P&T Committee Meeting Minutes
Medicaid
May 21, 2024

Present (via Teams):	**Absent:**
Bret Yarczower, MD, MBA – Chair	Alyssa Cilia, RPh
Amir Antonius, Pharm.D.	Michael Evans, RPh
Emily Bednarz, Pharm.D.	Kelly Faust, Pharm.D.
Kristen Bender, Pharm.D.	Nichole Hossler, MD
Jeremy Bennett, MD	Jason Howay, Pharm.D.
Kim Castelnovo, RPh	Tyreese McCrea, Pharm.D.
Kimberly Clark, Pharm.D.	Perry Meadows, MD
Bhargavi Degapudi, MD	Mark Mowery, Pharm.D.
Michael Dubartell, MD	William Seavey, Pharm.D.
Tricia Heitzman, Pharm.D.	Angela Scarantino
Keith Hunsicker, Pharm.D.	Aubrielle Smith-Masri Pharm.D.
Kelli Hunsicker, Pharm.D.	Michael Spishock, RPh
Derek Hunt, Pharm.D.	Robert Strony, MD MBA
Emily Jacobson, Pharm.D.	Brandon Whiteash, Pharm.D.
Dennis Janosczyk, Pharm.D.	Margaret Whiteash, Pharm.D.
Kerry Ann Kilkenny, MD	
Philip Krebs, R.EEG T	
Briana LeBeau, Pharm.D.	
Ted Marines, Pharm.D.	
Lisa Mazonkey, RPh	
Jamie Miller, RPh	
Austin Paisley, Pharm.D.	
Jonas Pearson, RPh	
Lauren Pheasant, Pharm.D.	
Kimberly Reichard, Pharm.D.	
Melissa Sartori, Pharm.D.	
Kristen Scheib, Pharm.D.	
Michael Shepherd, MD	
Leslie Shumlas, Pharm.D.	
Kirsten Smith, Pharm.D.	
Todd Sponenberg, Pharm.D.	
Jill Stone, Pharm.D.	
Luke Sullivan, DO	
Kevin Szczecina, RPh	
Amanda Taylor, MD	
Ariana Wendoloski, Pharm.D.	
Sherry Beagle (non-voting participant)	
Marika Bergenstock, DO	
Birju Bhatt, MD (non-voting participant)	
Abigail Chua MD	
Keri Donaldson (non-voting participant)	
Jeremy Garris, Pharm.D. (non-voting participant)	
Chidubem Ifeji (pharmacy resident)	

Call to Order: Dr. Bret Yarczower called the meeting to order at 1:05 p.m., Tuesday May 21, 2024.

Review and Approval of Minutes, Reviews, Fast Facts, and Updates: Dr. Bret Yarczower asked for a motion or approval to accept the March 19, 2024 minutes as written. Minutes approved unanimously. None were opposed.

DRUG REVIEWS

Adzynma (ADAMTS13, recombinant-krhn)

Review: Adzynma is a human recombinant "A disintegrin and metalloproteinase with thrombospondin motifs 13" (rADAMTS13) indicated for prophylactic or on demand enzyme replacement therapy (ERT) in adult and pediatric patients with congenital thrombotic thrombocytopenic purpura (cTTP). ADAMTS13 regulates the activating of von Willebrand factor (VWF) and reduces the platelet binding properties of VWF and its propensity to form microthrombi. Adzynma is the first approved treatment for cTTP, a disease which results from a deficiency in ADAMTS13 and that can be fatal if left untreated (mortality rate >90%). Prior to the approval of Adzynma, patients could be treated with prophylactic plasma-based therapy to reduce the risk of clotting.

Clinical Discussion: The committee unanimously voted to accept the recommendations.

Financial Discussion: The committee unanimously voted to accept the recommendations.

Outcome: Adzynma is a medical benefit that will be managed by GHP and will require a prior authorization. The following prior authorization criteria should apply.

- Medical record documentation that Adzynma is prescribed by a hematologist or oncologist AND
- Medical record documentation of a diagnosis congenital thrombotic thrombocytopenia purpura (TTP) and both of the following:
    - Documentation of confirmed molecular genetic testing AND
    - Documentation of ADATS13 activity less than 10% of normal activity as measured by the fluorescent resonance energy transfer-von Willebrand factor 73 (FRETS-VWF73) assay

AND

- Medical record documentation that member is currently receiving prophylactic therapy OR medical record documentation of at least one thrombotic thrombocytopenia purpura (TTP) event

GPI Level: GPI-12
Authorization Duration: Initial approval will be for **6 months** or less if the reviewing provider feels it is medically necessary. Subsequent approvals will be for an additional **12 months** or less if the reviewing provider feels it is medically necessary. Requests for continuation of coverage will be approved for members who meet the following criteria:

- Medical record documentation of a positive clinical response as defined by one of the following:
    - Documentation of a reduction in or improvement in acute and subacute thrombotic thrombocytopenia purpura (TTP) events OR
    - Documentation of an improvement in clinical symptoms of congenital thrombotic thrombocytopenia purpura (TTP) OR
    - If used for on-demand Adzynma treatment, documentation of improved platelet level to greater than or equal to 150,000/µL or platelet count within 25% of baseline (prior to the acute event)

Require RPH Sign off: Yes. Rph signoff will be required to ensure appropriate utilization

Additional evidence of the criteria used to make this decision can be found in the drug review presented to the committee.

Ixchiq (Chikungunya Vaccine, Live)

Review: Ixchiq was approved November 9, 2023, and is the first vaccine approved by the FDA indicated for the prevention of disease caused by the chikungunya virus (CHIKV) in individuals 18 years of age and older who are at increased risk of exposure to CHIKV. This indication is approved under accelerated approval based on anti-CHIKV neutralizing antibody titers. The CDC states that traditional approval would have been challenging and clinical development would likely have been delayed. CHIKV outbreaks are unpredictable and duration can be relatively short. Also, there was no established immunologic correlate of protection. Continued approval for this indication may be contingent upon verification and description of clinical benefit in confirmatory studies.

Clinical Discussion: The committee unanimously voted to accept the recommendations.

Financial Discussion: The committee unanimously voted to accept the recommendations.

Outcome: Ixchiq will be a medical benefit managed by GHP. No prior authorization criteria will apply.

Additional evidence of the criteria used to make this decision can be found in the drug review presented to the committee.

Fabhalta (iptacopan)

Review: Fabhalta is a complement factor B inhibitor indicated for the treatment of adult patients with paroxysmal nocturnal hemoglobinuria (PNH). It binds Factor B of the alternative complement pathway and regulates the cleavage of C3, controlling C3b-mediated extravascular hemolysis and terminal compliment-mediated intravascular hemolysis. Fabhalta is the first approved oral complement inhibitor indicated for PNH.

Clinical Discussion: The committee unanimously voted to accept the recommendations.

Financial Discussion: The committee unanimously voted to accept the recommendations.

Outcome: Fabhalta is a pharmacy benefit that will be managed by GHP and should be added to the Brand tier of the GHP Family formulary. The following prior authorization criteria should apply:

- 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.

AUTHORIZATION DURATION: Initial approval will be for 6 months. Subsequent authorizations will be for 6 months and will require:

- Medical record documentation of:

- Hemolysis control measured by lactic acid dehydrogenase (LDH) level less than 1.5 times the upper limit of normal (ULN) AND
- Reduced need or elimination of transfusion requirements OR
- Stabilization of hemoglobin levels

GPI Level: GPI-12
Quantity Limits: 2 capsules per day, 30 day supply per fill

Require RPH Sign off: Yes, RPH Sign off will be required to ensure appropriate utilization.

Additional evidence of the criteria used to make this decision can be found in the drug review presented to the committee.

Pombiliti (cipaglucosidase alfa-atga) and Opfolda (miglustat)

Review: Pombiliti and Opfolda are indicated in combination for the treatment of adults with late-onset Pompe disease (lysomal acid alpha-glucosidase [GAA] deficiency) weighing at least 40 kg and who are not improving on their current enzyme replacement therapy (ERT). Pombiliti provides an exogenous source of GAA. It binds M6P receptors on the cell surface, is internalized where it undergoes proteolytic cleavage, and then exerts enzymatic activity in cleaving glycogen. Opfolda is a stabilizer that reduces inactivation of Pombiliti in the blood after infusion.

Clinical Discussion: The committee unanimously voted to accept the recommendations.

Financial Discussion: The committee unanimously voted to accept the recommendations.

Outcome: Opfolda is a pharmacy benefit and should not be added to the GHP Family formulary. No additional prior authorization criteria based on cost will apply.

Pombiliti is a medical benefit. No additional prior authorization criteria based on cost will apply.

- 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 Pombiliti and Opfolda will not be used concurrently with other enzyme replacement therapy (e.g. Lumizyme, Nexviazyme)

AUTHORIZATION DURATION: Initial approval will be for 12 months or less if the reviewing provider feels it is medically appropriate. Subsequent approvals will be for an additional 12 months or less if the reviewing provider feels it is medically appropriate and will require the following:

- Medical record documentation of improvement or stabilization in percent-predicted forced vital capacity (% FVC) and/or 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 Pombiliti and Opfolda will not be used concurrently with other enzyme replacement therapy (e.g. Lumizyme, Nexviazyme)

GPI Level: GPI-12

Require RPH Sign off: Yes. Rph Signoff will be required to ensure appropriate utilization.

Additional evidence of the criteria used to make this decision can be found in the drug review presented to the committee.

Penbraya (Meningococcal Serotypes A,B,C,W and Y Vaccine iptacopan)

Review: Penbraya (Meningococcal Serotype A,B,C,W,Y) vaccine was FDA approved in 2023 and is indicated for active immunization to prevent invasive disease caused by *Neisseria meningitidis* serogroups A, B, C, W, and Y. Penbraya is approved for use in individuals 10 through 25 years of age who would generally be indicated to receive 2 different Meningococcal vaccines (Men B (Trumenba and Bexsero) and MenACWY(Menveo and Menquadfi) at the same clinic visit

Clinical Discussion: The committee unanimously voted to accept the recommendations.

Financial Discussion: The committee unanimously voted to accept the recommendations.

Outcome: Penbraya will be both a medical and pharmacy benefit for members aged 19 years or older. Penbraya will be a medical benefit only for members less than 19 years of age. It will be added as a covered medication.

Additional evidence of the criteria used to make this decision can be found in the drug review presented to the committee.

Amtagvi (lifileucel)

Review: Amtagvi is a tumor-derived autologous T cell immunotherapy indicated for the treatment of adult patients with unresectable or metastatic melanoma previously treated with a PD-1 blocking antibody, and if BRAF V600 mutation positive, a BRAF inhibitor with or without a MEK inhibitor. The indication was approved under accelerated approval based on objective response rate (ORR). Continued approval for the indication will be based

on verification and description of clinical benefit in a confirmatory trial. The specific mechanism of action of Amtagvi is unknown.

Clinical Discussion: The committee unanimously voted to accept the recommendations.

Financial Discussion: The committee unanimously voted to accept the recommendations.

Outcome: Amtagvi is a medical benefit managed by GHP and will require prior authorization. The following prior authorization criteria will apply:

- Medical record documentation that Amtagvi is prescribed by a hematologist or oncologist **AND**
- Medical record documentation of age greater than or equal to 18 years old **AND**
- Medical record documentation of a diagnosis of unresectable or metastatic melanoma **AND**
- Medical record documentation of previous treatment with an anti-programmed cell death protein 1/programmed cell death ligand 1 (PD-1/PD-L1) inhibitor **AND**
- If BRAF V600 mutation positive: Medical record documentation of previous treatment with a BRAF inhibitor with or without a MEK inhibitor **AND**
- Medical record documentation that the member has not received prior treatment with tumor-derived T cell therapy or other genetically modified T cell therapy.

Authorization Duration: Amtagvi will be approved for a one-time authorization for one administration of Amtagvi.

Require RPH Sign off: Yes

Formulary Alternatives: None

Additional evidence of the criteria used to make this decision can be found in the drug review presented to the committee.

Wainua (eplontersen)

Review: Wainua is a transthyretin (TTR)–directed antisense oligonucleotide (ASO) indicated for the treatment of polyneuropathy caused by hereditary transthyretin-mediated amyloidosis(hATTR) in adults. Hereditary ATTR (hATTR) amyloidosis is an inherited condition caused by the misfolding of the TTR protein. TTR is a protein made primarily in the liver that carries vitamin A and thyroid hormones throughout the body. In people with hATTR, unstable TTR protein breaks apart, misfolds, and forms amyloid fibrils that can build up and cause damage throughout the body. Clinical presentation of hATTR can involve a neuropathic phenotype, where patients experience polyneuropathy (hATTR-PN); a cardiac phenotype, where patients experience cardiomyopathy (hATTR-CM); or a mixed phenotype, where patients experience both cardiomyopathy and polyneuropathy. In hATTR-PN, amyloid fibrils deposit in the nervous system, causing pain, muscle weakness, and autonomic dysfunction. The disease is progressive, and historically, the average survival of a patient with untreated hATTR-PN ranged from 5 to 15 years. Wainua is a disease-modifying treatment that causes degradation of mutant and wild-type TTR mRNA through binding to the TTR mRNA, which results in a reduction of serum TTR protein and TTR protein deposits in tissues.

Clinical Discussion: The committee unanimously voted to accept the recommendations.

Financial Discussion: The committee unanimously voted to accept the recommendations.

Outcome: Wainua is a pharmacy benefit not subject to the PDL and should not be added to the Geisinger Medicaid formulary. The following additional prior authorization criteria should apply:

- 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

GPI Level: GPI-12
Authorization Duration: 12 months
Reauthorization Info: 12 months - The medication will no longer be covered if the member progresses to FAP stage 3 and/or polyneuropathy disability score indicating the patient is wheelchair-bound or bedridden.
Formulary Alternatives: Onpattro, Amvuttra, Tegesdi
Require RPH Sign off: Yes

NOTE TO REVIEWER:
FAP Stage:
1 - unimpaired ambulation
2 - assistance with ambulation
3 - wheelchair-bound or bedridden
Polyneuropathy Disability Score:
I - preserved walking, sensory disturbances
II - impaired walking without need for stick/crutches
IIIa - walking with 1 stick/crutch
IIIb - walking with 2 sticks/crutches
IV-wheelchair-bound or bedridden

Additional evidence of the criteria used to make this decision can be found in the drug review presented to the committee.

Class Review

Fast Facts

Updates

Ycanth Update

Recommendation: DHS required removal of the dermatologist criteria from the Ycanth medical benefit policy. The GHP P&T Committee had included the dermatologist prescriber requirement to ensure appropriate and judicious use of Ycanth. With the removal of the prescriber requirement, it is recommended that failure of other first-line treatments commonly used upon initial diagnosis be added to the Policy. The following changes are recommended to be added to the Ycanth Medical Benefit Policy:

Prior Authorization Criteria

- Medical record documentation of age greater than or equal to 2 years AND
- ~~Medical record documentation that Ycanth is prescribed by a dermatologist AND~~
- Medical record documentation of a diagnosis of molluscum contagiosum (MC) AND
- Medical record documentation of treatment failure of at least one other treatment modality (including but not limited to cryotherapy, curettage, or podofilox) or reason why other treatments cannot be used

Outcome: The committee unanimously voted to accept the recommendations.

Additional evidence of the criteria used to make this decision can be found in the drug review presented to the committee.

Medical Benefit Policy Update

Recommendation: The following policies were modified following PARP review:

Policy	**DHS Identified Issue**	**Changes to Policy**
MBP 23.0 Velcade (bortezomib)	How can a member have therapeutic failure to the inactive ingredients?	Updated policy criteria to eliminate "therapeutic failure on"
MBP 36.0 Abraxane (paclitaxel protein bound particles)	How can a member have therapeutic failure to the inactive ingredients?	Updated policy criteria to eliminate "therapeutic failure on"
MBP 38.0 Clolar (clofarabine)	How can a member have therapeutic failure to the inactive ingredients?	Updated policy criteria to eliminate "therapeutic failure on"
MBP 62.0 Remodulin IV (treprostinil)	How can a member have therapeutic failure to the inactive ingredients?	Updated policy criteria to eliminate "therapeutic failure on"

MBP 90.0 Benlysta (belimumab)	Please revise to reflect the wording in the package labeling: "The efficacy of BENLYSTA has not been evaluated in patients with severe active central nervous system (CNS) lupus. Use of BENLYSTA is not recommended in this situation."	Updated policy to accurately reflect labeling
MBP 132.0 Avycaz (cetfazidime/avibactam)	HABP and VABP should be an “or” instead of “and”	Updated policy to accurately reflect labeling/indication
MBP 233.0 Pepaxto (melphalan flufenamide)	The FDA announced withdrawal of approval of Pepaxto. There are no eligible NDC’s of Pepaxto available and CMS terminated their labeler agreement effective 1/1/22 and the NDC is obsolete as of 10/22/21.	Policy Retired (FDA withdrew approval effective 2/23/24 [published in federal register on 4/18/24]).
MBP 307.0 Elevidys (delandistrogene moxeparvovec-rokl)	While extremely rare, female patients may have defective genes in both x chromosomes that result in DMD.	At DHS’ direction, “male based on assigned sex at birth” requirement was deleted; however, diagnostic criteria was updated to appropriately confirm a DMD diagnosis in female patients

Outcome: The committee unanimously voted to accept the recommendations.

Additional evidence of the criteria used to make this decision can be found in the drug review presented to the committee.

05.2024 DUR/Adherence Update

The May 2024 P&T DUR/Adherence Update was submitted to the Committee for review.

Additional evidence of the criteria used to make this decision can be found in the drug review presented to the committee.

April ELECTRONIC VOTE

An electronic vote was held from April 15, 2024, to April 19, 2024. Responses were received from 27 members (out of 50 members) and all voted to approve. Additional evidence of the criteria used to make this decision can be found in the drug review presented to the committee.

Besponsa

Updated Indication: Besponsa is now indicated for the treatment of relapsed or refractory CD22-positive B-Cell precursor acute lymphoblastic leukemia (ALL) in pediatric patients 1 year and older.

Recommendation: update age criterion to be ≥1 year of age

Additional evidence of the criteria used to make this decision can be found in the drug review presented to the committee.

Rybrevant

Updated Indication: Rybrevant was previously indicated as a single agent for the treatment of adult patients with locally advanced or metastatic non-small cell lung cancer (NSCLC) with epidermal growth factor receptor (EGFR) exon 20 insertion mutations, as detected by an FDA-approved test, whose disease progressed on or after platinum-based chemotherapy. Rybrevant is now also indicated in combination with carboplatin and pemetrexed for the first-line treatment of adult patients with locally advanced or metastatic non-small cell lung cancer (NSCLC) with epidermal growth factor receptor (EGFR) exon 20 insertion mutations, as detected by an FDA-approved test. Padcev received approval for the expansion of the indication for urothelial cancer to the following: Padcev in combination with pembrolizumab for the treatment of adult patients with locally advanced or metastatic urothelial cancer. Previously this indication was an accelerated approval limited to patients who were not eligible for cisplatin-containing chemotherapy. There are no changes for the indications where Padcev is given as a single agent.

Recommendation: Update the Rybrevant policy to include the new indication as follows:

- Medical record documentation that Rybrevant is prescribed by a hematologist or oncologist **AND**
- Medical record documentation of age greater than or equal to 18 years **AND**
- Medical record documentation of a diagnosis of with locally advanced or metastatic non-small cell lung cancer (NSCLC) **AND**
- Medical record documentation of epidermal growth factor receptor (EGFR) exon 20 insertion mutations as determined by an FDA approved test* **AND**
- One of the following:
    - Medical record documentation of disease progression on or following prior treatment with a platinum-based chemotherapy AND that Rybrevant will be used as a single agent

OR

    - Medical record documentation that Rybrevant is being used as first line treatment AND that Rybrevant will be used in combination with carboplatin and pemetrexed

Additional evidence of the criteria used to make this decision can be found in the drug review presented to the committee.

Medical Benefit Update

The following updates were proposed based on Onco Health's review to capture rituximab's use in other standard of care oncology disease states. These changes will affect MBP 48.0 and Part B Step Therapy.

Recommendation: It is recommended to approve the following updates:

For Acute Lymphoblastic Leukemia, Hairy Cell Leukemia, and Chronic Lymphoid Leukemia:

Note: Prior authorization is not required for Ruxience, Riabni or Truxima for diagnosis codes C91.00 through C91.02, C91.10 through C91.12, or C91.40 through C91.42. In the event of a request for the rituximab reference product (i.e. Rituxan), OR in the event a requestor would like a medical necessity review completed, the following criteria would apply:

- Medical record documentation of a diagnosis of Acute Lymphoblastic Leukemia, Hairy Cell Leukemia, or Chronic Lymphocytic Leukemia (CLL)

AND

- For rituximab reference product requests (i.e. Rituxan), medical record documentation of a therapeutic failure on, intolerance to, or contraindication to rituximab-pvvr (Ruxience) AND rituximab-arrx (Riabni) AND rituximab-abbs (Truxima).

For Hodgkin Lymphoma

Note: Prior authorization is not required for Ruxience, Riabni or Truxima for diagnosis codes C81.00 through C81.09. In the event of a request for the rituximab reference product (i.e. Rituxan), OR in the event a requestor would like a medical necessity review completed, the following criteria would apply:

- Medical record documentation of a diagnosis of Hodgkin Lymphoma

AND

- For rituximab reference product requests (i.e. Rituxan), medical record documentation of a therapeutic failure on, intolerance to, or contraindication to rituximab-pvvr (Ruxience) AND rituximab-arrx (Riabni) AND rituximab-abbs (Truxima).

Additional evidence of the criteria used to make this decision can be found in the drug review presented to the committee.

GHP Family Update

Recommendation: It is recommended the committee approve the following updates.

Sucraid

During the annual formulary review DHS requested we make the following update to account for an abnormal carbon-13 sucrose breath test.

- Order is written by a Gastroenterologist, Endocrinologist or Genetic Specialist **AND**
- 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

- Member has medical documentation of a diagnosis of congenital sucrose-isomaltase deficiency characterized by stool pH less than 6 **AND**

- Has an increase in breath hydrogen of greater than 10ppm when challenged with sucrose after fasting **AND**
- Has a negative lactose breath test

OR

- Has an abnormal carbon-13 sucrose breath test

OR

- Has a diagnosis of congenital sucrose-isomaltase deficiency characterized by low sucrose activity on duodenal biopsy **AND**
- Other disaccharidases normal on same duodenal biopsy.

Korlym

During the annual formulary review DHS requested we remove the requirement for failure on a sulfonylurea and TZD due to them no longer being recommended for treatment of Cushing's disease with concurrent diabetes mellitus (removed criteria highlighted in red).

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

Sirturo

During the annual formulary review DHS requested we account for the use of Sirturo along with pretomanid and linezolid as supported by current World Health Organization recommendations.

• Prescription is written by a physician specializing in infectious disease AND
• Medical record documentation of one of the following:
o Age greater than or equal to 18 years OR
o 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:
o 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**
o 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 **OR**
o In the case of documented resistance to fluroquinolones or if fluroquinolones are unavailable, or there is a contraindication/intolerance to fluroquinolones, Sirturo is being prescribed with pretomanid and linezolid.

Additional evidence of the criteria used to make this decision can be found in the drug review presented to the committee.

Meeting adjourned at 4:06 pm

Future Scheduled Meetings

The next bi-monthly scheduled meeting will be held on July 16, 2024 at 1:00 p.m.

Meetings will be held virtually via phone/Microsoft Teams