P&T Committee Meeting Minutes
Medicaid
March 15, 2022

Present (via Teams):	**Absent:**
Kimberly Clark, Pharm.D. – facilitator	Holly Bones, Pharm.D.
Megan Ammon, Pharm.D.	Kim Castelnovo
Emily Antosh, Pharm.D.	Dean Christian, MD
Kristen Bender, Pharm.D.	Michael Evans, RPh
Jeremy Bennett, MD	Nichole Hossler, MD
Briana Blaisure, Pharm.D.	Jason Howay, Pharm.D.
Alyssa Cilia, RPh	Jonas Pearson, RPh
Rajneel Farley, Pharm.D.	Angela Scarantino
Kelly Faust Pharm.D.	William Seavey, Pharm.D.
Tricia Heitzman, Pharm.D.	Michael Shepherd, MD
Emily Hughes, Pharm.D.	Jill Stone, Pharm.D.
Keith Hunsicker, Pharm.D.	Bret Yarczower, MD, MBA
Kelli Hunsicker, Pharm.D.	
Derek Hunt, Pharm.D.	
Phillip Krebs, R.EEG T	
Ted Marines, Pharm.D.	
Lisa Mazonkey, RPh	
Tyreese McCrea, Pharm.D.	
Perry Meadows, MD	
Jamie Miller, RPh	
Mark Mowery, Pharm.D.	
Austin Paisley, Pharm.D.	
Kimberly Reichard, Pharm.D.	
Melissa Renn, Pharm.D.	
Kristen Scheib, Pharm.D.	
Leslie Shumlas, Pharm.D.	
Richard Silbert, MD	
Aubrielle Smith Pharm.D.	
Michael Spishock, RPh	
Todd Sponenberg, Pharm.D.	
Robert Strony, MD MBA	
Kevin Szczecina, RPh	
Amanda Taylor, MD	
Brandon Whiteash, Pharm.D.	
Travis Baughn (non-voting participant)	
MeiLing Montross, Pharm.D. (Pharmacy Resident)	

Call to Order:
Kim Clark called the meeting to order at 1:03 p.m., Tuesday, March 15, 2022.

Review and Approval of Minutes, Reviews, Fast Facts, and Updates: Kim asked for a motion or approval to accept the January 18th, 2022 minutes as written. Minutes approved unanimously.

DRUG REVIEWS

Tavneos (avacopan)

Review: Tavneos is a complement 5a receptor (C5aR) antagonist indicated as an adjunctive treatment of adult patients with severe active anti-neutrophil cytoplasmic autoantibody (ANCA)-associated vasculitis (granulomatosis with polyangiitis [GPA] and microscopic polyangiitis [MPA]) in combination with standard therapy including glucocorticoids. Tavneos does not eliminate glucocorticoid use. Tavneos is the first orally administered complement inhibitor and the first drug approved in over 10 years for the GPA and MPA variants of ANCA-associated vasculitis. It is not approved for EPGA at this time. Treatment guidelines have not been updated since the approval of Tavneos, but it is likely that Tavneos will be used during induction therapy with rituximab or cyclophosphamide and glucocorticoids to mitigate the use of high-dose glucocorticoids typically used to induce remission. Although Tavneos was designed as a potential alternative to steroids, the FDA approved labeling specifically states that it does not eliminate glucocorticoid use. The efficacy of Tavneos was evaluated in the ADVOCATE trial, a double-blind active-controlled phase 3 clinical trial in 330 adult patients with newly diagnosed or relapsed ANCA-associated vasculitis. Patients were randomized 1:1 to receive treatment with Tavneos (n=166)30 mg twice daily for 52 weeks plus prednisone-matching placebo for 20 weeks or avacopan-matched placebo twice daily for 52 weeks plus prednisone (tapered from 60 mg/day to 0 over 20 weeks). Patients in both groups received treatment with a standard immunosuppressive regimen. The primary endpoints were disease remission at Week 26 and sustained disease remission at Week 52. Disease remission was defined as a BVAS of 0 and no use of glucocorticoids for treatment of ANCA-associated vasculitis from Week 22 to Week 26. Sustained remission was remission at Week 26 sustained through Week 52 without relapse (BVAS score of 0 and no use of glucocorticoids for treatment of ANCA-associated vasculitis from Week 48 to Week 52). Relapse was occurrence of one BVAS major item, at least 3 BVAS non-major items, or 1 or 2 BVAS non-major items for at least 2 consecutive visits after remission was achieved. Remission was achieved by 72.3% of patients in the Tavneos group compared to 70.1% of patients in the prednisone group by Week 26 (treatment difference: 3.4%, 95% CI [-6.0%, 12.8%]). At Week 52, a significantly higher percentage of patients had sustained remission in the Tavneos group (65.7%) compared to prednisone (54.9%) (Table 2). There are no black box warnings for Tavneos. Warnings and precautions include risk of hepatotoxicity, hypersensitivity reactions, hepatitis B virus reactivation, and risk of serious infections. Tavneos is contraindicated in patients with serious hypersensitivity reaction to avacopan. During clinical trials of Tavneos, the most frequent serious adverse reactions that were reported were pneumonia, GPA, acute kidney injury, and urinary tract infection. The most common adverse reactions occurring in at least 5% of patients and were higher for Tavneos compared to prednisone were headache, nausea, diarrhea, vomiting, hypertension, rash, fatigue, upper abdominal pain, dizziness, increased blood creatinine, and paresthesia. During the ADVOCATE trial, 19 patients (11.6%) in the prednisone group and 22 patients (13.3%) in the Tavneos group had hepatic-related adverse reactions, including hepatobiliary adverse reactions and liver enzyme abnormalities. Study medication was paused or permanently discontinued by 9 patients in the Tavneos group and serious hepatic-related adverse reactions were reported in 9 patients in the Tavneos group. During the ADVOCATE trial, 2 patients developed angioedema and one event was serious adverse reaction requiring hospitalization.

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

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

Outcome: Tavneos is a pharmacy benefit and will be managed by GHP. It should not be added to the GHP Family formulary. The following prior authorization criteria will be required.

- 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 such as, but not limited to rituximab, cyclophosphamide, methotrexate, mycophenolate, or azathioprine, and/or glucocorticoids

Authorization Duration: Initial approval will be given for six months. Subsequent approvals will be for an additional twelve months and will require:

- Medical record documentation of continued disease improvement or lack of disease progression AND
- Medical record documentation that the member is responding positively to therapy as evidenced by a reduction in the Birmingham Vasculitis Activity Score (BVAS)
- Medical record documentation that Tavneos will continue to be administered in combination with standard therapy such as, but not limited to rituximab, cyclophosphamide, methotrexate, mycophenolate, or azathioprine, and/or glucocorticoids

The medication will no longer be covered if patient experiences toxicity or worsening of disease.

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

Livmarli (maralixibat)

Review: Clinical Summary Livmarli is an IBAT inhibitor indicated for the treatment of cholestatic pruritus in patients with ALGS 1 year of age and older. Livmarli is the first FDA-approved therapy for the treatment of ALGS. It is currently in phase 3 trials for the treatment of PFIC and in phase 2 trials for treatment of biliary atresia. Bylvay, another ileal bile acid transporter, is currently in phase III trials for the treatment of ALGS. Bylvay is approved for PFIC. Livmarli and Bylvay will compete, however the long-term use will be contingent upon their success in preventing liver-related outcomes. Diagnosis ALGS can be suspected in patients who have a reduced number of bile ducts upon liver biopsy. Symptoms of liver disease or cholestasis, heart defect, bone abnormality, eye abnormality, and distinctive facial features can be used to further support diagnosis. Diagnosis can be confirmed through molecular genetic testing; however, while some patients present with mutations in the *JAG1* or *NOTCH2* gene, in rare cases, patients do not present with these mutations and a diagnosis is made upon clinical presentation alone. Patients with ALGS require comprehensive care, given that multiple organ systems are affected. For patients with cholestatic liver disease, patients can trial ursodiol, cholestyramine, rifampin, naltrexone, diphenhydramine, and sertraline. However, pruritus is often resistant to treatment. In severe cases of cirrhosis or where other therapies are unsuccessful, patrial external biliary diversion (PEBD) surgery or liver transplant may be required. Vitamin and specialty nutrition supplementation to support growth and development is usually provided for patients with

Alagille syndrome. Livmarli is supplied as 9.5 mg of maralixibat per mL in a 30 mL bottle. The recommended dose is 380 mcg/kg once daily, taken 30 minutes before the first meal of the day. The starting dose is 190 mcg/kg administered orally once daily; after one week, increase to 380 mcg/kg once daily, as tolerated. The maximum daily dose volume for patients above 70 kg is 3 mL or 28.5 mg per day. Livmarli was studied in an 18-week open label treatment period; a 4-week randomized, double-blind, placebo-controlled drug withdrawal period; a subsequent 26-week open-label treatment period; and a long-term open-label extension period. The trial included 31 pediatric ALGS patients with cholestasis and pruritus. Approximately 90.3% of patients received at least one medication to treat pruritus at study entry. All patients had JAGGED1 mutation. Randomized patients had a median age of 5 years (range 1 to 15 years). Patents were included in the trial if their average pruritus score was greater than 2.0 (moderate) in the 2 weeks prior to baseline. A single-item observer-reported outcome was used to measure patients' pruritus symptoms as observed by their caregiver twice daily on the Itch Reported Outcome Instrument. For randomized patients, the mean (SD) at baseline (pre-treatment) was 3.1 (0.5) and the mean (SD) at Week 18 (pre-randomized withdrawal period) was 1.4 (0.9). On average, patients administered Livmarli for 22 weeks maintained pruritus reduction whereas those in the placebo group who were withdrawn from Livmarli after Week 18 returned to baseline pruritus scores by Week 22. After re-entering the open-label treatment phase, both randomized treatment groups had similar mean pruritus scores by Week 28, the first week placebo patients received the full dosage of Livmarli after withdrawal. There are no contraindications to Livmarli use. Livmarli has warnings for liver test abnormalities, gastrointestinal adverse reactions, and fat-soluble vitamin deficiency. The most common adverse reactions (≥ 5%) are diarrhea, abdominal pain, vomiting, fat-soluble vitamin deficiency, liver test abnormalities, gastrointestinal bleeding, and bone fractures. The safety and effectiveness of Livmarli have been established in pediatric patients 1 to 15 years of age.

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

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

Outcome: Livmarli will be a pharmacy benefit. It is recommended to not add Livmarli to the GHP Family formulary. The following prior authorization criteria will apply.

- 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 of age greater than or equal to 1 year 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

*Note to reviewing pharmacist: The recommended dose of Livmarli is shown in the table below.

Patient Weight (kg)	Days 1-7 (190 mcg/kg once daily)		Beginning Day 8 (380 mcg/kg once daily)	
	Volume QD (mL)	Dosing dispenser size (mL)	Volume QD (mL)	Dosing dispenser size (mL)
5 to 6	0.1	0.5	0.2	0.5
7 to 9	0.15		0.3	
10 to 12	0.2		0.45	
13 to 15	0.3		0.6	1
16 to 19	0.35		0.7	
20 to 24	0.45		0.9	
25 to 29	0.5		1	
30 to 34	0.6	1	1.25	3
35 to 39	0.7		1.5	
40 to 49	0.9		1.75	
50 to 59	1		2.25	
60 to 69	1.25	3	2.5	
70 or higher	1.5		3	

Authorization Duration: Initial approval will be for 6 months or less if the reviewing provider feels it is medically appropriate. Subsequent approvals will be for an additional 6 months or less if the reviewing provider feels it is medically appropriate and will require the following:

- Medical record documentation of improvement in pruritus from baseline AND
- Medical record documentation that the member is receiving an appropriate dose* based on the patient's weight

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

Kimmtrak (tebentafusp-tebn)

Review: Kimmtrak is a bispecific gp100 peptide-HLA-directed CD3 T cell engager indicated for the treatment of HLA-A*02:01-positive adult patients with unresectable/metastatic uveal melanoma. Uveal melanoma is the most common primary ocular cancer. There are approximately 1,275 – 1,700 uveal melanomas diagnosed in the U.S. annually. Up to 50% of patients with uveal melanoma will have recurrence of distant metastases, most often developing in the liver. The prognosis is often poor. Patients with metastatic disease have a mean OS of approximately 1 year. Treatment for uveal melanoma depends on tumor size and symptoms. Before the approval of Kimmtrak, there were no FDA-approved systemic therapies for unresectable/metastatic uveal melanoma. Clinical trials were recommended as the preferred option for systemic therapy. If a clinical trial was not appropriate, other systemic therapies were then considered. The most comparable systemic therapy option available in terms of efficacy is Opdivo (nivolumab) + Yervoy (ipilimumab). These agents are not FDA approved to treat unresectable/metastatic uveal melanoma but are rated category 2A by NCCN. The recommended dose of Kimmtrak is 20 mcg intravenously on Day 1, 30 mcg intravenously on Day 8, 68 mcg intravenously on Day 15, and 68 mcg intravenously once every week thereafter. Kimmtrak is an intravenous infusion that must diluted prior to administration and must be initially administered in a health care setting. The first three infusions should be administered over 15 to 20 minutes and patients must be monitored during the infusion and for at least 16 hours after the infusion. If the patient does not experience Grade 2 or worse hypotension after the third infusion, subsequent doses may be administered in an ambulatory care setting, where patients should be monitored at least 30 minutes after each infusion. Kimmtrak was studied in a randomized, open-label, multicenter trial. 378 adult patients with HLA-A*0201–positive (identified by a central assay), previously untreated, advanced uveal melanoma were randomized (2:1) to receive Kimmtrak (N=252) or Investigator's choice (N=126) of Keytruda (pembrolizumab), Yervoy (ipilimumab), or dacarbazine. The major efficacy endpoint was overall survival (OS). The median OS of

patients treated with Kimmtrak was 21.7 months (95% CI 18.6, 28.6), while the OS for patients in the investigator's choice arm was 16 months (hazard ratio [HR] = 0.51; 95% CI: 0.37, 0.71; P <0.0001). Kimmtrak carries a black box warning for Cytokine Release Syndrome (CRS), which may be serious or life threatening if not appropriately managed. It is important to monitor patients during and for 16 hours following the first three infusions for signs or symptoms of CRS. Kimmtrak also has warnings/precautions for potential skin reactions, elevated liver enzymes, and embryo-fetal toxicity. Patients should be monitored for and aware of the potential for such reactions. Among the patients treated with Kimmtrak, the most common Grade 3 or higher adverse reactions were rash (18%), pyrexia (4%), and pruritus (5%). In the 245 patients who received Kimmtrak, Grade 3 CRS occurred in <1% of patients and was generally well-managed. There were no Grade 4 or fatal CRS events observed in the Phase 3 trial. Dose modifications do exist to address adverse reactions depending on severity.

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

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

Outcome: Kimmtrak is a medical benefit. The following prior authorization criteria should apply:
Prior Authorization Criteria

- Prescription written by a hematologist/oncologist AND
- Medical record documentation that patient is ≥ 18 years of age AND
- Medical record documentation of a diagnosis of unresectable or metastatic uveal melanoma AND
- Medical record documentation of HLA-A*02:01–positive disease AND
- Medical record documentation that Kimmtrak is not being used in combination with any other agents for the treatment of unresectable or metastatic uveal melanoma

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

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

Vuity (pilocarpine hydrochloride)

Review: Vuity is the first and only FDA-approved eye drop specifically indicated for the treatment of presbyopia in adults. Prior to approval the only treatments of presbyopia have included corrective lenses, such as eyeglasses or contact lenses, or laser vision refractive surgery. Newer treatments have included corneal inlays, which are tiny devices implanted into the cornea of the eye. Vuity is supplied as a 1.25% ophthalmic solution given 1 drop in both eyes daily. The efficacy of Vuity was evaluated in two 30-Day Phase 3, randomized, double-masked, vehicle-controlled studies, which showed that Vuity can improve DCNVA starting as soon as 15 minutes after administration and lasting up to 6 hours. The most common side effects in studies were headache, conjunctival hyperemia, blurred vision, eye pain, visual impairment, eye irritation and increased lacrimation.

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

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

Outcome: Vuity will be a pharmacy benefit. Vuity is not currently a PDL managed drug. It is recommended to not add Vuity to formulary. Vuity will require a prior authorization with 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.

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

FAST FACTS

Cutaquig

Updated Indication: Cutaquig is now indicated for the treatment of primary humoral immunodeficiency (PI) in adults and pediatric patients 2 years of age and older. Cutaquig was previously indicated for treatment of primary humoral immunodeficiency (PI) in adults.

Recommendation: There are no changes recommended to the formulary placement, authorization duration or prior authorization criteria of intravenous immune globulin as outlined by MBP 4.0

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.

Updates

Nexviazyme and Lumizyme

Recommendation: the following updates are based on feedback from Dr. Priya Kishnani, pediatric medical genetics specialist at Duke:

Nexviazyme: There are no changes to formulary status or authorization duration. However, it is recommended to update the prior authorization criteria for the Nexviazyme policy based on Dr. Kishnani's feedback.

- 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
- 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 1 year AND
- Medical record documentation of baseline pulmonary function testing and muscle strength evaluation (e.g. percent-predicted forced vital capacity (% FVC), 6-minute walk test (6MWT), GSGC (gait stairs, gower, chair)) AND
- Medical record documentation that the member is receiving an appropriate dose* based on patient's weight AND

- Medical record documentation that Nexviazyme will not be used in combination with other enzyme replacement therapy (e.g. Lumizyme)

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 pulmonary function testing and/or muscle strength evaluation (e.g. percent-predicted forced vital capacity (% FVC), 6-minute walk test (6MWT), GSGC (gait stairs, gower, chair)) AND
- Medical record documentation that the member is receiving an appropriate dose* based on patient's weight AND
- Medical record documentation that Nexviazyme will not be used in combination with other enzyme replacement therapy (e.g. Lumizyme)

*Note to reviewing pharmacist: For patients weighing ≥30 kg, the recommended dosage is 20 mg/kg (of actual body weight) every two weeks. For patients weighing < 30 kg, the recommended dosage is 40 mg/kg (of actual body weight) every two weeks

Lumizyme: There are no changes to formulary status or authorization duration. However, it is recommended to update the prior authorization criteria for Lumizyme based on Dr. Kishnani's feedback.

- Physician provided documentation of a diagnosis of late-onset (non-infantile) Pompe disease OR a diagnosis of infantile-onset Pompe disease supported by:
    - GAA assay performed on dried blood spots, skin fibroblasts or muscle biopsy; and
    - Baseline pulmonary function testing (PFT) and muscle strength evaluation (e.g. percent-predicted forced vital capacity (% FVC), 6-minute walk test (6MWT), GSGC (gait stairs, gower, chair)); and
    - For late-onset Pompe disease only – Genetic testing to identify the specific mutation to confirm the diagnosis of late-onset Pompe disease; and
- Physician provided documentation of a consultation with a metabolic specialist and/or biochemical geneticist; and
- Medical record documentation that the member is receiving an appropriate dose* based on patient's weight AND
- Medical record documentation that Lumizyme will not be used in combination with other enzyme replacement therapy (e.g. 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 pulmonary function testing and/or muscle strength evaluation (e.g. percent-predicted forced vital capacity (% FVC), 6-minute walk test (6MWT), GSGC (gait stairs, gower, chair)) AND
- Medical record documentation that the member is receiving an appropriate dose* based on patient's weight AND
- Medical record documentation that Lumizyme will not be used in combination with other enzyme replacement therapy (e.g. Nexviazyme)

*Note to reviewing pharmacist: The recommended dose is 20 mg/kg intravenously every 2 weeks.

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.

Medical Benefit Policy Updates

Recommendation: It is recommended that the Committee approve the following updates:

MBP 48.0 Rituxan (rituximab), Truxima (rituximab-abbs), Ruxience (rituximab-pvvr), and Riabni (rituximab-arrx):

9. **For Pemphigus Vulgaris (PV)**
    - Prescription written by a dermatologist **AND**
    - Member is 18 years of age or older **AND**
    - Medical record documentation of a diagnosis of moderate to severe pemphigus vulgaris **AND**
    - ~~Medical record documentation of a contraindication to, intolerance to, or therapeutic failure on corticosteroids AND a 12-week trial of at least one (1) nonsteroidal immunomodulatory medication (e.g. azathioprine, cyclophosphamide, or mycophenolate).~~
    - Medical record documentation of use in combination with corticosteroids or a contraindication or intolerance to corticosteroids.

MBP 92.0 Off-Label Drug Use for Oncologic Indications

4. The proposed drug use is supported by any one or more of the following:
    - The National Comprehensive Cancer Network Practice Guidelines™ in Oncology category 1, 2A, or 2B recommendation; **OR**
    - The National Comprehensive Cancer Network Drug & Biologics Compendium™ category of Evidence and consensus 1, 2A, or 2B; **OR**
    - The American Hospital Formulary Service – Drug Information; **OR**
    - Thompson Micromedix DrugDEx Compendium (DrugDex®) class I or IIa indication; or
    - Elsevier Gold Standard's Clinical Pharmacology Compendium (Clinical Pharmacology®)

MBP 198.0 Gamifant (emapalumab-lzsg)

- Medical record documentation of a diagnosis of primary hemophagocytic lymphohistiocytosis (HLH) based on one of the following:
    - A molecular diagnosis (HLH gene mutations) **OR**
    - A family history consistent with primary HLH (X-linked lymphoproliferative syndrome) **OR**
    - 5 out of the following 8 criteria fulfilled:
        - Fever ≥ 38.5ºC
        - Splenomegaly
        - Cytopenias affecting 2 of 3 lineages in the peripheral blood; hemoglobin <9 g/dL, platelets <100 x 10^9/L, neutrophils <1 x 10^9/L
        - Hypertriglyceridemia (fasting triglycerides > 3 mmol/L or ≥ 265 mg/dL) and/or ~~hyper~~hypofibrinogenemia (≤1.5 g/dL)
        - Hemophagocytosis in bone marrow, spleen, or lymph nodes with no evidence of malignancy
        - Low or absent NK-cell activity
        - Ferritin ≥ 500 mcg/L

- Soluble CD25 level (i.e. soluble IL-2 receptor) of ≥ 2,400 U/mL or two standard deviations above age-adjusted laboratory-specific norms

MBP 230.0 Darzalex Faspro (daratumumab/hyaluronidase)

- Medical Record documentation that the patient does NOT have New York Heart Association (NYHA) Class IIIB (defined by marked limitation of physical activity, comfortable at rest, less than ordinary activity causes fatigue, palpitation, dyspnea, or anginal pain, symptomatic with recent history of dyspnea at rest) or Class IV heart failure, or mayo cardiac stage IIIB* **AND**

MBP 249.0 Saphnelo (anifrolumab-fnia)

Medical record documentation that Saphnelo is being prescribed by or in consultation with a

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.

Kerendia

Recommendation: DHS noted that members started on Kerendia prior to coverage through Geisinger could be maintained on a 10 mg or 20 mg dose as long as serum potassium is less than or equal to 5.5 mEq/L and questioned our rationale for failure on three different SGLT-2 inhibitors. It is recommended the Committee approve the following updates (underlined):

- 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 <u>or ≤ 5.5 mEq/L if previously established on therapy **AND**</u>
- Medical record documentation ~~of therapeutic failure on, intolerance to, or contraindication to three (3) of the preferred sodium-glucose cotransporter 2 (SGLT-2) inhibitors FDA-approved for the member's diagnosis~~ <u>of therapeutic failure on one (1) of the preferred sodium-glucose cotransporter 2 (SGLT-2) inhibitors FDA-approved for the member's diagnosis **OR** intolerance to, or contraindication to two (2) of the preferred sodium-glucose cotransporter 2 (SGLT-2) inhibitors FDA-approved for the member's diagnosis</u>

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.

Xywav

Recommendation: Based on feedback from DHS and Dr. Sreelatha Naik that amphetamines/stimulants should be avoided for treatment of narcolepsy it is recommended that the following update to the Xywav policy be approved: 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
  - ~~For patients 18 years and older, medical record documentation of failure on, intolerance to, or contraindication to one of the following: modafinil AND methylphenidate immediate release or amphetamine/dextroamphetamine immediate release **OR**~~
  - ~~For patient 7-17 years, medical record documentation of failure on, intolerance to methylphenidate immediate release or amphetamine/dextroamphetamine immediate release~~

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.

February Electronic Vote

Due to the volume of full drug reviews, fast facts, and updates that must reviewed by the P&T Committee an additional electronic vote was held from February 21, 2022, to February 28, 2022. Responses were received from 30 members (out of 44) and all voted to approve.

Covid 19 New Drug Reviews and Updates

On February 4, 2020, the HHS Secretary determined that COVID-19 was a public health emergency with significant potential to affect national security or the health and security of U.S. citizens living abroad. An Emergency Use Authorization (EUA) is an FDA authorization for the emergency use of an unapproved product or unapproved use of an approved product during a public health emergency. Criteria for issuing an EUA include:

• The biological agent(s) can cause a serious or life-threatening disease or condition.
• Based on the totality of the available scientific evidence (including data from adequate and well controlled clinical trials, if available), it is reasonable to believe that:
  o The product may be effective in diagnosing, treating, or preventing the serious or life threatening disease or condition; and
  o The known and potential benefits of the product – when used to diagnose, prevent, or treat such disease or condition – outweigh the known and potential risks of the product, taking into consideration the material threat posed by the biological agent(s);
• There is no adequate, approved, and available alternative to the product for diagnosing, preventing, or treating the serious or life-threatening disease or condition.

A current list of the medications with an EUA can be found on the FDA website at https://www.fda.gov/emergency-preparedness-and-response/mcm-legal-regulatory-and-policyframework/emergency-use-authorization. The FDA will continue to closely monitor the variants and will determine whether use in a geographic region of the U.S. which is consistent with the scope of the EUA. EUAs for medications may be revoked or limited based on clinical data. SARS-CoV-2 variant frequency data for states and jurisdictions can be assessed on the CDC website.

Patients with symptomatic COVID-19 infections can experience a wide range of clinical manifestations but may progress to pneumonia, respiratory failure, multi-organ failure, and death. Severe and critical illness in patients is defined as worsening pulmonary status requiring hospitalization,

supplemental oxygen, non-invasive ventilation, high-flow oxygen devices, invasive mechanical ventilation, or ECMO. Medical conditions which place patient at a higher risk of progression to severe COVID-19 can include:

- Older age
- Obesity or being overweight
- Pregnancy
- Chronic kidney disease
- Diabetes
- Immunosuppressive disease or immunosuppressive treatment
- Cardiovascular disease or hypertension
- Chronic lung diseases
- Sickle cell disease
- Neurodevelopmental disorders or other conditions that confer medical complexity
- Having a medical-related technological dependence (for example, tracheostomy, gastrostomy, or positive pressure ventilation (not related to COVID-19)

Recommendations:

Sotrovimab, Bebtelovimab, and Evusheld will be covered as medical benefits and will not be added to the GHP Family pharmacy formulary. Sotrovimab, Bebtelovimab, and Evusheld will not require a prior authorization**.**

Paxlovid and Molnupiravir are pharmacy benefits. They will be free to patients who qualify under the Emergency Use Authorization parameters issued by the FDA. They will be added to the formulary to cover the cost of administration only.

Comirnaty and Spikevax will be covered as medical or pharmacy benefits and will not require a prior authorization.

Veklury is currently available without a prior authorization as a medical benefit. No changes are recommended.

The EUA for **Olumiant** is limited to inpatient use and Olumiant for the treatment of COVID-19 will be provided to inpatient pharmacies only by Lilly Authorized Specialty Distributors. Olumiant for the treatment of COVID-19 will not be available at retail pharmacies and is not authorized for outpatient use. The following note for the reviewer should be added to Policy 530.0: "Note to Reviewer* If Olumiant is being prescribed for COVID-19, see the FDA website for Emergency Use Authorizations at https://www.fda.gov/emergency-preparedness-and-response/mcm-legal-regulatory-and-policy-framework/emergency-use-authorization#coviddrugs for current FDA authorized use. Olumiant is authorized for inpatient use only for COVID-19 and would not be covered for outpatient use."

As of January 24, 2022, **REGEN-COV (Casirivimab/imdevimab)** and **Bamlanivimab/Etesevimab** are not currently authorized for use in any U.S. region due to the high frequency of the Omicron variant and the markedly reduced activity of these agents against the omicron variant. These drugs may not be administered for treatment or post-exposure preventions under the EUA until further notice. The FDA will continue to closely monitor the variants and will determine whether use in a geographic region of the U.S. which is consistent with the scope of the EUA. Updates will be available on the FDA website for Emergency Use Authorizations for Drug and Non-Vaccine Biological Products at https://www.fda.gov/emergency-preparedness-and-response/mcm-legal-regulatory-and-policy-framework/emergency-use-authorization#coviddrugs The EUA has not been revoked as these products may retain activity against future circulating SARS-CoV-2 variants which may shift over time. REGEN-COV (Casirivimab/imdevimab), and Bamlanivimab/Etesevimab are unavailable

in Darwin which is consistent with the status of the EUA. No changes are needed at this time, since they are medical benefits and are not currently on the pharmacy formularies.

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

Meeting adjourned at 4:37 pm

Future Scheduled Meetings
The next bi-monthly scheduled meeting will be held on May 17th, 2022 at 1:00 p.m.

Meetings will be held virtually via phone/Microsoft Teams