P&T Committee Meeting Minutes
Commercial/Marketplace/GHP Kids
November 16, 2021

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

Call to Order:
Dr. Bret Yarczower called the meeting to order at 1:02 p.m., Tuesday, November 16, 2021.

Review and Approval of Minutes:
Dr. Bret Yarczower asked for a motion or approval to accept the September 21, 2021 and October 20, 2021 minutes as written. Minutes approved unanimously. None were opposed.

DRUG REVIEWS

KERENDIA (finerenone)

Review: Kerendia is a non-steroidal MRA indicated to reduce the risk of sustained eGFR decline, end stage kidney disease, cardiovascular death, non-fatal myocardial infarction, and hospitalization for heart failure in adult patients with CKD associated with T2D. Kerendia is supplied as 10 mg and 20 mg tablets. Serum potassium levels and estimated glomerular filtration rate (eGFR) need to be measured before initiation. Treatment should not be initiated if serum potassium is > 5.0 mEq/L or eGFR < 25 mL/min/1.73m^2. Depending on eGFR and serum potassium, the starting dose can be 10 mg or 20 mg once daily. The target daily dose of Kerendia is 20 mg once daily.

Kerendia is the first mineralocorticoid receptor antagonist and the third medication approved for the treatment of chronic kidney disease in patients with type 2 diabetes. Kerendia will directly complete with Invokana and Farxiga. Although the Farxiga indication does not call out chronic kidney disease with type 2 diabetes, 68% of patients in the clinical trials had type 2 diabetes. Jardiance is expected to complete its trial in patients with CKD with or without type 2 diabetes in 2022. Kerendia will likely be reserved for patients who cannot use or have failed a SLGT2 inhibitor.

Kerendia was studied in the FIDELIO-DKD trial, which was a randomized, double-blind, placebo-controlled trial in adult patients (n=5,674) with CKD associated with T2D. Patients were to be receiving standard of care background therapy, including a maximum tolerated ACEi or ARB (99.8%). Patients were excluded with chronic heart failure with reduced ejection fraction and persistent symptoms (NYHA class II to IV). Approximately 5% were on an SLGT2 inhibitor. Patients received Kerendia or placebo and were followed for 2.6 years. Kerendia reduced the incidence of the primary composite endpoint of sustained decline in eGFR of ≥40%, kidney failure, or renal death (HR 0.82, 95% CI 0.73-0.93, p=0.001). Kerendia reduced the incidence of the composite endpoint of cardiovascular (CV) death, non-fatal myocardial infarction (MI), non-fatal stroke or hospitalization for heart failure (HR 0.86, 95% CI 0.75-0.99, p=0.034). The treatment effect on the primary and secondary composite endpoints was generally consistent across subgroups.

Kerendia was also studied in a Phase 3 trial, which investigated the efficacy and safety versus placebo in addition to an ACEI or ARB in the reduction of cardiovascular morbidity and mortality in an additional 7,437 patients with CKD and T2D. Compared with FIDELIO-DKD the trial included more patients at earlier stages of CKD. Patients in the trial were on a maximal tolerated renin-angiotensin system blocker. Approximately 8% were on an SGLT2 inhibitor. Patients with heart failure with reduced ejection fraction with NYHA class II-IV were excluded. Patients were randomized to finerenone or placebo for 3.4 years. The primary endpoint was time to first occurrence of the compositive endpoint of cardiovascular death and nonfatal cardiovascular events (myocardial infarction, stroke, or hospitalization for heart failure) and the composite endpoint occurred in 12.4% of patients in the finerenone group compared to 14.2% in placebo group (HR 0.87, 95% CI 0.76-0.98, p=0.03).

Results from the pooled analysis from both trials, indicate that finerenone is efficacious for CV outcomes for patients with T2D and CKD, who are on background RAS blockade therapy, mostly due to the reduction in hospitalization for heart failure. There was also reduction in end stage renal disease and a higher incidence of hyperkalemia. Patients with symptomatic heart failure were excluded from both trials.

Kerendia is contraindicated in patients who are receiving concomitant treatment with strong CYP3A4 inhibitors and with adrenal insufficiency. Adverse reactions occurring in ≥ 1% of patients on Kerendia and more frequently than placebo are hyperkalemia, hypotension, and hyponatremia. Hyperkalemia led to

permanent discontinuation of treatment in 2.3% of patients receiving Kerendia and was the most frequent adverse reaction (18.3%) in the study overall. The safety and efficacy of Kerendia have not been established in patients below 18 years of age.

According to the American Diabetes Association (ADA), patients with type 2 diabetes and kidney disease, the use of a SGLT2 inhibitor should be considered in those with an eGFR ≥ 30 mL/min/1.73m^2 and UACR > 300 mg/g (Level of Evidence A). According to the Kidney Disease: Improving Global Outcomes (KDIGO), treatment with an ACEI or an ARB may be initiated in patients with diabetes, hypertension, and albuminuria (Level of Evidence 1B). In patients with type 2 diabetes, CKD, an eGFR ≥ 30 mL/min per 1.73m^2, treatment with a SLGT2 inhibitor should be considered (1A).

A Clinical Review including Clinical Information, Efficacy Evidence, Safety Evidence, Other Considerations and a Financial Review Based on Cost Analysis were presented.

Clinical Discussion: If one does or doesn't see a rise in potassium early on, does that predict what happens later on? There are dose adjustment recommendations based on serum potassium. They recommend monitoring 4 weeks after a dose adjustment and starting therapy. These patients do have kidney disease so it will need to be monitored throughout therapy. No additional comments or questions. The committee unanimously voted to accept the recommendations as presented. None were opposed.

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

Outcome: Kerendia will be covered as a pharmacy benefit which will not be added to the formulary. Kerendia will require prior authorization with the following criteria:

- Medical record documentation of a diagnosis of chronic kidney disease associated with type 2 diabetes **AND**
- Medical record documentation of age greater than or equal to 18 years **AND**
- Medical record documentation of serum potassium ≤ 5.0 mEq/L **AND**
- Medical record documentation of therapeutic failure on, intolerance to, or contraindication to two (2) of the preferred sodium-glucose cotransporter 2 (SGLT-2) inhibitors FDA-approved for the member's diagnosis

QUANTITY LIMIT: 1 tablet per day

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

ORIAHNN (elagolix/estradiol/norethindrone acetate capsules; elagolix capsules)

Review: Oriahnn is the first oral GnRH antagonist indicated for heavy bleeding due to uterine fibroids. Oriahnn also contains estradiol and norethindrone, or low hormonal "add-back" therapy, to help mitigate the hypoestrogenic side effects of elagolix. It provides an alternative for short-term management of heavy menstrual bleeding due to fibroids to delay the need for surgery. Oriahnn will compete with Myfembree, a second GnRH antagonist containing relugolix/estradiol/norethindrone acetate approved for the same indication. Compared to GnRH agonists, Oriahnn and Myfembree with have a quicker onset and a shorter duration of effect (readily reversed upon discontinuation) as well as a reduction of the hypoestrogenic side effects. Patients most likely to benefit the most from these agents are patients who are close to menopause where it will act as a transitional therapy to avoid surgery or in patients who have an

inadequate response to combined hormonal contraceptives or progestin-releasing intrauterine devices to delay the need for surgery.

The efficacy of Oriahnn was evaluated in two randomized, double-blind, placebo-controlled studies in 790 premenopausal women with heavy menstrual bleeding and ultrasonography-confirmed diagnosis of uterine fibroids. Patients were randomized 2:1:1 to receive Oriahnn (at recommended dosage), elagolix 300 mg (without "add-back" therapy), or placebo for 6 months. All bleeding endpoints were assessed by means of the alkaline hematin method during the treatment period. The primary endpoint was the proportion of responders, defined as women who achieved both MBL volume less than 80 mL at the final month and a 50% or greater reduction in MBL volume from baseline to the final month (last 28 days before and included the last treatment visit date or last dose date). A higher proportion of women treated with Oriahnn were responders compared to placebo-treated women. In both studies, women taking Oriahnn had a mean reduction in the MBL volume from baseline to the final month compared to placebo (Study UF-1: -177 mL for Oriahnn and 1 mL for placebo; Study UF-2: -169 mL for Oriahnn and -4 mL for placebo). Both studies also showed a greater proportion of women receiving Oriahnn experienced suppression of bleeding (no bleeding besides spotting) at the final month (57% in Study UF-1 and 61% in Study UF-2) compared to placebo (4% and 5%, respectively). A greater proportion of anemic patients (baseline Hgb $\leq$ 10.5 g/dL) treated with Oriahnn achieved an increase > 2 g/dL from baseline to month 6 compared to placebo.

Oriahnn has a black box warning for thromboembolic disorders and vascular events. During clinical trials, two thrombotic events occurred in 453 Oriahnn-treated women (thrombosis in calf and pulmonary embolism). Medications containing estrogen and progestin combinations, including Oriahnn, increase the risk of thrombotic or thromboembolic disorders. In general, the risk is greatest in women over 35 years of age who smoke, and women with uncontrolled hypertension, dyslipidemia, vascular disease, or obesity. Oriahnn should be discontinued if arterial or venous thrombosis, cardiovascular, or cerebrovascular events occur or are suspected. Oriahnn is contraindicated at women who are at high risk of arterial, venous thrombotic, or thromboembolic disorders.

Oriahnn is also contraindicated in women who are pregnant, with known osteoporosis (due to risk of further bone loss), with a current or history of breast cancer or hormonally-sensitive malignancies, with known hepatic impairment or disease, with undiagnosed abnormal uterine bleeding, or with known hypersensitivity to Oriahnn or its components.

Warnings and precautions include decreases in bone mineral density, increased risk for hormonally-sensitive malignancies, suicidal ideation or behavior and exacerbation of mood disorders, hepatic impairment and transaminase elevations, elevated blood pressure, gallbladder disease or history of cholestatic jaundice, effects on carbohydrate and lipid metabolism, alopecia, and effects on other laboratory results. Oriahnn effects the menstrual bleeding pattern and may delay the ability to recognize the occurrence of pregnancy.

During clinical trials of Oriahnn, serious adverse events were reported in three (0.8%) patients treated with Oriahnn. Two women had heavy menstrual bleeding and required blood transfusion due to anemia and one woman with a history of bariatric surgery had a laparoscopic cholecystectomy due to cholelithiasis. Two women were diagnosed with breast cancer after receiving Oriahnn. Oriahnn was discontinued due to adverse reactions in 10% of patients compared to 7% of placebo-treated women. The most common adverse reactions were hot flush, headache, fatigue, and metrorrhagia.

During Studies UF-1 and UF-2, there was a greater decrease in bone mineral density in women treated with Oriahnn for 6 months compared to placebo-treated women. Study UF-3, a 6-month extension study of patients who had completed 6 months of treatment with Oriahnn in UF-1 or UF-2, showed that

continued bone loss was observed in some women who received Oriahnn for 12 consecutive months. Twelve months after cessation of Oriahnn treatment, continued bone loss was observed at the lumbar spine (24%), total hip (32%), and femoral neck (40%). Partial recovery was observed in 46%, 33%, and 38% and full recovery was observed in 30%, 35%, and 22% of women at these same sites.

A Clinical Review including Clinical Information, Efficacy Evidence, Safety Evidence, Other Considerations and a Financial Review Based on Cost Analysis were presented.

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

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

Outcome: Oriahnn is a pharmacy benefit and will be added to the formulary on the Specialty Tier or the Brand Non-Preferred Tier for members with a three-tier benefit. Oriahnn will require prior authorization with the following criteria:

- Medical record documentation that Oriahnn is prescribed by a gynecologist **AND**
- Medical record documentation of age greater than or equal to 18 years **AND**
- Medical record documentation that patient is premenopausal **AND**
- Medical record documentation of a diagnosis of heavy menstrual bleeding associated with uterine leiomyomas (fibroids) **AND**
- Medical record documentation of therapeutic failure on, intolerance to, or contraindication to at least one prior treatment to reduce menstrual bleeding, including but not limited to:
    - Oral contraceptives **OR**
    - Oral or injectable progesterone **OR**
    - Progestin-releasing intrauterine system **OR**
    - Tranexamic acid tablets **OR**
    - Gonadotropin-releasing hormone (GnRH) agonists

QUANTITY LIMIT: 56 capsules per 28 days

AUTHORIZATION DURATION: Initial authorization will be 24 months (or less if there is medical record documentation of a previous incomplete course of therapy with a gonadotropin-releasing hormone (GnRH) receptor antagonist (i.e., relugolix or elagolix).

REAUTHORIZATION: Medical record documentation that the patient has not been treated for more than a total of 24 months with a gonadotropin-releasing hormone (GnRH) receptor antagonist (i.e., relugolix or elagolix) **OR** documentation of medical or scientific literature to support the use of this agent beyond the FDA-approved treatment duration.

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

MYFEMBREE (relugolix/estradiol/norethindrone)

Review: Myfembree is the second oral GnRH antagonist indicated for heavy bleeding due to uterine fibroids after Oriahnn. It also contains estradiol and norethindrone, or low hormonal "add-back" therapy, to help mitigate the hypoestrogenic side effects of relugolix. Like Oriahnn, Myfembree will provide an

alternative treatment for short-term management of heavy menstrual bleeding due to fibroids to delay the need for surgery. Oriahnn and Myfembree have a quicker onset and a shorter duration of effect (readily reversed upon discontinuation) as well as a reduction of the hypoestrogenic side effects compared to GnRH agonists (Lupron Depot). Patients most likely to benefit the most from these agents are patients who are close to menopause where it will act as a transitional therapy to avoid surgery or in patients who have an inadequate response to combined hormonal contraceptives or progestin-releasing intrauterine devices to delay the need for surgery.

Myfembree and Oriahnn have not been directly compared in clinical trials, so it is unclear if either agent has a clinical advantage in efficacy. Myfembree has an advantage in convenience with a dosing regimen of once daily compared to Oriahnn which is dosed as one elagolix 300 mg/estradiol 1 mg/norethindrone capsule in the morning and one elagolix 300 mg capsule in the evening. Currently both products have a recommended treatment duration of 24 months due to the risk of bone loss that may not be completely reversible.

The efficacy and safety of Myfembree were evaluated in LIBERTY 1 and LIBERTY 2, two replicate, 24-week, randomized, double-blind, placebo-controlled studies in 768 premenopausal women with heavy menstrual bleeding associated with uterine fibroids. Patients were randomized 1:1:1 to received once daily relugolix 40 mg/estradiol 1 mg/norethindrone 0.5 mg for 24 weeks, placebo for 24 weeks, or relugolix 40 mg monotherapy for 12 weeks followed by Myfembree for 12 weeks. Treatment for all patients was initiated within the first seven days after the onset of menses.

In both trials, a statistically higher proportion of patients treated with Myfembree achieved the primary endpoint of both MBL volume < 80 mL and at least 50% reduction from baseline MBL volume compared to placebo. Amenorrhea was achieved by 50.0% of Myfembree patients in LIBERTY 1 and 50.4% of patients in LIBERTY 2 compared to 6.2% and 3.1% treated with placebo, respectively. The mean reduction in MBL volume from baseline to week 24 was 82.0% in LIBERTY 1 and 84.2% in LIBERTY 2 compared to 19.1% and 15.1% with placebo, respectively. A statistically higher proportion of patients treated with Myfembree compared to placebo had >2 g/dL improvement in hemoglobin levels.

Myfembree has black box warning for increased risk of thromboembolic disorders, PE, DVT, stroke, and MI, especially in women with other risk factors. Myfembree is contraindicated in women with a high risk of arterial, venous thrombotic, or thromboembolic disorders. Myfembree is also contraindicated in women who are pregnant, have known osteoporosis (risk of further bone loss), have a current or history of breast cancer or hormonally-sensitive malignancies, have known hepatic impairment or disease, have undiagnosed abnormal uterine bleeding or have a known hypersensitivity to Myfembree.

Warnings and precautions for Myfembree are similar to Oriahnn and include decreases in bone mineral density, increased risk for hormonally-sensitive malignancies, suicidal ideation or behavior and exacerbation of mood disorders, hepatic impairment and transaminase elevations, elevated blood pressure, gallbladder disease or history of cholestatic jaundice, effects on carbohydrate and lipid metabolism, alopecia, and effects on other laboratory results. The most commonly reported adverse reactions were hot flush, hyperhidrosis, or night sweats, abnormal uterine bleeding, alopecia, and decreased libido. In LIBERTY-1, -2, and an open-label LIBERTY Extension study, continued bone loss was observed with 12 months of continued treatment with Myfembree.

Clinical Review including Clinical Information, Efficacy Evidence, Safety Evidence, Other Considerations and a Financial Review Based on Cost Analysis were presented.

Clinical Discussion: Was the bone loss to the point where you entered the high risk of fracture zone and was there an observance of increased fractures in those patients? Unsure, most patients did not have a

significant percentage of bone lose. Contraindicated in patients who have osteoporosis at the onset of therapy. Additionally, bone loss is progressive. Will need to look into study details further. No comments or questions. The committee unanimously voted to accept the recommendations as presented. None were opposed.

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

Outcome: Myfembree is a pharmacy benefit and will be added to the formulary on the Specialty Tier or the Brand Non-Preferred Tier for members with a three-tier benefit. Myfembree will require prior authorization with the following criteria:

- Medical record documentation of a diagnosis of attention deficit disorder (ADD) or attention deficit hyperactivity disorder (ADHD) **AND**
- Medical record documentation of therapeutic failure on, intolerance to, or contraindication to atomoxetine **OR** documentation that member has difficulty swallowing **AND**
- Medical record documentation of therapeutic failure on, intolerance to, or contraindication to amphetamine-dextroamphetamine ER **AND** methylphenidate ER unless precluded by a valid pre-existing medical condition (e.g. personal or family history of substance use disorder, substance misuse, etc.)

QUANTITY LIMIT: 28 capsules per 28 days

AUTHORIZATION DURATION: Initial authorization will be 24 months (or less if there is medical record documentation of a previous incomplete course of therapy with a gonadotropin-releasing hormone (GnRH) receptor antagonist (i.e., relugolix or elagolix).

REAUTHORIZATION: Medical record documentation that the patient has not been treated for more than a total of 24 months with a gonadotropin-releasing hormone (GnRH) receptor antagonist (i.e., relugolix or elagolix) **OR** documentation of medical or scientific literature to support the use of this agent beyond the FDA-approved treatment duration.

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

WEGOVY (semaglutide)

Review: Wegovy is the second glucagon-like peptide-1 (GLP-1) receptor agonist indicated for chronic weight management. It works by promoting the secretion of the GLP-1, making the patient feel satiated and secondarily increasing insulin release in response. Wegovy is only indicated as adjunct therapy to reduced calorie diet and increased physical activity for chronic weight management in adult patients with an initial body mass index (BMI) of 30 kg/m^2 or greater (obesity), 27 kg/m^2 or greater (overweight) in the presence of at least one weigh-related comorbid condition (e.g., hypertension, type 2 diabetes mellitus or dyslipidemia). Wegovy is not indicated for treatment of chronic weight management, in combination with semaglutide containing products or any other GLP-1 receptor agonist, in combination with other products for weight loss, as safety and efficacy of coadministration has not been established, or in patients with a history of pancreatitis.

The safety and efficacy of Wegovy for chronic weight management in conjunction with a reduced calorie diet and increased physical activity were evaluated in 3 identical, 68-week, randomized, double-blind,

placebo-controlled studies, and one 68-week, randomized, double-blind, placebo withdrawal trial. Studies 1, 3, and 4 included patients aged 18 or older with obesity or with overweight and at least one weight-related comorbid condition, such as treated or untreated dyslipidemia or hypertension, patients with type 2 diabetes mellitus were excluded. Study 2 included patients aged 18 years or older with type 2 diabetes mellitus and BMI greater than or equal to 27 kg/m^2.
After enrollment, in studies 1, 2, and 3 patients were randomized to receive Wegovy or placebo escalated to 2.4 mg subcutaneously weekly during a 16-week period followed by 52 weeks on maintenance dose. Study 4 escalated patients on Wegovy during a 20-week run-in period and patients who reached Wegovy 2.4 mg after the run-in period were randomized to either continued treatment with Wegovy, or with placebo, for 48 weeks.

Efficacy analysis was conducted in 4 trials across a combined 4,281 patients in which most patients were treated for up to 68 weeks. The primary endpoint evaluating patients achieving ≥ 5% weight loss from baseline to week 68 with Wegovy was reached by 83.5%, 67.4%, and 84.8% of patients in studies 1, 2, and 3 respectively. This was supported by results of the other primary endpoint evaluating mean percent change in body weight from baseline to week 68 in studies 1, 2, 3, and 4 all being statistically significant for superiority to placebo.

There is a black box warning for Thyroid C-cell Tumors. Contraindications to Wegovy include personal or family history of medullary thyroid carcinoma or in patients with Multiple Endocrine Neoplasia syndrome type 2 and known hypersensitivity to semaglutide or any of the excipients. Warnings and precautions thyroid C-cell tumors, acute pancreatitis, acute gallbladder disease, hypoglycemia, acute kidney injury, hypersensitivity, diabetic retinopathy, heart rate increase, and suicidal behavior and ideation. The most common adverse reactions were nausea, diarrhea, vomiting, constipation, abdominal pain, headache, fatigue, dyspepsia, dizziness, abdominal distension, eructation, hypoglycemia with type 2 diabetes, flatulence, gastroenteritis, GERD, gastritis, viral gastroenteritis, and hair loss.

Clinical Review including Clinical Information, Efficacy Evidence, Safety Evidence, Other Considerations and a Financial Review Based on Cost Analysis were presented.

Clinical Discussion: Dr. Silbert – Were patients with eating disorders included in the clinical trials? No information in exclusion criteria from trial. Asking because he historically had patients with bariatric surgery competing with one another for who got the most significant result. Dr. Yarczower – During the course of the study did they measure any clinical endpoints to show that this treatment resulted in a clinically significant reduction in clinical measures? They were studied, study includes several clinical measures, but no documentation of statistical significance. Results from 3 of the 4 studies were combined in the recorded data. Derek noted that a 5% change in weight was a consistent measure amongst similar medications. Dr. Silbert and Dr. Yarczower questioned if the risk outweighs the benefit for this medication? No additional comments or questions. The committee voted 26 to 4 in favor of accepting the recommendations as presented.

Financial Discussion: No comments or questions. The committee voted 25 to 4 in favor of accepting the recommendations as presented.

Outcome: Wegovy is a pharmacy benefit and will be excluded from the Commercial, Exchange, and GHP Kids pharmacy formulary except for certain TPA clients that request this benefit (weight loss). The following prior authorization criteria will apply:

- Medical record documentation of age greater than or equal to 18 years **AND**
- Medical record documentation of use as adjunct therapy to reduced calorie diet and increased physical activity for chronic weight management **AND**
- Medical record documentation of one of the following:

- Medical record documentation of body mass index (BMI) of ≥ 30 kg/m^2
- Medical record documentation of body mass index (BMI) of ≥ 27 kg/m^2 and at least one weight-related comorbid condition (e.g., hypertension, type 2 diabetes mellitus, or dyslipidemia)

QUANTITY LIMIT: 3 mL per 28 days

NOTE: Wegovy is not indicated for treatment of chronic weight management:

- In combination with semaglutide containing products or any other GLP-1 receptor agonist
- In combination with other products for weight loss, as safety and efficacy of coadministration has not been established
- In patients with a history of pancreatitis

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

TIVDAK (tisotumab vedotin-tftv)

Review: Tivdak is the first tissue factor (TF)-directed antibody drug conjugate (ADC) approved for recurrent or metastatic cervical cancer. Tivdak is indicated as a second-line or later treatment option following platinum-containing chemotherapies, which are the preferred agents for first line treatment of recurrent or metastatic disease. NCCN recommends Keytruda and Opdivo as preferred treatment options in the second-line or later setting, but only in select patients (PD-L1 positive or MSI-H/dMMR tumors for Keytruda and PD-L1 positive tumors for Opdivo).

The efficacy of Tivdak was evaluated in innovaTV 204, an open-label, single-arm trial that treated 101 patients with recurrent or metastatic cervical cancer who had received no more than two prior systemic regimens, including one prior platinum-based chemotherapy regimen. Patients received Tivdak 2 mg/kg intravenously every 3 weeks until disease progression or unacceptable toxicity. The major efficacy outcome measuring overall response rate was 24%, with 7% of patients having a complete response and 17% having a partial response. The median duration of response was 8.3 months.

There are no black box warnings or contraindications for Tivdak. Warnings and precautions include ocular adverse reactions, peripheral neuropathy, hemorrhage, pneumonitis, and embryo fetal toxicity. During clinical trials of Tivdak, serious adverse reactions occurred in 43% of patients and fatal adverse reactions occurred in 4% of patients, including septic shock, pneumonitis, sudden death, and multisystem organ failure. Adverse reactions led to permanent discontinuation in 13% of patients. Dose interruptions occurred in 47% of patients and dose reductions occurred in 23% of patients. The most common adverse reactions were decreased hemoglobin, fatigue, decreased lymphocytes, nausea, peripheral neuropathy, alopecia, epistaxis, conjunctival adverse reactions, hemorrhage, decreased leukocytes, increased creatinine, dry eye, increased prothrombin international normalized ration, prolonged active partial thromboplastin time, diarrhea, and rash.

Clinical Review including Clinical Information, Efficacy Evidence, Safety Evidence, Other Considerations and a Financial Review Based on Cost Analysis were presented.

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

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

Outcome: Tivdak is a medical benefit. When Tivdak is processed at a specialty pharmacy, it will be processed on the Specialty tier or the Brand Non-preferred tier for members with a three tier benefit. Tivdak will require prior authorization with the following criteria:

- Medical record documentation that Tivdak is prescribed by a hematologist or oncologist **AND**
- Medical record documentation of age greater than or equal to 18 years **AND**
- Medical record documentation recurrent or metastatic cervical cancer **AND**
- Medical record documentation that member has disease progression on or after chemotherapy

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.

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

KIMYRSA (oritavancin)

Review: Kimyrsa is indicated for the treatment of adult patients with acute bacterial skin and skin structure infections (ABSSSI) caused by or suspected to be caused by susceptible isolates of designated Gram-positive microorganisms including: *Staphylococcus aureus* (including methicillin-susceptible and methicillin-resistant isolates), *Streptococcus pyogenes, Streptococcus agalactiae, Streptococcus dysgalactiae, Streptococcus anginosus group* (includes *S. anginosus, S. intermedius*, and *S. constellatus*), and *Enterococcus faecalis* (vancomycin-susceptible isolates only).

Kimyrsa is a single dose IV infusion of oritavancin, used for the treatment of ABSSSI caused by susceptible Gram-positive microorganisms. It exhibits concentration-dependent bactericidal activity by inhibiting the polymerization and crosslinking involved in cell wall biosynthesis and causing disruption of bacterial membrane integrity.

Kimyrsa is the second available product of oritavancin, the other being Orbactiv, a single dose IV infusion of oritavancin. The key difference between the two products is total infusion time, as well as other differences including dose strengths, reconstitution and dilution instructions, and compatible diluents.

Treatment options that offer one-time dosing regimens for ABSSSI include oritavancin (Kimyrsa and Orbactiv) and dalbavancin (Dalvance). Kimyrsa is infused over 1 hour, Orbactiv is infused over 3 hours and Dalvance is infused over 30 minutes. All three intravenous options offer the potential to provide treatment without hospital admission. Due to high costs and concerns about safety, these agents are generally reserved for second-line therapy behind vancomycin for the empiric treatment of severe ABSSSI where methicillin-resistant *Staphylococcus aureus* (MRSA) is suspected or as targeted therapy when MRSA infection is confirmed. The Infectious Disease Society of America (IDSA) does not include oritavancin or dalbavancin in the treatment algorithm for management of Skin and Soft Tissue Infections, created in 2014, before FDA approval of these medications.

No new clinical trials were conducted with Kimyrsa. FDA approval of Kimyrsa was based on a pharmacokinetic study comparing Kimyrsa to Orbactiv.

The safety of Kimyrsa has been established from adequate and well-controlled trials of the previously approved oritavancin product, Orbactiv. Kimyrsa does not carry any new contraindications, warnings and precautions, adverse reactions or drug interactions compared to Orbactiv. Kimyrsa does not carry any new safety information for use in specific populations including pregnancy, lactation, pediatric use, geriatric use, renal impairment and hepatic impairment.

Clinical Review including Clinical Information, Efficacy Evidence, Safety Evidence, Other Considerations and a Financial Review Based on Cost Analysis were presented.

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

Financial Discussion: No comments or questions. The committee voted 29 to 1 in favor of accepting the recommendations as presented.

Outcome: Kimyrsa is a medical benefit. When Kimyrsa is processed at a specialty pharmacy, it will be processed on the Specialty tier or the Brand Non-preferred tier for members with a three tier benefit. Kimyrsa will require prior authorization with the following criteria:

- Medical record documentation that patient is ≥ 18 years of age **AND**
- Medical record documentation of a diagnosis of an acute bacterial skin and skin structure infection (including cellulitis/erysipelas, wound infection, and major cutaneous abscess) caused by: *Staphylococcus aureus, Streptococcus pyogenes, Streptococcus agalactiae, Streptococcus dysgalactiae, Streptococcus anginosus, Streptococcus intermedius, Streptococcus constellatus,* or *Enterococcus faecalis* (vancomycin susceptible strains) which has been diagnosed and documented with Infectious Disease consultation **AND**
- Medical record documentation of a culture and sensitivity showing the patient's infection is not susceptible to alternative antibiotic treatments **OR** a documented history of previous intolerance to or contraindication to other antibiotics shown to be susceptible on the culture and sensitivity **AND**
- Medical record documentation of intolerance to or contraindication to Orbactiv (oritavancin)

AUTHORIZATION DURATION/QUANTITY LIMIT: Approval will be for **one (1) week** and will be limited to one (1) treatment course (up to 1,200 mg as a single dose) (Facets RX count 120, Darwin RX count 1.

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

LYBALVI (olanzapine and samidorphan)

Review: Lybalvi is a single-tablet combination of olanzapine and the opioid antagonist samidorphan. Olanzapine is a second generation antipsychotic which has shown efficacy in the treatment of both schizophrenia and bipolar I disorder. Samidorphan is a new entity which is structurally related to naltrexone with a five-fold greater affinity for the mu-opioid receptor. The opioid system has been implicated in modulating metabolism and samidorphan was studied for use in mitigating weight gain and metabolic effects associated with olanzapine treatment.

While Lybalvi offers an alternative that prevents some of the weight gain that is associated with olanzapine treatment, there are other atypical antipsychotics available that also have a low to moderate propensity for causing weight gain. Lybalvi can mitigate some of the olanzapine-associated weight gain, but it does not cause weight loss and the weight effect of switching a patient stabilized on olanzapine to Lybalvi is unknown. Additionally, long-term clinical trials of olanzapine have shown that weight gain stabilizes after about 1 year of therapy and Lybalvi treatment would not be expected to have any benefit once weight gain has stabilized.

The efficacy of Lybalvi in the treatment of schizophrenia in adults is based on adequate and well-controlled studies of orally administered olanzapine and a 4-week, randomized, double-blind, placebo- and active-controlled study (ENLIGHTEN-1). Weight changes in patients with schizophrenia treated with Lybalvi were evaluated in the ENLIGHTEN-2 trial**.** ENLIGHTEN-1 included adult patients who met DSM-5 criteria for schizophrenia. Patients were randomized 1:1:1 to Lybalvi, olanzapine, or placebo for 4 weeks of daily dosing based on clinical response and tolerability for the first 2 weeks of the study. The study was designed to compare Lybalvi with placebo, not olanzapine. Compared to placebo, patients treated with Lybalvi had a statistically significant improvement in the change from baseline in PANSS total score at week 4. Patients treated with Lybalvi also had a statistically significant improvement in CGI-S score at Week 4. The inclusion of samidorphan did not appear to negatively impact the antipsychotic efficacy of olanzapine.

ENLIGHTEN-2 randomized adult patients who met the DSM-5 criteria for schizophrenia 1:1 to Lybalvi or olanzapine for 24 weeks of daily dosing. The study did not specifically study patients on stable, chronic olanzapine therapy so the weight effect of switching from olanzapine to Lybalvi is unknown. Treatment with Lybalvi was associated with statistically significant less weight gain than treatment with olanzapine and with a smaller proportion of patients who gained ≥ 10% body weight.

The efficacy of Lybalvi in the treatment of adult patients with bipolar I disorder has been established based on adequate and well-controlled studies of orally administered olanzapine. The efficacy of olanzapine as monotherapy and in combinations with lithium or valproate for treatment of manic or mixed episodes was established in 4 short-term placebo controlled studies in adult patients which showed that olanzapine was superior to placebo in reduction of the Youngs Mania Rating Scale (Y-MRS) which assesses manic symptomatology.

Lybalvi has a black box warning for increased mortality in elderly patients with dementia-related psychosis based on results from clinical trials of olanzapine which showed an increased rate of cerebrovascular adverse reactions and death. Lybalvi is contraindicated in patients who are using opioids or who are undergoing acute opioid withdrawal. Other warnings and precautions are consistent with olanzapine and other atypical antipsychotics and include neuroleptic malignant syndrome, Drug Reactions with Eosinophilia and Systemic Symptoms (DRESS), metabolic changes, including hyperglycemia, diabetes mellitus, dyslipidemia, and body weight gain, tardive dyskinesia, orthostatic hypotension and syncope, increase risk of falls, leukopenia and neutropenia, dysphagia, seizures, potential for cognitive and motor impairment, body temperature dysregulation, anticholinergic effects, and hyperprolactinemia.

During short term (4-week) clinical trials of Lybalvi for the treatment of schizophrenia, the most common adverse reactions were weight gain, somnolence, dry mouth, and headache. Additional adverse reactions reported in long term (24-week) olanzapine-controlled clinical trials include increased appetite, increased blood creatine phosphokinase, lethargy, sedation, akathisia, increased AST and ALT, constipation, dizziness, fatigue, increased blood pressure, increased insulin, and dyslipidemia. Safety information for Lybalvi for the treatment of bipolar I disorder (mixed or manic) as monotherapy and adjunct to lithium or

valproate relies on information from adequate and well-controlled short-term studies of olanzapine tablets in bipolar I disorder.

Clinical Review including Clinical Information, Efficacy Evidence, Safety Evidence, Other Considerations and a Financial Review Based on Cost Analysis were presented.

Clinical Discussion: Dr. Silbert – Nothing to add as he hasn't used it himself. Opioid blockers decreasing weight gain are relatively new reports, so not sure of the clinical significance. Most docs in behavioral health believe it to be the second most effective agent, but it's often avoided due to weight gain. Abilify is a reasonable alternative if a provider is concerned about weight gain. No comments or questions. The committee voted 24 to 2 in favor of accepting the recommendations as presented.

Financial Discussion: No comments or questions. The committee voted 25 to 1 in favor of accepting the recommendations as presented.

Outcome: Lybalvi will be covered as a pharmacy benefit which will not be added to the formulary. Lybalvi will require prior authorization with the following criteria:

- Medical record documentation of age greater than or equal to 18 years **AND**
- Medical record documentation that Lybalvi is being used for one of the following:
    - Schizophrenia **OR**
    - Acute treatment of manic or mixed episodes associated with bipolar I disorder **OR**
    - Maintenance treatment of bipolar I disorder

AND

- Medical record documentation of a therapeutic failure on, intolerance to, or contraindication to three (3) generic, formulary atypical antipsychotics, one of which must be olanzapine

QUANTITY LIMIT: 1 tablet per day

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

INPEN (insulin delivery system)

Review: InPen is a reusable pen injector for single-patient home use by people with diabetes under the supervision of an adult caregiver, or by a patient age 7 and older for the self-injection of a desired dose of insulin. The pen injector is compatible with Lilly Humalog U-100 3.0 mL cartridges, Novo Nordisk Novolog U-100 3.0 mL cartridges, and Novo Nordisk Fiasp U-100 3.0 mL cartridges and single-use detachable and disposable pen needles (not included). The pen injector allows the user to dial the desired dose from 0.5 to 30 units in one-half (1/2) unit increments.

The InPen dose calculator, a component of the InPen App, is indicated for the management of diabetes by people with diabetes under the supervision of an adult caregiver, or by a patient age 7 and older for calculating an insulin dose or carbohydrate intake based on user entered data.

For an insulin dose based on amount of carbohydrates, a healthcare professional must provide patient specific target blood glucose, insulin-to-carbohydrate ratio, and insulin sensitivity parameters to be programmed into the software prior to use.

For an insulin dose based on fixed/variable meal sizes, a healthcare professional must provide patient specific fixed doses/meal sizes to be programmed into the software prior to use.

Key Features:

- Reusable for one year - no charging needed
- Keeps track of user's active insulin
- Reminds user to dose
- Monitors insulin temperature
- Automatically logs doses
- Integrates with CGMs
- Creates shareable reports with time-based meal analysis
- Integrates with Bluetooth-connected glucose meters
- Helps user make decisions based on their data

Clinical Review including Clinical Information, Efficacy Evidence, Safety Evidence, Other Considerations and a Financial Review Based on Cost Analysis were presented.

Clinical Discussion: Dr. Yarczower comments that endocrinology has reached out to us regarding coverage of InPen. No comments or questions. The committee unanimously voted to accept the recommendations as presented. None were opposed.

Financial Discussion: Keith recommended approving InPen at a more restrictive level so that pharmacies don't accidentally dispense the wrong InPen for the insulin the member is using. No comments or questions. The committee unanimously voted to accept the recommendations as presented. None were opposed.

Outcome: InPen will be covered as a pharmacy benefit which will not be added to the formulary. InPen will require prior authorization with the following criteria:

- Medical record documentation of a diagnosis of diabetes mellitus **AND**
- Medical record documentation that InPen is prescribed by or in consultation with an endocrinologist **AND**
- Medical record documentation of age greater than or equal to 7 years **OR** age less than 7 years and documentation that InPen will be utilized with adult supervision **AND**
- Medical record documentation that member has access to a device with the ability to install and use the InPen app (e.g. smartphone, tablet, etc. with iOS 10 or later or Android 6 or later) **AND**
- Medical record documentation that member has utilized multiple daily injections of insulin (i.e. at least 3 injections per day), with frequent self-adjustments of insulin dose for at least 6 months **AND**
- Medical record documentation that member has suboptimal blood sugar control despite appropriate management as demonstrated by at least one of the following:
    - Glycosylated hemoglobin level (HbA1c) > 7.0 %
    - History of recurring hypoglycemia
    - Wide fluctuations in blood glucose before mealtime
    - History of severe glycemic excursions

QUANTITY LIMIT: 1 pen per 365 days

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

FAST FACTS

BRIVIACT (brivaracetam)

Updated Indication: Briviact is indicated for the treatment of partial-onset seizures in patients 1 month of age and older.

Previously Briviact was indicated in patients 4 years of age and older.

Current formulary status: Briviact Tablets and Solution, Pharmacy benefit, NF; Briviact Intravenous Injection, Medical Benefit

Recommendation: No changes are needed to the formulary placement of Briviact. The following changes are recommended to Commercial Policy 422.0 to incorporate the new patient population.

- Medical record documentation of a diagnosis of partial-onset seizures **AND**
- Medical record documentation of age greater than or equal to ~~4 years~~ 1 month **AND**
- Medical record documentation of therapeutic failure on, intolerance to, or contraindication to at least three formulary alternatives, one of which must be levetiracetam **AND**
- Medical record documentation that Briviact is not being used in combination with levetiracetam

QUANTITY LIMIT: *No QLs need to be entered within the authorization unless the requested quantity exceeds the QL.*

- QL FOR LETTER ONLY: 2 tablets per day or 20 mL per day of oral solution

Discussion: No comments or questions.

Outcome: The committee unanimously voted to accept the recommendations as presented. None were opposed.

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

BIKTARVY (bictegravir/emtricitabine/tenofovir alafenamide)

Updated Indication: Biktarvy is indicated for the treatment of human immunodeficiency virus type 1 (HIV-1) infected adult and pediatric patients weighing at least 14 kilograms (kg).

Previously Biktarvy was indicated in HIV-1 infected adult and pediatric patients weighing at least 25 kg.

Current formulary status: Biktarvy 50/200/25mg tablet Brand preferred tier

Recommendation: No changes are needed to the formulary placement or quantity limits of Biktarvy 50/200/25mg tablet. It is recommended to add Biktarvy 30/120/15 mg to the formularies on the Brand preferred tier with a quantity limit of 1 tablet per day.

Discussion: No comments or questions.

Outcome: The committee unanimously voted to accept the recommendations as presented. None were opposed.

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

ERBITUX (cetuximab)

Updated Indication: Erbitux is now indicated, in combination with encorafenib, for the treatment of adult patients with metastatic colorectal cancer (CRC) with a BRAF V600E mutation, as detected by an FDA-approved test, after prior therapy.

Other indications for Erbitux include for the treatment of K-Ras wild-type, epidermal growth factor receptor (EGFR)-expressing, metastatic colorectal cancer (mCRC) and for the treatment of squamous cell carcinoma of the head and neck.

Current formulary status: Medical Benefit, when processed at specialty pharmacy, process on Specialty or Brand NP tier for members with three-tier benefit.

Recommendation: No changes are recommended to the formulary placement of Erbitux. Currently, Erbitux is available without a prior authorization and no changes are needed to incorporate the new indication.

Discussion: No comments or questions.

Outcome: The committee unanimously voted to accept the recommendations as presented. None were opposed.

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

DUPIXENT (dupilumab)

Updated Indication: Dupixent is now indicated as an add-on maintenance treatment of patients aged 6 years and older with moderate-to-severe asthma characterized by an eosinophilic phenotype or with oral corticosteroid dependent asthma.

Previously, Dupixent was only indicated in patients 12 years and older with moderate-to-severe asthma with an eosinophilic phenotype or with oral corticosteroid dependent asthma.

Current formulary status: Dupixent is a pharmacy benefit available at the Specialty tier or Brand Non-Preferred tier for members with a three tier benefit. Dupixent requires a prior authorization.

Recommendation: There are no changes to formulary status or authorization duration at this time. However, it is recommended to make the following updates to the asthma criteria and quantity limits.

- Medical record documentation that Dupixent is prescribed by or in consultation with an allergist, immunologist, or pulmonologist **AND**
- Medical record documentation of one of the following:
    - If the request is for Dupixent pre-filled pen: documentation of age greater than or equal to 12 years **OR**

    - If the request is for Dupixent pre-filled syringe: documentation of age greater than or equal to 6 years **AND**
- Medical record documentation of one of the following:
    - A diagnosis of moderate to severe eosinophilic asthma **AND** a blood eosinophilic count greater than or equal to 150 cells/microL **OR**
    - A diagnosis of oral corticosteroid dependent asthma **AND**
- Medical record documentation that Dupixent will be used as an add-on maintenance treatment **AND**
- Medical record documentation of one of the following:
    - Contraindication, intolerance to, or poorly (not well) controlled symptoms despite at least a 3-month trial of: maximally tolerated inhaled corticosteroids and/or oral systemic corticosteroids plus a long-acting beta agonist **OR**
    - One exacerbation in the previous 12 months requiring additional medical treatment (oral corticosteroids, emergency department or urgent care visits, or hospitalization) despite current therapy or intolerance to inhaled corticosteroids plus a long-acting beta agonist **AND**
- Medical record documentation that Dupixent will not be used in combination with Xolair, Fasenra, Nucala, or Cinqair

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 the member experiences unacceptable toxicity or worsening of disease.

QUANTITY LIMIT:

- 600 mg followed by 300 mg every other week
    - 8 mL per 42 days for one week; 4 mL per 28 days for maintenance
- 400 mg followed by 200 mg every other week
    - 4.56 mL per 42 days for one week; 2.28 mL per 28 days for maintenance
- 100 mg every other week (100 mg/0.67 mL syringe):
    - 1.34 mL per 28 days

Discussion: No comments or questions.

Outcome: The committee unanimously voted to accept the recommendations as presented. None were opposed.

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

MAVYRET (glecaprevir/pirbrentasvir)

Updated Indication: Mavyret is now approved in age 3 and up, Genotype 1, 2, 3, 4, 5 or 6 Chronic Hepatitis C infection. It was previously approved in patients age 12 and up.

Mavyret is a fixed-dose combination of glecaprevir, a hepatitis C virus (HCV) NS3/4A protease inhibitor, and pibrentasvir, an HCV NS5A inhibitor, and is indicated for the treatment of adult and pediatric patients

3 years and older with chronic HCV genotype (GT) 1, 2, 3, 4, 5 or 6 infection without cirrhosis or with compensated cirrhosis (Child-Pugh A).

Mavyret is indicated for the treatment of adult and pediatric patients 3 years and older with HCV genotype 1 infection, who previously have been treated with a regimen containing an HCV NS5A inhibitor or an NS3/4A protease inhibitor, but not both.

Updated Dosage Forms:
Tablets: 100 mg glecaprevir and 40 mg pibrentasvir
Oral Pellets: 50 mg glecaprevir and 20 mg pibrentasvir

Current formulary status: Mavyret **tablets** are a pharmacy benefit on the specialty tier for Marketplace and on the 4th tier for Commercial (will default to brand preferred tier for members with a 3-tier benefit) requiring prior authorization.

Recommendation: Tablets: There are no changes recommended to formulary placement, and authorization duration at this time. It is recommended **that Mavyret packets be added to the specialty tier for Marketplace and the 4th tier for commercial to match the placement of the tablets and update the current** prior authorization criteria and quantity limits to the following:

- Medical record documentation of age greater than or equal to 3 years **AND**
- If under the age of 12 or less than 45kg, medical record documentation that proper weight-based dosing is prescribed **AND**
- ~~Medical record documentation of age greater than or equal to 12 years **OR** weight greater than 45 kg **AND**~~

- If member is 12 years and older or weight ≥ 45kg and the request is for packets, medical record documentation of why tablets cannot be used.

MEDISPAN AUTHORIZATION LEVEL: GPI-12 (tablets and packets do not share same GPI 12)

QUANTITY LIMIT: *No QLs need to be entered within the authorization unless the requested quantity exceeds the QL.*

- QL for **TABLETS** for LETTER ONLY: three (3) tablets per day, 28 day supply per fill

- QUANTITY LIMIT (for packets) for LETTER only: six (6) packets per day, 28 day supply per fill

AUTHORIZATION DURATION: 8, 12, or 16 weeks consistent with current AASLD/IDSA guidelines or Food and Drug Administration (FDA) recommendations

NOTE: Per the prescribing information, treatment duration for liver or kidney transplant recipients is 12 weeks. Geisinger has been treating kidney transplant recipients for 8 weeks with success.
~~For genotype 1-infected patients who are NS5A inhibitor-experienced without prior treatment with an NS3/4A PI and genotype 3-infected patients who are prior treatment experienced with regimens containing (peg) interferon, ribavirin, and/or sofosbuvir, but no prior treatment experience with an HCV NS3/4A PI or NS5A inhibitor. Treatment duration is 16 weeks in these 2 cases~~.

Discussion: Are we going to approve the transplantation of pediatric patients with organs infected with hepatitis C. Will need to review the literature and discuss with medical director if cases come in. No additional comments or questions.

Outcome: The committee unanimously voted to accept the recommendations as presented. None were opposed.

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

EPCLUSA (sofosbuvir/velpatasvir)

Updated Indication: Epclusa is now approved in age 3 and up, Genotype 1, 2, 3, 4, 5 or 6 Chronic Hepatitis C infection. It was previously approved in patients age 6 and up.

Epcluse is a fixed-dose combination of sofosbuvir, a hepatitis C virus (HCV) nucleotide analog NS5B polymerase inhibitor, and velpatasvir, an HCV NS5A inhibitor, and is indicated for the treatment of adults and pediatric patients 3 years of age and older with chronic HCV genotype 1, 2, 3, 4, 5, or 6 infection:

- without cirrhosis or with compensated cirrhosis
- with decompensated cirrhosis for use in combination with ribavirin

Updated Dosage Forms:

- Tablets: 400 mg of sofosbuvir and 100 mg of velpatasvir; 200 mg of sofosbuvir and 50 mg of velpatasvir.
- Oral Pellets: 200 mg of sofosbuvir and 50 mg of velpatasvir; 150 mg of sofosbuvir and 37.5 mg of velpatasvir.

Current formulary status: sofosbuvir/velpatasvir 400/100mg tablets: Non-formulary, Specialty, Prior authorization required.

Recommendation: For 400/100mg tablets, there are no changes recommended to formulary placement, and authorization duration at this time. It is recommended **that Epclusa 100/50mg tablets and Epclusa packets (200/50mg and 150/37.5mg) not be added to formulary for commercial to match the placement of the 400/100mg tablets and update the current** prior authorization criteria and quantity limits to the following:

- Medical record documentation of age greater than or equal to 3 years **AND**
- Medical record documentation that proper weight-based dosing is being prescribed **AND**
- ~~Medical record documentation of age greater than or equal to 6 years or weight 17 kg or more **AND**~~
- Medical record documentation of a therapeutic failure on, intolerance to Mavyret, if clinically appropriate **AND**
- If member is 18 years and older or weight ≥ 30kg and the request is for 200/50 mg or 150mg/37.5mg strength, medical record documentation of why 400/100mg tablets cannot be used.

NOTE: Treatment-naïve, Genotype 3 patients with compensated cirrhosis requires NS5A RAS Y93H testing for velpatasvir

MEDISPAN AUTHORIZATION LEVEL: GPI-14, if request is for sofosbuvir/velpatasvir 400/100 include generic only.
QUANTITY LIMIT: *No QLs need to be entered within the authorization unless the requested quantity exceeds the QL.*

- QL for **tablets** FOR LETTER ONLY: one (1) tablet per day, 28 day supply per fill
- QL for packets FOR LETTER ONLY: 150/37.5mg, one (1) packet per day, 28 day supply per fill
- QL for packets FOR LETTER ONLY: 200/50mg, two (2) packets per day, 28 day supply per fill

Add QL Epclusa 100/50 tablets, QL of 1 tablet per day
Packets: Add QL of
150/37.5mg QL 1 per day
200/50mg QL 2 per day

Discussion: No comments or questions.

Outcome: The committee unanimously voted to accept the recommendations as presented. None were opposed.

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

JAKAFI (ruxolitinib)

Updated Indication: Jakafi is now indicated for treatment of chronic graft-versus-host disease (cGVHD) after failure of one or two lines of systemic therapy in adult and pediatric patients 12 years and older.

Other indications for Jakafi include for treatment of steroid-refractory acute graft-versus-host disease (aGVHD) in adult and pediatric patients 12 years and older and for the treatment myelofibrosis and polycythemia vera in adult patients.

Current formulary status: Oral Oncology Brand NP tier, requires a PA

Recommendation: No changes are recommended for the formulary placement, authorization duration, or quantity limit. The following changes are recommended for Commercial Policy 250.0 to incorporate the new indication:
For Graft versus Host Disease

- Medical record documentation that Jakafi is prescribed by a hematologist/oncologist or transplant specialist **AND**
- Medical record documentation of age greater than or equal to 12 years **AND**
- Medical record documentation of a diagnosis of steroid refractory graft-versus-host disease (GVHD) **OR**
- Medical record documentation of both of the following:
  - Documentation of a diagnosis of chronic graft-versus-host disease (cGVHD) **AND**
  - Documentation of therapeutic failure of one or two prior lines of systemic therapy

Discussion: No comments or questions.

Outcome: The committee unanimously voted to accept the recommendations as presented. None were opposed.

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

KEYTRUDA (pembrolizumab)

Updated Indication: Keytruda is a programmed death receptor-1 (PD-1)-blocking antibody now indicated:

- In combination with chemotherapy, with or without bevacizumab, for the treatment of patients with persistent, recurrent or metastatic cervical cancer whose tumors express PD-L1 (CPS ≥1) as determined by an FDA-approved test

This is in addition to the previously approved indication of Keytruda as a single agent for the treatment of patients with recurrent or metastatic cervical cancer with disease progression on or after chemotherapy whose tumors express PD-L1 (CPS ≥1) as determined by an FDA-approved test.

Current formulary status: Medical Benefit, requires prior authorization; When processed at a specialty pharmacy: Specialty tier or Brand NP tier.

Recommendation: There are no changes recommended to the formulary placement or authorization duration of Keytruda. The following changes are recommended to the criteria in the medical benefit policy (MBP) 119.0 for Keytruda to incorporate the new indication:

8. Cervical Cancer
    - Prescription written by a hematologist/oncologist **AND**
    - One of the following:
        - Medical record documentation of recurrent or metastatic cervical cancer **AND**
        - Medical record documentation that tumors express PD-L1 (CPS≥1) **AND**
        - Medical record documentation of disease progression after receiving at least one prior line of therapy

        OR
        - Medical record documentation of persistent, recurrent or metastatic cervical cancer **AND**
        - Medical record documentation that tumors express PD-L1 (CPS≥1) **AND**
        - Medical record documentation that Keytruda will be used in combination with chemotherapy (paclitaxel, cisplatin or carboplatin), with or without bevacizumab

    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.

Discussion: NCCN recommendation matches FDA approval which allows for use with or without bevacizumab. No other comments or questions.

Outcome: The committee unanimously voted to accept the recommendations as presented. None were opposed.

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

TIBSOVO (ivosidenib)

Updated Indication: Tibsovo is now indicated for the treatment of adult patients with previously treated, locally advanced or metastatic cholangiocarcinoma with an isocitrate dehydrogenase-1 (IDH1) mutation as detected by an FDA-approved test.

Current formulary status: Oral Oncology Brand NP tier, requires a PA

Recommendation: No changes are needed to the formulary placement, quantity limits, or authorization duration of Tibsovo. The following changes are recommended to the prior authorization criteria for Commercial Policy 528.0:

Locally Advanced or Metastatic Cholangiocarcinoma

- Medical record documentation that Tibsovo 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 locally advanced or metastatic cholangiocarcinoma **AND**
- Medical record documentation of an isocitrate dehydrogenase-1 (IDH1) mutation as detected by an FDA approved test **AND**
- Medical record documentation that member has been previously treated with at least one prior therapy

Discussion: No comments or questions.

Outcome: The committee unanimously voted to accept the recommendations as presented. None were opposed.

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

NOXAFIL (posaconazole)

Updated Indication: Noxafil is now FDA approved for prophylaxis of invasive *Aspergillus* and *Candida* infections in patients who are at high risk of developing these infections due to being severely immunocompromised, such as hematopoietic stem cell transplant (HSCT) recipients with graft-versus-host disease (GVHD) or those with hematologic malignancies with prolonged neutropenia from chemotherapy as follows:

- Noxafil injection: Patients aged 2 years and older
- Noxafil delayed-release tablets: Patients aged 2 years and older who weigh >40 kg
- Noxafil oral suspension: Patients aged 13 and older
- Noxafil PowderMix for delayed-release suspension: Patients aged 2 years and older who weigh >40 kg

These expanded patient populations are based on pharmacokinetic data with no new clinical trials. Previously, Noxafil was only indicated for the prophylaxis of invasive *Aspergillus* and *Candida* as follows:

- Noxafil injection: Patients aged 18 years and older
- Noxafil delayed-release tablets: Patients aged 13 and older
- Noxafil oral suspension: Patients aged 13 and older

Additionally, Noxafil injections and delayed-released tablets are now indicated for the treatment of invasive aspergillosis in adults and pediatric patient aged 13 years and older.

Current formulary status: Noxafil is a pharmacy benefit and is on the Specialty Tier, or the Brand Non-Preferred tier for members with a 3-tier benefit requiring a prior authorization.

Recommendation: No changes to formulary placement are recommended at this time. Formulary placement of Noxafil PowderMix will be reevaluated when it is commercially available. Recommend updating the existing criteria to the posaconazole policy to:

Prophylaxis of Invasise Aspergillus or Candida Infections:

- Medical record documentation that Noxafil is prescribed by an oncologist, hematologist, infectious disease specialist, or transplant service provider **AND**
- Medical record documentation of use for prophylaxis of invasive Aspergillus or Candida infections in patients at high risk of developing these infections due to being severely immunocompromised **AND**
- Medical record documentation of one of the following:
    - If the request is for Noxafil oral suspension: documentation of age greater than or equal to 13 years
      OR
    - If the request is for posaconazole delayed release tablets: documentation of age greater than or equal to 2 years **AND** documentation of weight >40 kg

Treatment of Invasive Aspergillosis

- Medical record documentation that Noxafil is prescribed by an oncologist, hematologist, infectious disease specialist, or transplant service provider **AND**
- Medical record documentation of use for treatment of invasive aspergillosis **AND**
- Medical record documentation of age greater than or equal to 13 years

Treatment of Oropharyngeal Candidiasis:

- Medical record documentation that Noxafil is prescribed by an oncologist, hematologist, infectious disease specialist, or transplant service provider **AND**
- Medical record documentation of treatment of oropharyngeal candidiasis with therapeutic failure on, contraindication to, or intolerance to fluconazole* or itraconazole* **AND**
- Medical record documentation of age greater than or equal to 13 years

AUTHORIZATION DURATION:

- **For prophylaxis of invasive aspergillus and candida infections:** Initial approval will be for 3 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. The medication will no longer be covered if the member recovers from neutropenia and/or immunosuppression.

- **For treatment of invasive aspergillus and candida infections:** 3 months or less if the reviewing provider feels it is medically appropriate
- **For oropharyngeal candidiasis:** One-time, 28 days authorization

Discussion: No comments or questions.

Outcome: The committee unanimously voted to accept the recommendations as presented. None were opposed.

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

COSENTYX (secukinumab)

Updated Indication: Cosentyx is now FDA approved for the treatment of children aged 6 years and older with plaque psoriasis.

Previously this was indicated for the treatment of adult patients with plaque psoriasis.

Current formulary status: Cosentyx is a pharmacy benefit and is on the Specialty Tier, or the Brand Non-Preferred tier for members with a 3-tier benefit.

Recommendation: Recommend adding Cosentyx 75 mg/0.5 mL prefilled syringe to the Specialty Tier, or the Brand Non-Preferred tier for members with a 3-tier benefit. Recommend updating the existing age criteria to the Cosentyx policy:

For Plaque Psoriasis

An exception for coverage of Cosentyx may be made for members who meet the following criteria:

- Medical record documentation that Cosentyx is prescribed by a dermatologist **AND**
- Medical record documentation of age greater than or equal to 6 years **AND**
- Medical record documentation of a diagnosis of moderate to severe plaque psoriasis characterized by greater than or equal to 5 % of body surface area involved or disease involving crucial body areas such as the hands, feet, face, or genitals **AND**
- Medical record documentation that Cosentyx is not being used concurrently with a tumor necrosis factor (TNF) blocker or other biologic agent **AND**
- Medical record documentation of therapeutic failure on, intolerance to, or contraindication to topical corticosteroids **AND** at least two to three months of systemic therapy (including but not limited to methotrexate and/or cyclosporine or phototherapy **OR** medical record documentation of therapeutic failure on or intolerance to prior biologic therapy

MEDISPAN AUTHORIZATION LEVEL: NDC-11

QUANTITY LIMIT

- **Initial Approval –** *Two authorizations must be entered.*
  - 75 mg every 4 weeks
    1. In PA Hub: Add ST, PA, PE, OQL, and 1 mL per 28 days (max quantity 1, min/max day supply 28). Start date of this authorization is one-day after loading dose ends.
    2. In Darwin: Add ST, PA, PE, OQL, enter 1 in max number of claims

authorized, and 2 mL per 28 days (max quantity 2, min/max day supply 28) with a duration of one-week.

- QL FOR LETTER: Loading dose: 2 mL per 28 days; Maintenance dose: 1 mL per 28 days

- 150 mg every 4 weeks

  1. In PA Hub: Add ST, PA, PE, OQL, and 2 mL per 56 days (max quantity 2, min/max day supply 56). Start date of this authorization is one-day after loading dose ends.
  2. In Darwin: Add ST, PA, PE, OQL, enter 1 in max number of claims authorized, and 4 mL per 28 days (max quantity 4, min/max day supply 28) with a duration of one-week.
     - QL FOR LETTER: Loading dose: 4 mL per 28 days; Maintenance dose: 2 mL per 56 days

- 300 mg every 4 weeks

  1. In PA Hub: Add ST, PA, and PE. No QLs need to be entered within the authorization unless the requested quantity exceeds the QL. Start date of this authorization is one-day after loading dose ends.
  2. In Darwin: Add ST, PA, PE, OQL, enter 1 in max number of claims authorized, and 8 mL per 28 days (max quantity 8, min/max day supply 28) with a duration of one-week.
     - QL FOR LETTER: Loading dose: 8 mL per 28 days; Maintenance dose: 2 mL per 28 days

- **Renewal**
  - 75 mg every 4 weeks – *QLs must be entered within the authorization.*
    1. In PA Hub: Add ST, PA, PE, OQL, and 1 mL per 28 days (max quantity 1, min/max day supply 28.
       - QL FOR LETTER: 1 mL per 28 days
  - 150 mg every 4 weeks – *QLs must be entered within the authorization.*
    1. In PA Hub: Add ST, PA, PE, OQL, and 2 mL per 56 days (max quantity 2, min/max day supply 56.
       - QL FOR LETTER: 2 mL per 56 days
  - 300 mg every 4 weeks – *NO QLs need to be entered within the authorization unless the requested quantity exceeds the QL.*
    1. In PA Hub: Add ST, PA, and PE.
       - QL FOR LETTER: 2 mL per 28 days

AUTHORIZATION DURATION: Approval will be given for an initial duration of six (6) months. For continuation of coverage, medical record documentation of clinical improvement or lack of progression in the signs and symptoms of plaque psoriasis on six (6) months of Cosentyx therapy is required.

After the initial six (6) month approval, subsequent approvals will be for a duration of one (1) year, requiring medical record documentation of continued or sustained improvement in signs and symptoms of plaque psoriasis while on Cosentyx therapy.

Discussion: No comments or questions.

Outcome: The committee unanimously voted to accept the recommendations as presented. None were opposed.

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

TASIGNA (nilotinib)

Updated Indication: Tasigna is now indicated for the treatment of pediatric patients greater than or equal to 1 year of age with chronic phase AND accelerated phase Philadelphia chromosome positive chronic myeloid leukemia (Ph+ CML) with resistance or intolerance to prior tyrosine-kinase inhibitor (TKI) therapy. Previously Tasigna was only indicated in chronic phase Ph+ CML in the pediatric population.

Other indications which remain unchanged are for adult and pediatric patients greater than or equal to 1 year of age with newly diagnosed Ph+ CML in chronic phase and for adult patients with chronic phase and accelerated phase Ph+ CML resistant or intolerant to prior therapy that included imatinib.

Current formulary status: Oral Oncology Brand NP tier ($0 Copay), requires a prior authorization

Recommendation: No changes are recommended for the formulary placement, authorization duration, or quantity limits for Tasigna. The following changes are recommended to Commercial Policy 174.0 to incorporate the new indication:

- Medical record documentation that Tasigna is prescribed by a hematologist or oncologist **AND**
- Medical record documentation of the use of Tasigna to treat newly diagnosed (not previously treated) chronic phase Philadelphia chromosome-positive chronic myelogenous leukemia (Ph+ CML) in adult or pediatric patients greater than or equal to 1 year of age **OR**
- Medical record documentation of the use of Tasigna to treat chronic or accelerated phase Ph+ CML in adult patients with resistance to prior therapy including Gleevec (imatinib) **OR**
- Medical record documentation of the use of Tasigna to treat chronic or accelerated phase Philadelphia chromosome-positive chronic myelogenous leukemia (Ph+ CML) in pediatric patients greater than or equal to 1 year of age with resistance or intolerance to prior tyrosine-kinase inhibitor therapy

MEDISPAN AUTHORIZATION LEVEL: GPI-12

QUANTITY LIMIT: *No QLs need to be entered within the authorization unless the requested quantity exceeds the QL.*

- QL FOR LETTER ONLY:
  - 50 mg capsule: 4 capsules per day, 30 day supply per fill
  - 150 mg and 200 mg capsule: 4 capsules per day, 28 day supply per fill

Discussion: No comments or questions.

Outcome: The committee unanimously voted to accept the recommendations as presented. None were opposed.

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

TECARTUS (brexucabtagene autoleucel)

Updated Indication: Tecartus is now indicated for the treatment of adult patients with relapsed or refractory B-cell precursor acute lymphoblastic leukemia (ALL).

Previously, Tecartus was only indicated (under the accelerated approval process) for the treatment of adult patients with relapsed or refractory mantle cell lymphoma (MCL).

Current formulary status: Tecartus is a medical benefit requiring prior authorization.

Recommendation: No changes are recommended to the formulary placement of Tecartus at this time. For all lines of business, it is recommended that the criteria of MBP 224.0 Tecartus (brexucabtagene autoleucel) are updated to account for the new indication as outlined below:

Mantle Cell Lymphoma (MCL)

- Medical record documentation that Tecartus is prescribed by a hematologist/oncologist **AND**
- Medical record documentation of age greater than or equal to 18 years **AND**
- Medical record documentation of a diagnosis of relapsed or refractory mantle cell lymphoma (MCL)

Acute Lymphoblastic Leukemia (ALL)

- Medical record documentation that Tecartus is prescribed by a hematologist/oncologist **AND**
- Medical record documentation of age greater than or equal to 18 years **AND**
- Medical record documentation of a diagnosis of relapsed or refractory B-cell precursor acute lymphoblastic leukemia (ALL)

AUTHORIZATION DURATION: One-time authorization for one administration of Tecartus

Discussion: No comments or questions.

Outcome: The committee unanimously voted to accept the recommendations as presented. None were opposed.

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

TRIKAFTA (elexacaftor, tezacaftor, and ivacaftor tablets; ivacaftor tablets)

Updated Indication: Trikafta is indicated for the treatment of cystic fibrosis (CF) in patients aged 6 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. If the patient's genotype is unknown, an FDA-cleared CF mutation test should be used to confirm the presence of at least one *F508del* mutation or a mutation that is responsive based on *in vitro* data.

Previously, Trikafta was indicated for the treatment of CF in patients aged 12 years and older.

NOTE: In December 2020, the indication for Trikafta was updated to the treatment of CF in patients aged 12 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. Initially, it was only indicated for patients who have at least one *F508del* mutation in the *CFTR* gene. This updated indication was not presented at P&T.

Current formulary status: Trikafta is a pharmacy benefit available at the Specialty tier or Brand Non-Preferred tier for members with a three tier benefit. Trikafta requires a prior authorization.

Recommendation: There are no changes to formulary status, quantity limits, or authorization duration at this time. However, it is recommended to update the prior authorization criteria to the following.

- Medical record documentation of age greater than or equal to 6 years **AND**
- Medical record documentation of a diagnosis of cystic fibrosis **AND**
- Medical record documentation that the medication is prescribed by, or in consultation with, a pulmonologist or a physician who specializes in the treatment of cystic fibrosis **AND**
- Medical record documentation of one of the following, as detected by an FDA cleared cystic fibrosis mutation test:
    - Medical record documentation that the patient has at least one F508del mutation in the cystic fibrosis transmembrane conductance regulator (CFTR) gene **OR**
    - Medical record documentation that the patient has a mutation in the cystic fibrosis transmembrane conductance regulator (CFTR) gene that is responsive based on *in vitro* data per product labeling

Note to reviewer: List of CFTR mutations that is responsive to Trikafta

3141del9	*E822K*	*G1069R*	*L967S*	*R117L*	*S912L*
546insCTA	*F191V*	*G1244E*	*L997F*	*R117P*	*S945L*
A46D	*F311del*	*G1249R*	*L1077P*	*R170H*	*S977F*
A120T	*F311L*	*G1349D*	*L1324P*	*R258G*	*S1159F*
A234D	*F508C*	*H139R*	*L1335P*	*R334L*	*S1159P*
A349V	*F508C;S1251N*†	*H199Y*	*L1480P*	*R334Q*	*S1251N*
A455E	*F508del**	*H939R*	*M152V*	*R347H*	*S1255P*
A554E	*F575Y*	*H1054D*	*M265R*	*R347L*	*T338I*
A1006E	*F1016S*	*H1085P*	*M952I*	*R347P*	*T1036N*
A1067T	*F1052V*	*H1085R*	*M952T*	*R352Q*	*T1053I*
D110E	*F1074L*	*H1375P*	*M1101K*	*R352W*	*V201M*
D110H	*F1099L*	*I148T*	*P5L*	*R553Q*	*V232D*
D192G	*G27R*	*I175V*	*P67L*	*R668C*	*V456A*
D443Y	*G85E*	*I336K*	*P205S*	*R751L*	*V456F*
D443Y;G576A;R668C†	*G126D*	*I502T*	*P574H*	*R792G*	*V562I*
D579G	*G178E*	*I601F*	*Q98R*	*R933G*	*V754M*
D614G	*G178R*	*I618T*	*Q237E*	*R1066H*	*V1153E*
D836Y	*G194R*	*I807M*	*Q237H*	*R1070Q*	*V1240G*
D924N	*G194V*	*I980K*	*Q359R*	*R1070W*	*V1293G*
D979V	*G314E*	*I1027T*	*Q1291R*	*R1162L*	*W361R*
D1152H	*G463V*	*I1139V*	*R31L*	*R1283M*	*W1098C*
D1270N	*G480C*	*I1269N*	*R74Q*	*R1283S*	*W1282R*
E56K	*G551D*	*I1366N*	*R74W*	*S13F*	*Y109N*
E60K	*G551S*	*K1060T*	*R74W;D1270N*†	*S341P*	*Y161D*
E92K	*G576A*	*L15P*	*R74W;V201M*†	*S364P*	*Y161S*
E116K	*G576A;R668C*†	*L165S*	*R74W;V201M;D1270N*†	*S492F*	*Y563N*
E193K	*G622D*	*L206W*	*R75Q*	*S549N*	*Y1014C*
E403D	*G628R*	*L320V*	*R117C*	*S549R*	*Y1032C*
E474K	*G970D*	*L346P*	*R117G*	*S589N*	
E588V	*G1061R*	*L453S*	*R117H*	*S737F*	

* *F508del* is a responsive *CFTR* mutation based on both clinical and *in vitro* data *[see Clinical Studies (14)]*.
† Complex/compound mutations where a single allele of the *CFTR* gene has multiple mutations; these exist independent of the presence of mutations on the other allele.

Discussion: No comments or questions.

Outcome: The committee unanimously voted to accept the recommendations as presented. None were opposed.

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

BRUKINSA (zanubrutinib)

Updated Indication: Brukinsa is a kinase inhibitor now indicated for the treatment of adult patients with:

- Waldenström's macroglobulinemia AND
- Relapsed or refractory marginal zone lymphoma (MZL) who have received at least one anti-CD20-based regimen.

Brukinsa is also indicated for the treatment of mantle cell lymphoma.

Current formulary status: Oral Oncology Brand NP tier ($0 Copay), requires a PA

Recommendation: There are no changes recommended for the formulary placement, authorization duration, or quantity limits for Brukinsa. The following changes are recommended to Commercial Policy 608.0 to incorporate the new indications:

Waldenström's macroglobulinemia

- Medical record documentation of age greater than or equal to 18 years AND
- Medical record documentation that Brukinsa is prescribed by a hematologist or oncologist AND
- Medical record documentation of a diagnosis of Waldenström's macroglobulinemia

Marginal Zone Lymphoma (MZL)

- Medical record documentation of age greater than or equal to 18 years AND
- Medical record documentation that Brukinsa is prescribed by a hematologist or oncologist AND
- Medical record documentation of a diagnosis of relapsed or refractory marginal zone lymphoma (MZL) AND
- Medical record documentation of therapeutic failure on or intolerance to one prior anti-CD20-based regimen.

Discussion: No comments or questions.

Outcome: The committee unanimously voted to accept the recommendations as presented. None were opposed.

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

UPDATES

AMYLOIDOSIS CENTER OF EXCELLENCE DRUG POLICY UPDATE

Background: Medications for the treatment of amyloidosis:

- Onpattro – treatment of the polyneuropathy of hereditary transthyretin-mediated amyloidosis in adults
- Tegsedi – treatment of the polyneuropathy of hereditary transthyretin-mediated amyloidosis in adults
- Vyndamax/Vyndaqel – treatment of the cardiomyopathy of wild type or hereditary-mediated amyloidosis (ATTR-CM) in adults to reduce cardiovascular mortality and cardiovascular-related hospitalization

A Center of Excellence (COE) model for the treatment of amyloidosis has been developed and approved in coordination with this committee and the GHP Credentialing Committee. Member benefit documents have been updated to reflect that members must be seen at a COE.

Recommendation: It is recommended that the following criteria is added to the above referenced drug policies:

- Medical record documentation that member has been evaluated and treated by a contracted Center of Excellence in amyloidosis management

NOTE: Center of Excellence (COE) requirements do not apply to strategic partner TPA plans (i.e., Northern Light Health).

Discussion: Keith asked how we would handle members currently on therapy. All current utilization is in the Medicare Part D LOB where this does not apply. No additional comments or questions.

Outcome: The committee unanimously voted to accept the recommendations as presented. None were opposed.

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

PCSK9 INHIBITOR UPDATE

Background: We were contacted by a family physician, Dr. Paul Tayoun, that had a concern regarding our PCSK-9 inhibitor policies. He mentioned that the PCSK-9 inhibitor class will no longer need to be written by a cardiologist for Medicaid plans starting January 1, 2022. He requested for us to consider this change for Commercial and Medicare plans as well. He said several of his Cardiology colleges in the Hazelton and Wilkes-Barre area believe that primary care physicians should be managing patient's cholesterol. There is a small number of general cardiologists in the area, which can delay treatment for high-risk patients. He mentioned his patients also incur additional expenses in co-payments, missed work, and additional driving expenses.

We discussed this at a pharmacist meeting and we decided to move forward with this change. Since the PCSK-9 inhibitors are also indicated for primary hyperlipidemia, it would be appropriate to allow primary care to prescribe these medications, because they will most likely be the ones to identify and diagnosis primary hyperlipidemia. We also do not want to delay care for members that cannot been seen within a reasonable timeframe by cardiology.

Recommendation: The following changes are recommended:

- Praluent (policy 392.0)
  - Removal of "…Medical record documentation that Praluent is prescribed by a cardiologist or lipidologist AND…"
- Repatha (policy 393.0)
  - Removal of "...Medical record documentation that Repatha is prescribed by a cardiologist or lipidologist AND…"

Discussion: No comments or questions.

Outcome: The committee unanimously voted to accept the recommendations as presented. None were opposed.

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

SITE OF CARE POLICY UPDATE

Background: On October 1st, 2019 Geisinger Health Plan (GHP) implemented a new site of care program for infliximab products and intravenous/subcutaneous immune globulin products, which direct members to the most cost-effective, yet clinically appropriate location to receive drug infusions under the medical benefit. The site of care program is administered as part of the existing prior authorization program which requires clinical approval of the medication as well as approval at hospital based outpatient facilities via the following prior authorization criteria. Since that time, additional drugs have been added to the site of care program in phases.

On December 15, 2021 GHP will implement Phase 9 drugs (Amondys 45, Radicava, Exondys 51, Vyondys 53, Viltepso) to the site of care program, The current Site of Care Policy (MBP 181.0) will apply in addition to the drugs' respective existing clinical prior authorization program.

Recommendation: It is recommended that the following changes (highlighted in green) be made to MBP 181.0 so that this policy may apply to the Phase 9 drugs (Amondys 45, Radicava, Exondys 51, Vyondys 53, Viltepso). No changes are recommended to the criteria for self-injected drugs.

To provide a policy of coverage regarding the use of hospital based outpatient facilities as a site of care for drugs that require administration via intravenous infusion or injection. This policy applies to these medications:

1. Abatacept (Orencia IV)
2. Agalsidase Beta (Fabrazyme)
3. Alglucosidase Alfa (Lumizyme)
4. Alpha$_1$-Proteinase Inhibitor [Human] products
5. Belimumab (Benlysta IV)
6. Benralizumab (Fasenra)
7. C1 esterase Inhibitor [Human] (Cinryze)
8. Casimersen (Amondys 45)
9. Canakinumab (Ilaris)
10. Certolizumab (Cimzia)
11. Denosumab (Prolia, Xgeva)
12. Edaravone (Radicava)
13. Eptinezumab (Vyepti)
14. Eteplirsen (Exondys 51)
15. Galsulfase (Naglazyme)
16. Golodirsen (Vyondys 53)
17. Golimumab (Simponi Aria)
18. Immune Globulin (IVIG)
19. Imiglucerase (Cerezyme)
20. Infliximab & infliximab biosimilar products
21. Laronidase (Aldurazyme)
22. Mepolizumab (Nucala)
23. Omalizumab (Xolair)
24. Tildrakizumab (Ilumya)
25. Tocilizumab (Actemra IV)
26. Ustekinumab (Stelara)
27. Vedolizumab (Entyvio)
28. Viltolarsen (Viltepso)

Discussion: No comments or questions.

Outcome: The committee unanimously voted to accept the recommendations as presented. None were opposed.

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

Meeting adjourned at 4:15 pm

Future Scheduled Meetings

The next bi-monthly scheduled meeting will be held on January 18th, 2022 at 1:00 p.m.

All of these meetings are scheduled to be held at Geisinger Health Plan, Hughes Center North and South Buildings; 108 Woodbine Lane; Danville, PA 17821 or will be held virtually.