P&T Committee Meeting Minutes
Commercial, Exchange, CHIP
March 21, 2023

Present (via Teams):	**Absent:**
Bret Yarczower, MD, MBA – Chair	Kristen Bender, Pharm.D.
Amir Antonious, Pharm.D.	Jeremy Bennett, MD
Emily Antosh, Pharm.D.	Kim Castelnovo
Alyssa Cilia, RPh	Kimberly Clark, Pharm.D.
Bhargavi Degapudi, MD	Holly Bones, Pharm.D.
Michael Dubartell, MD	Michael Evans, RPh
Kelly Faust Pharm.D.	Rajneel Farley, Pharm.D.
Tricia Heitzman, Pharm.D.	Jason Howay, Pharm.D.
Nichole Hossler, MD	Derek Hunt, Pharm.D.
Emily Hughes, Pharm.D.	Kerry Ann Kilkenny, MD
Keith Hunsicker, Pharm.D.	Briana LeBeau, Pharm.D.
Kelli Hunsicker, Pharm.D.	Tyreese McCrea, Pharm.D.
Philip Krebs, R.EEG T	Jamie Miller, RPh
Ted Marines, Pharm.D.	Jonas Pearson, RPh
Lisa Mazonkey, RPh	William Seavey, Pharm.D.
Perry Meadows, MD	Michael Shepherd, MD
Mark Mowery, Pharm.D.	Kevin Szczecina, RPh
Austin Paisley, Pharm.D.	
Kimberly Reichard, Pharm.D.	
Melissa Sartori, Pharm.D.	
Angela Scarantino	
Kristen Scheib, Pharm.D.	
Leslie Shumlas, Pharm.D.	
Aubrielle Smith Pharm.D.	
Kirsten Smith, Pharm.D.	
Michael Spishock, RPh	
Todd Sponenberg, Pharm.D.	
Jill Stone, Pharm.D.	
Robert Strony, MD, MBA	
Luke Sullivan, DO	
Amanda Taylor, MD	
Ariana Wendoloski, Pharm.D.	
Brandon Whiteash, Pharm.D.	
Margaret Whiteash, Pharm.D.	
Jeremy Garris, Pharm.D. (non-voting participant)	
Marianne Linko (non-voting participant)	
Dionardo Medina Encarnacion, MD (non-voting participant)	
Mary Hoang (student)	
Devaney Taylor (Wood) (student)	
Sarah Tucker (Pharmacy Resident)	

Call to Order:
Dr. Bret Yarczower called the meeting to order at 1:02 p.m., Tuesday, March 21, 2023.

Review and Approval of Minutes:
Dr. Bret Yarczower asked for a motion or approval to accept the January 17th, 2023 and February 2023 e-vote minutes as written. Minutes approved unanimously. None were opposed.

DRUG REVIEWS

ORSERDU (elacestrant)

Review: Orserdu is an estrogen receptor antagonist indicated for the treatment of postmenopausal women or adult men with ER-positive, HER2-negative, ESR1-mutated advanced or metastatic breast cancer with disease progression following at least one line of endocrine therapy. Orserdu offers a more effective treatment option for patients with ERS1 mutations compared to intramuscular fulvestrant. NCCN recommends Orserdu for recurrent unresectable or metastatic HR+, HER2-, breast cancer with an ESR1-mutation after progression on one or two prior lines of therapy, including one line containing a CDK4/6 inhibitor (Category 2A, Table 4). Per NCCN, men with breast cancer should be treated the same as postmenopausal women, except that an aromatase inhibitor is ineffective without concomitant suppression of testicular steroidogenesis. While there are other options for treatment of ER+, HER2-advanced or metastatic breast cancer, Orserdu is the only option indicated specifically for patients with ESR1 mutations.

The recommended dosage of Orserdu is 345 mg orally once daily with food until disease progression or unacceptable toxicity. In the event of adverse reactions, Orserdu can be decreased to 258 mg once daily, then 172 mg once daily, then if further reduction is required Orserdu should be permanently discontinued. Orserdu is supplied as 86 mg tablets and 345 mg tablets.

The efficacy of Orserdu was evaluated in the EMERALD trial, a randomized, open-label, active-controlled, trial in 478 postmenopausal women and men with ER+, HER2-, advanced or metastatic breast cancer of which 228 patients had ESR1 mutations. Patients were required to have disease progression on one or two prior lines of endocrine therapy, including one line containing a CDK4/6 inhibitor. Patients were randomized (1:1) to receive Orserdu (n=239) or investigator's choice of endocrine therapy (n=239), including fulvestrant (n=166) or an aromatase inhibitor (n=73; anastrozole, letrozole, or exemestane). The major efficacy outcome was progression-free survival (PFS) assessed by BIRC. Overall survival was also assessed. Efficacy results are shown in Table 5.

Warnings and Precautions for Orserdu include dyslipidemia which includes hypercholesterolemia and hypertriglyceridemia and embryo-fetal toxicity. During clinical trials of Orserdu, serious adverse reactions occurred in 12% of patients receiving Orserdu, including musculoskeletal pain and nausea. Fatal adverse reactions occurred in 1.7% of patients, including cardiac arrest, septic shock, diverticulitis, and unknown cause. Discontinuation occurred in 6%, dose interruptions occurred in 15%, and dose reductions occurred in 3% of patients. The most common adverse reactions were musculoskeletal pain, nausea, increased cholesterol, increased AST, increased triglycerides, fatigue, decreased hemoglobin, vomiting, increased ALT, decreased sodium, increased creatinine, decreased appetite, diarrhea, headache, constipation, abdominal pain, hot flush, and dyspepsia.

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

Clinical Discussion: Dr. Bret Yarczower commented that ESR1 mutations are common amongst patients who have already failed endocrine therapy. Kim Reichard, PharmD, commented that she does not know the prevalence but would agree if the mutations are common, we would see this drug frequently. 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: Orserdu is a pharmacy benefit and will be added to the Oral Oncology Brand Non Preferred tier ($0 copay) Commercial, Marketplace, and GHP Kids formulary. The following prior authorization criteria will apply:

- Medical record documentation that Orserdu 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 ER-positive, HER2-negative, ESR1-mutated advanced or metastatic breast cancer **AND**
- Medical record documentation that Orserdu is being prescribed in postmenopausal women OR men **AND**
- Medical record documentation of disease progression following at least one prior endocrine therapy

AUTHORIZATION DURATION: Orserdu will be configured as a prior authorization for new starts only. Orserdu will no longer be covered if it is identified that the member is not receiving appropriate follow-up care from the prescribing specialist or if the member has greater than or equal to a 90 day break in therapy.

- Medical record documentation that the member is receiving appropriate follow-up care from the prescribing specialist

GPI Level: GPI-12

Quantity Limits: 86 mg tablets: 3 tablets daily; 345 mg tablets: 1 tablet per day

Require RPH Sign off: Yes

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

ASPRUZYO SPRINKLE (ranolazine ER granules)

Review: Aspruzyo Sprinkle is an antianginal indicated for the treatment of chronic angina and is available as white to off-white coated, extended-release granules in sachets of 500mg or 1000mg. Aspruzyo Sprinkle should be dosed at 500mg twice daily and may be increased to a maximum of 1000mg twice daily, as needed based on clinical symptoms. To administer, the granules should either be sprinkled on one tablespoonful of soft food and consumed immediately or given via nasogastric of gastrostomy/gastric tube in combination with water, as specified in the product labeling.

Ranolazine products, such as Aspruzyo Sprinkle, are intended to be used as chronic therapy for control of angina and will not treat an acute angina episode. The efficacy of ranolazine for the treatment of patients with chronic angina was demonstrated in two clinical trials, CARISA and ERICA.

CARISA (Combination Assessment of Ranolazine In Stable Angina) was a study in 823 chronic angina patients randomized to receive 12 weeks of treatment with twice-daily ranolazine 750 mg, 1000 mg, or placebo, who also continued on daily doses of atenolol 50 mg, amlodipine 5 mg, or diltiazem CD 180 mg. Sublingual nitrates were used in this study as needed. In this trial, statistically significant ($p < 0.05$) increases in modified Bruce treadmill exercise duration and time to angina were observed for each ranolazine dose versus placebo, at both trough (12 hours after dosing) and peak (4 hours after dosing) plasma levels, with minimal effects on blood pressure and heart rate. Exercise treadmill results showed no increase in effect on exercise at the 1000 mg dose compared to the 750-mg dose. Tolerance to ranolazine did not develop after 12 weeks of therapy. Rebound increases in angina, as measured by exercise duration, have not been observed following abrupt discontinuation of ranolazine.

In the ERICA (Efficacy of Ranolazine In Chronic Angina) trial, 565 patients with chronic angina who remained symptomatic despite treatment of maximum dose of an antianginal agent were randomized to receive an initial dose of ranolazine 500 mg twice daily or placebo for 1 week, followed by 6 weeks of treatment with ranolazine 1000 mg twice daily or placebo, in addition to concomitant treatment with amlodipine 10 mg once daily. In addition, 45% of the study population also received long-acting nitrates. Sublingual nitrates were used as needed to treat angina episodes. Statistically significant decreases in angina attack frequency ($p = 0.028$) and nitroglycerin use ($p = 0.014$) were observed with ranolazine compared to placebo. These treatment effects appeared consistent across age and use of long-acting nitrates.

Effects on angina frequency and exercise tolerance were considerably smaller in women than in men. In CARISA, the improvement in Exercise Tolerance Test (ETT) in females was about 33% of that in males at the 1000 mg twice-daily dose level. In ERICA, where the primary endpoint was angina attack frequency, the mean reduction in weekly angina attacks was 0.3 for females and 1.3 for males.

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: Aspruzyo Sprinkle is a pharmacy benefit and will not be added to the commercial/exchange or CHIP formularies. The following prior authorization criteria will apply:

- Medical record documentation that Aspruzyo Sprinkle is being used to treat chronic angina in patients 18 years and older **AND**
- Medical record documentation of therapeutic failure on, intolerance to, or contraindication ranolazine ER tablets **OR** documentation member is unable to swallow tablets

GPI Level: GPI-12

Quantity Limit: 2 packets per day

Formulary Alternatives: ranolazine ER tablets

Require RPH Sign off: No

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

LYVISPAH (baclofen oral granules)

Review: Lyvispah (baclofen oral granules) is indicated for the treatment of spasticity resulting from multiple sclerosis (MS), particularly for the relief of flexor spasms and concomitant pain, clonus, and muscular rigidity. Lyvispah may also be of some value in patients with spinal cord injuries and other spinal cord diseases. Lyvispah is not indicated in the treatment of skeletal muscle spasm resulting from rheumatic disorders.

Lyvispah is supplied in single dose packets of strawberry flavored granules containing 5mg, 10mg, or 20mg each. The entire contents of the packet should be emptied into the mouth. The granules will dissolve in the mouth or can be swallowed. Lyvispah can also be taken with liquids or soft foods. The contents of 1 packet can be emptied and mixed with up to 15mL of liquid or soft food. This mixture should

be administered no more than 2 hours after mixing. If multiple packets are needed to achieve a certain dosage, each packet must be mixed with a separate volume of liquid or soft food.
The efficacy of Lyvispah is based upon a bioavailability study in healthy adults comparing baclofen oral tablets to Lyvispah. Pharmacokinetic studies in heathy adult subjects under fasting conditions at 20 mg dose demonstrated similar bioavailability for baclofen oral granules and oral tablets. Because clinical trials are conducted under widely varying conditions, adverse reaction rates observed in the clinical trials of a drug cannot be directly compared to rates in the clinical trials of another drug and may not reflect the rates observed in practice. The most common adverse reaction is transient drowsiness. In one controlled study of 175 patients, transient drowsiness was observed in 63% of those receiving baclofen compared to 36% of those in the placebo group. Other common adverse reactions (up to 15%) are dizziness and weakness. Table 1 includes adverse reactions with a frequency of ≥ 1%.

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 voted to accept the recommendations as presented with a majority.

Financial Discussion: Dr. Bret Yarczower questioned why baclofen tablets were Tier 2 for Exchange. Kim Reichard, PharmD, responded that Tier 2 for Exchange is still a generic tier, just that Tier 1 is reserved for preferred generics. The committee unanimously voted to accept the recommendations as presented. None were opposed.

Outcome: Lyvispah is a pharmacy benefit that will not be added to the Commercial/Exchange/CHIP formularies. It will be added to Policy 733.0 Baclofen Oral Solution (generic Ozobax) and prior authorization criteria will remain the same.

Policy 733.0 Baclofen Oral Solution (generic Ozobax)

- Medical record documentation of a diagnosis of spasticity from multiple sclerosis OR spinal cord injuries and/or diseases AND
- Medical record documentation of an age greater than or equal to 12 years AND
- Medical record documentation of one of the following:
    - Medical record documentation of inability to tolerate or swallow tablets OR
    - Medical record documentation of therapeutic failure on, or contraindication to the preferred formulary alternatives, both baclofen tablets and tizanidine tablets

Quantity Limit: 4 packets daily

Formulary Alternatives: baclofen tablets, tizanidine tablets

GPI Level: GPI-12

Require RPH Sign off: No

Other Recommendations:

- For Commercial/Exchange/Chip, it is recommended to also add Fleqsuvy to Policy 733.0 Baclofen Oral Solution (generic Ozobax)
- For Commercial/Exchange/Chip, it is recommended to retire Policy 121.0 Fleqsuvy

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

TRIJARDY XR (empagliflozin/linagliptin/metformin HCl ER)

Review: Trijardy XR is a combination medication consisting of 3 medications, empagliflozin (Jardiance), linagliptin (Tradjenta), and metformin HCl. Empagliflozin is a sodium-glucose co-transporter 2 (SGLT2) inhibitor. Linagliptin is a dipeptidyl peptidase-4 (DPP-4) inhibitor, and metformin hydrochloride (HCl) ER is a biguanide. This medication is FDA approved as an adjunct medication to diet and exercise to improve glycemic control in adults with type II diabetes mellitus. Additionally, empagliflozin is FDA approved to reduce risk of cardiovascular death in adults with type 2 diabetes mellitus and establish cardiovascular disease. Per the FDA, Trijardy XR is not recommended to be used in patients with type I diabetes mellitus due to increased risk of diabetic ketoacidosis. Its' use should also be limited in those with history of pancreatitis due to lack of studies in that patient population.

Trijardy XR should be dosed once daily and initiated at a starting dose based on the patient's current regimen. For patients on metformin HCl, with or without linagliptin, should start Trijardy XR containing a similar total dose of metformin HCl and a total daily dose of empagliflozin 10 mg and linagliptin 5 mg. For patients on metformin HCl and any regimen containing empagliflozin, with or without linagliptin, should start Trijardy XR containing similar total daily dose of metformin HCl, the same daily dose of empagliflozin and linagliptin 5 mg. The recommended maximum daily dose is 25 mg empagliflozin, 5 mg linagliptin, and 2000 mg metformin HCl. Due to it being an extended-release tablet, Trijardy XR should be swallowed whole, and should not be split, crushed, dissolved, or chewed.

Trijardy XR was studied for its' safety profile regarding concomitant administration of empagliflozin, linagliptin, and metformin. In an active-controlled clinical trial, 686 patients with type 2 diabetes mellitus were evaluated for up to 52 weeks in those taking either 10 mg empagliflozin/5 mg linagliptin/1000 mg metformin HCl ER or 25 mg empagliflozin/5 mg linagliptin/1000 mg metformin HCl ER. Hypoglycemia of less than 54 mg/dL was reported in 0.7% patients taking either strength with no report of severe hypoglycemia requiring assistance. All other reported side effects were as anticipated with what you'd find with each medication individually.

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: Trijardy XR is a pharmacy benefit that will be added to the Commercial, Exchange, and CHIP formularies as a Tier 2, Brand Preferred medication.

Quantity Limit:

- Trijardy XR 5 mg/2.5 mg/1000 mg: 2 tablets per day
- Trijardy XR 10 mg/5 mg/1000 mg: 1 tablet per day
- Trijardy XR 12.5 mg/2.5 mg/1000 mg: 2 tablets per day
- Trijardy XR 25 mg/5 mg/1000 mg: 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.

PEDMARK (sodium thiosulfate)

Review: Pedmark is the first and only FDA-approved medication indicated to reduce the risk of ototoxicity associated with cisplatin in pediatric patients 1 month of age and older with localized, non-metastatic solid

tumors. The safety and efficacy of Pedmark have not been established when administered following cisplatin infusions longer than 6 hours. Pedmark may not reduce the risk of ototoxicity when administered following longer cisplatin infusions, because irreversible ototoxicity may have already occurred. Pedmark is not substitutable with other sodium thiosulfate products.

Pedmark is manufactured as a 12.5 grams/100ml single-dose vial for injection. The recommended dose of Pedmark is based on body surface area according to actual body weight. Pedmark is administered as an intravenous infusion over 15 minutes starting 6 hours after the completion of cisplatin infusions that are 1 to 6 hours in duration. For multiday cisplatin regimens, administer Pedmark 6 hours after each cisplatin infusion but at least 10 hours before the next cisplatin infusion. Do not start Pedmark if less than 10 hours before starting the next cisplatin infusion. Pedmark must be administered as stated above to minimize the potential interference with the antitumor activity of cisplatin.

SIOPEL 6 was a multicenter, randomized, controlled, open-label study. Eligible patients were between 1 month and 18 years of age and were receiving cisplatin-based chemotherapy for standard-risk hepatoblastoma. Patients were randomized 1:1 to receive 6 cycles of perioperative cisplatin-based chemotherapy without (cisplatin alone arm) or with Pedmark (Pedmark+cisplatin arm). Patients received Pedmark per package labeling. A total of 114 patients were randomized, 61 patients to the Pedmark+cisplatin arm and 53 patients to the cisplatin alone arm. The median age was 1.1 years (range: 1.2 months to 8.2 years). The major efficacy outcome measure was hearing loss defined as a Brock Grade ≥ 1. Hearing loss was assessed using pure tone audiometry after study treatment or at an age of at least 3.5 years, whichever was later. The incidence of hearing loss was lower in the Pedmark+cisplatin arm compared with the cisplatin alone arm. Efficacy results are shown in Table 2.

COG ACCL0431 was a multicenter, randomized, controlled, open-label study. Eligible patients were between 1 and 18 years of age and were receiving a chemotherapy regimen that included a cumulative cisplatin dose of 200 mg/m2 or higher, with individual cisplatin doses to be infused over 6 hours or less. Patients were randomized 1:1 to receive cisplatin-based chemotherapy without (cisplatin alone arm) or with Pedmark (Pedmark+cisplatin arm). Cisplatin was administered according to each site's disease-specific treatment protocols. A total of 125 pediatric patients were randomized, 61 patients to the Pedmark+cisplatin arm and 64 patients to the cisplatin alone arm. The median age was 8 years (range: 1 to 18). Underlying diagnosis included medulloblastoma, osteosarcoma, germ cell tumor, neuroblastoma, hepatoblastoma, atypical teratoid/rhabdoid tumor, choroid plexus carcinoma, and anaplastic astrocytoma. The major efficacy outcome measure was hearing loss assessed by American Speech-Language-Hearing Association (ASHA) criteria. Hearing was assessed at baseline and 4 weeks after the final course of cisplatin. The efficacy was evaluated in patients with localized disease in the intent-to-treat (ITT) population (N=77). The incidence of hearing loss was lower in the Pedmark+cisplatin arm compared with the cisplatin alone arm. Efficacy results are shown in Table 3.

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: Pedmark will be a medical benefit and will be added to the medical benefit cost share list. If processed at a specialty pharmacy, Pedmark will process at the Specialty tier or the Brand Non-preferred tier for members with a three-tier benefit. The following prior authorization criteria will apply:

- Documentation of age greater than or equal to 1 month but less than 18 years of age **AND**
- Prescribed by or in consultation with a hematologist or oncologist **AND**
- Medical record documentation of a localized, non-metastatic solid tumor **AND**
- Medical record documentation that the patient will receive a cisplatin infusion with an infusion time less than or equal to 6 hours **AND**

- Medical record documentation that Pedmark is being used to reduce the risk of ototoxicity associated with cisplatin **AND**
- Medical record documentation of a prescribed dose and administration that is consistent with FDA-approved package labeling, nationally recognized compendia, or peer-reviewed medical literature

Authorization Duration: Initial approval will be for **6 months** or less if the reviewing provider feels it is medically appropriate. Subsequent approvals will be for an additional **6 months** and will require medical record documentation of clinical improvement or lack of progression and documentation that the patient is continuing to receive a cisplatin-based chemotherapy regimen. The medication will no longer be covered if the patient experienced toxicity. worsening of disease, or if the member is not to continue on a cisplatin-based chemotherapy regimen.

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

SEZABY (phenobarbital sodium)

Review: Sezaby is a barbiturate indicated for the treatment of neonatal seizures in term and preterm infants. The recommended dose of Sezaby is summarized in Table 1. Sezaby is supplied as a lyophilized powder for reconstitution in a single-dose vial containing 100mg (10mg/mL) of phenobarbital sodium.

Sezaby is the injectable formulation of phenobarbital indicated specifically for neonatal seizures approved on November 17th, 2022. With the approval, Sezaby becomes the first and only medication specifically approved for the indication of neonatal seizures in term and preterm infants. Neonatal seizures typically occur within the first 28 days of life, with an incidence of approximately 1-4 per 1,000 babies. Poor outcomes such as cerebral palsy, global developmental delay and epilepsy are possible in babies who suffer from seizures.

Phenobarbital for neonatal seizures was evaluated in a randomized, double-blind, active-controlled study (NCT01720667) in 106 patients who were neonates younger than 14 days of age. Gestational ages of the patients ranged from 36 to 44 weeks, 52% were male, 56% were white, 9% were Native Hawaiian or other Pacific Islander, 5% were Black or African American, 5% were Asian and 22% were classified as other or missing/unknown. Exclusion criteria was significant for patients with previous anticonvulsants, serum creatinine level >1.6 mg/dL, or seizures due to correctable metabolic abnormalities (eg. hypoglycemia or hyperglycemia). Only neonates with electrographically confirmed seizures were treated. Seizures were defined as EEG activity lasting longer than 10 seconds with a change in 2 of the following: amplitude, frequency, or spatial distribution.

were randomized to receive either intravenous (IV) phenobarbital (N=42) at 20mg/kg or IV levetiracetam at 40 mg/kg (N=64). After the initial doses, if seizures persisted or recurred within 15 minutes, another loading dose was administered for either drug. Maintenance doses were then given regardless of whether seizures subsided and were 1.5 mg/kg/dose for phenobarbital and 10 mg/kg/dose for levetiracetam every 8 hours for up to 5 days. Mean duration of treatments was 4.3 days for phenobarbital and 4 days for levetiracetam. The primary endpoint was the percentage of neonates whose seizures terminated for at minimum 24 hours, without the need of a second drug for treatment. Results are summarized in table 2. The phenobarbital group had a statistically significantly greater percentage of patients reach the primary efficacy endpoint as compared to the levetiracetam group.

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: Sezaby is a medical benefit, not requiring prior authorization. If processed at a specialty pharmacy, Sezaby will process at the Specialty tier or the Brand Non-preferred tier for members with a three tier benefit. No prior authorization criteria will apply.

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

JAYPIRCA (pirtobrutinib)

Review: Jaypirca is a kinase inhibitor indicated of the treatment of adult patients with relapsed or refractory mantle cell lymphoma (MCL) after at least two lines of systemic therapy, including a BTK inhibitor. BTK is a signaling protein of the B-cell antigen receptor and cytokine receptor pathways. Jaypirca binds to wild type BTK and BTK harboring C481 mutations and leads to inhibition of BTK kinase activity. It showed dose-dependent anti-tumor activities in BTK wild type and BTK C481S mutant mouse xenograft models. NCCN recommends Jaypirca as third-line and subsequent therapy for relapse or refractory disease if there was no response or progressive disease following second-line therapy or greater, including treatment with other BTK inhibitors or intolerance to prior treatment with a covalent BTKi (Category 2A).

The efficacy of Jaypirca was evaluated as monotherapy in the BRUIN Trial, an open-label, single arm study in patients with MCL. Efficacy was based on 120 patients with MCL treated with Jaypirca who had previously been treated with a BTK inhibitor. Jaypirca was given to patients at a dose of 200 mg once daily until disease progression or unacceptable toxicity. Patients with central nervous system lymphoma or allogeneic hematopoietic stem cell transplantation or CAR-T therapy within 60 days were excluded. Patients included in the trial had a median number of 3prior lines of therapy with 93% having received 2 or more prior lines. All patients received 1 or more prior lines of therapy containing a BTK inhibitor, most commonly ibrutinib, acalabrutinib, and zanubrutinib. Efficacy was based on the overall response rate (ORR) and duration of response (DOR) assess by independent review committee (IRC) using 2014 Lugano criteria, Efficacy is shown in Table 4. Additionally, the Kaplan-Meier estimate for the DOR rate at 6 months was 65.3% (95% CI: 49.8,77.1).

Jaypirca carries warnings and precautions for fatal and serious infections and opportunistic infections, fatal and serious hemorrhage, Grade 3 or 4 cytopenias, atrial fibrillation and flutter, secondary primary malignancies, and embryo-fetal toxicity. During the BRUIN trial in 583 patients with hematologic malignancies treated with Jaypirca, the most common adverse reactions were decreased neutrophil count, decreased hemoglobin, decreased platelet count, fatigue, musculoskeletal pain, decreased lymphocyte count, bruising, and diarrhea. In 128 patients treated for MCL who received a prior BTK inhibitor, serious adverse reactions occurred in 38% of patients and included pneumonia, COVID-19, musculoskeletal pain, hemorrhage, pleural effusion, and sepsis. Fatal reactions within 28 days of the last dose of Jaypirca occurred in 7% of patients, most commonly due to infections, including COVID-19. Dose reduction occurred in 4.7%, treatment interruption occurred in 32%, and discontinuation occurred in 9% of patients. The most common adverse reactions were fatigue, musculoskeletal pain, diarrhea, edema dyspnea, pneumonia, and bruising. Clinically relevant adverse reactions occurring in less than 10% of patients included vision changes, memory changes, headache, urinary tract infection, herpesvirus infection, and tumor lysis syndrome. The most common laboratory abnormalities were decreased hemoglobin, platelets, neutrophils, and lymphocytes, decreased calcium, potassium, and sodium, and increased creatinine, AST, ALT, lipase, ALK, and potassium.

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: Jaypirca is a pharmacy benefit and will be added to the Oral Oncology Brand non-preferred tier ($0 copay) of the Commercial, Marketplace, and GHP Kids formularies. The following prior authorization criteria will apply:

- Medical record documentation that Jaypirca is prescribed by a hematologist or oncologist **AND**
- Medical record documentation of age greater than or equal to 18 years **AND**
- Medical record documentation of a diagnosis of mantle cell lymphoma (MCL) **AND**
- Medical record documentation of at least two lines of systemic therapy, including a BTK inhibitor

AUTHORIZATION DURATION: Jaypirca will be configured as a prior authorization for new starts only. Jaypirca will no longer be covered if it is identified that the member is not receiving appropriate follow-up care from the prescribing specialist or if the member has greater than or equal to a 90 day break in therapy.

- Medical record documentation that the member is receiving appropriate follow-up care from the prescribing specialist

GPI Level: GPI- 12

Quantity Limits:

- 50 mg tablets: 1 tablet per day
- 100 mg tablets: 2 tablets per day

Require RPH Sign off: Yes

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

LYUMJEV (insulin lispro-aabc)

Review: Lyumjev (insulin lispro-aabc) is a rapid-acting human insulin analog indicated to improve glycemic control in adult and pediatric patients with diabetes mellitus. Lyumjev is available as a U-100 insulin (100 units/mL) as 10 mL multiple dose vials, 3 mL single-patient-use KwikPens, 3 mL single-patient-use Junior KwikPens, 3 mL single-patient-use Tempo Pens, and 3 mL single-patient-use cartridges. Lyumjev is also available as a U-200 insulin (200 units/mL) as 3 mL single-patient-use KwikPens. Lyumjev U-100 or U-200 should be administered at the start of a meal or within 20 minutes after starting a meal, subcutaneously into the abdomen, upper arm, thigh, or buttocks. Lyumjev should generally be used in regimens with an intermediate or long-acting insulin, with the dosage individualized and adjusted based on the patient's metabolic needs, glucose monitoring results, and glycemic control goal. Lyumjev U-100 can be used for continuous subcutaneous infusion via insulin pump, as well as intravenous infusion (when diluted to a concentration of 1 unit/mL). Lyumjev U-200 should not be used for intravenous infusion or continuous subcutaneous infusion.

PRONTO-T1D was a 26 week, randomized, active controlled, treat-to-target, multinational trial that evaluated the efficacy of Lyumjev in 1222 adult patients with Type 1 Diabetes. Patients were randomized 4:4:3 to received blinded mealtime Lyumjev (n=451), blinded mealtime Humalog (n=442), or open-label post-meal Lyumjev (n=329), all in combination with either insulin glargine or insulin degludec. At week 26, treatment with mealtime Lyumjev provided a mean reduction in Hemoglobin A1C (HbA1c) that met the pre-specified non-inferiority margin (0.4%). In addition, post-meal Lyumjev met the prespecified non-

inferiority margin (0.4%) compared to mealtime Humalog (see Table 1). Insulin doses were similar in all treatment groups at baseline and at 26 weeks.

PRONTO-T2D was a 26-week, randomized, active controlled, treat-to-target, multinational trial that evaluated the efficacy of Lyumjev in 673 adult patients with Type 2 Diabetes who at study entry were on multiple daily injections with either basal insulin and at least one prandial insulin injection or premixed insulin with at least two injections daily. Patients may also have been treated with up to 3 oral anti-diabetic medications (OAMs) in addition to insulin. Patients were allowed to continue on metformin and/or a SGLT2 inhibitor and were randomized 1:1 to either mealtime Lyumjev (n=336) or to mealtime Humalog (n=337), both in combination with insulin glargine or insulin degludec in a basal-bolus regimen. At week 26, treatment with mealtime Lyumjev provided a mean reduction in HbA1c from baseline that met the pre-specified non-inferiority margin (0.4%) compared to mealtime Humalog (see Table 2). Insulin doses were similar in both treatment groups at baseline and at 26 weeks
PRONTO-Pump-2 was a 16-week, randomized, active controlled, treat-to-target, multinational trial that evaluated the efficacy of Lyumjev in 432 adult patients with Type 1 diabetes currently using continuous subcutaneous insulin injection. Patients were randomized 1:1 to either blinded Lyumjev (n=215) or blinded Humalog (n=217). At week 16, treatment with Lyumjev provided a mean reduction in HbA1c that met the pre-specified non-inferiority margin (0.4%) compared to mealtime Humalog (see Table 3). Total daily insulin doses were similar for both treatment groups at baseline and at 16 weeks.

PRONTO-Peds was a 26-week, randomized, active controlled, treat-to-target, multinational trial that evaluated the efficacy of Lyumjev in 716 pediatric patients with Type 1 Diabetes. Patients were randomized 2:2:1 to either blinded mealtime Lyumjev (n=280), blinded mealtime Humalog (n=298), or open-label post-meal Lyumjev (n=138), all in combination with basal insulin (insulin glargine, insulin degludec, or insulin detemir). At week 26, treatment with mealtime Lyumjev provided a mean change in HbA1c that met the pre-specified non-inferiority margin (0.4%) (see Table 4). In addition, post-meal Lyumjev met the pre-specified non-inferiority margin (0.4%) compared to mealtime Humalog. Insulin doses were similar in all treatment groups at baseline and at 26 weeks.

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: Lyumjev is a pharmacy benefit that will not be added to formulary. Lyumjev will be added to Policy 96.0 Lilly Insulin which has the following criteria:

- Medical record documentation that the requested insulin requires dilution **OR**
- Medical record documentation of a therapeutic failure on, contraindication to, or intolerance to comparable Novo Nordisk brand insulin (**with the exception of Fiasp**)

GPI Level: GPI-10

Formulary Alternatives: Novo Nordisk Insulins: Novolin R, Novolin N, Novolin 70/30, Novolog, Novolog Flexpen, NovoLog Mix 70/30, Novolog Mix 70/30 Flexpen

Require RPH Sign off: No

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

SEMGLEE (insulin glargine-yfgn)

Review: Semglee is FDA approved for glycemic control in adult and pediatric patients with diabetes mellitus. It is supplied in 10 mL multiple-dose vials as well as 3 mL single-patient-use prefilled pens. Normally long acting insulins are a part of a multiple dose insulin injection regimen for patients with type 1 diabetes. They are generally second or third line in the ADA guidelines. Also, early introduction of insulin should be considered if there is evidence of ongoing weight loss, if symptoms of hyperglycemia are present, or when A1c levels are over 10%. Semglee was given interchangeability status which all biosimilars do not receive. This means it can be substituted like a brand to generic at point of sale without having approval from a doctor.

INSTRIDE 1 and INSTRIDE 2 trials were non-inferiority studies to compare efficacy and safety of Mylan's Insulin Glargine (MYL-1501D) with Lantus in type one diabetes and type two diabetes. INSTRIDE 1 enrolled 558 patients and INSTRIDE 2 enrolled 560. One group would be given insulin lispro and Mylan's Insulin Glargine (MYL-1501D) vs the second group getting insulin lispro and Lantus. Important endpoints included measuring levels of antidrug antibodies (ADA) and anti-host cell protein (anti-HCP) antibodies. Incidence of total and cross-reactive ADA was comparable between treatment groups in both studies. A similar proportion of patients had anti-HCP antibodies in both treatment groups in INSTRIDE 1 at week 52 and INSTRIDE 2 at week 24. There were also similar secondary endpoints, including hypoglycemia and nocturnal hypoglycemia, and local and systemic reactions. PK and PD similarity between MYL-1501D and US-Lantus were demonstrated in healthy subjects using the pre-filled pen formulation. PK comparability between MYL-1501D vial formulation and MYL-1501D prefilled pen formulation were demonstrated in healthy subjects (Study MYL-1501D-1004). PD comparability was evaluated and also demonstrated. Safety considerations include hyperglycemia or hypoglycemia with a change in insulin regimen, allergic reactions, and hypokalemia.

A Clinical Review including Clinical Information, Efficacy Evidence, Safety Evidence, Other Considerations and a Financial Review Based on Cost Analysis were presented.. With the geriatric patient population, the only difference with outcomes came from cardiovascular events being higher in this population.

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

Financial Discussion: Dr. Yarczower inquired about biosimilars. If a branded product was heavily rebated to offer competition to biosimilars will that deter the biosimilar market. Ted Marines, PharmD, responded that this will work towards more fair pricing of biologics in the future versus rebating their products to be competitive. Keith Hunsicker, PharmD, commented that we will see pricing differences year to year to continue to evaluate. Jeremy Garris, RPh, stated that he agreed with Ted about the biosimilar competition and also the original reference biologic trying to continue one upping each other. No comments or questions. The committee unanimously voted to accept the recommendations as presented. None were opposed.

Outcome: Semglee is a pharmacy benefit and will not be added to Commercial, Marketplace, or GHP Kids formulary. It will be added to Commercial Policy 474.0 Basaglar. No changes need to be made to the PA Criteria as outlined in the policy below:

- Medical record documentation of therapeutic failure on, intolerance to, or contraindication to Lantus **OR** Toujeo

MEDISPAN AUTHORIZATION LEVEL: NDC-9

FORMULARY ALTERNATIVES: Lantus, Toujeo, Tresiba, Levemir

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

AUVELITY (dextromethorphan hydrobromide and bupropion hydrochloride)

Review: Auvelity is a combination product containing a non-competitive N-methyl D-aspartate (NMDA) receptor antagonist and a norepinephrine and dopamine reuptake inhibitor with an indication for treatment of major depression disorder (MDD) in adults. While bupropion is approved as monotherapy for treatment of depression, its primary function in this combination product is to increase the bioavailability of dextromethorphan.

Auvelity is supplied as an oral, fixed-dose, extended-release tablet containing 45 mg of dextromethorphan hydrobromide and 105 mg of bupropion hydrochloride which is administered one to two times per day. The recommended dosing schedule is 1 tablet daily in the morning for 3 days followed by an increase to maximum recommended dose of one tablet twice daily. The prescribing information recommends that patients with moderate renal impairment (eGFR 30-59 mL/min) as well as patients who are known poor CYP2D6 metabolizers remain on 1 tablet daily in the morning. This medication has not been studied and is not recommended to be used in patients with severe renal or hepatic dysfunction.

The efficacy of Auvelity was evaluated in the ASCEND (Phase 2, 80 participants) and GEMINI (Phase 3, 318 participants) trials, both of which were randomized, double-blind, multicenter studies conducted on adults 18 to 65 years of age with moderate to severe MDD. Patients with bipolar disorder, panic disorder, obsessive compulsive disorder, treatment resistant depression (TRD), substance use disorder within the past year, or clinically significant risk of suicide were excluded from the trials. Patients in the ASCEND trial were assigned 1:1 to receive either Auvelity or bupropion 105 mg while patients in GEMINI were assigned 1:1 to receive Auvelity or placebo; all participants took their assigned treatment daily for three days, then increasing to twice daily.

The primary efficacy endpoint in these trials was change in total Montgomery-Asberg Depression Rating Scale (MADRS) score from baseline to week six. Patients treated with Auvelity had a significantly greater average reduction in MADRS score than their counterparts in both trials (ASCEND: 17.2 point reduction (Auvelity group) vs 12.1 point reduction (bupropion group); GEMINI: 15.9 point reduction (Auvelity group) vs 12.1 point reduction (placebo group)). Additionally, the difference in MADRS total scores was found to be statistically significant starting at Week 2 in ASCEND and Week 1 in GEMINI.

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: Auvelity is a pharmacy benefit which will be added to the brand non-preferred tier. The follow prior authorization criteria will apply

- Medical record documentation of age greater than or equal to 18 years old **AND**
- Medical record documentation of major depressive disorder **AND**
- Medical record documentation of a therapeutic failure or intolerance to at least three antidepressant classes

GPI Level: GPI-12

Quantity Limit: 2 tablets per day (180 tabs per 90 days)

Require RPH Sign off: No

Formulary Alternatives:

- **SSRIs:** citalopram, fluoxetine, paroxetine, sertraline, escitalopram
- **MAOIs:** phenelzine, tranylcypromine
- **SNRIs:** venlafaxine hcl, venlafaxine er, duloxetine, desvenlafaxine ER (generic Pristiq)
- **Tricyclics:** amitriptyline, nortriptyline, desipramine, doxepin, imipramine
- **Bupropion:** bupropion hcl, bupropion xl, bupropion sr
- **Other:** trazodone, nefazodone, mirtazapine

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

TYVASO DPI (treprostinil inhalation powder)

Review: Tyvaso DPI is indicated for the treatment of pulmonary arterial hypertension (PAH; WHO Group 1) to improve exercise ability. Studies with Tyvaso establishing effectiveness predominately included patients with NYHA Functional Class III symptoms and etiologies of idiopathic or heritable PAH (56%) or PAH associated connective tissue diseases (33%). The effects diminish over the minimum recommended dosing interval of 4 hours; treatment timing can be adjusted for planned activities. While there are long-term data on use of treprostinil by other routes of administration, nearly all clinical experience with inhaled treprostinil has been on a background of an endothelin receptor antagonist (ERA) and/or a phosphodiesterase type 5 (PDE-5) inhibitor. The controlled clinical experience with Tyvaso was limited to 12 weeks in duration. Tyvaso DPI is also indicated for the treatment of pulmonary hypertension associated with interstitial lung disease (PH-ILD; WHO Group 3) to improve exercise ability. The study with Tyvaso establishing effectiveness predominately included patients with etiologies of idiopathic interstitial pneumonia (IIP) (45%) inclusive of idiopathic pulmonary fibrosis (IPF), combined with pulmonary fibrosis and emphysema (CPFE) (25%), and WHO Group 3 connective tissue disease (22%).

The Tyvaso DPI inhaler is individually packaged in a clear overwrap and is fully assembled with a removable mouthpiece cover. The inhaler can be used up to 7 days from the date of first use. After 7 days, the inhaler must be discarded and replaced with a new inhaler. Tyvaso DPI is administered using a single inhalation per cartridge. It should be administered in 4 separate, equally spaced treatment sessions per day, during waking hours. The sessions should be approximately 4 hours apart. If the dose is higher than 64 mcg per treatment, more than 1 cartridge would need to be used per session. Tyvaso DPI therapy should begin with one 16 mcg cartridge per treatment session, 4 times daily. The dose may be increased by an additional 16 mcg per treatment session at 1-2 week intervals. The target maintenance dose is usually 48 mcg to 64 mcg per session.

Tyvaso DPI is a new formulation and inhalation device for inhaled treprostinil, a prostacyclin analog, and this is the first FDA-approved dry powder inhaler for use in PAH and PH-ILD. Tyvaso DPI utilizes an inhaler device licensed from MannKind Corporation. The inhaler uses the same technology that is used in MannKind's Afrezza (insulin human) inhalation powder. Tyvaso's nebulization device requires the use of a battery or electricity to operate. The Tyvaso DPI inhaler is smaller, more portable, breath-activated, and can be administered more quickly compared to Tyvaso. Both Tyvaso and Tyvaso DPI are administered 4 times daily. In PAH, Ventavis is another inhaled prostacyclin analog on the market that also requires nebulization. Other PAH medications targeting the prostacyclin pathway are administered orally or by continuous intravenous or subcutaneous infusions. The continuous infusion products are the only options available generically. In PH-ILD, there are no other approved therapies besides Tyvaso and Tyvaso DPI. In July 2021 there was a Citizen's Petition concerned with the excipient fumaryl diketopiperazine (FDKP) in Tyvaso DPI. The petition claimed FDKP poses a serious risk of acute bronchospasm in patients with chronic lung disease. This excipient is also in Afrezza, which has a boxed warning regarding acute bronchospasms in patients with asthma and chronic obstructive pulmonary disease (COPD). The approved Tyvaso DPI label dose not contain a boxed warning but does include a warning about bronchospasm.

Tyvaso DPI was studied in a 3-week, open-label, single-sequence, safety and tolerability study (BREEZE) conducted in 51 patients on a stable dose of Tyvaso Inhalation Solution who switched to a corresponding dose of Tyvaso DPI. The most common reported adverse events on Tyvaso DPI during the 3-week treatment phase included cough, headache, dyspnea, and nausea. Patient tolerability, as assessed by incidence of new adverse events following transition to Tyvaso DPI, was consistent with the expected known safety profile of Tyvaso Inhalation Solution. The safety of Tyvaso DPI was also studied in an extension phase trial in which 49 patients were dosed for a duration of 43 patient-years. Fifty-nine percent (59%) of patients achieved a dose of 64 mcg, 4 times daily or higher. The adverse events during this long-term, extension phase were similar to those observed in the 3-week treatment phase.

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: Tyvaso DPI will be a pharmacy benefit. Tyvaso DPI will be added to the Commercial/Exchange/CHIP formularies at the Specialty tier or the Brand Non-Preferred tier for those with a three-tier benefit. Tyvaso DPI will be added to policy 210.0 and require a prior authorization with the following criteria.

Class III or IV Pulmonary Arterial Hypertension

- Medical record documentation that Tyvaso DPI is prescribed by a cardiologist or pulmonologist **AND**
- Medical record documentation of a diagnosis of functional class III or IV pulmonary arterial hypertension **AND**
- Medical record documentation of therapeutic failure on, intolerance to, or contraindication to, or use in combination with sildenafil* **OR** bosentan*

Pulmonary Hypertension associated with Interstitial Lung Disease

- Medical record documentation that Tyvaso DPI is prescribed by a cardiologist or pulmonologist **AND**
- Medical record documentation of a diagnosis of pulmonary hypertension associated with interstitial lung disease (World Health Organization Group 3 Pulmonary Hypertension)

Medispan Authorization Level: GPI-12

Quantity Limit:

- For the 16 mcg, 32 mcg, 48 mcg, and 64 mcg maintenance kit: 112 cartridges per 28 days
- For the 32 and 48 mcg maintenance kit (40170080002960): 224 cartridges per 28 days
- For the 16 and 32 mcg titration kit (40170080002970): 196 cartridges per 28 days
- For the 16, 32, and 48 mcg titration kit (GPI 40170080002980): 252 cartridges per 28 days

RPh sign-off: yes

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

TOSYMRA (sumatriptan)

Review: Tosymra is a serotonin (5-HT1B/1D) receptor agonist (triptan) indicated for the acute treatment of migraine with or without aura in adults. Tosymra should only be used if there is a clear diagnosis of

migraine headaches and is not indicated for the preventive treatment of migraine or the treatment of cluster headache. Tosymra is available as a single dose 10 mg nasal spray. The recommended dose is 10 mg given as a single spray in one nostril. The maximum daily dose in a 24-hour period is 30 mg, with doses separated by at least 1 hour.

Approval of Tosymra is based upon the relative bioavailability of Tosymra nasal spray compared to previous clinical trials of sumatriptan subcutaneous injection (4 mg) in healthy adults. No additional clinical trials were completed.

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: Tosymra is a pharmacy benefit and will not be added to the Commercial, Marketplace, or GHP Kids formularies. The following prior authorization criteria will apply:

- Medical record documentation of age 18 years or older **AND**
- Medical record documentation that Tosymra is being used for the acute treatment of migraines with or without aura **AND**
- Medical record documentation of therapeutic failure on, intolerance to, or contraindication to three (3) generic formulary triptans, one of which much be generic sumatriptan nasal spray

Medispan Authorization Level: GPI-14

Quantity Limit: 16 per 28 days

Formulary Alternatives: naratriptan, rizatriptan, sumatriptan, zolmitriptan

RPh Sign Off: No

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

RELYVRIO (sodium phenylbutyrate/taurursodiol)

Review: Relyvrio is a combination of sodium phenylbutyrate and taurursodiol indicated for the treatment of amyotrophic lateral sclerosis (ALS) in adults. The exact mechanism of action In the treatment of ALS is unknown but may reduce neuronal cell death by mitigating endoplasmic reticulum stress and mitochondrial dysfunction. Taurursodiol is a nutritional supplement that was shown to lessen the decline in the ALSFRS-R at 52 weeks in a small pilot study and was already
being used by some ALS patients prior to the Relyvrio approval. Relyvrio is the fourth FDA approved medication for ALS following riluzole, Radicava, and Radicava ORS. Relyvrio is also being evaluated for the treatment of Alzheimer's disease in the PEGASUS trial.

The recommended initial dosage of Relyvrio is 1 packet for oral suspension daily for the first three weeks, then increase to a maintenance dosage of 1 packet twice daily. The suspension is supplied as single dose packets containing 3 grams of sodium phenylbutyrate and 1 gram of taurursodiol. The contents of the packet are emptied into 8 ounces of room temperature water and taken orally or via feeding tube within 1 hour of preparation.

The efficacy of Relyvrio was evaluated in the CENTUAR trial, a 24-week, randomized, double-blind, placebo controlled, parallel-group study that evaluated Relyvrio in adult patients with ALS. Patients included in the trial had a diagnosis of sporadic or familial ALS with symptom onset within the past 18 months, and slow vital capacity (SVC) greater than 60% of predicted at screening. The trial randomized 137 patients 2:1 to receive Relyvrio (n=89) or placebo (n=48) for 24 weeks. At or prior to study entry, 71% of patients were taking riluzole and 34% were taking edaravone. The prespecified primary efficacy endpoint was comparison of rate of reduction in the ALSFRS-R total scores from baseline to Week 24 in the mITT population. There was a statistically significant difference in the rate of reduction from baseline to Week 24 in Relyvrio treated patients compared to placebo treated patients.

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

Clinical Discussion: Kim Reichard, PharmD, stated she was in favor of removing the baseline functional status criterion from Relyvrio and Radicava. Keith Hunsicker, PharmD, offered insight as to why the decision was made to include this upon the initial review of Radicava in 2017 but said he would be okay removing it. Aubrielle Smith, PharmD, stated she did not think it was necessary to include in initial criteria if we aren't looking at it upon reauthorization. Dr. Nichole Hossler agreed. 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: Relyvrio is a pharmacy benefit and will be added to the Specialty tier or Brand Non-preferred tier for members with a three-tier benefit of the Commercial, Exchange, and GHP Kids formularies. The following prior authorization criteria will be required:

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

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 criteria:

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

Quantity Limits: 2 packets per day

GPI Level: GPI-12

Formulary Alternatives: riluzole, Radicava ORS

Other Recommendations: Previously, generic riluzole tablets were in a high cost generic bucket which placed them on the specialty tier for Commercial members with a four-tier benefit. There is now MAC pricing for generic riluzole tablets and it is recommended that they be moved to the generic tier for all Commercial lines of business.

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

ZYNTEGLO (betibeglogene autotemcel)

Review: Zynteglo is indicated for the treatment of adult and pediatric patients with beta- thalassemia who require regular RBC transfusions. Zynteglo is composed of up to four infusion bags which contain 2.0 to

20 X 106 cells/mL suspended in cryopreservation solution. Each infusion bag contains approximately 20 mL of Zynteglo. A single dose of Zynteglo contains a minimum of 5.0 X 106 CD34+ cells per kg of body weight, suspended in cryopreservation solution. Dosing of Zynteglo is based on the number of CD34+ cells in the infusion bag(s) per kg of body weight. The target number of CD34+ cells to be collected is ≥ 12 X 106 CD34+ cells/kg. The minimum recommended dose is 5.0 × 106 CD34+ cells/kg.

The approval of Zynteglo was based on the results of two Phase 3, open-label, single-arm, 24-month, multicenter trials, Northstar-2 and Northstar-3 and a long-term follow-up study, LTF-303. Northstar-2 and 3 included 41 patients with beta-thalassemia requiring regular transfusions. Northstar-2 enrolled patients with non- β0/ β0 genotypes and a baseline transfusion frequency of 16 (12-37) transfusions per year. Northstar-3 enrolled patients with β0/ β0 genotypes or non- β0/ β0 genotypes and a baseline transfusion frequency of 17 (11-40) transfusions per year. Both trials included patients 50 years old or less. Patients enrolled in the trials had transfusion dependent thalassemia with a history of ≥ 100 mL/kg/year of pRBCs or ≥ 8 transfusions of pRBCs per year in the 2 years preceding enrollment. Also, patients were clinically stable and able to undergo HSCT. In Northstar-2, 91% received transfusion independence. In Northstar-3, 86% received transfusion independence. All patients with transfusion independence exhibited normal or near-normal total hemoglobin levels with a median (min, max) unsupported total Hb of 11.4 (9.5, 14.8) g/dL at last follow-up. Long term studies support durable transfusion independence with up to 7 years of follow-up across all studies.

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

Clinical Discussion: Keith Hunsicker, PharmD, questioned if we are requiring a stem cell transplant before receiving the drug. Aubrielle Smith, PharmD, confirmed we would only require stem cell transplant for members with a matched family donor. 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: Zynteglo will be a medical benefit. It is recommended to add Zynteglo to the medical benefit cost share list. Zynteglo will require a prior authorization with the following criteria.

- Prescription written by a hematologist and/or stem cell transplant specialist **AND**
- Medical record documentation of age greater than or equal to 4 years and less than or equal to 50 years **AND**
- Medical record documentation of a diagnosis of transfusion dependent beta-thalassemia **AND** one of the following:
    - Medical record documentation of a history of ≥ 100 mL/kg/year of packed red blood cells in the prior 2 years **OR**
    - Medical record documentation of a history of ≥ 8 transfusions of packed red blood cells per year in the prior 2 years **AND**
- Medical record documentation that the member has not had a prior hematopoietic stem cell transplant **AND**
- Medical record documentation the member is a candidate for a hematopoietic stem cell transplant but ineligible due to absence of Human Leukocyte Antigen (HLA)-matched family donor* **AND**
- Medical record documentation that the member has a negative serology test for Human Immunodeficiency Virus (HIV)

Authorization Duration: One (1) time approval per lifetime; Requests for authorizations exceeding these limits will require the following medical record documentation of peer-reviewed literature citing well-designed clinical trials to indicate that the member's healthcare outcome will be improved by dosing beyond the FDA-approved treatment duration.

*Note to reviewer: The package insert recommends confirming that hematopoietic stem cell transplantation (HSCT) is appropriate prior to Zynteglo since patients will be going through similar

steps (mobilization, apheresis, and myeloablative) required for a HSCT. However, the clinical trials excluded patients who had a known and available HLA-matched family donor. Considering that HSCT has been available for longer and has more evidence supporting its use, it may be appropriate to require HSCT as an alternate to Zynteglo. While it is possible for patients to have a matched unrelated donor, outcomes are best with matched related donors.

RPh Sign Off: Yes

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

XELSTRYM (dextroamphetamine)

Review: Xelstrym is the first FDA approved dextroamphetamine patch indicated for ADHD and approved for use in children and adults aged 6 years and older. However, there are no studies available which demonstrated safety for use in adults aged 65 years and up. Because of this, it is recommended to start at the lowest effective dose in this population and titrate slowly to effect. Xelstrym is formulated in four strengths that include 4.5 mg/9hr, 9 mg/9hr,13.5mg/9hr and 18mg/9hr. In studied populations, it is recommended to titrate dose by 4.5mg/9hr weekly to a maximum dose of 18mg/9h. The starting dose for children and adolescents aged 6-17 years is 4.5 mg/9hr while for adults, the starting dose is 9mg/9hr. Application of Xelstrym patch should be applied 2 hours before effect of stimulant is needed and removed within 9 hours as the patch provides an additional 3 hours of effect after the patch is removed. Application sites include hip, upper arm, chest, upper back, or flank. It is recommended to rotate sites for each new application of patch.

Efficacy of Xelstrym was established by using data from comparative bioavailability studies between Lisdexamfetamine (Vyvanse) and Xelstrym, and via a single clinical trial. Per pharmacokinetic bridging during bioavailability studies between Lisdexamfetamine and Xelstrym, the concentrations of maximum dose Xelstrym at 18 mg/9hr were within the approved concentration range of Lisdexamfetamine 30-70mg, indicating the maximum effective dose of Xelstrym may be effective. The clinical trial comparing Xelstrym to placebo involved a 5-week dose optimization phase for patients aged 6-17 years that met the diagnostic criteria for ADHD DSM-IV-TR. Information on criteria and limitations determining dose optimization per monitored participant during the 5 weeks could not be identified and was not noted. Treatment sequences for cross-over during the study included 1) Xelstrym (optimized dose) followed by placebo, each for one week, or 2) placebo followed by Xelstrym (optimized dose), each for one week. Efficacy was assessed at the end of each week using the Swanson, Kotkin, Agler, M. Flynn, and Pelham (SKAMP) total score, a validated 13-item rating scale to assess manifestations of ADHD in a classroom setting. Items are specific to place (classroom setting) and time (during a typical classroom period), and the scale is used to assess multiple ratings taken within a day. Efficacy was solely based on data from Period 1, which was the first week of the two-week double-blind, placebo-controlled, crossover treatment phase. A statistically significant separation from placebo was observed with use of Xelstrym.

Contraindications to Xelstrym include use of MAOI within 14 days of use and hypersensitivity reactions to amphetamine products. Application site reactions and skin reactions can occur as well. Several warnings and precautions exist which include potential for abuse and dependence, cardiovascular reactions, blood pressure and heart rate increases, psychiatric exacerbations or onset, suppression of growth in pediatric patients' peripheral vascular issues as wells as serotonin syndrome.

Adverse events for Xelstrym include >2% incidence in children aged 6-17 include decreased appetite, headache, insomnia, tic, abdominal pain, vomiting, nausea, irritability, blood pressure increased, and heart rate increased. Since safety data was bridged based on pharmacokinetic data from both Vyvanse and Adderall XR adverse effects were cross-referenced from these two drugs as well to include >5% incidence in adults Most common adverse reactions (incidence ≥5% and at a rate at least twice placebo)

in adults treated with Lisdexamfetamine were decreased appetite, insomnia, dry mouth, diarrhea, nausea, and anxiety.

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: Xelstrym is a pharmacy benefit and is will not to be added to the Commercial/Exchange/CHIP formularies. It will require a prior authorization and the following criteria will apply under the current Commercial Policy 94.0 Stimulants for ADHD.

- 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 Methylphenidate CD (generic Metadate CD) AND amphetamine/dextroamphetamine SR combination

Medispan Authorization Level: GPI-12

Quantity Limit: 1 patch per day

Formulary Alternatives: dextroamphetamine, dextroamphetamine/amphetamine combination, dextroamphetamine/amphetamine SR combination, methylphenidate, methylphenidate sustained-release, methylphenidate extended-release, Metadate CD, guanfacine ER, atomoxetine

Require RPH Sign off: Yes

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

UPDATES

EMGALITY PROVIDER UPDATE

Background: At December 2022 P&T, it was recommended to remove the prescriber requirement for migraines from the Commercial/Exchange/CHIP policy 533.0 for rebate purposes. Emgality is also indicated for episodic cluster headache, and it requires that Emgality is prescribed by or in consultation with a neurologist or headache specialist. In order to secure the rebates, we need to remove the prescriber requirement from the episodic cluster headache section of the policy as well. Most patients will be seen by neurologist for episodic cluster headaches and our additional criteria will prevent inappropriate use.
Recommendation: It is recommended to remove the prescriber requirement for Emgality Policy 533.0 under section "Episodic Cluster Headache". There will be no changes to authorization duration and quantity limits.

- ~~Medical record documentation that Emgality is prescribed by or in consultation with a neurologist or headache specialist 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.

EMGALITY, AJOVY, AND AIMOVIG QL UPDATE

Background: The recommended dose of Aimovig is 70 mg or 140 mg once monthly. Aimovig is supplied as 70 mg/mL in a prefilled autoinjector or prefilled syringe and 140 mg/mL autoinjector. The current quantity limit is 1 mL per 30 days.

The recommended dose of Emgality is 240 mg as a single dose and 120 mg once monthly for migraine. The recommended dose of Emgality is 300 mg once monthly for cluster headache. It is supplied as 120 mg/mL prefilled syringe and auto-injector and 100 mg/mL prefilled syringe. The current quantity limit is 1 mL per 30 days for the 120 mg/mL strength and 3 mL per 30 days for the 100 mg/mL strength.

The recommended dose of Ajovy 225 mg monthly or 675 mg every 3 months. Ajovy is available as 225 mg/1.5 mL prefilled syringe and auto-injector. The current quantity limit is 0.05 mL per day.

Occasionally, providers write prescriptions for 1 injection every 28 days (4 weeks). If a claim is billed for 1 injection per 28 days, it will deny due to the current quantity limits. Since the recommended dose is "once per month" for all medications, it is recommended to update the quantity limit to 1 injection per 28 days for Aimovig, Emgality, and Ajovy.

Recommendation:

Aimovig: It is recommended to update the quantity limit to 1 mL per 28 days for all strengths.

Emgality:

- For 100 mg/mL: It is recommended to update the quantity limit to 3 mL per 28 days.
- For 120 mg/mL: It is recommended to update the quantity limit to 1 mL per 28 days.

Ajovy: It is recommended to update the quantity limit to 1.5 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.

NULOJIX (belatacept)

Background: It is recommended to update the criteria for use of the Nulojix policy MBP 93.0 with the addition of policy criteria and one note. The update to the Nulojix policy is intended to capture clinical scenarios when an immunosuppressive agent other than mycophenolate is being used in combination with Nulojix. The update is also intended to capture the medically accepted off label use of conversion from a calcineurin inhibitor to Nulojix.

Recommendation:
MBP 93.0 Nulojix (belatacept)
Nulojix (belatacept) will be considered medically necessary for the prophylaxis of organ rejection in adult patients with:

- Physician provided documentation of kidney transplant; **AND**
- Documentation of Epstein-Barr virus (EBV) seropositivity; **AND**
- ~~Documentation of planned use in combination with basiliximab induction, mycophenolate, and corticosteroids~~
- Documentation of planned use in combination with a complete immunosuppressive regimen including basiliximab induction (for patients new to immunosuppressive therapy), corticosteroids, AND mycophenolate (or other immunosuppressant such as azathioprine, everolimus, or sirolimus)

AUTHORIZATION DURATION: Initial approval will be for 1 year or less if the reviewing provider feels it is medically appropriate. Subsequent approvals will be for an additional 1 year or less if the reviewing provider feels it is medically appropriate and will require medical record documentation of continued use in combination with mycophenolate (or other immunosuppressant such as azathioprine, everolimus, or sirolimus) & corticosteroids, lack of organ rejection, and lack of toxicity. The medication will no longer be covered if patient discontinues mycophenolate(or other immunosuppressant such as azathioprine, everolimus, or sirolimus) and/or corticosteroids, experiences toxicity, or symptoms of organ rejection.

LIMITATIONS:

- Nulojix® (belatacept) is contraindicated in transplant recipients who are EBV seronegative or are of unknown serostatus.
- Nulojix® (belatacept) is contraindicated for all transplants other than kidney.

NOTE: According to Lexi-Drugs, phase 2 and 3b randomized controlled trials showed that patients 6 to 60 months post kidney transplant can be safely converted from a calcineurin inhibitor to Nulojix. Patients had stable kidney function (eGFR 30 to 75 mL/minute/1.73 m^2) or absence of proteinuria (≤500 mg/day in diabetic patients or ≤1,000 mg/day in nondiabetic patients) for at least 3 months without a history of rejection. In clinical trials, mycophenolate or other immunosuppressant was continued in combination with Nulojix.

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.

TEZSPIRE (tezepelumab)

Background: Tezspire is now available as a 210 mg/1.91 mL (110 mg/mL) single-dose prefilled pen that is able to be administered by patients or caregivers in addition to healthcare providers. The previous formulations of Tezspire [210 mg/1.91 mL (110 mg/mL) vials and pre-filled syringes] can only be administered by healthcare professionals. There are no changes to the dosage for the new formulation.

Recommendation: Tezspire Prefilled Pen is a pharmacy benefit and will be added to the Specialty tier or Brand NP tier for Commercial, Marketplace, and GHP Kids. The following prior authorization criteria will apply:

- Medical record documentation that prescription is written by or in consultation with an allergist, immunologist, or pulmonologist **AND**
- Medical record documentation of age greater than or equal to 12 years **AND**
- Medical record documentation of severe asthma **AND**
- Medical record documentation that Tezspire will be used as an add-on maintenance treatment **AND**
- Medical record documentation of one of the following:
    - Poor control or intolerance, despite a 3 month trial of: medium –high dose inhaled corticosteroids and another controller medication (long-acting beta agonists, long-acting muscarinic antagonist, or leukotriene receptor antagonists) with or without oral corticosteroids **OR**
    - Two or more asthma exacerbations requiring systemic corticosteroid treatment or one asthma exacerbation resulting in hospitalization in the past 12 months despite current therapy to medium- high inhaled corticosteroids and another controller medication (long-acting beta agonists, long-acting muscarinic antagonist, or leukotriene receptor antagonists)

AND

- Medical record documentation that Tezspire will not be used in combination with another biologic medication indicated for asthma treatment (e.g. Xolair, Nucala, Fasenra, Dupixent, Cinqair)

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 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.

Quantity Limit: 1.91 mL (210 mg) every 28 days

Discussion: No comments or questions.

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

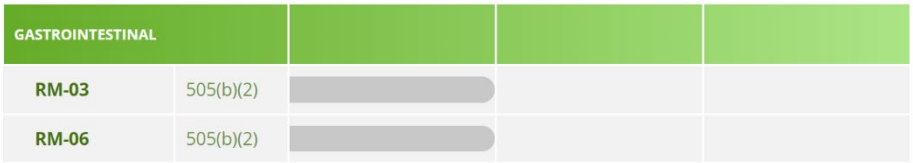
Additional evidence of the criteria used to make this decision can be found in the drug review presented to the committee.

FIRST COMPOUNDING KITS UPDATE

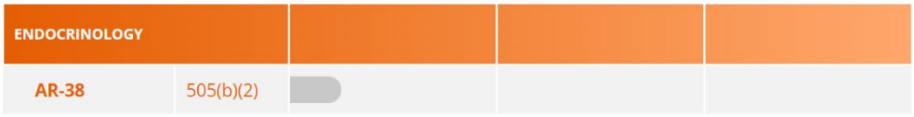
Background: First Omeprazole and First Vancomycin are being utilized at the health system pharmacies and we wanted to review First compounding kits to see if they should be added to Geisinger Health Plan coverage.

- Omeprazole
    - There is an FDA approved product (from the same manufacturer, Azurity) to be available in Q1 of 2023. (https://konvomep.com)

    - If this product follows the same pattern seen with the baclofen first kit product, the first kit product will become discontinued when the commercial product becomes available.
        - Additionally, per FDAMA, we won't be able to enforce that we only cover the hand compounded product vs a commercially available product.
- **Metronidazole**
    - There is no other FDA approved product available.
    - After cross checking Azurity's pipeline product page, it does not appear they will have a commercially available product that will be released in the near future.
- **Mouthwash BLM**
    - There is no other FDA approved product available.
    - After cross checking Azurity's pipeline product page, it does not appear they will have a commercially available product that will be released in the near future.
    - Cost: $90 per kit for the 119 mL package size, $114 per kit for the 237 mL package size
- **Lansoprazole**
    - There is no other FDA approved product available.
    - There are two GI products in Azurity's pipeline



- **Progesterone**
    - There are commercial products and alternative agents available.
    - There is one Endocrinology product in Azurity's pipeline



Recommendation:

First Compounding Kit	Formulary Recommendation
Omeprazole	**Do not add**
Metronidazole	**Do not add**
Mouthwash BLM	**Add to non-preferred brand tier for Commercial/Exchange/CHIP/Medicaid**
Lansoprazole	**Do not add**
Progesterone	**Do not add**

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.

PPI UPDATE

Background: Recommend step-therapy with lansoprazole ODT before utilizing Tier 2 packets of esomeprazole, based on cost (Esomeprazole packets cost ~ $7.09 vs lansoprazole ODT cost ~ $3.54). Per Lexicomp lansoprazole information, orally disintegrating tablets: Should not be swallowed whole, broken, cut, or chewed. Place tablet on tongue; allow to dissolve (with or without water) until particles can

be swallowed. Orally-disintegrating tablets may also be administered via an oral syringe: Place the 15 mg tablet in an oral syringe and draw up ~4 mL water or place the 30 mg tablet in an oral syringe and draw up ~10 mL water. After tablet has dispersed, administer within 15 minutes. Refill the syringe with water (2 mL for the 15 mg tablet; 5 mL for the 30 mg tablet), shake gently, then administer any remaining contents.

Recommendation:

- **Dexlansoprazole DR Capsules:**
  - Medical record documentation of a contraindication to, intolerance to, or therapeutic failure on the maximal doses of omeprazole, pantoprazole, lansoprazole, rabeprazole, and esomeprazole ~~(in that order).~~
- **Esomeprazole, Nexium, Pantoprazole, & Prilosec Packets, Rabeprazole Sprinkle Capsules:** Create new policy for non-preferred PPIs with the following criteria:
  - Medical record documentation of therapeutic failure on, intolerance to, or contraindication to lansoprazole ODT **AND**
  - Medical record documentation of one of the following:
    - Medical record documentation that member has difficulty swallowing or has an NG tube **OR**
    - Medical record documentation of therapeutic failure on, intolerance to, or contraindication to two generic formulary alternatives (omeprazole capsules, pantoprazole tablets, lansoprazole capsules, esomeprazole capsules, or rabeprazole tablets), one of which must contain the same active ingredient as the product requested, if available
- **Lansoprazole ODT:** Remove PA from Marketplace.

Discussion: Keith Hunsicker, PharmD, asked about potentially keeping ST rather than PA for esomeprazole packets to potentially cut down on manual PAs. Dr. Hossler asked about if Peds GI was consulted as they use a lot of non-tablet/capsule formulations of PPIs. She suggested ensuring providers were appropriately educated on that various modalities of how Lansoprazole ODT could be given beyond dissolving in mouth. Leslie Shumlas, PharmD, responded that we can review with pediatric GI providers and bring back any needed changes. We can also consider adding a note to the policy that would include information about lansoprazole ODT being dissolved and given via syringe.

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.

MEDICAL BENEFIT POLICY UPDATE

Background: Policies were updated at the direction of DHS during PARP submission process.

Recommendation:

- **MBP 2.0 Synagis (palivizumab)**
  - Dosing beyond 5 consecutive doses will be reviewed on a case-by case basis based on CDC surveillance reports, state/local health department recommendations, and other current medical literature.
- **MBP 15.0 Zevalin (Ibritumomab tiuxetan (IDEC Y2B8))**
  - Zevalin® is approved for the treatment of patients with relapsed or refractory, low-grade or follicular B-cell non-Hodgkin's lymphoma (NHL) including patients with Rituxan (rituximab) refractory follicular non-Hodgkin's lymphoma, when **ALL of the following criteria are met:**
- **MBP 36.0 Abraxane (paclitaxel protein bound particles)**
  - Medical record documentation that the member has a baseline neutrophil count ~~>~~ greater than or equal to 1,500 cells/mm3 **AND**

- **MBP 180.0 Kanuma (sebelipase alfa)**
  - **QUANTITY LIMITS:**
    - **Rapidly progressing/Wolman disease (patients initially presenting within the first 6 months of life):** Kanuma will initially be approved for quantity sufficient for up to ~~3~~ 5 mg/kg once weekly. These requests should be approved for a total of 4 visits per month.
    - **Late onset/CESD:** Patients 4 years of age and older will be approved for ~~1~~ up to 3 mg/kg every other week. These requests should be approved for a total of 2 visits per month.

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.

QUARTERLY CASE AUDIT

The Quarterly Case Audit for 4th quarter 2022 was held on March 2nd, 2023. There were no formulary changes proposed at this meeting. We will continue to look for opportunities to create more drug specific policies at future quarterly case audit meetings.

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 3:46 pm.

The next bi-monthly scheduled meeting will be held on May 16th, 2023 at 1:00 p.m.

Meeting will be held virtually via phone/Microsoft Teams.