P&T Committee Meeting Minutes
Medicaid
July 18, 2023

Present (via Teams):	**Absent:**
Bret Yarczower, MD, MBA – Chair	Jeremy Bennett, MD
Amir Antonius, Pharm.D.	Holly Bones, Pharm.D.
Emily Antosh, Pharm.D.	Kim Castelnovo, RPh
Kristen Bender, Pharm.D.	Kimberly Clark, Pharm.D.
Alyssa Cilia, RPh	Bhargavi Degapudi, MD
Michael Dubartell, MD	Michael Evans, RPh
Rajneel Farley, Pharm.D.	Nichole Hossler, MD
Kelly Faust Pharm.D.	Jason Howay, Pharm.D.
Tricia Heitzman, Pharm.D.	Keith Hunsicker, Pharm.D.
Emily Hughes, Pharm.D.	Kelli Hunsicker, Pharm.D.
Derek Hunt, Pharm.D.	Perry Meadows, MD
Kerry Ann Kilkenny, MD	Jonas Pearson, RPh
Philip Krebs, R.EEG T	William Seavey, Pharm.D.
Briana LeBeau, Pharm.D.	Michael Shepherd, MD
Ted Marines, Pharm.D.	Todd Sponenberg, Pharm.D.
Lisa Mazonkey, RPh	Jill Stone, Pharm.D.
Tyreese McCrea, Pharm.D.	Robert Strony, MD, MBA
Jamie Miller, RPh	Luke Sullivan, DO
Mark Mowery, Pharm.D.	
Austin Paisley, Pharm.D.	
Kimberly Reichard, Pharm.D.	
Melissa Sartori, Pharm.D.	
Angela Scarantino	
Kristen Scheib, Pharm.D.	
Leslie Shumlas, Pharm.D.	
Aubrielle Smith Pharm.D.	
Kirsten Smith, Pharm.D.	
Michael Spishock, RPh	
Kevin Szczecina, RPh	
Amanda Taylor, MD	
Ariana Wendoloski, Pharm.D.	
Brandon Whiteash, Pharm.D.	
Margaret Whiteash, Pharm.D.	
Benjamin Andrick, Pharm.D. (non-voting participant)	
Birju Bhatt MD (non-voting participant)	
Morgan Marie Casciole (pharmacy resident)	
Abigail Chua DO (non-voting participant)	
Alfred Denio DO (non-voting participant)	
Daniele Francisko (pharmacy resident)	
Jeremy Garris, Pharm.D. (non-voting participant)	
Kristen Mascaritola (pharmacy resident)	

Call to Order: Dr. Bret Yarczower called the meeting to order at 1:03 p.m., Tuesday, July 18, 2023.

Review and Approval of Minutes, Reviews, Fast Facts, and Updates: Dr. Bret Yarczower asked for a motion or approval to accept the May 16, 2023 minutes as written. Minutes approved unanimously. None were opposed.

DRUG REVIEWS

Qalsody (tofersen)

Review: Qalsody is an antisense oligonucleotide indicated for the treatment of amyotrophic lateral sclerosis (ALS) in adults who have a mutation in the superoxide dismutase 1 (SOD1) gene. Qalsody is thought to cause degradation of SOD1 mRNA through binding to SOD1 mRNA, which results in a reduction of SOD1 synthesis. Qalsody is the first medication manufactured that targets this mutation. The clinical trial, however, did not meet the primary endpoint. This indication is approved under accelerated approval based on reduction in plasma neurofilament light chain observed in patients treated with Qalsody. Continued approval for this indication may be contingent upon verification of clinical benefit in confirmatory trial(s).

Clinical Discussion: No comments or questions. The committee unanimously voted to accept the recommendations as presented. None were opposed.

Financial Discussion: There was one vote to reject, all other votes were in favor to accept the recommendations.

Outcome: Qalsody will be a medical benefit and should not be added to the formulary. Qalsody will require a prior authorization with the following criteria.

- Documentation of age greater than or equal to 18 years AND
- Medical record documentation of a consultation with a neurologist, neuromuscular specialist, or physician specializing in the treatment of amyotrophic lateral sclerosis (ALS) AND
- Diagnosis of amyotrophic lateral sclerosis (ALS) with a confirmed mutation in the superoxide dismutase 1 (SOD1) gene
- 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

Authorization Duration (ALL LOB): Initial approval will be for 12 months or less if the reviewing provider feels it is medically appropriate. Subsequent approvals will be for 12 months or less if the reviewing provider feels it is medically appropriate and will require the following criteria:

- Medical record documentation that member is tolerating and compliant with prescribed Qalsody regimen AND
- Medical record documentation of regular physician follow-up

GPI Level: GPI-12

Require RPH Sign off: Yes

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

Epkinly (epcoritamab-bysp)

Review: Epkinly is a T-cell engaging bispecific antibody indicated for the treatment of adult patients with relapsed or refractory diffuse large B-cell lymphoma (DLBCL), not otherwise specified, including DLBCL arising from indolent lymphoma, and high-grade B-cell lymphoma after two or more lines of systemic therapy. Epkinly binds the

CD3 receptor expressed on the surface of T-cells and CD20 expressed on the surface of lymphoma cells and healthy B-lineage cells. In vitro, Epkinly-activated T-cells cause the release of proinflammatory cytokines and induced lysis of B-cells.

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

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

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

- Medical record documentation of age greater than or equal to 18 years AND
- Medical record documentation that Epkinly is written by a hematologist or oncologist AND
- Medical record documentation of a diagnosis of relapsed or refractory diffuse large B-cell lymphoma (DLBCL), not otherwise specified, including DLBCL arising from indolent lymphoma AND
- Medical record documentation of prior therapy with at least two lines of systemic therapy

GPI Level: GPI-12

Authorization Duration: Initial approval will be for 6 months or less if the reviewing provider feels it is medically appropriate. Subsequent approvals will be for an additional 12 months or less if the reviewing provider feels it is medically appropriate and will require medical record documentation of continued disease improvement or lack of disease progression. The medication will no longer be covered if patient experiences toxicity or worsening of disease.

Require RPH Sign off: Yes. 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.

Daybue (trofenetide)

Review: Daybue is a synthetic analog of glycine-proline-glutamate, the N-terminal tripeptide of insulin-like growth factor indicated for Rett syndrome (RTT) for patients 2 years of age and older. The mechanism is unknown but actions such as anti-inflammatory, anti-oxidant, and trophic effects that stabilize dendritic morphology, synaptic protein synthesis, and neuronal signaling are observed. Daybue is administered orally or through gastrostomy tube twice daily according to weight-based dosing. Daybue is provided in a 450 mL bottle. Rett syndrome (RTT) is a neurodevelopmental disorder that occurs almost exclusively in females with mutations in the MECP2 gene. Patients will see normal development initially followed by loss of speech and purposeful hand use, stereotypic hand movements, and gait abnormalities. Deceleration of head growth, seizures, autistic features, and breathing abnormalities are also observed. RTT is not classified as a degenerative disorder but a progressive disorder with multisystem symptom evolution over the lifespan. It is broken up into typical and atypical with the typical being more of an all-encompassing term and atypical is being used for variants of RTT that have many but not all clinical features of typical RTT. Most patients with RTT survive well into adulthood with the median survival age between typical and atypical being 45 years while some studies have seen survival into 50s for patients. This disease prevalence is varying from 1 in 10,000 girls by 12 years of age and 1 in 22,000 between 2 and 18 years of age. According to the manufacturer there are 6,000 to 9,000 people with RTT in the US, although other sources have estimated 15,000 girls and women total in the US have the disease. Before the approval of Daybue, there are no

FDA-approved treatments for RTT. Treatment normally focuses on management of symptoms as well as supportive care.

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

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

Outcome: Daybue is a pharmacy benefit managed by GHP and should not be added to the pharmacy formulary. The following prior authorization criteria should apply.

- 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 behavioural 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

GPI Level: GPI-12

Authorization Duration:
Initial approval will be for 3 months or less if the provider feels it is medically appropriate. For continued coverage, the following criteria is required.

- Medical record documentation of clinical improvement in Rett syndrome symptoms as measured by an appropriate rating scale (compared to previous measurement)

Subsequent approvals will be for an additional 12 months or less if the reviewing provider feels it is medically appropriate. For continued coverage, the follow criteria is required.

- Medical record documentation of clinical improvement in Rett syndrome symptoms as measured by an appropriate rating scale (compared to previous measurement)

Formulary Alternatives: None
Require RPH Sign off: Yes

ATTENTION REVIEWER: Below outlines diagnosis of classic, or typical Rett Syndrome

1. A period of regression followed by recovery or stabilization **AND**
2. ALL of the following
    a. Partial or complete loss of acquired purposeful hand skills
    b. Partial or complete loss of acquired spoken language
    c. Gait abnormalities: Impaired (dyspraxic) or absence of ability
    d. Stereotypic hand movements such as hand wringing/squeezing, clapping/tapping, mouthing, and washing/rubbing automatisms **AND**
3. NONE of the following
    a. Brain injury secondary to trauma (peri- or postnatally), neurometabolic disease, or severe infection that causes neurologic problems
    b. Grossly abnormal psychomotor development in the first six months of life

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

Skyclarys (omaveloxolone)

Review: Skyclarys is a once daily oral nuclear factor erythroid 2-related factor 2 (Nrf2) activator indicated for the treatment of Friedreich's ataxia (FA or FRDA) in adults and adolescents 16 years of age and older. Skyclarys is the first FDA approved therapy for patients with FA. Skyclarys is available as a 50 mg capsule and the recommended dosage is 150 mg (3 capsules) by mouth once daily. Skyclarys should be administered on an empty stomach at least 1 hour before eating and should be swallowed whole. Friedreich's ataxia is an ultra-rare, inherited progressive genetic neurodegenerative disorder and the most common form of hereditary ataxia. Mutations in the frataxin (FXN) gene cause FA. The Frataxin gene is responsible for encoding the mitochondrial protein frataxin and with a deficiency of the frataxin protein there is a dysregulation of antioxidative defense mechanisms and in turn decreased function of the cerebellum, spinal cord, and peripheral nervous system. Genetic testing for the Frataxin gene is imperative for a FA diagnosis. Patients are typically diagnosed anywhere from two to fifty years of age. As time progresses these patients will see issues with muscle coordination, balance, speech, difficulty walking, fatigue, curvature of the spine (scoliosis), foot deformities (pes cavus-claw foot) increased risk of diabetes and cardiovascular disease. Patients with FA rapidly progress, although the exact timeline varies from person to person, issues with mobility are often seen 10-20 years from disease onset. The average life expectancy is 40 years of age. "Interim data from the largest natural history study of FA, the Clinical Outcome Measures in Friedreich's ataxia trial (FA-COMS; NCT03090789), demonstrated that patients progress an average of 1 to 2 points per year on mFARS over time and do not improve. In the MOXIe extension trial, improved mFARS scores were observed in patients who received Skyclarys after 3 years relative to a matched set of untreated patients from the FA-COMS natural history study."

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

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

Outcome: Skyclarys will be a pharmacy benefit that will be managed by GHP. It is recommended to add Skyclarys to the GHP Family formulary at the Brand tier. The following prior authorization criteria will be required:

- 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

GPI Level: GPI-12

Authorization Duration: Initial approval will be for 12 months. Subsequent approvals will be for an additional 12 months with medical record documentation that the member is responding positively to therapy as evidenced by slowed disease progression or documentation of a positive clinical response (ex. through mFARS-modified functional assessment rating scale)

Reauthorization info:

- Medical record documentation that the member is responding positively to therapy as evidenced by slowed disease progression or documentation of a positive clinical response (ex. through mFARS-modified

functional assessment rating scale)

Require RPH Sign off: Yes

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

Elfabrio (pegunigalsidase alfa-iwxj)

Review: Elfabrio is a hydrolytic lysosomal neutral glycosphingolipid-specific enzyme indicated for the treatment of adults with confirmed Fabry disease. Elfabrio provides an exogenous source of alpha-galactosidase A which is deficient in Fabry disease. Elfabrio is internalized and transported into lysosomes where it is thought to exert enzymatic activity and reduce accumulated globotriaosylceramide (Gb3). It is the second enzyme replacement therapy (ERT) approved for the treatment of Fabry Disease after Fabrazyme was approved in 2003. Elfabrio is considered a "biobetter" to Fabrazyme and was designed to have a longer half-life, lower immunogenicity, and an improved safety profile. Elfabrio is administered as a 1 mg/kg intravenous infusion every two weeks based on actual body weight. Infusion rate is based on previous ERT experience. Patients who are ERT naïve should consider pretreatment with antihistamines, antipyretics, and/or corticosteroids. Patients who are ERT-experienced and who previously used pretreatment with antihistamines, antipyretics, and/or corticosteroids should consider similar pretreatment before the first several Elfabrio infusions.

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

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

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

- Medical record documentation of a diagnosis of Fabry disease AND
- Prescribed by a metabolic specialist with experience in treating Fabry disease

GPI Level: GPI-12
Authorization Duration: Initial approval will be for 6 months. Subsequent approvals will be for an additional 6 months and will require medical record documentation of continued disease improvement or lack of disease progression. The medication will no longer be covered if the member experiences unacceptable toxicity or worsening of disease.

Require RPH Sign off: Yes. RPH Sign off will be required for Elfabrio 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.

Filspari (sparsenten)

Review: Filspari is a novel dual endothelin angiotensin receptor antagonist (DEARA) that inhibits both endothelin receptor type A (ET_AR) and angiotensin II receptor type 1 (AT_1R). In kidney diseases like IgAN and focal

segmental glomerulosclerosis (FSGS), blockade of both ET_A and AT_1 pathways have been shown to reduce proteinuria, protect podocytes, and prevent glomerulosclerosis and mesangial cell proliferation. Filspari is now the first and only non-immunosuppressive agent approved for the treatment of IgAN.

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

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

Outcome: Filspari is a pharmacy benefit and will not be managed by the PDL. It is recommended that Filspari be added to the Medicaid formulary at the Brand Tier. The following prior authorization criteria should apply:

- 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 m^2 **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

GPI Level: GPI-12

Authorization Duration: Initial approval will be for nine (9) months and subsequent approvals will be for twelve (12) months. Requests for continuation of coverage will be approved for members who meet the following criteria:

- Medical record documentation of continued disease improvement or lack of disease progression according to prescriber (i.e. decreased levels of proteinuria from baseline or decreased UPCR from baseline) 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

Require RPH Sign off: Yes

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

Lamzede (velmanase alfa-tycv)

Review: Lamzede is the first enzyme replacement therapy approved in the United States for the treatment of non-central nervous system manifestations of alpha-mannosidosis (AM) in adult and pediatric patients. Lamzede is lysosomal alpha-mannosidase produced by recombinant DNA technology in Chinese Hamster Ovary cells. The

amino acid sequence of the monomeric protein is identical to the naturally occurring human enzyme, alpha-mannosidase.

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

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

Outcome: Lamzede will be a medical benefit managed by GHP. The following prior authorization criteria will apply:

- Medical record documentation of a diagnosis of alpha-mannosidosis supported by:
    - Enzyme assay demonstrating alpha-mannosidase activity less than 10% of normal activity (<0.54 nmol/min/mg)

    OR
    - Molecular genetic testing that reveals pathogenic variants in the MAN_2B_1 gene

AND

- Medical record documentation that the patient is being treated for non-central nervous system manifestations of alpha-mannosidosis **AND**
- Medical record documentation of a consultation with a metabolic specialist and/or biochemical geneticist **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

AUTHORIZATION DURATION: Initial approval will be for 6 months or less if the reviewing provider feels it is medically appropriate. Subsequent approvals will be for 12 months or less if the reviewing provider feels it is medically appropriate and will require medical record documentation of continued disease improvement or lack of disease progression (i.e., improvement or stabilization in motor function, improvement in forced vital capacity % (FVC), reduction in frequency of infections, etc.)

Require RPH Sign off: Yes

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

Omisirge (omidubicel-onlv)

Review: Omisirge (omidubicel-onlv) is a blood-based stem cell therapy derived from a single banked umbilical cord blood (UCB) unit. It is designed to accelerate neutrophil recovery and reduce the risk for infection in patients with hematologic malignancies who are planned for myeloablative allogeneic hematopoietic stem cell transplantation (allo-HSCT). The therapy uses Gamida Cell's proprietary nicotinamide-based expansion technology that enables donor cells to grow while maintaining functionality. Each one-time, patient-specific dose consists of at least 12×10^8 live cells, which include $CD34^+$ and $CD3^+$ cells. The final cryopreserved product, administered intravenously (IV), includes nicotinamide-expanded hematopoietic stem cells and differentiated immune cells, including T cells.

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

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

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

- Medical record documentation that Omisirge is prescribed by a hematologist and/or oncologist AND
- Medical record documentation of age greater than or equal to 12 years of age AND
- Medical record documentation of a diagnosis of a hematological malignancy planned for umbilical cord blood transplantation following myeloablative conditioning AND
- Medical record documentation that a matched related donor (MRD), matched unrelated donor (MUD), mismatched unrelated donor (MMUD), or haploidentical donor is not readily available AND
- Medical record documentation that patient has not had a prior allogeneic hematopoietic stem cell transplantation (HSCT)

GPI Level: GPI-12
Quantity Limits: One time authorization for one administration of Omisirge
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.

Fast Facts

Enjaymo

Updated Indication: ENJAYMO (sutimlimab-jome) is now indicated for the treatment of hemolysis in adults with cold agglutinin disease (CAD).

Recommendation: Update the medical benefit policy to:
Medical record documentation of age greater than or equal to 18 years AND
• Medical record documentation that Enjaymo is prescribed by or in consultation with hematologist AND
• Medical record documentation of a diagnosis of primary cold agglutinin disease (CAD). confirmed by all of the following:
    o Evidence of chronic hemolysis (examples: high reticulocyte count, High LDL, high indirect bilirubin, low haptoglobin) AND
    o Positive polyspecific direct antiglobulin test (DAT) AND
    o Positive monospecific DAT specific for C3d AND
    o Cold agglutinin titer ≥ 64 at 4 degrees Celsius
AND
• Medical record documentation of hemoglobin level ≤ 10.0 g/dL
AND
• Medical record documentation that secondary causes of cold agglutinin disease (CAD) have been ruled out AND
• Medical record documentation of a prescribed dose that is consistent with Food and Drug Administration (FDA)-approved package labeling, nationally recognized compendia, or peer-reviewed medical literature AND
• Medical record documentation that Enjaymo will not be used in combination with rituximab ± bendamustine or fludarabine AND
• Medical record documentation that patient is vaccinated against encapsulated bacteria (e.g., Streptococcus pneumoniae, Neisseria meningitidis, and Haemophilus influenzae subgroup B) at least 2 weeks prior to treatment AND
• Medical record documentation of a therapeutic failure on, intolerance to, or contraindication to rituximab ± bendamustine or fludarabin

Outcome: There was one vote to reject, all other votes were in favor to accept the recommendation

Updates

Trastuzumab

Recommendation: It is recommended that a prior authorization be added and a policy created for Herceptin for Commercial/Exchange/CHIP/Medicaid. The proposed policy is included below:

Herceptin Policy

- For trastuzumab reference product requests (i.e. Herceptin), medical record documentation of a therapeutic failure of, intolerance to, or contraindication to **all** of the following: trastuzumab-anns (Kanjinti), trastuzumab-dkst (Ogivri), trastuzumab-dttb (Ontruzant), trastuzumab-qyyp (Trazimera), or trastuzumab-pkrb (Herzuma)

Authorization Duration:

For adjuvant treatment:

Authorization will be for one (1) 12 month approval. Authorization of Herceptin for adjuvant treatment should not exceed the FDA-approved treatment duration of 1 year (12 months). For requests exceeding the above limit, medical record documentation of the following is required:

- Peer-reviewed literature citing well-designed clinical trials to indicate that the member's healthcare outcome will be improved by dosing beyond the FDA-approved treatment duration

For all other indications:

Authorization will be open-ended

Outcome: The committee unanimously voted to accept the recommendation

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

June ELECTRONIC VOTE

An electronic vote was held from June 16, 2023, to June 23, 2023. Responses were received from 31 members (out of 51 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.

Keytruda

Updated Indication**:** Keytruda is now indicated in combination with enfortumab vedotin (Padcev), for the treatment of adult patients with locally advanced or metastatic urothelial carcinoma who are not eligible for cisplatin-containing chemotherapy.

Outcome**:** The following criteria should be added to Medical Benefit Policy 119.0:

Urothelial Carcinoma

- Prescription written by a hematologist/oncologist **AND**
- Medical record documentation that patient is ≥ 18 years of age **AND**
- Medical record documentation of locally advanced or metastatic urothelial carcinoma **AND**

- Medical record documentation of one of the following:
    - Disease progression during or following platinum-containing chemotherapy

OR

    - Disease progression within 12 months of neoadjuvant or adjuvant treatment with platinum-containing chemotherapy

OR

    - Patient is not eligible for any platinum-containing chemotherapy

OR

    - Patient has high-risk, non-muscle invasive bladder cancer (NMIBC)** **AND**
    - Patient's disease is unresponsive to an adequate trial of Bacillus Calmette-Guerin (BCG) therapy** **AND**
    - Patient is ineligible for or has elected not to undergo cystectomy

OR

    - Patient is not eligible for cisplatin-containing chemotherapy **AND**
    - Use in combination with Padcev

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

Padcev

Updated Indication: Padcev is now indicated in combination with pembrolizumab (Keytruda), for the treatment of adult patients with locally advanced or metastatic urothelial carcinoma who are not eligible for cisplatin-containing chemotherapy.

Outcome: The following criteria should be added to Medical Benefit Policy 209.0:

- Medical record documentation that prescription is written by a hematologist or oncologist **AND**
- Medical record documentation of age greater than or equal to 18 years **AND**
- Medical record documentation of locally advanced or metastatic urothelial cancer **AND**
    - Medical record documentation of one of the following: Medical record documentation that member has received a programmed death receptor-1 (PD-1) or programmed death-ligand 1 (PD-L1) inhibitor, and a platinum-containing chemotherapy in the neoadjuvant/adjuvant, locally advanced or metastatic setting **OR**
    - Medical record documentation that member has received at least one prior line of therapy and is ineligible for cisplatin-containing chemotherapy **OR**
    - Medical record documentation that member is ineligible for cisplatin-containing chemotherapy AND medical record documentation that Padcev will be prescribed in combination with Keytruda

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

Polivy

Updated Indication: Polivy is now approved in combination with a rituximab product, cyclophosphamide, doxorubicin, and prednisone for the treatment of adult patients who have previously untreated DLBCL, NOS, or HGBL and who have an International Prognostic Index score of 2 or greater

Outcome: It is recommended to update policy MBP 200.0 to include the following changes:

Diffuse Large B-Cell Lymphoma, Relapsed or Refractory

- Prescription written by an oncologist/hematologist AND

- Medical record documentation of age ≥ 18 years AND
- Medical record documentation of relapsed or refractory diffuse large B-cell lymphoma, not otherwise specified AND
- Medical record documentation that Polivy will be used in combination with bendamustine and rituximab AND
- Medical record documentation Polivy will be used as subsequent therapy after a trial of ≥ 2 prior therapies

Diffuse Large B-Cell Lymphoma, Previously Untreated

- Medical record documentation that the prescription is written by an oncologist/hematologist AND
- Medical record documentation of age ≥ 18 years AND
- Medical record documentation of previously untreated diffuse large B-cell lymphoma (DLBCL), not otherwise specified or high-grade B-cell lymphoma (HGBL) AND
- Medical record documentation of an International Prognostic Index score of 2 or greater AND
- Medical record documentation Polivy will be used in combination with rituximab, cyclophosphamide, doxorubicin and prednisone (R-CHP).

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

Kalydeco

Updated Indication: Kalydeco (ivacaftor) is now indicated for the treatment of cystic fibrosis (CF) in patients age 1 month and older who have at least one mutation in the CFTR gene that is responsive to Kalydeco based on clinical and/or in vitro assay data.

Outcome: It is recommended to update the required age in the policy to 1 month

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

Trikafta

Updated Indication: Trikafta is now indicated for the treatment of cystic fibrosis (CF) in patients aged 2 years and older who have at least one *F508del* mutation in the CFTR gene or a mutation in the CFTR gene that is responsive based on *in vitro* data.

Outcome: It is recommended to update the required age in the policy to 2 years.

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

Andexxa

Discussion: Upon annual review, it is recommended to update the criteria for use of the Andexxa policy MBP 183.0. The update to the Andexxa policy is intended to accurately represent the current verbiage in the FDA-approved indication.

Recommendation:

MBP 183.0 Andexxa (andexanet alfa)

Andexxa (andexanet alfa) will be considered medically necessary when ALL of the following criteria are met:

- Medical record documentation that Andexxa is being used for the reversal of anticoagulation due to life-threatening or uncontrolled bleeding in patients treated with rivaroxaban ~~and~~ or apixaban

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

Kerendia

Discussion: Kerendia (branded product of finerenone) is a nonsteroidal mineralocorticoid receptor antagonist approved for treatment of chronic kidney disease (CKD) associated with type 2 diabetes mellitus (T2DM).1 The medication has been shown to reduce the risk of progression of CKD, development of end stage renal disease, cardiovascular death, nonfatal myocardial infarction, and hospitalization for heart failure in adults with diabetic kidney disease (DKD).

The two major studies that evaluated the effect of finerenone in this population (FIDELIO-DKD and FIGARO-DKD) required participants to be on maximum tolerated doses of an angiotensin-converting enzyme inhibitor (ACEi) or angiotensin receptor blocker (ARB) prior to study enrollment. While there are no direct comparator trials of finerenone versus a sodium/glucose cotransporter 2 inhibitor (SGLT2i) for treatment of DKD, a meta-analysis of placebo-controlled trials suggests that SGLT2is are superior to finerenone in delaying progression of renal disease and preventing adverse cardiac outcomes. Subgroup analysis of the FIDELITY-DKD trial showed renal and cardiovascular effects of finerenone were similar regardless of treatment with an SGLT2i and a reduced incidence of hyperkalemia in the patients taking both medications versus finerenone monotherapy. This analysis, as well as a study in rats with hypertension induced CKD, suggests combination therapy with an SGLT2i and finerenone may provide increased efficacy in reducing risks associated with DKD than either agent alone.

The use of finerenone in adults with DKD who experience albuminuria (albumin creatinine ratio > 30mg/g) despite being treated with an SGLT2i and maximally tolerated renin-angiotensin system inhibitor, such as an ACEi or an ARB, is supported by ADA and KDIGO clinical practice guidelines. While SGLT2i's were not first line therapy for DKD at the initiation of the FIDELIO-DKD and FIGARO-DKD trials, these agents are now considered standard of care for patients with DKD regardless of glycemic status.

Specialist Feedback: Geisinger nephrology was consulted and is supportive of the updated recommendations requiring maximally tolerated ACEi/ARB and one SGLT-2 inhibitor. They additionally provided input on the definition of persistent albuminuria and recommended utilizing an albumin creatinine ratio greater than 30 mg/g.

Recommendation: The following changes are recommended to existing policies based on updated guidelines and the recommendation of Geisinger nephrology:

- 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) **AND**
    - One sodium-glucose co-transporter 2 (SGLT-2) inhibitor with proven kidney or cardiovascular benefit
- ~~Medical record documentation of therapeutic failure on, intolerance to, or contraindication to two (2) of the preferred sodium-glucose cotransporter-2 (SGLT-2) inhibitors Food and Drug Administration (FDA) approved for the member's diagnosis~~

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

GHP Family Update

Discussion: During a recent review of policies by DHS it was requested that the change noted below be made to be consistent with the drug's indication.

Recommendation: It is recommended the Committee approve the following changes:

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

- Medical record documentation that Odactra is prescribed by or in consultation with an allergist, immunologist, or other physician qualified to prescribe allergy immunotherapy **AND**
- Medical record documentation of age greater than or equal to ~~18~~ 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

It was also recommended that the table of CFTR Gene Mutations that Produce CFTR Protein and are Responsive to SYMDEKO be removed and replaced with:

Note to reviewer: please see package insert for list of CFTR Gene Mutations that Produce CFTR Protein and are Responsive to SYMDEKO https://www.symdeko.com/ .

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

Meeting adjourned at 4:36 pm

Future Scheduled Meetings
The next bi-monthly scheduled meeting will be held on September 19, 2023 at 1:00 p.m.

Meetings will be held virtually via phone/Microsoft Teams