0F
SECTION: Pharmacy – GHP Family Drug Policies
SUBJECT: Qbrexza

PROCEDURE:
Prior authorization of Qbrexza will be made for members who meet the following criteria:
- Medical record documentation that the patient is 9 years of age and older AND
- Medical record documentation of the diagnosis of primary axillary hyperhidrosis AND
- Medical record documentation of a therapeutic failure on, intolerance to, or contraindication to at least one prescription antiperspirant (aluminum chloride hexahydrate 6.25% [Xerac AC]), 20% [Drysol])

Authorization Duration: not applicable

Quantity Limit: 1 per day

Formulary Alternatives: glycopyrrolate, oxybutynin, propantheline, propranolol, clonidine tablets, diltiazem, Drysol, Xerac AC

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

Reviewer should refer to the process and procedure in GHP Family Policy 4.0F Geisinger Health Plan (GHP) Formulary Exception/Prior Authorization for additional information.

This policy will be maintained in compliance with the standards of any applicable state and federal regulatory entities.
PROCEDURE:
Prior authorization of Xepi will be made for members who meet the following criteria:
- A diagnosis of impetigo AND
- Patient is 2 months of age or older AND
- Therapeutic failure on, intolerance to, or contraindication to mupirocin ointment AND oral antibiotic therapy.

Authorization Duration: 5 days

Quantity Limit: 1 fill per Rx

Formulary Alternatives: mupirocin ointment, gentamicin cream and ointment, cephalexin, dicloxacillin, erythromycin, clarithromycin, clindamycin, sulfamethoxazole/trimethoprim, doxycycline

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

Reviewer should refer to the process and procedure in GHP Family Policy 4.0F Geisinger Health Plan (GHP) Formulary Exception/Prior Authorization for additional information.

This policy will be maintained in compliance with the standards of any applicable state and federal regulatory entities.
PROCEDURE:
Prior authorization of Tegsedi will be made for members who meet the following criteria:

- Prescription written 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 diagnosis of hereditary transthyretin-mediated amyloidosis as confirmed by genetic testing to confirm a pathogenic mutation in TTR AND one of the following:
  - Biopsy of tissue/organ to confirm amyloid presence OR
  - A clinical manifestation typical of hATTR (Neuropathy and/or CHF) 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.

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

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.

Quantity Limit: 6 mL per 28 days

Formulary Alternatives: not applicable
If an exception is made, Tegsedi will be paid for under the member’s prescription drug benefit.

Reviewer should refer to the process and procedure in GHP Family Policy 4.0F Geisinger Health Plan (GHP) Formulary Exception/Prior Authorization for additional information.

This policy will be maintained in compliance with the standards of any applicable state and federal regulatory entities.
PROCEDURE:
Prior authorization of Firdapse will be made for members who meet the following criteria:

• Medical record documentation of age 18 or older **AND**
• Medical record documentation that Firdapse is being prescribed by a neurologist **AND**
• Medical record documentation of diagnosis of Lambert-Eaton myasthenic Syndrome confirmed by one of the following:
  o Medical record documentation of post-exercise facilitation test showing increase in compound muscle action potential (CMAP) amplitude of at least 60 percent compared to pre-exercise baseline value **OR**
  o Medical record documentation of high-frequency Repetitive Nerve Stimulation (RNS) showing increase in compound muscle action potential (CMAP) of at least 60 percent **OR**
  o Medical record documentation of positive anti-P/Q type voltage-gated calcium channel antibody test.

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.

Quantity Limit: 8 tablets/day, maximum day supply of 30 days per fill

Formulary Alternatives: Pyridostigmine

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

Reviewer should refer to the process and procedure in **GHP Family Policy 4.0F Geisinger Health Plan (GHP) Formulary Exception/Prior Authorization** for additional information.

This policy will be maintained in compliance with the standards of any applicable state and federal regulatory entities.
PROCEDURE:
Prior authorization of Tiglutik will be made for members who meet the following criteria:
- Prescription written by or in consultation with neurologist AND
- Medical record documentation of age 18 year or older AND
- Medical record documentation of diagnosis of ALS AND
- Medical record documentation of therapeutic failure on, intolerance to, or contraindication to riluzole tablets OR
- Medical record documentation that patient has dysphagia or is unable to swallow tablets

Authorization Duration: not applicable

Quantity Limit: 600 milliliters/30 days

Formulary Alternatives: Riluzole

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

Reviewer should refer to the process and procedure in GHP Family Policy 4.0F Geisinger Health Plan (GHP) Formulary Exception/Prior Authorization for additional information.

This policy will be maintained in compliance with the standards of any applicable state and federal regulatory entities.
PROCEDURE:
Prior authorization of Aemcolo will be made for members who meet the following criteria:
• Medical record documentation of age 18 or older AND
• Medical record documentation of use for treatment of travelers’ diarrhea AND
• Medical record documentation of therapeutic failure on, intolerance to, or contraindication to azithromycin and one oral fluoroquinolones

Authorization Duration: 3 days

Quantity Limit: 4 tablets per day

Formulary Alternatives: Ciprofloxacin, Azithromycin (tablets), Levofloxacin, Xifaxan*
*prior authorization required

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

Reviewer should refer to the process and procedure in GHP Family Policy 4.0F Geisinger Health Plan (GHP) Formulary Exception/Prior Authorization for additional information.

This policy will be maintained in compliance with the standards of any applicable state and federal regulatory entities.
PROCEDURE:
Prior authorization of Daraprim will be made for members who meet the following criteria:

For Treatment of Toxoplasmosis
- Prescription written 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 contraindication to a sulfonamide

**Authorization Duration:** Initial approval will be for six (6) weeks and subsequent approval will be for six (6) months. Requests for continuation of coverage will be approved for members who meet the following criteria:
- Medical record documentation of clinical syndrome (e.g. headache and/or other neurologic symptoms) **OR**
- Medical record documentation of persistent radiographic disease **OR**
- If HIV positive, medical record documentation of CD4 count < 200 cells/mm³ **AND** medical record documentation that the member is taking anti-retroviral therapy (ART)

For Primary Prophylaxis of Toxoplasmosis with HIV:
- Prescription written by or in consultation with an infectious disease specialist **AND**
- Medical record documentation of diagnosis of HIV **AND**
- Medical record documentation of CD4 count < 200 cells/microL **AND**
- Medical record documentation of therapeutic failure on, intolerance to, or contraindication 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 < 200 cells/mm³ **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 week or after gestation and may be up administered until delivery

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

Reviewer should refer to the process and procedure in GHP Family Policy 4.0F Geisinger Health Plan (GHP) Formulary Exception/Prior Authorization for additional information.

This policy will be maintained in compliance with the standards of any applicable state and federal regulatory entities.
PROCEDURE:
Prior authorization of Cablivi will be made for members who meet the following criteria:

Currently on PEX Therapy:
- Prescription written 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:
- Prescription written 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.

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.

Reauthorization Criteria:

Currently on PEX
- 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 >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

Quantity Limit: 1 kit per day

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

Formulary Alternatives: none

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

Reviewer should refer to the process and procedure in GHP Family Policy 4.0F Geisinger Health Plan (GHP) Formulary Exception/Prior Authorization for additional information.

This policy will be maintained in compliance with the standards of any applicable state and federal regulatory entities.
PROCEDURE:
Prior authorization of Osphena will be made for members who meet the following criteria:

- 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 estradiol cream and Premarin cream

**Authorization Duration:** none

**Quantity Limit:** one tablet daily

**Formulary Alternatives:** estradiol cream, Premarin Cream

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 GHP Family Policy 4.0F Geisinger Health Plan (GHP) Formulary Exception/Prior Authorization for additional information.

This policy will be maintained in compliance with the standards of any applicable state and federal regulatory entities.
PROCEDURE:
Prior authorization of Vyndaqel or Vyndamax will be made for members who meet the following criteria:
- Prescription written by or in consultation with a cardiologist **AND**
- Medical record documentation of 18 years of age or older **AND**
- Medical record documentation of cardiomyopathy resulting from wild type transthyretin-mediated amyloidosis **OR** hereditary transthyretin-mediated amyloidosis as confirmed by **ONE** of the following:
  - Bone scan (scintigraphy) strongly positive for myocardial uptake of 99mTcPYP/DPD *(Note: Strongly positive defined as heart to contralateral lung \([H/CL]\) ratio of at least 1.5 or Grade 2 or greater localization to the heart using the Perugini Grade 1-3 scoring system)* **OR**
  - Biopsy of tissue of the affected organ to confirm amyloid presence **AND** chemical typing to confirm presence of transthyretin (TTR) protein **AND**
- Medical record documentation that the patient has New York Heart Association (NYHA) Class I, II, or III heart failure

**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.

**Quantity Limit:**
- Vyndaqel: 4 tablets per day; maximum 30-day supply per fill
- Vyndamax: 1 tablet per day; maximum 30-day supply per fill

**Formulary Alternatives:** not applicable

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

Reviewer should refer to the process and procedure in GHP Family Policy 4.0F Geisinger Health Plan (GHP) Formulary Exception/Prior Authorization for additional information.

This policy will be maintained in compliance with the standards of any applicable state and federal regulatory entities.
PROCEDURE:
Prior authorization of Freestyle Libre will 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

Authorization Duration: not applicable

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).
- Freestyle Libre 10 or 14 day reader: 1 reader every 2 years (1 per 730 days)
- Freestyle Libre 10 day sensors: 1 sensor per 10 days (0.1 per day)
- Freestyle Libre 14 day sensors: 1 sensor per 14 days (0.072 per day)

Formulary Alternatives: not applicable

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

Reviewer should refer to the process and procedure in GHP Family Policy 4.0F Geisinger Health Plan (GHP) Formulary Exception/Prior Authorization for additional information.

This policy will be maintained in compliance with the standards of any applicable state and federal regulatory entities.
PROCEDURE:
Prior authorization of Siklos will be made for members who meet the following criteria:
- Prescription written by or in consultation with a hematologist AND
- Medical record documentation of the member being ≥ 2 years of age 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).

Authorization Duration: not applicable
Quantity Limit: not applicable
Formulary Alternatives: Hydroxyurea

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

Reviewer should refer to the process and procedure in GHP Family Policy 4.0F Geisinger Health Plan (GHP) Formulary Exception/Prior Authorization for additional information.

This policy will be maintained in compliance with the standards of any applicable state and federal regulatory entities.
PROCEDURE:
Prior authorization of Trikafta will be made for members who meet the following criteria:
- Medical record documentation that the patient is ≥ 12 years of age 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.

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 or, based on the prescriber’s assessment, the member continues to benefit from Trikafta.

Quantity Limit: 3 tablets per day, 34 days supply per fill.

Formulary Alternatives: Kalydeco, Orkambi, Symdeko

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

Reviewer should refer to the process and procedure in GHP Family Policy 4.0F Geisinger Health Plan (GHP) Formulary Exception/Prior Authorization for additional information.

This policy will be maintained in compliance with the standards of any applicable state and federal regulatory entities.
PROCEDURE:
Prior authorization of Xenleta Tablets will be made for members who meet the following criteria:

- Prescription is written by or in consultation with Infectious Disease
- 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 that patient is ≥18 years of age 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

Authorization Duration: 5 days

Quantity Limit: 10 tablets per 5 days

Alternatives: amoxicillin, amoxicillin/clavulanate, azithromycin, cefdinir, cefpodoxime, clarithromycin, doxycycline, levofloxacin, penicillin, Eryped Suspension

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

Reviewer should refer to the process and procedure in GHP Family Policy 4.0F Geisinger Health Plan (GHP) Formulary Exception/Prior Authorization for additional information.

This policy will be maintained in compliance with the standards of any applicable state and federal regulatory entities.
PROCEDURE:
Prior authorization of Pretomanid will be made for members who meet the following criteria:

• Prescription written by or in consultation with an infectious disease specialist AND
• Medical record documentation of age greater or equal to 18 years AND
• Medical record documentation of pulmonary infection due to *Mycobacterium tuberculosis* AND
• Medical record documentation of one of the following:
  o Extensively drug resistant tuberculosis (XDR-TB) OR
  o 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

Authorization Duration: 26 weeks

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) tablet per day

Note to Reviewer:
• Ti/NR MDR-TB (Treatment-Intolerant or Nonresponsive Multi-Drug Resistant TB). MDR-TB organisms are resistant to rifampin and isoniazid and possibly additional agents.
• XDR-TB (Extensively Drug Resistant TB). These organisms are resistant to isoniazid, rifampin, and fluoroquinolones as well as either aminoglycosides and/or capreomycin.

Alternatives: not applicable

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

Reviewer should refer to the process and procedure in *GHP Family Policy 4.0F Geisinger Health Plan (GHP) Formulary Exception/Prior Authorization* for additional information.

This policy will be maintained in compliance with the standards of any applicable state and federal regulatory entities.
PROCEDURE:
Prior authorization of Oxbryta will be made for members who meet the following criteria:

- Prescription written by or in consultation with a hematologist AND.
- Medical record documentation of the member being ≥ 12 years of age AND
- Medical record documentation of diagnosis of sickle cell disease AND
- Medical record documentation of baseline hemoglobin 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 AND
- Medical record documentation of intolerance to, or contraindication to, or therapeutic failure on a minimum 3 month trial of generic hydroxyurea AND
- Medical record documentation of therapeutic failure on, intolerance to, or contraindication to Endari.

Authorization Duration: Each treatment period will be defined as 12 months. Re-review will occur every 12 months. The following criteria is recommended for reauthorization:

- Medical record documentation of an increase in hemoglobin from baseline or an improvement in complications of sickle cell disease (e.g. decrease in 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.

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

Alternatives: hydroxyurea, Siklos* (*prior authorization required)

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

Reviewer should refer to the process and procedure in GHP Family Policy 4.0F Geisinger Health Plan (GHP) Formulary Exception/Prior Authorization for additional information.

This policy will be maintained in compliance with the standards of any applicable state and federal regulatory entities.
PROCEDURE:
Prior authorization of Ubrelvy will 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) preferred antimigraine agents, triptans

Authorization Duration: not applicable

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

Alternatives: per Statewide PDL

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

Reviewer should refer to the process and procedure in GHP Family Policy 4.0F Geisinger Health Plan (GHP) Formulary Exception/Prior Authorization for additional information.

This policy will be maintained in compliance with the standards of any applicable state and federal regulatory entities.
PROCEDURE:
Prior authorization of Oxervate will be made for members who meet the following criteria:

- Prescription written by an ophthalmologist AND
- Medical record documentation of age greater than or equal to 2 years AND
- Medical record documentation of diagnosis of neurotrophic keratitis (NK) as confirmed by a decrease or loss in corneal sensitivity AND one of the following:
  - Superficial keratopathy
  - Persistent epithelial defects
  - Corneal ulcers
- 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 the Statewide PDL preferred Ophthalmics, Immunomodulators (e.g. Restasis Droperette)

Authorization Duration: 8 weeks. Reauthorization Criteria: 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.

Quantity Limit: 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

Alternatives: per PDL (Ophthalmics, Immunomodulators)

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

Reviewer should refer to the process and procedure in GHP Family Policy 4.0F Geisinger Health Plan (GHP) Formulary Exception/Prior Authorization for additional information.

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