Geisinger

Pharmacy – GHP Family

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1566.0F	RELYVIO
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1572.0F	JOENJA
1573.0F	LUMRYZ
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1575.0F	FUROSCIX
1576.0F	VOWST
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1579.0F	XDEMVY
1580.0F	JESDUVROCK
1582.0F	FABHALTA
1583.0F	OPFOLDA
1584.0F	WAINUA
1585.0F	ZILBRYSK
1586.0F	REZDIFFRA
1587.0F	RIVFLOZA
1589.0F	XOLREMDI
1590.0F	WINREVAIR

1591.0F	VOYDEYA
1592.0F	AREXVY
1593.0F	MRSEVIA
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1599.0F	AQNEURSA

Geisinger PHARMACY POLICY & PROCEDURE MANUAL	POLICY NUMBER: 1008.0F SECTION: Pharmacy – GHP Family Drug Policies SUBJECT: Pulmozyme

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.

Geisinger PHARMACY POLICY & PROCEDURE MANUAL	POLICY NUMBER: 1031.0F SECTION: Pharmacy – GHP Family Drug Policies SUBJECT: Kuvan

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.

Geisinger PHARMACY POLICY & PROCEDURE MANUAL	POLICY NUMBER: 1054.0F SECTION: Pharmacy – GHP Family Drug Policies SUBJECT: Kalydeco

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 1 month **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.

Geisinger PHARMACY POLICY & PROCEDURE MANUAL	POLICY NUMBER: 1073.0F SECTION: Pharmacy – GHP Family Drug Policies SUBJECT: Sucraid

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

1. Order is written by a Gastroenterologist, Endocrinologist or Genetic Specialist **AND**
2. Medical record documentation that Sucraid is prescribed with a dose and duration of therapy that is consistent with FDA-approved package labeling, nationally recognized compendia, or peer-reviewed medical literature **AND**
3. Member has medical documentation of a diagnosis of congenital sucrose-isomaltase deficiency characterized by stool pH less than 6 **AND**
4. Has an increase in breath hydrogen of greater than 10ppm when challenged with sucrose after fasting **AND**
5. Has a negative lactose breath test **OR**
6. Has a diagnosis of congenital sucrose-isomaltase deficiency characterized by low sucrose activity on duodenal biopsy **AND**
7. Other disaccharidases normal on same duodenal biopsy.

Geisinger PHARMACY POLICY & PROCEDURE MANUAL	POLICY NUMBER: 1074.0F SECTION: Pharmacy – GHP Family Drug Policies SUBJECT: Bexarotene

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 the 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

Geisinger PHARMACY POLICY & PROCEDURE MANUAL	POLICY NUMBER: 1078.0F SECTION: Pharmacy – GHP Family Drug Policies SUBJECT: Coverage of Compounded Prescriptions

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

Geisinger PHARMACY POLICY & PROCEDURE MANUAL	POLICY NUMBER: 1086.0F SECTION: Pharmacy – GHP Family Drug Policies SUBJECT: Elmiron

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.

Geisinger PHARMACY POLICY & PROCEDURE MANUAL	POLICY NUMBER: 1088.0F SECTION: Pharmacy – GHP Family Drug Policies SUBJECT: Actimmune

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

Geisinger PHARMACY POLICY & PROCEDURE MANUAL	POLICY NUMBER: 1095.0F SECTION: Pharmacy – GHP Family Drug Policies SUBJECT: Somavert

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*

Geisinger PHARMACY POLICY & PROCEDURE MANUAL	POLICY NUMBER: 1117.0F SECTION: Pharmacy – GHP Family Drug Policies SUBJECT: Moviprep and Suprep

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.

Geisinger PHARMACY POLICY & PROCEDURE MANUAL	POLICY NUMBER: 1120.0F SECTION: Pharmacy – GHP Family Drug Policies SUBJECT: Veregen

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)

Geisinger Health Plan PHARMACY POLICY & PROCEDURE MANUAL	POLICY NUMBER: 1121.0F SECTION: Pharmacy – GHP Family Drug Policies SUBJECT: Xyrem

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 medical record documentation of failure on, intolerance to or contraindication to modafinil

Geisinger PHARMACY POLICY & PROCEDURE MANUAL	POLICY NUMBER: 1161.0F SECTION: Pharmacy – GHP Family Drug Policies SUBJECT: Masks, Spacers for MDI

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

Geisinger PHARMACY POLICY & PROCEDURE MANUAL	POLICY NUMBER: 1169.0F SECTION: Pharmacy – GHP Family Drug Policies SUBJECT: Cycloset

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

Geisinger PHARMACY POLICY & PROCEDURE MANUAL	POLICY NUMBER: 1170.0F SECTION: Pharmacy – GHP Family Drug Policies SUBJECT: Korlym

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

Geisinger PHARMACY POLICY & PROCEDURE MANUAL	POLICY NUMBER: 1173.0F SECTION: Pharmacy – GHP Family Drug Policies SUBJECT: Brand Coverage when AB-rated Generic Available

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.

Geisinger PHARMACY POLICY & PROCEDURE MANUAL	POLICY NUMBER: 1194.0F SECTION: Pharmacy – GHP Family Drug Policies SUBJECT: Albendazole

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*

Geisinger PHARMACY POLICY & PROCEDURE MANUAL	POLICY NUMBER: 1195.0F SECTION: Pharmacy – GHP Family Drug Policies SUBJECT: H.P. Acthar Gel

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

Geisinger PHARMACY POLICY & PROCEDURE MANUAL	POLICY NUMBER: 1210.0F SECTION: Pharmacy – GHP Family Drug Policies SUBJECT: Gattex

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

Geisinger PHARMACY POLICY & PROCEDURE MANUAL	POLICY NUMBER: 1212.0F SECTION: Pharmacy – GHP Family Drug Policies SUBJECT: Mytesi

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

Geisinger PHARMACY POLICY & PROCEDURE MANUAL	POLICY NUMBER: 1213.0F SECTION: Pharmacy – GHP Family Drug Policies SUBJECT: Signifor

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)

Geisinger PHARMACY POLICY & PROCEDURE MANUAL	POLICY NUMBER: 1223.0F SECTION: Pharmacy – GHP Family Drug Policies SUBJECT: Sirturo

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 5 years and weighing at least 15 kg **AND**
- Medical record documentation of resistance to isoniazid **AND** rifampin **AND**

- Medical record documentation that an effective treatment regimen cannot be attained with other available treatment options **AND**
- Medical record documentation of one of the following:
  - Sirturo is being prescribed in combination with at least 3 other drugs to which the patient's multi-drug resistant tuberculosis (MDR-TB) isolate has been shown to be susceptible to in vitro **OR**
  - If in vitro testing results are unavailable, Sirturo is being prescribed in combination with at least 4 other drugs to which the patient's MDR-TB isolate is likely to be susceptible

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**
- Medical record documentation of one of the following:
  - Medical record documentation of intolerance to Cystagon and one of the following:
    - If intolerance is gastrointestinal-related, medical record documentation of therapeutic failure on 4 months of Cystagon and a proton-pump inhibitor (e.g. omeprazole, esomeprazole) OR
    - If intolerance is not gastrointestinal-related, justification supported by peer-review literature citing well-designed clinical trials that the member's intolerance will be improved by switching therapy to Procysbi

    OR

  - Medical record documentation of therapeutic failure on Cystagon by all of the following:
    - Medical record documentation of failure to achieve WBC cystine levels < 1 nmol half-cystine/mg protein on maximally tolerated dose of Cystagon AND
    - Claims history or attestation from the provider that the patient is adherent to Cystagon at an every 6 hour dosing interval

Geisinger PHARMACY POLICY & PROCEDURE MANUAL	POLICY NUMBER: 1239.0F SECTION: Pharmacy – GHP Family Drug Policies SUBJECT: Mirvaso

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

- Medical record documentation that Mirvaso is being use for the treatment of persistent (nontransient) facial erythema of rosacea **AND**
- Medical record documentation that Mirvaso is prescribed with a dose and duration of therapy that is consistent with FDA-approved package labeling, nationally recognized compendia, or peer-reviewed medical literature **AND**
- Medical record documentation of age ≥ 18

Geisinger PHARMACY POLICY & PROCEDURE MANUAL	POLICY NUMBER: 1244.0F SECTION: Pharmacy – GHP Family Drug Policies SUBJECT: Valchlor

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.

Geisinger PHARMACY POLICY & PROCEDURE MANUAL	POLICY NUMBER: 1265.0F SECTION: Pharmacy – GHP Family Drug Policies SUBJECT: Myalept

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

Geisinger 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 a dose and duration of therapy that is consistent with FDA-approved package labeling, nationally recognized compendia, or peer-reviewed medical literature **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.

Geisinger PHARMACY POLICY & PROCEDURE MANUAL	POLICY NUMBER: 1268.0F SECTION: Pharmacy – GHP Family Drug Policies SUBJECT: Oralair

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.

AND

- Medical record documentation of a dose and duration of therapy that is consistent with FDA-approved package labeling, nationally recognized compendia, or peer-reviewed medical literature

Geisinger PHARMACY POLICY & PROCEDURE MANUAL	POLICY NUMBER: 1269.0F SECTION: Pharmacy – GHP Family Drug Policies SUBJECT: Ragwitek

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.

AND

- Medical record documentation of a dose and duration of therapy that is consistent with FDA-approved package labeling, nationally recognized compendia, or peer-reviewed medical literature

Geisinger PHARMACY POLICY & PROCEDURE MANUAL	POLICY NUMBER: 1275.0F SECTION: Pharmacy – GHP Family Drug Policies SUBJECT: Sivextro Oral

PROCEDURE:

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

- Documentation of that patient is ≥ 12 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 say: 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

Geisinger PHARMACY POLICY & PROCEDURE MANUAL	POLICY NUMBER: 1276.0F SECTION: Pharmacy – GHP Family Drug Policies SUBJECT: Karbinal ER

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

Geisinger PHARMACY POLICY & PROCEDURE MANUAL	POLICY NUMBER: 1277.0F SECTION: Pharmacy – GHP Family Drug Policies SUBJECT: Droxidopa

PROCEDURE:
Prior authorization of Droxidopa 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

Geisinger PHARMACY POLICY & PROCEDURE MANUAL	POLICY NUMBER: 1312.0F SECTION: Pharmacy – GHP Family Drug Policies SUBJECT: Corlanor

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

- Must be prescribed by a cardiologist **AND**
- Medical record documentation of being in sinus rhythm with resting heart rate greater than or equal to the lower limit of the normal range based on age* **AND**
- Medical record documentation of one of the following:
    - Medical record documentation of age greater than or equal to 18 years **AND**
    - Medical record documentation of stable, symptomatic heart failure with a left ventricular ejection fraction less than or equal to 35% **AND**
    - Medical record documentation of hospitalization for worsening heart failure within the previous 12 months.

    OR
    - Medical record documentation of age greater than or equal to 6 months and less than 18 years **AND**
    - Medical record documentation of stable, symptomatic heart failure due to dilated cardiomyopathy **AND**
    - Medical record documentation of class II to IV heart failure according to New York Heart Association [NYHA] functional class or Ross classification **AND**
    - Medical record documentation of a left ventricular ejection fraction less than or equal to 45%.

    AND
    - Medical record documentation of therapeutic failure on, intolerance to, or contraindication to the maximum tolerated dose of 2 formulary beta-blockers one of which must be carvedilol **AND**
    - If the request is for Corlanor Solution: Medical record documentation of one of the following:
    - Medical record documentation of patient weight less than 40 kg **OR**
    - Medical record documentation of therapeutic failure on, intolerance to, or contraindication to Corlanor tablets **OR**
    - Medical record documentation that patient has dysphagia or is unable to swallow tablets

Geisinger PHARMACY POLICY & PROCEDURE MANUAL	POLICY NUMBER: 1329.0F SECTION: Pharmacy – GHP Family Drug Policies SUBJECT: Orkambi

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

Geisinger PHARMACY POLICY & PROCEDURE MANUAL	POLICY NUMBER: 1337.0F SECTION: Pharmacy – GHP Family Drug Policies SUBJECT: Keveyis

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 **AND**
- Medical record documentation of a dose and duration of therapy that is consistent with FDA-approved package labeling, nationally recognized compendia, or peer-reviewed medical literature

Geisinger PHARMACY POLICY & PROCEDURE MANUAL	POLICY NUMBER: 1341.0F SECTION: Pharmacy – GHP Family Drug Policies SUBJECT: Quantity Limit

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

Geisinger PHARMACY POLICY & PROCEDURE MANUAL	POLICY NUMBER: 1348.0F SECTION: Pharmacy – GHP Family Drug Policies SUBJECT: Strensiq

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

Table 2. Typical Lowest Normal Reference Values for Serum Alkaline Phosphatase Activity in North America

Age	Lowest Normal Total Serum or Plasma Alkaline Phosphatase Activity (U/L)	
	Male	Female
0-30 days	60	60
1-11 months	70	70
1-3 years	125	125
4-11 years	150	150
12-13 years	160	110
14-15 years	130	55
16-19 years	60	40
>20 years	40	40

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POLICY NUMBER: 1360.0F

SECTION: Pharmacy – GHP Family Drug Policies

SUBJECT: Xuriden

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:
  - o 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**
  - o Orotic acid crystals visualized in the urine via microscopy

AND

- 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

AND

- Medical record documentation of a dose and duration of therapy that is consistent with FDA-approved package labeling, nationally recognized compendia, or peer-reviewed medical literature

*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.

Geisinger PHARMACY POLICY & PROCEDURE MANUAL	POLICY NUMBER: 1362.0F SECTION: Pharmacy – GHP Family Drug Policies SUBJECT: Treprostinil SQ

PROCEDURE:
Prior authorization of Treprostinil SQ will be made for members who meet the following criteria:

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

- o Prescription is written by a pulmonologist or cardiologist **AND**
- o Medical record documentation that Treprostinil SQ is being administered subcutaneously **AND**
- o Medical record documentation of a diagnosis of class 4 pulmonary arterial hypertension **OR**
- o Medical record documentation of a diagnosis of class 2 or 3 pulmonary arterial hypertension with therapeutic failure on, intolerance to or contraindication to one (1) preferred agent which is approved or medically accepted for the beneficiary's diagnosis or indication, from any of the following classes of medications

    - Endothelin Receptor Antagonist
    - Phosphodiesterase-5 Enzyme Inhibitor
    - Prostacyclin

OR

- o Medical record documentation that the individual require transition from Flolan, to reduce the rate of clinical deterioration. The risks and benefits of each drug should be carefully considered prior to transition

Geisinger PHARMACY POLICY & PROCEDURE MANUAL	POLICY NUMBER: 1363.0F SECTION: Pharmacy – GHP Family Drug Policies SUBJECT: Impavido

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 casued 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

Geisinger PHARMACY POLICY & PROCEDURE MANUAL	POLICY NUMBER: 1373.0F SECTION: Pharmacy – GHP Family Drug Policies SUBJECT: Nuedexta

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)

Geisinger PHARMACY POLICY & PROCEDURE MANUAL	POLICY NUMBER: 1375.0F SECTION: Pharmacy – GHP Family Drug Policies SUBJECT: Emverm

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).

Geisinger PHARMACY POLICY & PROCEDURE MANUAL	POLICY NUMBER: 1380.0F SECTION: Pharmacy – GHP Family Drug Policies SUBJECT: Non-caloric Oral Dietary Supplements

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 (ie. 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

Geisinger PHARMACY POLICY & PROCEDURE MANUAL	POLICY NUMBER: 1393.0F SECTION: Pharmacy – GHP Family Drug Policies SUBJECT: Xermelo

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)

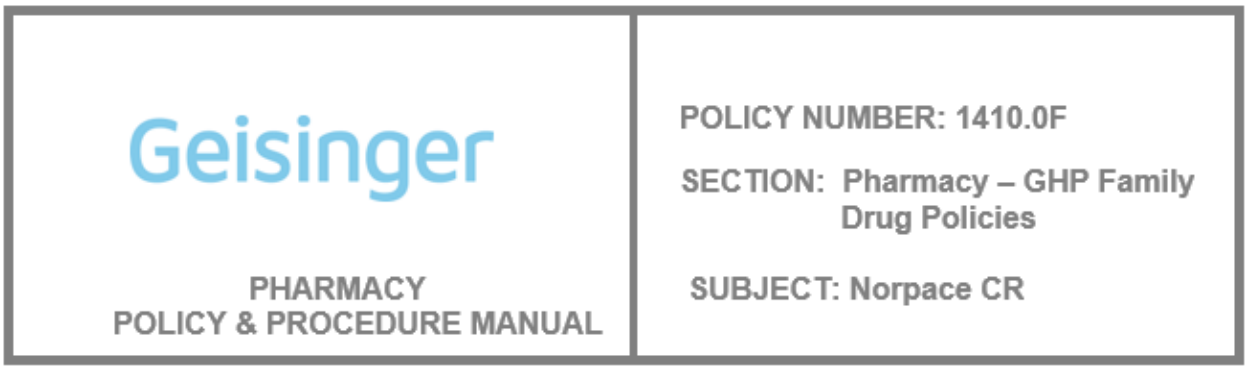
Geisinger PHARMACY POLICY & PROCEDURE MANUAL	POLICY NUMBER: 1409.0F SECTION: Pharmacy – GHP Family Drug Policies SUBJECT: Benlysta Subcutaneous

PROCEDURE:
Prior authorization of Benlysta SQ will be made for members who meet the following criteria:
Systemic Lupus Erythematosus:

- Medical record documentation of age ≥ 5 years **AND**
- If Benlysta syringes are prescribed: medical record documentation of age greater than or equal to 18 years **AND**
- Medical record documentation of systemic lupus erythematosus **AND**
- Medical record documentation that the patient has active disease **OR** recurrent flares **OR** inability to wean steroids in system lupus erythematosus **AND**
- Positive ANA and/or anti-dsDNA antibody **AND**
- Medical record documentation that Benlysta is being used in combination with, or patient has a contraindication or intolerance to, standard therapy (e.g. corticosteroid, NSAID, anti-malarial or immunosuppressant **AND**
- No severe CNS involvement **AND**
- Prescribed by a rheumatologist **AND**
- Medical record documentation of a dose and duration of therapy that is consistent with FDA-approved package labeling, nationally recognized compendia, or peer-reviewed medical literature

Lupus Nephritis:

- Medical record documentation of a diagnosis of active lupus nephritis, Class III, IV, V alone or in combination, confirmed by a kidney biopsy AND
- Medical record documentation of age greater than or equal to 18 AND
- Prescription written by or in consultation with a rheumatologist or nephrologist AND
- Medical record documentation that Benlysta will be prescribed in combination with standard therapy (e.g. mycophenolate mofetil (MMF), corticosteroids, cyclophosphamide, azathioprine) AND
- Medical record documentation of a dose and duration of therapy that is consistent with FDA-approved package labeling, nationally recognized compendia, or peer-reviewed medical literature



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

AND

- Medical record documentation of a dose and duration of therapy that is consistent with FDA-approved package labeling, nationally recognized compendia, or peer-reviewed medical literature

Geisinger PHARMACY POLICY & PROCEDURE MANUAL	POLICY NUMBER: 1412.0F SECTION: Pharmacy – GHP Family Drug Policies SUBJECT: Nityr

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

Geisinger PHARMACY POLICY & PROCEDURE MANUAL	POLICY NUMBER: 1413.0F SECTION: Pharmacy – GHP Family Drug Policies SUBJECT: Orfadin

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

Geisinger POLICY & PROCEDURE MANUAL	POLICY NUMBER: 1425.0F SECTION: Pharmacy – GHP Family Drug Policies SUBJECT: Cinacalcet

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

Geisinger POLICY & PROCEDURE MANUAL	POLICY NUMBER: 1426.0F SECTION: Pharmacy – GHP Family Drug Policies SUBJECT: Benznidazole

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 of a dose and duration of therapy that is consistent with FDA-approved package labeling, nationally recognized compendia, or peer-reviewed medical literature **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*;

Geisinger POLICY & PROCEDURE MANUAL	POLICY NUMBER: 1433.0F SECTION: Pharmacy – GHP Family Drug Policies SUBJECT: Odactra

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 12 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 **AND**
▪ Medical record documentation of a dose and duration of therapy that is consistent with FDA-approved package labeling, nationally recognized compendia, or peer-reviewed medical literature

Geisinger POLICY & PROCEDURE MANUAL	POLICY NUMBER: 1450.0F SECTION: Pharmacy – GHP Family Drug Policies SUBJECT: Nocdurna

PROCEDURE:
Prior authorization of Nocdurna 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 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/1.73m^2 **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 are not being used in combination with a loop diuretic or systemic or inhaled glucocorticoids

Geisinger POLICY & PROCEDURE MANUAL	POLICY NUMBER: 1451.0F SECTION: Pharmacy – GHP Family Drug Policies SUBJECT: Symdeko

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

Geisinger POLICY & PROCEDURE MANUAL	POLICY NUMBER: 1460.0F SECTION: Pharmacy – GHP Family Drug Policies SUBJECT: Tolvaptan

PROCEDURE:

Prior authorization of Tolvaptan 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 of a dose and duration of therapy that is consistent with FDA-approved package labeling, nationally recognized compendia, or peer-reviewed medical literature **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

Geisinger POLICY & PROCEDURE MANUAL	POLICY NUMBER: 1469.0F SECTION: Pharmacy – GHP Family Drug Policies SUBJECT: Palynziq

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*

Geisinger POLICY & PROCEDURE MANUAL	POLICY NUMBER: 1478.0F SECTION: Pharmacy – GHP Family Drug Policies SUBJECT: Galafold

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).

Geisinger POLICY & PROCEDURE MANUAL	POLICY NUMBER: 1488.0F SECTION: Pharmacy – GHP Family Drug Policies SUBJECT: Tegesdi

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 of a dose and duration of therapy that is consistent with FDA-approved package labeling, nationally recognized compendia, or peer-reviewed medical literature **AND**
- Medical record documentation that Tegsedi will not be used in combination with other RNA interference treatment.

Geisinger POLICY & PROCEDURE MANUAL	POLICY NUMBER: 1489.0F SECTION: Pharmacy – GHP Family Drug Policies SUBJECT: Firdapse

PROCEDURE:
Prior authorization of Firdapse will be made for members who meet the following criteria:
• Medical record documentation of age 6 or older **AND**
• Medical record documentation that Firdapse is being prescribed by a neurologist AND
• Medical record documentation of a dose and duration of therapy that is consistent with FDA-approved package labeling, nationally recognized compendia, or peer-reviewed medical literature **AND**
• Medical record documentation of diagnosis of Lambert-Eaton myasthenic Syndrome confirmed by one of the following:

- Medical record documentation of post-exercise facilitation test showing increase in compound muscle action potential (CMAP) amplitude of at least 60 percent compared to pre-exercise baseline value **OR**
- Medical record documentation of high-frequency Repetitive Nerve Stimulation (RNS) showing increase in compound muscle action potential (CMAP) of at least 60 percent **OR**
- Medical record documentation of positive anti-P/Q type voltage-gated calcium channel antibody test.

Geisinger POLICY & PROCEDURE MANUAL	POLICY NUMBER: 1491.0F SECTION: Pharmacy – GHP Family Drug Policies SUBJECT: Tiglutik

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 a dose and duration of therapy that is consistent with FDA-approved package labeling, nationally recognized compendia, or peer-reviewed medical literature **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

Geisinger POLICY & PROCEDURE MANUAL	POLICY NUMBER: 1496.0F SECTION: Pharmacy – GHP Family Drug Policies SUBJECT: Pyrimethamine

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

<u>For Treatment of Toxoplasmosis</u>
- Prescription written by or in consultation with an infectious disease specialist **AND**
- Medical record documentation of diagnosis of toxoplasmosis **AND**
- Medical record documentation that Pyrimethamine will be used in combination with leucovorin and a sulfonamide OR therapeutic failure on, intolerance to, or contraindication to a sulfonamide

<u>For Primary Prophylaxis of Toxoplasmosis with HIV:</u>
- 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

Geisinger POLICY & PROCEDURE MANUAL	POLICY NUMBER: 1497.0F SECTION: Pharmacy – GHP Family Drug Policies SUBJECT: Cablivi

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

<u>Currently on PEX Therapy:</u>
- 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 a dose and duration of therapy that is consistent with FDA-approved package labeling, nationally recognized compendia, or peer-reviewed medical literature **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 a dose and duration of therapy that is consistent with FDA-approved package labeling, nationally recognized compendia, or peer-reviewed medical literature **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.

Geisinger POLICY & PROCEDURE MANUAL	POLICY NUMBER: 1499.0F SECTION: Pharmacy – GHP Family Drug Policies SUBJECT: Osphena

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 of a dose and duration of therapy that is consistent with FDA-approved package labeling, nationally recognized compendia, or peer-reviewed medical literature **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

Geisinger POLICY & PROCEDURE MANUAL	POLICY NUMBER: 1506.0F SECTION: Pharmacy – GHP Family Drug Policies SUBJECT: Vyndaqel and Vyndamax

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

Geisinger POLICY & PROCEDURE MANUAL	POLICY NUMBER: 1521.0F SECTION: Pharmacy – GHP Family Drug Policies SUBJECT: Trikafta

PROCEDURE:

Prior authorization of Trikafta will be made for members who meet the following criteria:
- Medical record documentation that the patient is ≥ 2 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 or a mutation in the CFTR gene that is responsive based on in vitro data. (If the patient's genotype is unknown, an FDA-cleared CF mutation test should be used to confirm the presence of at least one F508del mutation or a mutation that is responsive based on in vitro data) **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.

Geisinger POLICY & PROCEDURE MANUAL	POLICY NUMBER: 1522.0F SECTION: Pharmacy – GHP Family Drug Policies SUBJECT: Xenleta Tablets

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 **AND**
- Medical record documentation of a diagnosis of community-acquired bacterial pneumonia (CABP) caused by the following susceptible microorganisms: *Streptococcus pneumoniae, Staphylococcus aureus* (methicillin-susceptible isolates)*, Haemophilus influenzae, Legionella pneumophila, Mycoplasma pneumoniae,* and *Chlamydophila pneumoniae* **AND**
- Medical record documentation that patient is ≥18 years of age **AND**
- Medical record documentation of a dose and duration of therapy that is consistent with FDA-approved package labeling, nationally recognized compendia, or peer-reviewed medical literature **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

Geisinger POLICY & PROCEDURE MANUAL	POLICY NUMBER: 1524.0F SECTION: Pharmacy – GHP Family Drug Policies SUBJECT: Pretomanid

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 a dose and duration of therapy that is consistent with FDA-approved package labeling, nationally recognized compendia, or peer-reviewed medical literature **AND**
- Medical record documentation of pulmonary infection due to *Mycobacterium tuberculosis* **AND**
- Medical record documentation of one of the following:
    - Extensively drug resistant tuberculosis (XDR-TB) **OR**
    - Treatment-intolerant or nonresponsive multidrug-resistant tuberculosis (TI/NR MDR-TB) **AND**
- Medical record documentation that Pretomanid will be used in combination with Sirturo (bedaquiline) and linezolid

Geisinger POLICY & PROCEDURE MANUAL	POLICY NUMBER: 1527.0F SECTION: Pharmacy – GHP Family Drug Policies SUBJECT: Oxervate

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 a dose and duration of therapy that is consistent with FDA-approved package labeling, nationally recognized compendia, or peer-reviewed medical literature **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

  AND
- Medical record documentation of therapeutic failure on, intolerance to, or contraindication to at least one conventional non-surgical treatment for neurotrophic keratitis (NK) (e.g. preservative-free artificial tears, gels/ointments; discontinuation of preserved topical drops and medications that can decrease corneal sensitivity; therapeutic contact lenses) **AND**
- Medical record documentation of therapeutic failure on, intolerance to, or contraindication to the Statewide PDL preferred Ophthalmics, Immunomodulators (e.g. Restasis Droperette)

Geisinger POLICY & PROCEDURE MANUAL	POLICY NUMBER: 1528.0F SECTION: Pharmacy – GHP Family Drug Policies SUBJECT: Palforzia

PROCEDURE:
Prior authorization of Palforzia will be made for members who meet the following criteria:
- Medical record documentation that Palforzia is prescribed by an allergist, immunologist, or a physician qualified to prescribe allergy immunotherapy **AND**
- Medical record documentation of a dose and duration of therapy that is consistent with FDA-approved package labeling, nationally recognized compendia, or peer-reviewed medical literature **AND**
- If the request is for initial dose escalation: Medical record documentation that member is greater than or equal to 4 years of age to less than 18 years of age **OR**
- If the request is for up-dosing or maintenance dose: Medical record documentation that member is greater than or equal to 4 years of age

AND

- Medical record documentation of confirmed diagnosis of peanut-allergy with history of allergic reaction from peanuts **AND** one of the following:
    - positive skin test **OR**
    - *in vitro* testing for peanut-specific IgE antibodies

AND
- Medical record documentation that Palforzia will be used in conjunction with peanut-avoidant diet **AND**
- Medical record documentation that the member has (or will receive) a prescription for an epinephrine auto-injector **AND**
- Medical record documentation that the member does not have severe, unstable, or uncontrolled asthma **AND**
- Medical record documentation that the member has not experienced severe or life-threatening anaphylaxis within 60 days of Palforzia initiation.

Geisinger POLICY & PROCEDURE MANUAL	POLICY NUMBER: 1531.0F SECTION: Pharmacy – GHP Family Drug Policies SUBJECT: Isturisa

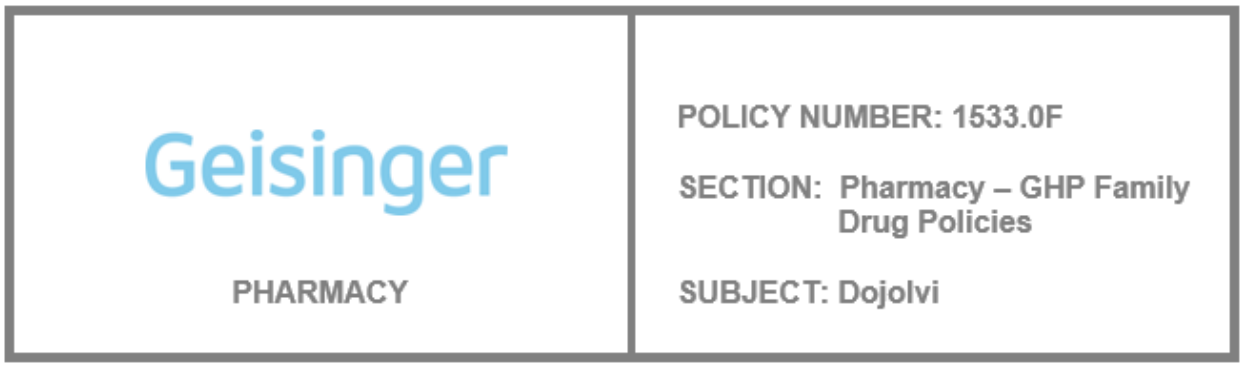
PROCEDURE:
Prior authorization of Isturisa will be made for members who meet the following criteria:

- Medical record documentation of age 18 years or older **AND**
- Prescription written by an endocrinologist **AND**
- Medical record documentation of a diagnosis of Cushing's disease **AND**
- Medical record documentation of a dose and duration of therapy that is consistent with FDA-approved package labeling, nationally recognized compendia, or peer-reviewed medical literature **AND**
- Medical record documentation that pituitary surgery is not an option or has not been curative **AND**
- Medical record documentation of therapeutic failure on, intolerance to, or contraindication to two (2) of the following: ketoconazole, metopirone, Signifor, Signifor LAR

Geisinger POLICY & PROCEDURE MANUAL	POLICY NUMBER: 1532.0F SECTION: Pharmacy – GHP Family Drug Policies SUBJECT: Inqovi

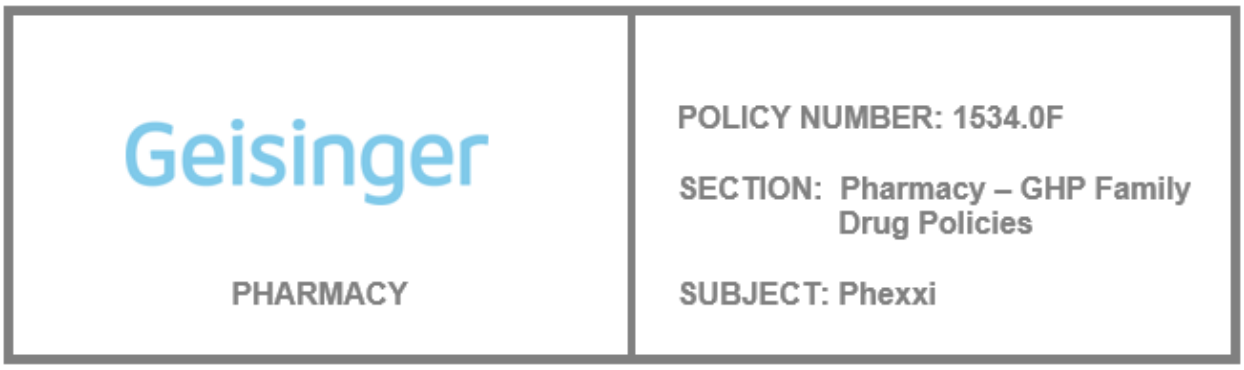
PROCEDURE:
Prior authorization of Inqovi will be made for members who meet the following criteria:

• Prescription written by or in consultation with an oncologist or hematologist **AND**
• Medical record documentation of age greater than or equal to 18 years **AND**
• Medical record documentation of a dose and duration of therapy that is consistent with FDA-approved package labeling, nationally recognized compendia, or peer-reviewed medical literature **AND**
• Medical record documentation of a diagnosis of myelodysplastic syndromes (MDS), including previously treated and untreated, de novo and secondary MDS with the following French-American-British subtypes (refractory anemia, refractory anemia with ringed sideroblasts, 16 refractory anemia with excess blasts, and chronic myelomonocytic leukemia [CMML]) and intermediate-1, intermediate-2, and high-risk International Prognostic Scoring System groups.



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

- Prescription written by or in consultation with a metabolic disease specialist or a physician who specializes in the management of long-chain fatty acid oxidation disorders **AND**
- Medical record documentation of a diagnosis of long-chain fatty acid oxidation disorders (LC-FAOD) confirmed by at least two of the following:
    - Disease specific elevation of acylcarnitines on a newborn blood spot or in plasma
    - Low enzyme activity in cultured fibroblasts
    - One or more known pathogenic mutations in a gene associated with a long-chain fatty acid oxidation disorder (e.g. *CPT2, ACADVL, HADHA,* or *HADHB)*
- Medical record documentation that the member is currently managed on a treatment regimen, which may include a low-fat, high carbohydrate; avoidance of fasting; and/or medium-chain triglyceride (MCT) oil.



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

- Medical record documentation of a therapeutic failure on, intolerance to, or contraindication to three (3) formulary alternatives.

Geisinger Health Plan PHARMACY	POLICY NUMBER: 1536.0F SECTION: Pharmacy – GHP Family Drug Policies SUBJECT: Evrysdi

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

- Medical record documentation that Evrysdi is prescribed by a neurologist or pediatric neurologist **AND**
- Medical record documentation that Evrysdi is prescribed with a dose and duration of therapy that is consistent with FDA-approved package labeling, nationally recognized compendia, or peer-reviewed medical literature **AND**
- Medical record documentation of a confirmed diagnosis of 5q Spinal Muscular Atrophy (SMA) by genetic testing with results showing one of the following:
    - Homozygous exon 7 gene deletion OR
    - Homozygous exon 7 conversion mutation OR
    - Compound heterozygous exon 7 mutation

OR

- Medical record documentation of diagnostic testing confirming zero (0) SMN1 copies

AND

- Medical record documentation that the patient has not received prior treatment with gene therapy (e.g. Zolgensma)*
- Medical record documentation that patient will not receive routine concomitant SMN modifying therapy (e.g. Spinraza)

Geisinger Health Plan PHARMACY	POLICY NUMBER: 1537.0F SECTION: Pharmacy – GHP Family Drug Policies SUBJECT: Enspryng

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

- Medical record documentation that Enspryng is prescribed by or in consultation with a neurologist **AND**
- Medical record documentation that Enspryng is prescribed with a dose and duration of therapy that is consistent with FDA-approved package labeling, nationally recognized compendia, or peer-reviewed medical literature **AND**
- Medical record documentation of age of greater than or equal to 18 years **AND**
- Medical record documentation of diagnosis of Neuromyelitis Optica Spectrum Disorder (NMOSD) **AND**
- Medical record documentation that the member is anti-aquaporin-4 (AQP4) antibody positive **AND**
- Medical record documentation of failure on, intolerance to, or contraindication to rituximab or rituximab biosimilar

Geisinger PHARMACY	POLICY NUMBER: 1538.0F SECTION: Pharmacy – GHP Family Drug Policies SUBJECT: Lampit

PROCEDURE:
Prior authorization of Lampit will be made for members who meet the following criteria:
• Prescribed by or in consultation with an infectious disease specialist **AND**
• Medical record documentation of age less than or equal to 18 years **AND**
• Medical record documentation of weight greater than or equal to 2.5 kg **AND**
• Medical record documentation that Lampit is prescribed with a dose and duration of therapy that is consistent with FDA-approved package labeling, nationally recognized compendia, or peer-reviewed medical literature **AND**
• Medical record documentation of a diagnosis of Chagas disease confirmed by one (1) of the following diagnostic tests:
  o Detection of circulating T. cruzi trypomastigotes on microscopy **OR**
  o Detection of T. cruzi DNA by polymerase chain reaction assay **OR**
  o 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

Geisinger PHARMACY	POLICY NUMBER: 1539.0F SECTION: Pharmacy – GHP Family Drug Policies SUBJECT: Xywav

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

- Medical record documentation of excessive daytime sleepiness in a patient with narcolepsy or cataplexy with narcolepsy **AND**
- Medical record documentation that Xywav is prescribed with a dose and duration of therapy that is consistent with FDA-approved package labeling, nationally recognized compendia, or peer-reviewed medical literature **AND**
- Medical record documentation of one of the following:
    - Medical record documentation of therapeutic failure on, intolerance to, or contraindication to Xyrem **OR**
    - Medical record documentation the patient requires a low sodium diet due to a concomitant diagnosis of heart failure, hypertension, or renal impairment

AND

- Medical record documentation of one of the following:
    - For cataplexy with narcolepsy, medical record documentation of failure on, intolerance to, or contraindication to one of the following: venlafaxine XR or fluoxetine **OR**
    - For excessive daytime sleepiness with narcolepsy: medical record documentation of failure on, intolerance to, or contraindication to modafinil

OR

- Medical record documentation of a diagnosis of idiopathic hypersomnia **AND**
- Medical record documentation that Xywav is prescribed with a dose and duration of therapy that is consistent with FDA-approved package labeling, nationally recognized compendia, or peer-reviewed medical literature **AND**
- Medical record documentation of an age greater than or equal to 18 **AND**
- Medical record documentation that member was evaluated and treated for other etiologies of excessive daytime sleepiness **AND**
- Medical record documentation of therapeutic failure on, intolerance to, or contraindication to modafinil

Geisinger PHARMACY	POLICY NUMBER: 1540.0F SECTION: Pharmacy – GHP Family Drug Policies SUBJECT: Zokinvy

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

- Medical record documentation of a confirmed diagnosis through genetic testing of one of the following:
  - Hutchinson-Gilford Progeria Syndrome
  - Processing-deficient progeroid laminopathy with either:
    - Heterozygous *LMNA* mutation with progerin-like protein accumulation
    - Homozygous or compound heterozygous *ZMPSTE24* mutations **AND**
- Medical record documentation of age greater than or equal to 12 months **AND**
- Medical record documentation of body surface area of at least 0.39m^2 **AND**
- Medical record documentation that the requested dose is appropriate based on the patient's body surface area **AND**
- Medical record documentation that all potential drug interactions have been addressed by the prescriber (such as discontinuation of the interacting drug, dose reduction of the

  interacting drug, or counseling of the beneficiary of the risks associated with the use of both medications when they interact)

Geisinger PHARMACY	POLICY NUMBER: 1541.0F SECTION: Pharmacy – GHP Family Drug Policies SUBJECT: Klisyri

PROCEDURE:
Prior authorization of Klisyri 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 actinic keratosis of the face or scalp **AND**

- Medical record documentation that Klisyri is prescribed with a dose and duration of therapy that is consistent with FDA-approved package labeling, nationally recognized compendia, or peer-reviewed medical literature **AND**
- Medical record documentation of greater than or equal to 4 lesions within a contiguous 25 cm2 area **AND**
- Medical record documentation of a therapeutic failure on, intolerance to, or contraindication to topical fluorouracil AND imiquimod.

Geisinger PHARMACY	POLICY NUMBER: 1542.0F SECTION: Pharmacy – GHP Family Drug Policies SUBJECT: Diclofenac 3% Gel

PROCEDURE:
Prior authorization of Diclofenac 3% Gel will be made for members who meet the following criteria:
- Medical record documentation of actinic keratosis **AND**
- Medical record documentation of a therapeutic failure on, intolerance to, or contraindication to topical fluorouracil AND imiquimod

Geisinger PHARMACY	POLICY NUMBER: 1543.0F SECTION: Pharmacy – GHP Family Drug Policies SUBJECT: Carglumic Acid

PROCEDURE:

Prior authorization of Carglumic Acid will be made for members who meet the following criteria:
<u>N-acetylglutamate synthase (NAGS) deficiency</u>
- Medical record documentation that Carglumic Acid is prescribed by a metabolic disorder specialist **AND**
- Medical record documentation of a diagnosis of hyperammonemia due to the deficiency of the hepatic enzyme N-acetylglutamate synthase (NAGS) **AND**
- Medical record documentation that Carglumic Acid is prescribed with a dose of therapy that is consistent with FDA-approved package labeling, nationally recognized compendia, or peer-reviewed medical literature

Propionic Acidemia (PA) or Methylmalonic Acidemia (MMA)

- Medical record documentation that Carglumic Acid is prescribed by a metabolic disorder specialist **AND**
- Medical record documentation of a diagnosis of propionic acidemia (PA) or methylmalonic acidemia (MMA**) AND**
- Medical record documentation of plasma ammonia level greater than or equal to 50 micromol/L **AND**
- Medical record documentation that Carglumic Acid is being prescribed as adjunctive treatment to standard of care (including but not limited to intravenous glucose, insulin, L-carnitine, protein restriction, and dialysis) **AND**
- Medical record documentation that Carglumic Acid is prescribed with a dose and duration of therapy that is consistent with FDA-approved package labeling, nationally recognized compendia, or peer-reviewed medical literature

Geisinger PHARMACY	POLICY NUMBER: 1544.0F SECTION: Pharmacy – GHP Family Drug Policies SUBJECT: Nulibry

PROCEDURE:

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

- Medical record documentation that Nulibry is prescribed by a neonatologist, geneticist, or pediatric neurologist **AND**
- Medical record documentation of a diagnosis of molybdenum cofactor deficiency (MoCD) Type A as confirmed by genetic testing indicating a mutation in the molybdenum cofactor synthesis gene 1 (MOCS1) gene **OR**
- Medical record documentation of both of the following:
    - Documentation of biochemical and clinical features consistent with a diagnosis of molybdenum cofactor deficiency (MoCD) Type A, including but not limited to encephalopathy, intractable seizures, elevated urinary S-sulfocysteine levels, and decreased uric acid levels **AND**
    - Documentation that the member will be treated presumptively while awaiting genetic confirmation

Geisinger PHARMACY	POLICY NUMBER: 1546.0F SECTION: Pharmacy – GHP Family Drug Policies SUBJECT: Tranexamic Acid

PROCEDURE:
Prior authorization of Tranexamic Acid for use for heavy menstrual bleeding will be made for members who meet the following criteria:

- Medical record documentation of therapeutic failure on, intolerance to, or contraindication to one preferred contraceptive **AND** either naproxen 250mg or 500mg tablets **OR** ibuprofen 200mg or 600mg tablets

Geisinger PHARMACY	POLICY NUMBER: 1547.0F SECTION: Pharmacy – GHP Family Drug Policies SUBJECT: Empaveli

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

- Medical record documentation of a diagnosis of paroxysmal nocturnal hemoglobinuria (PNH)
- Medical record documentation of flow cytometry confirming diagnosis AND
- Medical record documentation that Empaveli is prescribed by a hematologist AND
- Medical record documentation that member has received vaccinations against encapsulated bacteria, including *Streptococcus pneumoniae, Neisseria meningitidis,* and *Haemophilus influenzae type B* AND
- Medical record documentation of one of the following:
    - member is transfusion-dependent (i.e., has at least 1 transfusion in the 24 months prior to initiation of pegcetacoplan due to documented hemoglobin less than 7 g/dL in persons without anemic symptoms or less than 9 g/dL in persons with symptoms from anemia) prior to initiation of pegcetacoplan treatment; or
    - there is a significant adverse impact on the insured individual's health such as end organ damage or thrombosis without other cause

Geisinger PHARMACY	POLICY NUMBER: 1548.0F SECTION: Pharmacy – GHP Family Drug Policies SUBJECT: Kerendia

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

- Medical record documentation of a diagnosis of chronic kidney disease associated with type 2 diabetes **AND**
- Medical record documentation of age greater than or equal to 18 years **AND**
- Medical record documentation of serum potassium ≤ 5.0 mEq/L or ≤ 5.5 mEq/L if previously established on therapy **AND**
- Medical record documentation of persistent albuminuria (albumin to creatinine ratio consistently greater than 30 mg/g) despite treatment with both of the following:
    - Maximally tolerated angiotensin-converting enzyme inhibitor (ACEi) or angiotensin receptor blocker (ARB) OR medical record documentation of contraindication or intolerance to one angiotensin-converting enzyme inhibitor (ACEi) or angiotensin receptor blocker (ARB AND
    - One sodium-glucose co-transporter 2 (SGLT-2) inhibitor with proven kidney or cardiovascular benefit OR medical record documentation of contraindication or intolerance to one sodium-glucose co-transporter 2 (SGLT-2) inhibitor with proven kidney or cardiovascular benefit

Geisinger PHARMACY	POLICY NUMBER: 1549.0F SECTION: Pharmacy – GHP Family Drug Policies SUBJECT: InPen

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

- Medical record documentation of a diagnosis of diabetes mellitus **AND**
- Medical record documentation that InPen is prescribed by or in consultation with an endocrinologist **AND**
- Medical record documentation of age greater than or equal to 7 years **OR** age less than 7 years and documentation that InPen will be utilized with adult supervision **AND**
- Medical record documentation that member has access to a device with the ability to install and use the InPen app (e.g. smartphone, tablet, etc. with iOS 10 or later or Android 6 or later) **AND**

- Medical record documentation that member has utilized multiple daily injections of insulin (i.e. at least 3 injections per day), with 3 or more self-adjustments of insulin dose for at least 6 months **AND**
- Medical record documentation that member has suboptimal blood sugar control despite appropriate management as demonstrated by at least one of the following:
    - Glycosylated hemoglobin level (HbA1c) > 7.0 %
    - History of recurring hypoglycemia
    - Wide fluctuations in blood glucose before mealtime
    - History of severe glycemic excursions

Geisinger PHARMACY	POLICY NUMBER: 1550.0F SECTION: Pharmacy – GHP Family Drug Policies SUBJECT: Bylvay

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

Progressive Familial Intrahepatic Cholestasis (PFIC)

- Prescription written by or consultation with a hepatologist or gastroenterologist **AND**
- Medical record documentation of diagnosis of progressive familial intrahepatic cholestasis (PFIC) confirmed by genetic testing **AND**
- Medical record documentation of the presence of moderate to severe pruritus **AND**
- Medical record documentation of age greater than or equal to 3 months **AND**
- Medical record documentation that the member is receiving an appropriate dose* based on the patient's weight **AND**
- Medical record documentation of concurrent use or therapeutic failure on, intolerance to, or contraindication to ursodiol.

Geisinger PHARMACY	POLICY NUMBER: 1551.0F SECTION: Pharmacy – GHP Family Drug Policies SUBJECT: Tavneos

PROCEDURE:
Prior authorization of Tavneos 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 severe active anti-neutrophil cytoplasmic autoantibody (ANCA)-associated vasculitis classified as one of the following variants:
    - granulomatosis with polyangiitis (GPA) OR
    - microscopic polyangiitis (MPA)

  AND

- Medical record documentation of both of the following:
    - Medical record documentation of a positive test for anti-proteinase 3 (PR3) or anti-myeloperoxidase (MPO) AND
    - Medical record documentation of at least 1 major item, 3 non-major items, or 2 renal items of proteinuria and hematuria on the Birmingham Vasculitis Activity Score (BVAS)

  AND

- Medical record documentation that Tavneos will be administered in combination with standard therapy that will include, but is not limited to rituximab or cyclophosphamide, and glucocorticoids

Geisinger PHARMACY	POLICY NUMBER: 1552.0F SECTION: Pharmacy – GHP Family Drug Policies SUBJECT: Livmarli

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

- Prescription written by or in consultation with a hepatologist or gastroenterologist AND
- Medical record documentation of diagnosis of Alagille Syndrome (ALGS) AND
- Medical record documentation of the presence of moderate to severe pruritus AND
- Medical record documentation that the member is receiving an appropriate dose* based on the patient's weight AND
- Medical record documentation of therapeutic failure on, intolerance to, or contraindication to ursodiol and one of the following: cholestyramine, rifampin, naltrexone, sertraline

Geisinger PHARMACY	POLICY NUMBER: 1553.0F SECTION: Pharmacy – GHP Family Drug Policies SUBJECT: Vuity

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

- Prescription written by or in consultation with an optometrist or ophthalmologist AND
- Medical record documentation of a diagnosis of Presbyopia AND
- Medical record documentation of age greater than or equal to 40 years AND
- Medical record documentation of intolerance to, or contraindication to corrective lenses.

Geisinger PHARMACY	POLICY NUMBER: 1554.0F SECTION: Pharmacy – GHP Family Drug Policies SUBJECT: Recorlev

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

- Medical record documentation of endogenous hypercortisolemia associated with Cushing's syndrome **AND**
- Medical record documentation of age 18 years or older **AND**
- Medical record documentation that Recorlev is being prescribed by or in consultation with an endocrinologist **AND**
- Medical record documentation that pituitary surgery is not an option or has not been curative **AND**
- Medical record documentation of a dose and duration of therapy that is consistent with FDA-approved package labeling, nationally recognized compendia, or peer-reviewed medical literature **AND**
- Medical record documentation of therapeutic failure on, intolerance to, or contraindication to two (2) of the following: ketoconazole, Metopirone, Signifor, Signifor LAR

Geisinger PHARMACY	POLICY NUMBER: 1555.0F SECTION: Pharmacy – GHP Family Drug Policies SUBJECT: Soaanz

PROCEDURE:
Prior authorization of Soaanz 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 Soaanz will be used for the treatment of edema associated with heart failure OR renal disease **AND**
- Medical record documentation of a dose and duration of therapy that is consistent with FDA-approved package labeling, nationally recognized compendia, or peer-reviewed medical literature **AND**
- Medical record documentation of therapeutic failure on, intolerance to, or contraindication to three (3) formulary alternatives, one of which must be generic torsemide

Geisinger PHARMACY	POLICY NUMBER: 1556.0F SECTION: Pharmacy – GHP Family Drug Policies SUBJECT: Voxzogo

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

- Medical record documentation of a diagnosis of achondroplasia with genetic testing confirming a mutation of FGFR3 **AND**
- Medical record documentation that Voxzogo is prescribed by a pediatric endocrinologist **AND**
- Medical record documentation that member is 5 to 18 years of age **AND**
- Medical record documentation of evidence that patient has open epiphyses **AND**
- Medical record patient has not received (within the past 18 months) or plans to receive limb-lengthening surgery **AND**
- Medical record documentation that Voxzogo will not be used in combination with human growth hormone products **AND**
- Medical record documentation of GFR > 60ml/min/1.73m^2 **AND**
- Medical record documentation of patient's current weight **AND**
- Medical record documentation that prescribed dose is appropriate for patient's current weight **AND**

- Medical record documentation of baseline annualized growth velocity (AGV), calculated based on standing height measured over the course of 6 months prior to request **AND**
- Medical record documentation of a dose and duration of therapy that is consistent with FDA-approved package labeling, nationally recognized compendia, or peer-reviewed medical literature

Geisinger PHARMACY	POLICY NUMBER: 1557.0F SECTION: Pharmacy – GHP Family Drug Policies SUBJECT: Pyrukynd

PROCEDURE:
Prior authorization of Pyrukynd will be made for members who meet the following criteria:
- Medical record documentation of age 18 years or older **AND**
- Medical record documentation of diagnosis of pyruvate kinase deficiency (PKD) **AND**
- Medical record documentation of at least 2 mutant alleles in the PKLR gene, with at least 1 being a missense mutation **AND**
- Medical record documentation that the member is not homozygous for the R479H mutation **AND**
- Medical record documentation that Pyrukynd is being prescribed by or in consultation with a hematologist **AND**
- Medical record documentation of hemoglobin level less than or equal to 10 g/dL **OR** the member is receiving regular RBC transfusions **AND**
- Medical record documentation of a dose and duration of therapy that is consistent with FDA-approved package labeling, nationally recognized compendia, or peer-reviewed medical literature.

Geisinger PHARMACY	POLICY NUMBER: 1558.0F SECTION: Pharmacy – GHP Family Drug Policies SUBJECT: Radicava ORS

PROCEDURE:
Prior authorization of Radicava ORS will be made for members who meet the following criteria:
- Prescription written by or in consultation with a neurologist **AND**

- Medical record documentation of a diagnosis of ALS (amyotrophic lateral sclerosis) **AND**
- Medical record documentation of baseline functional status (as evidenced by a scoring system such as ALSFRS-R, or by physician documentation of subjective reports on speech, motor function, pulmonary function, etc.) **AND**
- Medical record documentation that Radicava is being given in combination with riluzole OR intolerance or contraindication to riluzole **AND**

Medical record documentation of a dose and duration of therapy that is consistent with FDA-approved package labeling, nationally recognized compendia, or peer-reviewed medical literature.

Geisinger PHARMACY	POLICY NUMBER: 1559.0F SECTION: Pharmacy – GHP Family Drug Policies SUBJECT: Camzyos

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

- Medical record documentation that Camzyos is prescribed by a cardiologist **AND**
- Medical record documentation of age ≥18 years old **AND**
- Medical record documentation of diagnosis of NYHA class II-III obstructive hypertrophic cardiomyopathy **AND**
- Medical record documentation of left ventricular ejection fraction (LVEF) ≥55% **AND**
- Medical record documentation of therapeutic failure on, intolerance to, or contraindication to two of the following: beta-blockers, non-dihydropyridine calcium channel blockers, or disopyramide **AND**
- Medical record documentation of a dose and duration of therapy that is consistent with FDA-approved package labeling, nationally recognized compendia, or peer-reviewed medical literature

Geisinger PHARMACY	POLICY NUMBER: 1560.0F SECTION: Pharmacy – GHP Family Drug Policies SUBJECT: Imcivree

PROCEDURE:
Prior authorization of Imcivree will be made for members who meet the following criteria:
<u>Obesity due to Bardet-Biedl Syndrome</u>

• Medical record documentation of age greater than or equal to 6 years **AND**
• Medical record documentation of one of the following:
    o For patients 16 years and older: Medical record documentation of body mass index (BMI) of greater than or equal to 30kg/m2
    o For patients 6 years to less than 16 years: Medical record documentation of weight greater than or equal to 97th percentile using growth chart assessments

AND

• Medical record documentation of obesity due to Bardet-Biedl syndrome (BBS) **AND**
• Medical record documentation of a dose and duration of therapy that is consistent with FDA-approved package labeling, nationally recognized compendia, or peer-reviewed medical literature

<u>Obesity due to POMC, PCSK1, or LEPR Deficiency</u>

• Medical record documentation of age greater than or equal to 6 years **AND**
• Medical record documentation of one of the following:
    o For patients 18 years and older: Medical record documentation of body mass index (BMI) of greater than or equal to 30 kg/m2
    o For patients age 6 years to less than 18 years: Medical record documentation of weight greater than or equal to 95th percentile using growth chart assessments

AND

• Medical record documentation of a proopiomelanocortin (POMC), proprotein convertase subtilisin/kexin type 1 (PCSK1), or leptin receptor (LEPR) deficiency **AND**
• Medical record confirmation of genetic testing demonstrating variants in POMC, PCSK1, or LEPR genes that are interpreted as pathogenic, likely pathogenic, or of uncertain significance (VUS) **AND**
• Medical record documentation of a dose and duration of therapy that is consistent with FDA-approved package labeling, nationally recognized compendia, or peer-reviewed medical literature.

Geisinger PHARMACY	POLICY NUMBER: 1561.0F SECTION: Pharmacy – GHP Family Drug Policies SUBJECT: Epsolay and Zilxi

PROCEDURE:
Prior authorization of Epsolay or Zilxi will be made for members who meet the following criteria:

- Medical record documentation of a diagnosis of rosacea with inflammatory lesions AND
- Medical record documentation of therapeutic failure on, intolerance to, or contraindication to three (3) formulary alternatives

GPI Level: GPI-14 for Epsolay

Geisinger PHARMACY	POLICY NUMBER: 1562.0F SECTION: Pharmacy – GHP Family Drug Policies SUBJECT: CaroSpir

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

- Medical record documentation of an FDA approved indication **AND**
- Medical record documentation of therapeutic failure on, intolerance to, or contraindication to two (2) formulary diuretics, one of which must be spironolactone tablets **OR**
- If the member has trouble swallowing, medical record documentation of therapeutic failure on, intolerance to, or contraindication to furosemide oral liquid **OR**
- If the member has trouble swallowing, medical record documentation of a diagnosis of heart failure.

Geisinger PHARMACY	POLICY NUMBER: 1563.0F SECTION: Pharmacy – GHP Family Drug Policies SUBJECT: Verquvo

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

- Medical record documentation that Verquvo is prescribed by or in consultation with a cardiologist **AND**
- Medical record documentation of age greater than or equal to 18 years **AND**
- Medical record documentation of symptomatic chronic New York Heart Association Class II-IV heart failure **AND**
- Medical record documentation of one of the following:
    - Medical record documentation of hospital admission due to heart failure within the previous 6 months **OR**
    - Medical record documentation of outpatient intravenous (IV) diuretic treatment for heart failure within the previous 3 months

AND

- Medical record documentation of a left ventricular ejection fraction (LVEF) < 45% **AND**

- Medical record documentation of therapeutic failure on, intolerance to, or contraindication to at least one formulary angiotensin converting enzyme inhibitor (ACEi), angiotensin receptor blocker (ARB) or angiotensin receptor and neprilysin inhibitor (ARNI) **AND**
- Medical record documentation of therapeutic failure on, intolerance to, or contraindication to at least one formulary beta-blocker **AND**
- Medical record documentation of a dose and duration of therapy that is consistent with FDA-approved package labeling, nationally recognized compendia, or peer-reviewed medical literature

Geisinger PHARMACY	POLICY NUMBER: 1564.0F SECTION: Pharmacy – GHP Family Drug Policies SUBJECT: Vijoice

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

- Medical record documentation of age greater than or equal to 2 years **AND**
- Medical record documentation of diagnosis of PIK3CA-Related Overgrowth Spectrum (PROS) **AND**
- Medical record documentation of mutation in the catalytic α-subunit of PI3K (PIK3CA) gene **AND**
- Medical record documentation of severe or life-threatening disease which requires systemic treatment **AND**
- Medical record documentation of a dose and duration of therapy that is consistent with FDA-approved package labeling, nationally recognized compendia, or peer-reviewed medical literature

Geisinger PHARMACY	POLICY NUMBER: 1565.0F SECTION: Pharmacy – GHP Family Drug Policies SUBJECT: Dartisla ODT

PROCEDURE:
Prior authorization of Dartisla ODT will be made for members who meet the following criteria:

- Medical record documentation that Dartisla ODT will be given as an adjunct to treatment of peptic ulcer disease **AND**
- Medical record documentation of age greater than or equal to 18 years **AND**
- Medical record documentation of one of the following:
    - Medical record documentation of difficulty swallowing **OR**
    - Medical record documentation of a therapeutic failure on, intolerance to, or contraindication to glycopyrrolate tablets
      AND
- Medical record documentation of a dose and duration of therapy that is consistent with FDA-approved package labeling, nationally recognized compendia, or peer-reviewed medical literature

Geisinger PHARMACY	POLICY NUMBER: 1566.0F SECTION: Pharmacy – GHP Family Drug Policies SUBJECT: Relyvrio

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

- Medical record documentation of a diagnosis of amyotrophic lateral sclerosis (ALS) **AND**
- Medical record documentation that Relyvrio is prescribed in consultation with a neurologist **AND**

Medical record documentation of a dose and duration of therapy that is consistent with FDA-approved package labeling, nationally recognized compendia, or peer-reviewed medical literature

Geisinger PHARMACY	POLICY NUMBER: 1567.0F SECTION: Pharmacy – GHP Family Drug Policies SUBJECT: Hyftor

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

- Medical record documentation of age 6 years or older **AND**
- Medical record documentation of a diagnosis of facial angiofibroma associated with tuberous sclerosis **AND**
- Medical record documentation of age appropriate dosing (less than or equal to 600 mg per day for patients 6 to 11 years of age OR less than or equal to 800 mg per day for patients 12 years of age and older).

Geisinger PHARMACY	POLICY NUMBER: 1568.0F SECTION: Pharmacy – GHP Family Drug Policies SUBJECT: Daybue

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

- Medical record documentation of 2 years or older **AND**
- Medical record documentation of the *MECP2* gene **AND**
- Medical record documentation of diagnosis of classic, or typical Rett Syndrome **AND**
- Medical record documentation of a patients baseline symptoms using an appropriate rating scale (e.g., Rett syndrome behavioral questionnaire, simplified severity score, Clinical Global Impression-Improvement assessment) **AND**
- Medical record documentation that Daybue is appropriately dosed **AND**
- Medical record documentation that Daybue is prescribed by or in consultation with a neurologist.

Geisinger PHARMACY	POLICY NUMBER: 1569.0F SECTION: Pharmacy – GHP Family Drug Policies SUBJECT: Skyclarys

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

- Medical record documentation of age greater than or equal to 16 years **AND**
- Medical record documentation that the prescription is written by or in consultation with a Neurologist **AND**
- Medical record documentation of a diagnosis of Friedrich's Ataxia **AND**
- Medical record documentation of genetic testing confirming Frataxin (FXN) gene mutation **AND**
- Medical record documentation of baseline modified Friedreich's Ataxia Rating Scale (mFARS) score **AND**
- Medical record documentation that Skyclarys is prescribed with a dose and duration of therapy that is consistent with FDA-approved package labeling, nationally recognized compendia, or peer-reviewed medical literature

Geisinger	POLICY NUMBER: 1570.0F
	SECTION: Pharmacy – GHP Family Drug Policies
PHARMACY	SUBJECT: Filspari

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

- Medical record documentation of age ≥ 18 years **AND**
- Medical record documentation of primary immunoglobulin A nephropathy (IgAN) verified by biopsy **AND**
- Medical record documentation that the medication is prescribed by or in consultation with a nephrologist **AND**
- Medical record documentation that patient is at high risk of disease progression, defined as urine protein-to-creatinine ratio (UPCR) ≥ 1.5 g/g or proteinuria ≥ 1g/day **AND**
- Medical record documentation that patient has received ≥ 90 days of optimized supportive care, including blood pressure management, lifestyle modification, and cardiovascular risk modification **AND**
- Medical record documentation of eGFR ≥ 30 mL/min/1.73 m2 **AND**
- Medical record documentation that patient has received a stable dose of a RAS Inhibitor (ACE inhibitor or ARB) at a maximally tolerated dose for ≥ 90 days **AND**
- Medical record documentation that RAS inhibitor (ACE inhibitor or ARB) will be discontinued prior to initiation of treatment with Filspari **AND**
- Medical record documentation that Filspari will NOT be used in combination with any RAS inhibitors (ACE inhibitor or ARB), endothelin receptor antagonists, or aliskiren **AND**
- Medical record documentation that Filspari is prescribed with a dose and duration of therapy that is consistent with FDA-approved package labeling, nationally recognized compendia, or peer-reviewed medical literature.

Geisinger PHARMACY	POLICY NUMBER: 1571.0F SECTION: Pharmacy – GHP Family Drug Policies SUBJECT: Cuvrior

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

- Medical record documentation that the member is 18 years of age or older **AND**
- Medical record documentation of a diagnosis of Wilson's disease **AND**
- Medical record documentation of controlled Wilson's disease as evident by serum non-ceruloplasmin copper (NCC) level between ≥ 25 and ≤150 mcg/L **AND**
- Medical record documentation that the member is tolerant to penicillamine and that penicillamine will be discontinued prior to therapy with Cuvrior **AND**
- Medical record documentation of therapeutic failure on, intolerance to, or contraindication to trientine **AND**
- Medical record documentation that Cuvrior is prescribed with a dose and duration of therapy that is consistent with FDA-approved package labeling, nationally recognized compendia, or peer-reviewed medical literature.

Geisinger PHARMACY	POLICY NUMBER: 1572.0F SECTION: Pharmacy – GHP Family Drug Policies SUBJECT: Joenja

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

- Medical record documentation of age 12 years or older **AND**
- Medical record documentation of a diagnosis of activated phosphoinositide 3-kinase delta (PI3Kδ) syndrome (APDS) **AND**
- Medical record documentation of weight greater than or equal to 45 kg **AND**
- Medical record documentation of a mutation in PIK3CD OR PIK3R1 gene **AND**
- Medical record documentation that Joenja is prescribed with a dose and duration of therapy that is consistent with FDA-approved package labeling, nationally recognized compendia, or peer-reviewed medical literature.

Geisinger PHARMACY	POLICY NUMBER: 1573.0F SECTION: Pharmacy – GHP Family Drug Policies SUBJECT: Lumryz

PROCEDURE:
Prior authorization of Lumryz 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 one of the following:
  - Diagnosis of excessive daytime sleepiness associated with narcolepsy **OR**
  - Diagnosis of cataplexy with narcolepsy **AND**
- Medical record documentation that Lumryz is prescribed with a dose and duration of therapy that is consistent with FDA-approved package labeling, nationally recognized compendia, or peer-reviewed medical literature **AND**
- Medical record documentation of therapeutic failure on, intolerance to, or contraindication to Xyrem OR Xywav

Geisinger PHARMACY	POLICY NUMBER: 1574.0F SECTION: Pharmacy – GHP Family Drug Policies SUBJECT: Veozah

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

- Medical record documentation of age greater than 18 years **AND**
- Medical record documentation of diagnosis of menopause with moderate to severe vasomotor symptoms (VMS) **AND**
- Medical record documentation of therapeutic failure on, intolerance to, or contraindication to at least three 3 different medications from at least two of the following categories: i. Estrogens, ii. Non-Hormonal **AND**
- Medical record documentation that Veozah is prescribed with a dose and duration of therapy that is consistent with FDA-approved package labeling, nationally recognized compendia, or peer-reviewed medical literature.

Geisinger PHARMACY	POLICY NUMBER: 1575.0F SECTION: Pharmacy – GHP Family Drug Policies SUBJECT: Furoscix

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

- Medical record documentation that Furoscix is prescribed by or in consultation with a cardiologist **AND**
- Medical record documentation of age greater than or equal to 18 years **AND**
- Medical record documentation of New York Heart Association (NYHA) Class II or Class III chronic heart failure **AND**
- Medical record documentation of congestion due to fluid overload **AND**
- Medical record documentation that member is stable on background loop diuretic therapy **AND**
- Medical record documentation of provider attestation that member will use Furoscix for short-term use only and will be transitioned to oral diuretics as soon as practical.

Geisinger PHARMACY	POLICY NUMBER: 1576.0F SECTION: Pharmacy – GHP Family Drug Policies SUBJECT: Vowst

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

- Documentation of age greater than or equal to 18 years **AND**
- Prescribed by or in consultation with an infectious disease specialist or gastroenterologist AND
- Medical record documentation that Vowst will be used for the prevention of recurrence of C. difficile infections **AND**
- Medical record documentation of a diagnosis of recurrent C. difficile infection based on the results of an appropriate laboratory stool test within 30 days of prior authorization request **AND**
- Medical record documentation that an appropriate standard-of-care antibacterial regimen was used for the treatment of recurrent C. difficile infection (e.g., oral fidaxomicin, oral vancomycin, oral metronidazole) **AND**
- Medical record documentation of a prescribed dose and administration that is consistent with FDA-approved package labeling, nationally recognized compendia, or peer-reviewed medical literature.

Geisinger PHARMACY	POLICY NUMBER: 1578.0F SECTION: Pharmacy – GHP Family Drug Policies SUBJECT: Sohonos

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

- Medical record documentation that Sohonos is prescribed by or in consultation with an endocrinologist or a physician who specializes in connective tissue or bone diseases **AND**
- Medical record documentation of a diagnosis of fibrodysplasia ossificans progressive (FOP) **AND**
- Medical record documentation of confirmed Activin A Type 1 Receptor (ACVR1) R206H mutation **AND**
- Medical record documentation of age greater than or equal to 8 years for females OR greater than equal to 10 years for males **AND**
- Medical record documentation of a prescribed dose and administration that is consistent with FDA-approved package labeling, nationally recognized compendia, or peer-reviewed medical literature.

Geisinger PHARMACY	POLICY NUMBER: 1579.0F SECTION: Pharmacy – GHP Family Drug Policies SUBJECT: Xdemvy

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

- Medical record documentation of a diagnosis of chronic *Demodex* blepharitis (DB) evidenced by:
  - Presence of at least mild erythema of the upper eyelid margin **AND**
  - Presence of mites upon examination of eyelashes by light microscopy or presence of collarettes on slit lamp examination

  AND
- Medical record documentation that Xdemvy is prescribed by or in consultation with an ophthalmologist **AND**
- Medical record documentation of age greater than or equal to 18 years old **AND**
- Medical record documentation of a prescribed dose and administration that is consistent with FDA-approved package labeling, nationally recognized compendia, or peer-reviewed medical literature.

Geisinger PHARMACY	POLICY NUMBER: 1580.0F SECTION: Pharmacy – GHP Family Drug Policies SUBJECT: Jesduvroq

PROCEDURE:
Prior authorization of Jesduvroq 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 anemia due to chronic kidney disease **AND**
- Medical record documentation that member has been receiving dialysis for at least four months **AND**
- Medical record documentation of a Hemoglobin less than or equal to 11 g/dL **AND**
- Medical record documentation of ferritin greater than or equal to 100 ng/mL or transferrin saturation level greater than or equal to 20% or history of chelation therapy for iron **AND**
- Medical record documentation of a prescribed dose and administration that is consistent with FDA-approved package labeling, nationally recognized compendia, or peer-reviewed medical literature.

Geisinger PHARMACY	POLICY NUMBER: 1582.0F SECTION: Pharmacy – GHP Family Drug Policies SUBJECT: Fabhalta

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

- Medical record documentation of a diagnosis of paroxysmal nocturnal hemoglobinuria (PNH) **AND**
- Medical record documentation of flow cytometry confirming diagnosis **AND**
- Medical record documentation that Fabhalta is prescribed by a hematologist **AND**
- Medical record documentation that member has received vaccinations against encapsulated bacteria, including Streptococcus pneumoniae, Neisseria meningitidis, and Haemophilus influenzae type B **AND**
- Medical record documentation of one of the following:

- member is transfusion-dependent (i.e., has at least 1 transfusion in the 24 months prior to initiation of iptacopan due to documented hemoglobin less than 7 g/dL in persons without anemic symptoms or less than 9 g/dL in persons with symptoms from anemia) prior to initiation of iptacopan treatment; OR
- there is a significant adverse impact on the insured individual's health such as end organ damage or thrombosis without other cause

Medical record documentation of a prescribed dose and administration that is consistent with FDA-approved package labeling, nationally recognized compendia, or peer-reviewed medical literature.

Geisinger PHARMACY	POLICY NUMBER: 1583.0F SECTION: Pharmacy – GHP Family Drug Policies SUBJECT: Opfolda

PROCEDURE:

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

- Medical record documentation of a diagnosis of late-onset Pompe disease supported by:
  - Acid alpha-glucosidase (GAA) assay performed on dried blood spots, skin fibroblasts or muscle biopsy AND
  - Genetic testing showing a mutation in the GAA gene

AND

- Medical record documentation of a consultation with a metabolic specialist and/or biochemical geneticist AND
- Medical record documentation of age greater than or equal to 18 years AND
- Medical record documentation of baseline percent-predicted forced vital capacity (% FVC) and 6-minute walk test (6MWT) AND
- Medical record documentation of member weight ≥ 40 kg AND
- Medical record documentation that Opfolda and Pombiliti will be used in combination AND
- Medical record documentation that member is currently receiving enzyme replacement therapy (e.g. Lumizyme, Nexviazyme) and is not experiencing improvement AND
- Medical record documentation that Polmbiliti and Opfolda will not be used concurrently with other enzyme replacement therapy (e.g. Lumizyme, Nexviazyme) AND

Medical record documentation of a prescribed dose and administration that is consistent with FDA-approved package labeling, nationally recognized compendia, or peer-reviewed medical literature.

Geisinger PHARMACY	POLICY NUMBER: 1584.0F SECTION: Pharmacy – GHP Family Drug Policies SUBJECT: Wainua

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

- Medical record documentation that Wainua is prescribed by or in consultation with a neurologist, board-certified 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 one of the following**:**
    - Medical record documentation of biopsy of tissue or organ to confirm amyloid presence **OR**
    - Medical record documentation of a clinical manifestation typical of hATTR (i.e., neuropathy or congestive heart failure) without a better alternative explanation **AND**
- Medical record documentation that Wainua will be used to treat polyneuropathy **AND**
- Medical record documentation of one of the following:
    - Medical record documentation of familial amyloid polyneuropathy (FAP) stage 1-2 **OR**
    - Medical record documentation of polyneuropathy disability score (PND) indicating the patient is not wheelchair bound or bedridden **AND**
- Medical record documentation that Wainua will not be used in combination with other RNA interference treatments **AND**
- Medical record documentation of an intolerance to, contraindication to, or therapeutic failure of two (2) preferred formulary treatments for hATTR **AND**
- Medical record documentation of a prescribed dose and administration that is consistent with FDA-approved package labeling, nationally recognized compendia, or peer-reviewed medical literature.

Geisinger PHARMACY	POLICY NUMBER: 1585.0F SECTION: Pharmacy – GHP Family Drug Policies SUBJECT: Zilbrysq

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

- Medical record documentation of age 18 years or older **AND**

- Medical record documentation that Zilbrysq is prescribed by or in consultation with a neurologist **AND**
- Medical record documentation of a diagnosis of generalized myasthenia gravis (gMG) that is anti-acetylcholine receptor (AChR) positive **AND**
- Medical record documentation of Myasthenia Gravis Foundation of America Clinical Classification (MGFA) Class II to IV **AND**
- Medical record documentation of a baseline Myasthenia Gravis-Activities of Daily Living (MG-ADL) score greater than or equal to 6 **AND**
- Medical record documentation of therapeutic failure on, intolerance to, or contraindication to corticosteroids **AND**
- Medical record documentation of therapeutic failure on intolerance to, or contraindication to at least two (2) non-steroidal immunosuppressive therapies **OR** has failed at least one (1) immunosuppressive therapy and required chronic plasmapheresis or plasma exchange (PE) **AND**
- Medical record documentation of failure on, intolerance to, or contraindication to intravenous immunoglobulin (IVIG) **AND**
- Medical record documentation of a prescribed dose and administration that is consistent with FDA-approved package labeling, nationally recognized compendia, or peer-reviewed medical literature.

Geisinger PHARMACY	POLICY NUMBER: 1586.0F SECTION: Pharmacy – GHP Family Drug Policies SUBJECT: Rezdiffra

PROCEDURE:

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

- Medical record documentation of age 18 years or older **AND**
- Medical record documentation of a diagnosis of metabolic dysfunction-associated steatohepatitis (MASH) [formerly known as noncirrhotic nonalcoholic steatohepatitis (NASH)] **AND**
- Medical record documentation of moderate to advanced liver fibrosis (consistent with stages F2 to F3 fibrosis) **AND**
- Medical record documentation of chart notes showing that diagnosis is confirmed by 1 of the following:
    - Liver biopsy **OR**
    - Non-invasive test (NIT) (e.g. – ultrasound elastography [i.e., Fibroscan], magnetic resonance elastography [MRE], biomarker labs [i.e., Enhanced Liver Fibrosis (ELF) test, Fibrosure])

AND

- Medical record documentation that Rezdiffra will be used in combination with diet and exercise **AND**
- Medical record documentation that the patient does not have decompensated cirrhosis **AND**
- Medical record documentation that Rezdiffra is prescribed by or in consultation to an appropriate specialist (hepatologist or gastroenterologist).

Geisinger PHARMACY	POLICY NUMBER: 1587.0F SECTION: Pharmacy – GHP Family Drug Policies SUBJECT: Rivfloza

PROCEDURE:

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

- Medical record documentation of primary hyperoxaluria type 1 (PH1) as confirmed by one of the following:
    - Molecular genetic testing that confirms a mutation of alanin:glyoxylate aminotransferase (*AGXT*) gene* OR
    - A liver biopsy to confirm absent or significantly reduced alanin:glyoxylate aminotransferase (AGT)

  *Note: *AGXT* genotypes include but are not limited to: PR/RR, PR/M, PR/N, M/M, M/N, N/N

  AND
- Medical record documentation that Rivfloza is prescribed by or in consultation with an appropriate specialist with experience managing hyperoxaluria (i.e., a nephrologist, urologist, geneticist, or hepatologist) **AND**
- Medical record documentation of age greater than or equal to 9 years **AND**
- Medical record documentation of increased urinary oxalate excretion (i.e., generally greater than 0.7 mmol/1.73 m^2 per day or greater than the upper limit of normal) **AND**
- Medical record documentation of relatively preserved kidney function as defined by one of the following:
    - Medical record documentation patient has an eGFR ≥30 mL/min/1.73m^2 OR
    - If eGFR is not calculated due to age limitations, a serum creatine within the normal age-specific reference range

  AND
- Medical record documentation that the patient does not have a history of a liver transplant **AND**
- Medical record documentation that the member will not be receiving Rivfloza in combination with Oxlumo **AND**
- Medical record documentation of a prescribed dose and administration that is consistent with FDA-approved package labeling, nationally recognized compendia, or peer-reviewed medical literature **AND**
- Medical record documentation of failure, contraindication, or intolerance to Oxlumo **AND**
- Medical record documentation of a prescribed dose and administration that is consistent with FDA-approved package labeling, nationally recognized compendia, or peer-reviewed medical literature

Geisinger PHARMACY	POLICY NUMBER: 1589.0F SECTION: Pharmacy – GHP Family Drug Policies SUBJECT: Xolremdi

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

- Medical record documentation of a diagnosis of WHIM (warts, hypogammaglobulinemia, infections, and myelokathexis) syndrome **AND**
- Medical record documentation of symptoms and complications associated with WHIM syndrome **AND**
- Medical record documentation that member is 12 years of age or greater **AND**
- Medical Record documentation that Xolremdi is being prescribed by an immunologist, dermatologist, genetic specialist, or hematologist **AND**
- Medical record documentation of member's weight **AND**
- Medical record documentation of baseline absolute neutrophil count (ANC) and absolute lymphocyte count (ALC) **AND**
- Medical record documentation of a prescribed dose and administration that is consistent with FDA-approved package labeling, nationally recognized compendia, or peer-reviewed medical literature

Geisinger PHARMACY	POLICY NUMBER: 1590.0F SECTION: Pharmacy – GHP Family Drug Policies SUBJECT: Winrevair

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

- Medical record documentation that Winrevair is prescribed by a cardiologist or pulmonologist **AND**
- Medical record documentation of age greater than or equal to 18 years **AND**
- Medical record documentation of World Health Organization (WHO) Group 1 pulmonary arterial hypertension **AND**
- Medical record documentation of World Health Organization (WHO) functional class II, III, or IV symptoms at baseline **AND**

- Medical record documentation of **ONE** of the following:
    - Member is currently receiving at least 2 other PAH therapies from different pharmacologic categories [i.e., endothelin receptor antagonist (ERA), phosphodiesterase-5 inhibitor (PDE5i), soluble guanylate cyclase (sGC) stimulator, or prostacylin analogue)]

    OR
    - The member is currently receiving at least one other PAH therapy and the prescriber attests the member is unable to tolerate combination therapy with a phosphodiesterase type 5 inhibitors (PDE5i), endothelin receptor antagonists (ERAs), a soluble guanylate cyclase stimulator (sGCs), or prostacyclin analogues **AND**
- Medical record documentation of a prescribed dose and administration that is consistent with FDA-approved package labeling, nationally recognized compendia, or peer-reviewed medical literature

Geisinger PHARMACY	POLICY NUMBER: 1591.0F SECTION: Pharmacy – GHP Family Drug Policies SUBJECT: Voydeya

PROCEDURE:
Prior authorization of Voydeya 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 paroxysmal nocturnal hemoglobinuria (PNH) AND
- Medical record documentation that Voydeya is prescribed by a hematologist **AND**
- Medical record documentation that member has received vaccinations against encapsulated bacteria, including *Streptococcus pneumoniae and Neisseria meningitidis* **AND**
- Medical record documentation that member continues to experience clinically significant extravascular hemolysis (EVH)* despite at least 6 months of treatment with eculizumab or ravulizumab AND
- Medical record documentation that member will continue eculizumab or ravulizumab treatment in combination with Voydeya

Geisinger PHARMACY	POLICY NUMBER: 1592.0F SECTION: Pharmacy – GHP Family Drug Policies SUBJECT: Arexvy

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

- Medical record documentation that the member is 50 to 59 years of age AND
- Medical record documentation of a diagnosis of chronic pulmonary disease, chronic cardiovascular disease, diabetes, chronic kidney disease, or chronic liver disease AND
- Medical record documentation that the member is at an increased risk of lower respiratory tract disease (LRTD) caused by respiratory syncytial virus (RSV)

Geisinger PHARMACY	POLICY NUMBER: 1593.0F SECTION: Pharmacy – GHP Family Drug Policies SUBJECT: MResvia

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

- Peer -reviewed literature citing well-designed clinical trials to indicate that the member's healthcare outcome will be improved by administering to an individual with an age under the FDA-approved age

Geisinger PHARMACY	POLICY NUMBER: 1594.0F SECTION: Pharmacy – GHP Family Drug Policies SUBJECT: Duvyzat

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

- Medical record documentation that Duvyzat is prescribed by a neurologist or pediatric neurologist **AND**
- Medical record documentation of interdisciplinary team involvement including, but not limited to, neurology, pulmonology, and cardiology **AND**
- Medical record documentation of a diagnosis of Duchenne muscular dystrophy (DMD), confirmed by genetic testing **AND**
- Medical record documentation that the member has not received any previous gene therapy for Duchenne muscular dystrophy* **AND**
- Medical record documentation of age greater than or equal to 6 years **AND**
- Medical record documentation that member has been established on stable corticosteroid treatment for at least 6 months **AND**
- Medical record documentation of a prescribed dose and administration that is consistent with FDA-approved package labeling, nationally recognized compendia, or peer-reviewed medical literature.

Geisinger Drug Policies PHARMACY	POLICY NUMBER: 1595.0F SECTION: Pharmacy – GHP Family SUBJECT: Tryvio

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

- Medical record documentation of age 18 years or older **AND**
- Medical record documentation of diagnosis of resistant hypertension **AND**
- Medical record documentation of continued concurrent use of a medication from **ALL** the following antihypertensive classes at maximally tolerated doses:
    - Renin-angiotensin system [angiotensin-converting enzyme (ACE) inhibitor **OR** angiotensin II receptor blocker (ARB)]
    - Calcium channel blocker
    - Diuretic

AND

- Medical record documentation of therapeutic failure on intolerance to, or contraindication to at least two (2) additional formulary alternatives of different classes (i.e. beta blockers, aldosterone receptor antagonists, alpha-blockers, vasodilators, etc.). **AND**
- Medical record documentation of a prescribed dose and administration that is consistent with FDA-approved package labeling, nationally recognized compendia, or peer-reviewed medical literature

Geisinger PHARMACY	POLICY NUMBER: 1596.0F SECTION: Pharmacy – GHP Family Drug Policies SUBJECT: Yorvipath

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

- Medical record documentation of a diagnosis of hypoparathyroidism **AND**
- Medical record documentation of age ≥ 18 years **AND**
- Medical record documentation that Yorvipath is being prescribed by an endocrinologist **AND**
- Medical record documentation of a prescribed dose and administration that is consistent with FDA-approved package labeling, nationally recognized compendia, or peer-reviewed medical literature **AND**
- Medical record documentation of no increased baseline risk for osteosarcoma **AND**
- Medical record documentation of serum 25(OH) vitamin D within normal range within 2 weeks prior to the first dose **AND**
- Medical record documentation of albumin-corrected serum calcium ≥ 7.8 mg/dL within 2 weeks prior to the first dose **AND**
- Medical record documentation of one of the following:
    - Medical record documentation of therapeutic failure on, intolerance to, or contraindication to calcitriol **OR**
    - Medical record documentation that member will use Yorvipath in addition to calcitriol and/or elemental calcium

AND

- Medical record documentation of a prescribed dose and administration that is consistent with FDA-approved package labeling, nationally recognized compendia, or peer-reviewed medical literature

Geisinger PHARMACY	POLICY NUMBER: 1597.0F SECTION: Pharmacy – GHP Family Drug Policies SUBJECT: Vafseo

PROCEDURE:
Prior authorization of Vafseo 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 anemia due to chronic kidney disease **AND**
- Medical record documentation that member has been receiving dialysis for at least three months **AND**
- Medical record documentation of a Hemoglobin less than or equal to 11 g/dL **AND**
- Medical record documentation of ferritin greater than or equal to 100 ng/mL or transferrin saturation level greater than or equal to 20% or history of chelation therapy for iron **AND**
- Medical record documentation of a prescribed dose and administration that is consistent with FDA-approved package labeling, nationally recognized compendia, or peer-reviewed medical literature

Geisinger PHARMACY	POLICY NUMBER: 1598.0F SECTION: Pharmacy – GHP Family Drug Policies SUBJECT: Miplyffa

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

- Medical record documentation of age ≥2 years of age **AND**
- Medical record documentation of weight ≥ 8 kg and dose is weight appropriate **AND**
- Medical record documentation that medication is being prescribed by or in collaboration with a physician who specializes in the treatment of Niemann-Pick disease type C (NPC) or related disorders **AND**
- Medical record documentation of a diagnosis of NPC1 or NPC2, confirmed by genetic testing demonstrating one of the following:
    - Mutations in both alleles of NPC1 or NPC2 OR
    - Mutation in one allele AND either a positive filipin-staining or elevated cholestane triol/oxysterols (>2× ULN) **AND**
- Medical record documentation of at least one neurological sign of NPC (e.g., loss of fine motor skills, swallowing, speech, ambulation) **AND**

- Medical record documentation that member has completed the NPC Clinical Severity Scale (NPCCSS) assessment to determine baseline score of disease severity (note: higher score indicates greater impairment) **AND**
- Medical record documentation that member is currently receiving miglustat and Miplyffa will be used in combination with miglustat **AND**
- Medical record documentation that member is NOT using Miplyffa in combination with Aqneursa **AND**
- Medical record documentation of a prescribed dose and administration that is consistent with FDA-approved package labeling, nationally recognized compendia, or peer-reviewed medical literature

Geisinger PHARMACY	POLICY NUMBER: 1599.0F SECTION: Pharmacy – GHP Family Drug Policies SUBJECT: Aqneursa

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

- Medical record documentation of weight ≥ 15 kg and dose is weight appropriate **AND**
- Medical record documentation that medication is being prescribed by or in collaboration with a physician who specializes in the treatment of Niemann-Pick disease type C (NPC) or related disorders **AND**
- Medical record documentation of a diagnosis of NPC1 or NPC2, confirmed by genetic testing demonstrating one of the following:
    - Mutations in both alleles of NPC1 or NPC2 OR
    - Mutation in one allele AND either a positive filipin-staining or elevated cholestane triol/oxysterols (>2× ULN) **AND**
- Medical record documentation of at least one neurological sign of NPC (e.g., loss of fine motor skills, swallowing, speech, ambulation) **AND**
- Medical record documentation that member has completed the NPC Clinical Severity Scale (NPCCSS) assessment to determine baseline score of disease severity (note: higher score indicates greater impairment) **AND**
- Medical record documentation that member is NOT using Aqneursa in combination with Miplyffa **AND**
- Medical record documentation of a prescribed dose and administration that is consistent with FDA-approved package labeling, nationally recognized compendia, or peer-reviewed medical literature