P&T Committee Meeting Minutes
Commercial/Marketplace/GHP Kids
January 18, 2022

Present (via Teams):	**Absent:**
Bret Yarczower, MD, MBA – Chair	Kristen Bender, Pharm.D.
Megan Ammon, Pharm.D.	Holly Bones, Pharm.D.
Emily Antosh, Pharm.D.	Kim Castelnovo
Jeremy Bennett, MD	Dean Christian, MD
Briana Blaisure, Pharm.D.	Michael Evans, RPh
Alyssa Cilia, RPh	Jason Howay, Pharm.D.
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	
Emily Hughes, Pharm.D.	
Keith Hunsicker, Pharm.D.	
Kelli Hunsicker, Pharm.D.	
Derek Hunt, Pharm.D.	
Phillip Krebs, R.EEG T	
Tyreese McCrea, Pharm.D.	
Perry Meadows, MD	
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.	
Travis Baughn (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 1:01 p.m., Tuesday, January 18, 2022.

Review and Approval of Minutes:
Dr. Bret Yarczower asked for a motion or approval to accept the November 16, 2021 and December 17, 2021 minutes as written. Minutes approved unanimously. None were opposed.

DRUG REVIEWS

BESREMI (ropeginterferon alfa-2b-njft)

Review: Besremi is a novel monopegylated, long-acting interferon which exhibits a cellular effect on polycythemia vera in the bone marrow by binding a transmembrane receptor termed interferon alfa receptor (IFNAR). Besremi is the first FDA-approved drug for the treatment of polycythemia vera that patients can take regardless of their treatment history and the first interferon therapy that is FDA approved for PV. NCCN Treatment guidelines have not been updated since the approval of Besremi but it may have a similar place in therapy to Peginterferon alfa-2a.

The safety and efficacy of Besremi were evaluated in the PEGINVERA study, a prospective, single-arm trial in 51 adult patients with polycythemia vera. Of the included patients, 16% were newly diagnosed, while 84% had known disease with a median duration of 2.2 years. One-third of patients were undergoing treatment with hydroxyurea (HU) upon study entry.

The median duration of treatment was 61 months and 53% of patients completed at least 60 months of treatment. The efficacy was evaluated by assessing complete hematological response (CHR) defined as hematocrit < 45% and no phlebotomy in the preceding 2 months, platelets ≤ 400 x 109L and leukocytes ≤ 10 x 109L, normal spleen size (longitudinal diameter ≤ 12 cm for females and ≤ 13 cm for males) assessed by ultrasound and absence of thromboembolic events.

In the treated population, the CHR was 61% (31/51) during the treatment period and median duration of response was 14.3 months. Of those achieving CHR, median time to first response was 7.8 months and it required 1.2 years of treatment for 50% of hydroxyurea-naïve patients and 1.4 years for 50% of patients with prior hydroxyurea use to achieve a CHR. A hematological response based on hematocrit, platelets, and leukocytes was achieved in 80% (41/51) of patients and median duration of response was 20.8 months.

Warnings and precautions include risk of life-threatening or fatal psychiatric reactions, endocrine toxicity, cardiovascular toxicity, decreased peripheral blood counts, hypersensitivity reactions, pancreatitis, colitis, pulmonary toxicity, ophthalmologic toxicity, hyperlipidemia, hepatotoxicity, renal toxicity, dental and periodontal toxicity, dermatologic toxicity, and embryo-fetal toxicity. In the pooled safety data of two open label trials of Besremi (PEGINVERA, PROUD/CONTINUATION PV), the most common adverse reactions were liver enzyme elevations, leukopenia, thrombocytopenia, arthralgia, fatigue, myalgia, and influenza-like illness. In the PEGINVERA study, serious adverse reactions were reported in 16% of patients, most commonly urinary tract infection, transient ischemic attack, and depression.

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

Clinical Discussion: Did we receive any specialist feedback on this review? Requested but nothing was received. 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: Besremi is a pharmacy benefit and will be added to the Specialty tier or Brand Non-Preferred tier for members with a three-tier benefit. The following prior authorization criteria will apply to new starts only:

- Medical record documentation that Besremi 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 polycythemia vera **AND**
- Medical record documentation of an inadequate response or intolerance to hydroxyurea

QUANTITY LIMIT: 2 mL per 28 days, 28 day supply per fill

RE-AUTHORIZATION CRITERIA (Commercial/Exchange/CHIP): Besremi will be configured as a prior authorization for new starts only. Besremi 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

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

NEXVIAZYME (avalglucosidase alfa-ngpt)

Review: Nexviazyme is indicated for the treatment of patients 1 year of age and older with late-onset Pompe disease (lysosomal acid alpha-glucosidase [GAA] deficiency). Once Pompe disease is suspected, diagnosis is confirmed by blood and genetic testing. Testing includes GAA enzyme activity in the blood and/or other tissue and genetic sequencing. The presence of two pathogenic variants in the GAA gene is sufficient to diagnose Pompe disease. However, some patients may only have one pathogenic variant. In 2015, the US Secretary of Health and Human Services (HSS) approved the recommendation to include GAA deficiency in the Recommended Uniform Screening Panel for newborns. The only other ERT available for Pompe disease is Lumizyme (alglucosidase alfa). Unlike Lumizyme, Nexviazyme was only approved for the treatment of LOPD.

Prior to Nexviazyme administration, consider pretreating with antihistamines, antipyretics, and/or corticosteroids. Nexviazyme must be reconstituted and diluted prior to use. Nexviazyme is administered as an IV infusion. Nexviazyme is supplied as a one 100 mg vial in a carton. For patients weighing ≥30 kg, the recommended dosage is 20 mg/kg (of actual body weight) every two weeks. For patients weighing < 30 kg, the recommended dosage is 40 mg/kg (of actual body weight) every two weeks.

Nexviazyme was studied in randomized, double-blind, multinational, multicenter trial & an open-label, long-term, follow-up phase for up to 5 years. The trial included 100 treatment-naïve patients with LOPD. To be included in the trial, patients had confirmed GAA enzyme deficiency from any tissue source and/or 2 confirmed GAA gene mutations. Patients were randomized in a 1:1 ratio based on baseline forced vital capacity (FVC), gender, age, and country to receive 20 mg/kg of Nexviazyme (n=51) or alglucosidase alfa (n=49) administered intravenously once every two weeks for 49 weeks. In the open-label, long-term, follow-up trial, patients in the alglucosidase alfa arm were switched to Nexviazyme treatment. The primary endpoint was the change in FVC (% predicted) in the upright position from baseline to Week 49. At Week 49, the least squares (LS) mean change in FVC (% predicted) for patients treated with Nexviazyme and alglucosidase alfa was 2.9% and 0.5%, respectively. The estimated treatment difference was 2.4% (95% CI: -0.1, 5.0) favoring Nexviazyme. The key secondary endpoint of Study 1 was the

change in total distance walked in 6 minutes (6-Minute Walk Test, 6MWT) from baseline to Week 49. At Week 49, the LS mean change from baseline in 6MWT for patients treated with Nexviazyme and alglucosidase alfa was 32.2 meters and 2.2 meters, respectively. The estimated treatment difference was 30 meters (95% CI: 1.3, 58.7) favoring Nexviazyme.

There are warnings for hypersensitivity reactions including anaphylaxis. Nexviazyme also has warnings for infusion-associated reactions. Patients susceptible to fluid overload, or those with acute underlying respiratory illness or compromised cardiac or respiratory function for whom fluid restriction is indicated may be at risk of serious exacerbation of their cardiac or respiratory status during Nexviazyme infusion. The most common adverse reactions (≥ 5%) were headache, fatigue, diarrhea, nausea, arthralgia, dizziness, myalgia, pruritus, vomiting, dyspnea, erythema, paresthesia, and urticaria. The safety and effectiveness have been established in pediatric patients 1 year of age and older.

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: Propose addition of Nexviazyme to site of care policy due to inclusion of other drugs in the class. Given that the clinical trials showed non-inferiority to Lumizyme in lighter patients, should we consider failure of Lumizyme? Need to confirm that ideal body weight is still appropriate for Lumizyme before recommending changes related to Lumizyme. Discussion with specialist will occur this evening and any changes will be brought back to P&T. No comments or questions. The committee unanimously voted to accept the recommendations as amended. None were opposed.

Outcome: Nexviazyme is a medical benefit. Nexviazyme will be added to the medical benefit cost share list when processed on the medical benefit. If processed at a specialty pharmacy, Nexviazyme will process at the Specialty tier or Brand Non-Preferred tier for members with a three tier benefit. Nexviazyme will also be added to the site of care policy. Nexviazyme will require a prior authorization with the following criteria:

- Medical record documentation of a diagnosis of late-onset Pompe disease supported by:
    - Acid alpha-glucosidase (GAA) assay performed on dried blood spots, skin fibroblasts or muscle biopsy **AND**
    - Genetic testing showing a mutation in the *GAA* gene **AND**
- Medical record documentation of a consultation with a metabolic specialist and/or biochemical geneticist **AND**
- Medical record documentation of age greater than or equal to 1 year **AND**
- Medical record documentation of baseline percent-predicted forced vital capacity (% FVC) and 6-minute walk test (6MWT) **AND**
- Medical record documentation that the member is receiving an appropriate dose* based on patient's weight **AND**
- Medical record documentation that Nexviazyme will not be used in combination with other enzyme replacement therapy (e.g., Lumizyme)

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

- Medical record documentation of improvement or stabilization in percent-predicted FVC and/or 6MWT **AND**

- Medical record documentation that the member is receiving an appropriate dose* based on patient's weight **AND**
- Medical record documentation that Nexviazyme will not be used in combination with other enzyme replacement therapy (e.g., Lumizyme)

***NOTE TO REVIEWING PHARMACIST:** For patients weighing ≥30 kg, the recommended dosage is 20 mg/kg (of actual body weight) every two weeks. For patients weighing < 30 kg, the recommended dosage is 40 mg/kg (of actual body weight) every two weeks.

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

REZUROCK (belumosudil)

Review: Rezurock is indicated for treatment of adult and pediatric patients 12 years and older with chronic graft-versus-host disease (chronic GVHD) after failure of at least two prior lines of systemic therapy. First line agents include corticosteroids and ruxolitinib. Patients can remain on supportive care therapies and prophylaxis/standard care systemic chronic GVHD therapies if stabilized for at least 2 weeks prior to initiation of Rezurock. Rezurock should be used in caution with other medications and renal/hepatic disease as it has not been formally studied at this time. Clinical trials have demonstrated reduction in disease activity and symptom severity reported by patients.

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: Rezurock is a pharmacy benefit and will be added to the Specialty tier or Brand Non-Preferred tier for members with a three-tier benefit. The following prior authorization criteria will apply:

- Medical record documentation that Rezurock 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) **AND**
- Medical record documentation of therapeutic failure of two or more prior lines of systemic therapy **AND**
- If request is for 200mg twice daily dosing, one of the following applies:
    - Medical record documentation that member is concurrently receiving a strong CYP3A4 inducer **OR**
    - If concurrently taking with a proton pump inhibitor (PPI), medical record documentation that treatment with a PPI is medically necessary **AND** medical record documentation of therapeutic failure on, intolerance to, or contraindication to a H2 blocker

QUANTITY LIMIT:

- 200mg once daily dosing: 1 tablet per day, 30-day supply per fill

- 200mg twice daily dosing: 2 tablets per day, 30-day supply per fill

AUTHORIZATION DURATION: Initial approval will be given for 6 months or less if the reviewing provider feels it is appropriate. Subsequent approvals will be for an additional 12 months or less if the reviewing provider feels it is medically appropriate and will require the following:

- Medical record documentation of 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 **AND**
- If request is for 200mg twice daily dosing, one of the following applies:
    - Medical record documentation that member is concurrently receiving a strong CYP3A4 inducer **OR**
    - If concurrently taking with a proton pump inhibitor (PPI), medical record documentation that treatment with a PPI is medically necessary AND medical record documentation of therapeutic failure on, intolerance to, or contraindication to a H2 blocker

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

SAPHNELO (anifrolumab-fnia)

Review: Saphnelo IV infusion 300mg over 30 minutes every 4 weeks can be clinically used in adult patients with symptomatic moderate to severe systemic lupus erythematosus (SLE) despite being on standard therapy regimens. Patients with severe active lupus nephritis, patients who had severe active central nervous system lupus, and who use other biological agents and cyclophosphamide (needed at least 5 half-live wash-out period prior to enrollment) should not be prescribed Saphnelo at this time. No other biologics or live/live-attenuated vaccines should be co-administered while prescribed Saphnelo. Saphnelo should be used in caution with other medications and renal/hepatic disease as it has not been formally studied at this time. Clinical trials have demonstrated reduction in disease activity including skin and joint involvement and reduction in OCS use.

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: Propose addition of Saphnelo to site of care policy due to inclusion of other drugs in the class. No comments or questions. The committee unanimously voted to accept the recommendations as amended. None were opposed.

Outcome: Saphnelo is a medical benefit. Saphnelo will be added to the medical benefit cost share list when processed on the medical benefit. If processed at a specialty pharmacy, Saphnelo will process at the Specialty tier or Brand Non-Preferred tier for members with a three tier benefit. Saphnelo will also be added to site of care policy. Saphnelo will require a prior authorization with the following criteria:

- Medical record documentation of age greater than or equal to 18 years **AND**
- Medical record documentation of moderate to severe systemic lupus erythematosus (SLE) **AND**
- Medical record documentation that member does not have active lupus nephritis or severe active central nervous system lupus **AND**

- Medical record documentation that Saphnelo is being prescribed by a rheumatologist **AND**
- Medical record documentation that member is concurrently receiving a stable treatment regimen with corticosteroids, antimalarials, or immunosuppressants **AND**
- Medical record documentation that member is not being used concurrently with other biologic agents, including B-cell-targeted therapies

QUANTITY LIMIT: 2 mL every 4 weeks

AUTHORIZATION DURATION: 12 months. Subsequent approvals will require the following:
- Medical record documentation showing a clinical benefit of one of the following: improvement in functional impairment, decrease in number of exacerbations since starting Saphnelo, decrease in the daily required dose of oral corticosteroids

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

SCEMBLIX (oritavancin)

Review: Scemblix is a tyrosine kinase inhibitor indicated for the treatment of adult patients with Philadelphia chromosome-positive chronic myeloid leukemia (Ph+ CML) in chronic phase (CP) who have a T315I mutation or who have been previously treated with two or more tyrosine kinase inhibitors (TKIs). Scemblix offers a unique mechanism of action compared to other tyrosine kinase inhibitors approved in CML and may help patients with CML overcome treatment resistance.

The efficacy of Scemblix in the treatment of Ph+ CML in chronic phase (Ph+ CML-CP) which was previously treated with two or more tyrosine kinase inhibitors was evaluated in ASCEMBL, a randomized, active-controlled, open label study which randomized patients 2:1 to receive Scemblix 40 mg twice daily (n=157) or bosutinib 500 mg once daily (n=76).

Patients treated with Scemblix had a statistically significant higher rate of major molecular response (BCR-ABL1IS $\leq 0.1\%$) compared to bosutinib (25% vs. 13%). Complete cytogenic response (0% of Ph+ metaphases in bone marrow aspirate with at least 20 examined) was also higher for patients treated with Scemblix compared to bosutinib. At 48 weeks, the MMR rate for patients treated with Scemblix was 29% compared to 13% for bosutinib. At median follow-up of 20 months, the median duration of response was not reached for patients with MMR at the time.

The efficacy of Scemblix in patients with Ph+ CMP-CP with the T315I mutation was evaluated in CABL001X2101, an open label study in 45 patients. Patients were tested for the T315I mutation with a qualitative p210 BCR-ABL mutation test using Sanger Sequencing. Patients received Scemblix 200 mg twice daily until unacceptable toxicity or treatment failure. MMR was achieved by 24 weeks in 42% (19/45) of patients. MMR was achieved by 96 weeks in 49% (22/45) of patients. The median duration of treatment was 108 weeks.

There are no black box warnings or contraindications for Scemblix. Warnings and precautions include myelosuppression, pancreatic toxicity, hypertension, hypersensitivity, cardiovascular toxicity, and embryo-fetal toxicity. During the ASCEMBL clinical trial, serious adverse reactions occurred in 15% of patients, including pyrexia, congestive cardiac failure, thrombocytopenia, and urinary tract infection. Two patients had a fatal adverse reaction, one with mesenteric artery thrombosis and one with ischemic stroke. The most common adverse reactions were upper respiratory infection and musculoskeletal pain.

The most common laboratory abnormalities that worsened from baseline were decreased platelets, neutrophils, and hemoglobin and increased triglycerides, creatine kinase, and alanine aminotransferase (ALT). Clinically relevant adverse reactions which occurred in < 10% of patients included cough, dyspnea, pleural effusion, dizziness, peripheral neuropathy, edema, pyrexia, vomiting, constipation, dyslipidemia, decreased appetite, pruritus, urticaria, lower respiratory tract infection, influenza, urinary tract infection, pneumonia, hemorrhage, arrhythmia (including electrocardiogram QT prolonged), palpitations, cardiac failure congestive, vision blurred, dry eye, hypothyroidism, and febrile neutropenia During CABL001X2101, serious adverse reactions occurred in 23% of patients, including abdominal pain, vomiting, pneumonia, musculoskeletal pain, headache, hemorrhage, constipation, arrythmia, and pleural effusion. The most common reactions included musculoskeletal pain, fatigue, nausea, rash, and diarrhea. Laboratory abnormalities were comparable to those observed during the ASCEMBL trial but also included increased lipase, amylase, bilirubin, and aspartate aminotransferase (AST). Clinically relevant adverse reactions were consistent with those in the ASCEMBL trial.

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: Concern about configuring this drug as a prior authorization for new starts only given the high cost with the T315I mutation dosing. Consider configuring the cost override to only allow the standard dosing. Consider adding something to criteria that dosing is appropriate? Final recommendation is to update 40 mg tablet quantity limit to 2 tablets per day. Will also add quantity limit exception criteria for members who appropriately need up to 10 tablets per day. No comments or questions. The committee unanimously voted to accept the recommendations as amended. None were opposed.

Outcome: Scemblix is a pharmacy benefit and will be added to the Oral Oncology Brand Non-preferred tier ($0 copay). The following prior authorization criteria will apply for new starts only:

- Medical record documentation that Scemblix 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 Philadelphia chromosome-positive chronic myeloid leukemia (Ph+ CML) in chronic phase (CP) **AND** one of the following:
    - Medical record documentation of previous treatment with two or more tyrosine kinase inhibitors (TKIs) **OR**
    - Medical record documentation of a T315I cell mutation

QUANTITY LIMIT:

- 20 mg tablets: 2 tablets per day, 30 day supply per fill
- 40 mg tablets: 10 tablets per day, 30 day supply per fill

RE-AUTHORIZATION CRITERIA: Scemblix will be configured as a prior authorization for new starts only. Scemblix 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

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

EPRONTIA (topiramate oral solution)

Review: Eprontia is indicated for initial monotherapy for the treatment of partial-onset or primary generalized tonic-clonic seizures in patients 2 years of age and older AND as adjunctive therapy for the treatment of partial-onset seizures, primary generalized tonic clonic seizures and seizures associated with Lennox Gastaut syndrome in patients 2 years of age and older AND as preventative treatment of migraine in patients 12 years and older.

The safety and efficacy of EPRONTIA are based on the relative bioavailability of EPRONTIA compared to topiramate sprinkle capsules in healthy subjects. Topiramate sprinkle capsules have comparable bioavailability to topiramate tablets. The studies described in the following subsections were conducted using topiramate tablets or sprinkle capsules. Topiramate was shown to be effective in adult and pediatric patients 2 years of age and older as monotherapy treatment of partial-onset or primary generalized tonic-clonic seizures and as adjunctive therapy for the treatment of partial-onset seizures, primary generalized tonic clonic seizures and seizures associated with Lennox Gastaut syndrome. Topiramate also demonstrated efficacy as migraine prophylaxis in patients 12 years of age and older.

The warnings and precautions with Eprontia are similar to that of other topiramate products and include acute myopia & secondary angle closure glaucoma syndrome, risk of visual field defects, oligohidrosis & hyperthermia, metabolic Acidosis, suicidal behavior/ideation, cognitive/neuropsychiatric adverse reactions, fetal toxicity, withdrawal risk, serious skin reactions (including SJS & TEN), hyperammonemia & encephalopathy, kidney stones and hypothermia with concomitant valproic acid use.

In clinical trials, the most common adverse reactions observed with topiramate in the adult population were paresthesia, weight loss, anorexia, dizziness, speed disorders/related speech problems, somnolence, nervousness, psychomotor slowing, abnormal vision, taste perversion, diarrhea, difficulty with memory, hypoesthesia, and nausea. In pediatric patients, the most common adverse reactions were fever, weight loss, fatigue and somnolence, paresthesia, upper respiratory tract infection, anorexia and abdominal pain. It was noted that the incidence some reactions was dose-related and greater at higher than recommended topiramate dosing. Laboratory test abnormalities were observed in both adult and pediatric patients, indicating a need for monitoring of lab values while patient is receiving topiramate therapy.

In trials using topiramate as monotherapy for epilepsy, 21% of the adult population and 14% of the pediatric population discontinued therapy due to adverse reactions. In trials for migraine prophylaxis, 25% of the patients in the adult population discontinued therapy due to adverse reactions

Antiepileptic drugs, carbonic anhydrase inhibitors, CNS depressants, oral contraceptives, HCTZ, pioglitazone, lithium, amitriptyline

Clinical Discussion: It was recommended that a quantity limit be added to allow up to 400 mg/day. No additional comments or questions. The committee unanimously voted to accept the recommendations as presented. None were opposed.

Financial Discussion: Consider putting a note in the policy regarding the ability to open and dose sprinkle capsules. No comments or questions. The committee unanimously voted to accept the recommendations as presented. None were opposed.

Outcome: Eprontia is a pharmacy benefit and will be added to the Brand Non-Preferred tier. The following prior authorization criteria will apply:

For Seizures:

- Medical record documentation of a diagnosis of partial onset seizures, primary generalized tonic-clonic seizures, or Lennox Gastaut syndrome **AND**
- Medical record documentation that members is ≥ 2 years of age **AND**
- Medical record documentation of one of the following:
    - Therapeutic failure on, intolerance to, or contraindication to three formulary alternatives, one of which must be topiramate IR tablets or topiramate IR sprinkle capsule **OR**
    - Medical record documentation of difficulty swallowing tablets AND therapeutic failure on, intolerance to, or contraindication to three formulary alternatives, one of which must be topiramate IR sprinkle capsules

For Migraine prophylaxis:

- Medical record documentation of a diagnosis of use for migraine prophylaxis **AND**
- Medical record documentation that members is ≥ 12 years of age **AND**
- Medical record documentation of one of the following:
    - Therapeutic failure on, intolerance to, or contraindication to three formulary alternatives, one of which must be topiramate IR tablets or topiramate IR sprinkle capsule **OR**
    - Medical record documentation of difficulty swallowing tablets AND therapeutic failure on, intolerance to, or contraindication to three formulary alternatives, one of which must be topiramate IR sprinkle capsules

QUANTITY LIMIT: 16 mL per day

NOTE: Topiramate IR sprinkle capsules may be opened and sprinkled over one teaspoon of soft food for immediate administration without chewing.

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

Prevnar 20 (Pneumococcal 20-valent Conjugate Vaccine) and Vaxneuvance (Pneumococcal 15-valent Conjugate Vaccine)

Review:

Prevnar 20

Prevnar 20 is a vaccine indicated for active immunization for the prevention of pneumonia and invasive disease caused by Streptococcus pneumoniae serotypes 1, 3, 4, 5, 6A, 6B, 7F, 8, 9V, 10A, 11A, 12F, 14, 15B, 18C, 19A, 19F, 22F, 23F, and 33F in adults 18 years of age and older. Prevnar 20 protects against 7 additional serotypes compared to Prevnar 13 (8, 10A, 11A, 12F, 15B, 22F, 33F). In October 2021, the Advisory Committee on Immunization Practices (ACIP) approved recommendations for Prevnar 20 and Vaxneuvance for adults 19 to 64 years with certain underlying medical conditions or risk factors and in all adults 65 years and older who have not received a pneumococcal conjugate vaccine or whose previous history is unknown.

Efficacy of Prevnar 20 is based in part on the efficacy of Prevnar 13 since the vaccines are manufactured similarly and contain 13 of the same polysaccharide conjugates. Study 1 was a randomized, active-

controlled, double blind non-inferiority study evaluating the immunologic non-inferiority of Prevnar 20 to Prevnar 13 and PPSV23 in pneumococcal vaccine naïve adults 18 years or older. Patients were enrolled in 1 of 3 cohorts based on the age of enrollment and were randomized to receive Prevnar 20 or control. Patients 60 years and older were randomly assigned (1:1) to receive Prevnar 20 followed 1 month later with saline placebo or Prevnar 13 followed 1 month later with PPSV23.

In adults 60 years and older, immune responses to all 13 matched serotypes elicited by Prevnar 20 were non inferior to Prevnar 13 one month after vaccination. Immune response to 6 out of 7 additional serotypes induced by Prevnar 20 were noninferior to the immune responses induced by PPSV23 one month after vaccination. The effectiveness of Prevnar in adult patients age 50 to 59 years and 18 to 49 years was inferred following comparison of the immune response to each of the 20 vaccine serotypes in each of the age groups to those in patients over 60 years of age

The efficacy of Prevnar 20 in adult patients who were previously vaccinated with a pneumococcal vaccine was evaluated in Study 6, an open label clinical trial in adults 65 years and older who were previously vaccinated with PPSV23 ($\geq$ 1 to $\leq$ 5 years prior to enrollment) , previously vaccinated with Prevnar 13 ($\geq$6 months prior to enrollment), or previously vaccinated with Prevnar 13 followed by PPSV23 (with PPSV23 vaccination $\geq$1 year prior to enrollment). Results showed that OPA GMTs in participants who received PPSV23 1 to 5 years prior to Prevnar 20 were diminished compared to OPA GMTs in participants who received Prevnar 13 at least 6 months previously and compared to OPA GMTs in participants who received Prevnar 13 followed by PPSV23, with the last PPSV23 dose given at least 1 year prior to Prevnar 20.

There are no black box warnings for Prevnar 20. Warnings include the risk of acute allergic reactions and a contraindication in patients with a severe allergic reaction to a component of Prevnar 20 or diphtheria toxoid and the risk of reduced immune response in patients with altered immunocompetence. The most common adverse reactions reported with Prevnar 20 include pain at injection site, muscle pain, fatigue, headache, and arthralgia and injection site swelling.

<u>Vaxneuvance</u>

Vaxneuvance is a vaccine indicated for active immunization for the prevention of invasive disease caused by Streptococcus pneumoniae serotypes 1, 3, 4, 5, 6A, 6B, 7F, 9V, 14, 18C, 19A, 19F, 22F, 23F and 33F in adults 18 years of age and older. Vaxneuvance protects against 2 additional serotypes compared to Prevnar 13 (22F, 33F). In October 2021, the Advisory Committee on Immunization Practices (ACIP) approved recommendations for Prevnar 20 and Vaxneuvance for adults 19 to 64 years with certain underlying medical conditions or risk factors and in all adults 65 years and older who have not received a pneumococcal conjugate vaccine or whose previous history is unknown. When Vaxneuvance is used, ACIP recommends it be followed with a dose of PPSV23.

The efficacy of Vaxneuvance was evaluated in Study 1, a double-blind, active comparator-controlled study in pneumococcal vaccine-naïve patients 50 years of age and older. Patients were randomized 1:1 to receive Vaxneuvance (n=604) or Prevnar 13 (n=601). The study demonstrated noninferiority for Vaxneuvance to Prevnar 13 for the 13 shared serotypes and statistically significant greater OPA GMTs compared to Prevnar 13 for the shared serotype 3 and the 2 unique serotypes (22F, 33F).

Study 3 was a double-blind, active comparator-controlled, descriptive study in pneumococcal vaccine-naïve adults 50 years of age and older. Patients were randomized to receive Vaxneuvance (n=327) or Prevnar 13 (n=325), followed by Pneumovax 23 one year later. Following Pneumovax 23 vaccination, OPA GMTs were numerically similar between the two vaccination groups for the 15 serotypes in Vaxneuvance.

Study 4 was a double-blind descriptive study in adult patients aged 18 to 49 years, including those at increased risk of developing pneumococcal disease. Patients were randomized to receive Vaxneuvance (n=1,135) or Prevnar 13 (n=380), followed by Pneumovax 23 six months later. Among those who received Vaxneuvance, 620 participants had one risk factor and 228 participants had two or more risk factors for pneumococcal disease. Following Pneumovax 23 vaccination, OPA GMTs were numerically similar between the two vaccination groups for the 15 serotypes in Vaxneuvance

Study 6 was a double-blind, randomized study in adult patients 50 years of age and older who were randomized to receive Vaxneuvance concomitantly with a seasonal inactivated quadrivalent influenza vaccine (n=600) or Vaxneuvance 30 days after receiving QIV (n=600). GMTs were evaluated 30 days after administration of QIV. Noninferiority was met for the comparison of GMTS for the 15 pneumococcal serotypes in VAXNEUVANCE and for the 4 influenza vaccine strains tested.

There are no black box warnings for Vaxneuvance. Warnings are consistent with other conjugated pneumococcal vaccines and include a contraindication in patients with a severe allergic reaction to a component of Vaxneuvance or diphtheria toxoid and the risk of reduced immune response in patients with altered immunocompetence. The safety profile of Vaxneuvance was similar when administered with or without inactivated quadrivalent influenza vaccine.

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: Prevnar 20 and Vaxneuvance will be covered as medical or pharmacy benefits and will not require a prior authorization. They will be covered as a preventive vaccine for a $0 copay. The following quantity and age limits should apply:

QUANTITY LIMIT: 0.5 mL per 999 days

AGE LIMIT: 19 years and older

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

CLASS REVIEWS

RITUXIMAB CLASS REVIEW

Rituxan:
Updated Indication (for Rituxan)[1]: Rituxan is now indicated for the treatment of pediatric patients aged 6 months and older with previously untreated, advanced stage, CD20-positive diffuse large B-cell lymphoma (DLBCL), Burkitt lymphoma (BL), Burkitt-like lymphoma (BLL) or mature B-cell acute leukemia (B-AL) in combination with chemotherapy.

Rituxan was previously indicated for adult patients with Non-Hodgkin's Lymphoma (NHL), adult patients with Chronic Lymphocytic Leukemia (CLL), Rheumatoid Arthritis (RA) in combination with methotrexate in adult patients with moderately-to severely-active RA who have inadequate response to one or more TNF antagonist therapies, Granulomatosis with Polyangiitis (GPA) (Wegener's Granulomatosis) and Microscopic Polyangiitis (MPA) in adult and pediatric patients 2 years of age and older in combination with glucocorticoids, and moderate to severe Pemphigus Vulgaris (PV) in adult patients.

Ruxience and Riabni:
Review: Ruxience and Riabni are biosimilar CD20-directed antibodies that are highly similar to the US-licensed reference product Rituxan, indicated for Non-Hodgkin's Lymphoma (NHL), Chronic Lymphocytic Leukemia (CLL), Rheumatoid Arthritis (RA), Granulomatosis with Polyangiitis (GPA) (Wegener's Granulomatosis) and Microscopic Polyangiitis (MPA) and Pemphigus Vulgaris (PV). Ruxience is the third and Riabni is the fourth FDA approved rituximab biosimilar, the first being Truxima (rituximab-abbs). None of the rituximab biosimilars are interchangeable with Rituxan.

REFLECTIONS B328-01 was a Phase 1 randomized, double-blind pharmacokinetic and pharmacodynamic study to assess the safety of Ruxience compared to rituximab-US/-EU in subjects with active RA on a background of methotrexate who had an inadequate response to one or more TNF antagonist therapies. This study demonstrated Ruxience, rituximab-EU and rituximab-US were similar in terms of PK and pharmacodynamics (PD). This study also concluded that the overall safety and immunogenicity profile of Ruxience was similar to rituximab-US and rituximab-EU.

REFLECTIONS B328-04 was a Phase 1 randomized, double-blind extension study of PF-05280586 to assess the safety of Ruxience compared to rituximab-US/-EU in subjects with active RA on a background of methotrexate and who had an inadequate response to one or more TNF antagonist therapies. This study demonstrated Ruxience, rituximab-US and rituximab-EU were similar in terms of PD and efficacy (measured by Disease Activity Score (DAS) and remission rates). This study also concluded that the overall safety and immunogenicity profile of Ruxience was similar to rituximab-US and rituximab-EU.

REFLECTIONS B328-06 was a Phase 3 randomized, double-blind study to assess Ruxience compared to rituximab-EU as first line treatment in subjects with CD20-positive, low tumor burden, Follicular Lymphoma. This study demonstrated Ruxience and rituximab-EU were similar in terms of efficacy (response rates) and PK. This study also concluded that the overall safety and immunogenicity profile of Ruxience was similar to rituximab-EU.

Study 20130108 was a randomized, double-blind, active-controlled, 3-arm similarity study to assess the PK and PD of Riabni compared to rituximab-US/-EU in subjects with moderate to severe RA. This study demonstrated that Riabni is clinically equivalent to the rituximab-US/-EU with no clinically meaningful

differences between the products in terms of PK and PD. This study also concluded that the overall safety and immunogenicity profile of Riabni was similar to the rituximab-US/-EU.

Study 20130109 was a randomized, controlled study to assess clinical equivalence of Riabni compared to rituximab-US in adult subjects with grade 1, 2, or 3a follicular CD20+ B cell NHL with low tumor burden. This study demonstrated Riabni is clinically equivalent to rituximab-US with no clinically meaningful differences between the products in terms of efficacy. This study also concluded that the overall safety and immunogenicity profile of Riabni was similar to rituximab-US.

The safety considerations of Ruxience and Riabni are consistent with those of the other rituximab reference and biosimilar products. Ruxience and Riabni carry the black box warnings of Rituxan and Truxima, including Infusion-related reactions, severe mucocutaneous reactions, Hepatitis B virus (HBV) reactivation and progressive multifocal leukoencephalopathy (PML). In clinical trials, there were no meaningful differences in safety between Ruxience and Rituxan as well as Riabni and Rituxan.

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: Ruxience and Riabni will be medical benefits. Ruxience and Riabni will be added to the medical benefit cost share list when processed on the medical benefit. If processed at a specialty pharmacy, Ruxience and Riabni will be processed on the Specialty tier or the Brand Non-preferred tier for members with a three-tier benefit. Because all rituximab biosimilar products offer clinically similar safety and efficacy while also offering significant cost savings, it is recommended that a biosimilar parity position be adopted as outlined below. Note: MBP 48.0 will require medical PA for Rituxan for diagnoses of CLL, NHL, or MS. The following prior authorization criteria will apply:

Rituxan (rituximab), ~~and~~ Truxima (rituximab-abbs), Ruxience (rituximab-pvvr) and Riabni (rituximab-arrx) will be considered medically necessary when all of the following criteria are met:

1. **For Rheumatoid Arthritis:**

All of the following criteria must be met:

- Physician documentation of a diagnosis of moderate to severe rheumatoid arthritis in accordance with the American College of Rheumatology Criteria for the Classification and Diagnosis of Rheumatoid Arthritis; **AND**
- At least 18 years of age or older; **AND**
- Prescription written by a rheumatologist; **AND**
- Medical record documentation that an effective dose of methotrexate will be continued during rituximab therapy; **AND**
- Medical record documentation that Rituxan is not being used concurrently with a TNF blocker **AND**
- Physician documentation of an inadequate response to 12 weeks of therapy with Humira*, Rinvoq*, OR Xeljanz*

AND

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

LIMITATIONS:
If criteria are met, approval will be limited to one course of therapy defined as two infusions, one given on day 1 and another on day 15.
Additional courses may be considered medically necessary if the following criteria are met:

- At least 6 months has elapsed since the previous treatment course; **AND**
- Physician documentation of improvement or lack or progression in the signs and symptoms of rheumatoid arthritis; **AND**
- Physician documentation showing previous treatment course did not result in active infection.

2. **For Chronic Immunothrombocytopenia (ITP):**

All of the following criteria must be met:

- Diagnosis of primary chronic ITP **AND**
- Platelet count of < 30,000/mm^3 with active bleeding; or platelet count < 30,000/mm^3 and a documented history of significant bleeding**;** or platelet count < 20,000/mm^3 ~~with increased risk of bleeding~~ **AND**
- Medical record documentation of therapeutic failure on, intolerance to, or contraindication to corticosteroids AND IVIg* AND splenectomy (*prior authorization required)

AND

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

Authorization Duration*: If patient meets criteria for coverage, authorization will be given for one month of treatment with rituximab.

3. **For Chronic Lymphoid Leukemia:**

Note: Prior authorization is not required for Ruxience, Riabni or Truxima for diagnosis codes C91.10, C91.11 and C91.12. In the event of a request for the rituximab reference product (i.e. Rituxan), OR in the event a requestor would like a medical necessity review completed, the following criteria would apply:

- Medical record documentation of a diagnosis of Chronic Lymphocytic Leukemia (CLL)

AND

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

4. **For Microscopic Polyarteritis Nodosa (PAN)**

- Medical record documentation of a diagnosis of microscopic polyarteritis nodosa used in combination with glucocorticoids

AND

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

5. **For Granulomatosis with Polyangiitis (GPA) *(Wegener's Granulomatosis)* and Microscopic Polyangiitis (MPA)**

- Medical record documentation of a diagnosis of Granulomatosis with Polyangiitis (GPA) (Wegener's granulomatosis) or Microscopic Polyangiitis (MPA) used in combination with glucocorticoids

AND

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

6. **For Non-Hodgkin Lymphoma**

Note: Prior authorization is not required for Ruxience, Riabni or Truxima for diagnosis codes C82.00 through C85.99 and C86.0 through C88.9. In the event of a request for the rituximab reference product (i.e. Rituxan),OR in the event a requestor would like a medical necessity review completed, the following criteria would apply:

- Medical record documentation of a diagnosis of Non-Hodgkin Lymphoma

AND

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

7. **For Multiple Sclerosis (MS)**

Note: Prior authorization is not required for Ruxience, Riabni or Truxima for diagnosis code G35. In the event of a request for the rituximab reference product (i.e. Rituxan), OR in the event a requestor would like a medical necessity review completed, the following criteria would apply:

- Medical record documentation of a diagnosis of Multiple Sclerosis

AND

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

8. **For Refractory Chronic Debilitating Myasthenia Gravis**

- Medical record documentation of refractory Chronic Debilitating Myasthenia Gravis **AND**
- Prescribed by or in consultation with a neuromuscular specialist **AND**
- Medical record documentation of therapeutic failure on, intolerance to, or contraindication to at least one corticosteroid **AND**
- Medical record documentation of therapeutic failure on, intolerance to, or contraindication to at least one cholinesterase inhibitor **AND**
- Medical record documentation of therapeutic failure on, intolerance to, or contraindication to at least one non-steroidal immunosuppressive therapy

AND

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

Note: Corticosteroids: betamethasone, dexamethasone, methylprednisolone, prednisone
Cholinesterase inhibitors: pyridostigmine, neostigmine
Immunosuppressants: azathioprine, mycophenolate, cyclosporine, Rituxan

9. **For Pemphigus Vulgaris (PV)**

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

AND

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

AUTHORIZATION DURATION:

For Multiple Sclerosis: 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.

For all other indications: Initial approval will be for 6 months or less if the reviewing provider feels it is medically appropriate (*except for the diagnosis for ITP). Subsequent approvals will be for an additional ~~6 months~~ 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.

FAST FACTS

BYDUREON BCise (exenatide extended-release)

Updated Indication: Bydureon BCise is now indicated as an adjunct to diet and exercise to improve glycemic control in adults and pediatric patients aged 10 years and older with Type 2 diabetes mellitus.

Previously, Bydureon BCise was only indicated as an adjunct to diet and exercise to improve glycemic control in adults with Type 2 diabetes mellitus.

Current formulary status: Non-preferred Brand, requiring step therapy, quantity limits apply

Recommendation: There are no changes recommended to the formulary placement or quantity limits of Bydureon BCISE. It is recommended to make the following changes to Commercial Policy 350.0 to incorporate the new patient population:

- Electronic step therapy of on-line prescription drug claims history showing 15 days use of Victoza **AND** Ozempic or Rybelsus, within the previous 180 days. If this electronic step is met, the claim will automatically adjudicate **OR**
- If electronic step therapy criteria are not met, prescribing provider should request an exception for coverage indication one of the following:
  - For members 18 years of age and older: Medical record documentation of a therapeutic failure on, intolerance to, or contraindication to Victoza **AND** either Ozempic or Rybelsus **OR**
  - For members between 10 and 18 years of age: Medical record documentation of a therapeutic failure on, intolerance to, or contraindication to Victoza

Discussion: If step edit by age is not configurable, Bydureon BCise should be moved to non-formulary with the above criteria. Leslie confirmed that the quantity limits are still appropriate. 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.

XYWAV (calcium/magnesium/potassium/sodium oxybates)

Updated Indication: Xywav is now indicated for the treatment of idiopathic hypersomnia (IH) in adult patients. Previously, Xywav was indicated for cataplexy or excessive daytime sleepiness (EDS) in patients 7 years of age and older with narcolepsy.

Current formulary status: Specialty tier or brand non-preferred tier for members with a three-tier benefit, PA required, QL

Xywav 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 excessive daytime sleepiness in a patient with narcolepsy or cataplexy with narcolepsy AND
- Medical record documentation of therapeutic failure on modafinil AND methylphenidate immediate release or amphetamine/dextroamphetamine immediate release AND
- Medical record documentation of one of the following:
    - Medical record documentation of therapeutic failure on, intolerance to, or contraindication to Xyrem OR
    - Medical record documentation the patient requires a low sodium diet due to a concomitant diagnosis of heart failure, hypertension, or renal impairment

OR

- Medical record documentation of a diagnosis of idiopathic hypersomnia AND
- Medical record documentation of an age greater than or equal to 18 AND
- Medical record documentation that member was evaluated and treated for other etiologies of excessive daytime sleepiness AND
- Medical record documentation of therapeutic failure on, intolerance to, or contraindication to modafinil

Discussion: No comments or questions.

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

- Medical record documentation of a diagnosis of obstructive sleep apnea/hypopnea syndrome requiring treatment with nasal CPAP OR
- Medical record documentation of a diagnosis of narcolepsy OR
- Medical record documentation of a diagnosis of shift-work disorder OR
- Medical record documentation of fatigue associated with a diagnosis of multiple Sclerosis OR
- Medical record documentation of a diagnosis of idiopathic hypersomnia

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.

MVASI (bevacizumab-awwb)

Updated Indication: Mvasi is a biosimilar for Avastin and recently received the following indications:

- Epithelial ovarian, fallopian tube, or primary peritoneal cancer:
    - in combination with carboplatin and paclitaxel, followed by MVASI as a single agent, for stage III or IV disease following initial surgical resection
    - in combination with paclitaxel, pegylated liposomal doxorubicin, or topotecan for platinum-resistant recurrent disease who received no more than 2 prior chemotherapy regimens
    - in combination with carboplatin and paclitaxel or carboplatin and gemcitabine, followed by MVASI as a single agent, for platinum-sensitive recurrent disease

Current formulary status: Tier 5 not requiring PA (Marketplace), Tier 3 not requiring PA (Commercial/CHIP) or medical benefit

Recommendation: No changes are recommended.

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.

JARDIANCE (empagliflozin)

Updated Indication: Jardiance is now indicated to reduce the risk of cardiovascular mortality plus hospitalization for heart failure in adults with heart failure and reduced ejection fraction.

Previously, Jardiance was only indicated as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes and to reduce the risk of hospitalization for heart failure in adults with type 2 diabetes mellitus and established cardiovascular disease or multiple cardiovascular risk factors.

Current formulary status: Brand preferred, QL

Jardiance Recommendation: No changes are recommended for the formulary placement or quantity limits for Jardiance.

Farxiga Recommendation: Since Farxiga also has the approved indication for use in heart failure, recommend the following update to the commercial Farxiga policy, policy 328.0:

Heart Failure

- Medical record documentation of a diagnosis of New York Heart Association (NYHA) class II-IV heart failure **AND**
- Medical record documentation of age greater than or equal to 18 years **AND**
- Medical record documentation of reduced ejection fraction (left ventricular ejection fraction (LVEF) of less than or equal to 40%) **AND**
- Medical record documentation that the member is on optimized pharmacological therapy (e.g. combination of renin-angiotensin system inhibitor (ACEi/ARB/angiotensin receptor-neprilysin inhibitor), evidence based beta-blocker (metoprolol succinate/carvedilol/bisoprolol), and a mineralocorticoid receptor antagonist, diuretic) unless contraindication or not tolerated A**ND**
- Medical record documentation of therapeutic failure on, intolerance to, or contraindication to Jardiance

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.

LEXETTE (halobetasol propionate topical foam)

Updated Indication: Lexette is a corticosteroid indicated for the topical treatment of plaque psoriasis in patients twelve (12) years of age and older.

Previously Lexette was indicated in patients eighteen years of age and older.

Current formulary status: Non-formulary

Recommendation: No changes are recommended.

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 now indicated:

- For the adjuvant treatment of adult and pediatric (12 years and older) patients with Stage IIB, IIC, or III melanoma following complete resection. (Previously this was indicated for adult patients with melanoma with lymph node involvement following complete resection).
- For the adjuvant treatment of patients with RCC at intermediate-high or high risk of recurrence following nephrectomy or following nephrectomy and resection of metastatic lesions.

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

Recommendation: There are no changes to the formulary placement of Keytruda. The following changes are recommended to the prior authorization criteria and authorization duration in the Medical Benefit Policy 119.0 for Keytruda to incorporate the new indications:

1. **Melanoma**
   - Prescription written by a hematologist/oncologist **AND**
   - Medical record documentation of one of the following:

   Unresectable or metastatic melanoma:
     - Medical record documentation that patient is ≥ 18 years of age **AND**
     - A diagnosis of unresectable or metastatic melanoma **AND**
     - Keytruda is not being used in combination with any other agents for the treatment of unresectable or metastatic melanoma.

OR

Adjuvant treatment of completely resected ~~metastatic~~ melanoma
   - Medical record documentation that patient is ≥ 12 years of age **AND**

- A diagnosis of ~~metastatic~~ Stage IIB, IIC, or III melanoma with ~~lymph node involvement~~, which has been completely resected **AND**
- Keytruda is being used in the adjuvant setting (following lymph node resection) **AND**
- Keytruda is being used as a single agent.

12. **Renal Cell Carcinoma (RCC)**
    - Prescription written by a hematologist/oncologist **AND**
    - Medical record documentation that patient is ≥ 18 years of age **AND**
    - Medical record documentation of one of the following:

Advanced Renal Cell Carcinoma:

- Medical record documentation of a diagnosis of advanced renal cell carcinoma **AND**
- Medical record documentation that Keytruda is being used in combination with axitinib (Inlyta) OR lenvatinib (Lenvima) **AND**
- Medical record documentation that Keytruda in combination with axitinib (Inlyta) OR lenvatinib (Lenvima) is being used as first-line treatment for advanced disease

Note: In clinical trials, advanced disease included newly diagnosed or recurrent Stage IV renal cell carcinoma.

Adjuvant treatment of renal cell carcinoma

- A diagnosis of renal cell carcinoma AND
- Documentation of intermediate-high or high risk of recurrence following nephrectomy, or following nephrectomy and resection of metastatic lesions AND
- Keytruda is being used in the adjuvant setting AND
- Keytruda is being used as a single agent.

Note: In clinical trials, intermediate-high risk category included: pT2 with Grade 4 or sarcomatoid features; pT3, any Grade without nodal involvement (N0) or distant metastases (M0); and high risk included: pT4, any Grade N0 and M0; any pT, any Grade with nodal involvement and M0. The M1 no evidence of disease (NED) category includes patients with metastatic disease who had undergone complete resection of primary and metastatic lesions.

AUTHORIZATION DURATION:
For adjuvant treatment of metastatic melanoma (completely resected melanoma), neoadjuvant/adjuvant treatment of early-stage triple negative breast cancer, and adjuvant treatment of renal cell carcinoma: Initial approval will be for 6 months. One subsequent approval will be for an additional 6 months and will require medical record documentation of continued disease improvement or lack of disease progression. The medication will no longer be covered if patient experiences toxicity or worsening of disease.

Authorization of Keytruda for the adjuvant treatment of metastatic melanoma and renal cell carcinoma should not exceed the FDA-approved treatment duration of 1 year (12 months). Authorization of Keytruda for the treatment of early-stage triple negative breast cancer should not exceed the approved treatment duration of 24 weeks for neoadjuvant therapy and 27 weeks for adjuvant therapy. For requests exceeding the above limit, medical record documentation of the following is required:

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

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.

KYPROLIS (carfilzomib)

Updated Indication: Kyprolis is also indicated for the treatment of adult patients with relapsed or refractory multiple myeloma who have received one to three lines of therapy in combination with daratumumab and hyaluronidase-fihj and dexamethasone. Previously, it was only indicated in combination with lenalidomide and dexamethasone; or dexamethasone; or daratumumab and dexamethasone. Also, Kyprolis is indicated as a single agent for the treatment of patients with relapsed or refractory multiple myeloma who have received one or more lines of therapy.

Current formulary status: Kyprolis is a medical benefit and requires a prior authorization. If Kyprolis processes through a specialty pharmacy, it will process at the Specialty tier or the Brand Non-Preferred tier for members with a three tier benefit.

Recommendation: There are no changes to formulary status or authorization duration at this time. However, it is recommended to update the criteria to included the updated FDA-indication:
Multiple Myeloma:

- Must be prescribed by hematologist or oncologist **AND**
- Medical record documentation of relapsed or refractory multiple myeloma **AND**
- Medical record documentation of prior treatment with at least one therapy **AND**
- Medical record documentation that Kyprolis will be used:
    - As monotherapy **OR**
    - In combination with dexamethasone **OR**
    - In combination with dexamethasone and lenalidomide **OR**
    - In combination with daratumumab (Darzalex) and dexamethasone **OR**
    - In combination with daratumumab and hyaluronidase-fihj (Darzalex Faspro) and dexamethasone

Discussion: Is the requirement of prior therapy in the relapsed or refractory setting or can the failure be the first line? FDA indications statements patients should have failed one to three prior therapies. Agreement from committee that it is failure of only one required. 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.

DARZALEX FASPRO (daratumumab and hyaluronidase-fihj)

Updated Indication: Darzalex Faspro is now indicated for multiple myeloma in combination with carfilzomib and dexamethasone in patients with relapsed or refractory multiple myeloma who have received one to three prior lines of therapy.

Darzalex Faspro was previously indicated for the treatment of adult patients with multiple myeloma:

- in combination with bortezomib, melphalan and prednisone in newly diagnosed patients who are ineligible for autologous stem cell transplant (ASCT)
- in combination with lenalidomide and dexamethasone in newly diagnosed patients who are ineligible for autologous stem cell transplant and in patients with relapsed or refractory multiple myeloma who have received at least one prior therapy
- in combination with bortezomib, thalidomide, and dexamethasone in newly diagnosed patients who are eligible for autologous stem cell transplant
- in combination with bortezomib and dexamethasone in patients who have received at least one prior therapy
- in combination with pomalidomide and dexamethasone in patients who received at least one prior line of therapy including lenalidomide and proteasome inhibitor
- as monotherapy, in patients who have received at least three prior lines of therapy including a proteasome inhibitor (PI) and an immunomodulatory agent or who are double-refractory to a PI and an immunomodulatory agent

Darzalex Faspro was also previously indicated in combination with bortezomib, cyclophosphamide and dexamethasone for the treatment of adult patients with newly diagnosed light chain (AL) amyloidosis.

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

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

- Prescription written by a hematologist/oncologist **AND**
- Medical record documentation a diagnosis of multiple myeloma **AND**

If newly diagnosed multiple myeloma (transplant ineligible):

- Medical record documentation that the member is not eligible for stem-cell transplantation (e.g. coexisting conditions, age greater than 65, etc.) **AND**
- Medical record documentation that Darzalex Faspro will be given in combination with one of the following options:
    - Bortezomib (Velcade), melphalan, AND prednisone [VMP] **OR**
    - Lenalidomide (Revlimid) **AND** dexamethasone

OR

If newly diagnosed multiple myeloma (transplant eligible):

- Medical record documentation that the member is eligible for stem-cell transplantation **AND**
- Medical record documentation that Darzalex Faspro will be given in combination with bortezomib (Velcade), thalidomide, and dexamethasone (DVTd)

OR

If **relapsed/refractory multiple myeloma:**

- One of the following:
    - Medical record documentation of therapeutic failure on, intolerance to, or contraindication to at least three prior lines of therapy including a proteasome inhibitor (including but not limited to Velcade*, Kyprolis*, or Ninlaro*) and an immunomodulatory agent (including but not limited to Pomalyst*, Revlimid*, Thalomid*) **OR**
    - Medical record documentation that the patient is double-refractory to a proteasome inhibitor (including but not limited to Velcade*, Kyprolis*, or Ninlaro*) and an immunomodulatory agent (including but not limited to Pomalyst*, Revlimid*, Thalomid*) **OR**

- Medical record documentation of therpaeutic failure on, intolerance to, or contraindication to at least one prior line of therapy including lenalidomide and a proteasome inhibitor (including but not limited to Velcade*, Kyprolis*, or Ninlaro*) **AND** Darzalex Faspro will be prescribed in combination with pomalidomide and dexamethasone **OR**
- Medical record documentation of therapeutic failure on, intolerance to, or contraindication to at least 1 prior therapy including a proteasome inhibitor (including but not limited to Velcade*, Kyprolis*, or Ninlaro*) or an immunomodulatory agent (including but not limited to Pomalyst*, Revlimid*, Thalomid*) **AND** one of the following:
  - Medical record documentation that Darzalex Faspro will be prescribed in combination with lenalidomide and dexamethasone **OR**
  - Medical record documentation that Darzalex Faspro will be prescribed in combination with bortezomib and dexamethasone **OR**
  - Medical record documentation that Darzalex Faspro will be prescribed in combination with carfilzomib (Kyprolis) and dexamethasone

OR

If light-chain (AL) amyloidosis:

- Prescription written by or in consultation with and hematologist/oncologist **AND**
- Medical record documentation of a diagnosis of light-chain (AL) amyloidosis **AND**
- Medical Record documentation that the patient does NOT have New York Heart Association (NYHA) Class IIIB (as defined by slight limitation during daily living activity and comfortable at rest) or Class IV heart failure, or mayo cardiac stage IIIB* **AND**
- Medical record documentation that Darzalex Faspro will be used in combination with bortezomib, cyclophosphamide and dexamethasone

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

DUPIXENT

Discussion: It is recommended to update the quantity limits for all of the Dupixent indications to make sure all dosing options are accounted for. The labeling includes the following dosing:

Atopic Dermatitis

Dosage in Adults

- Recommended dosage is an initial dose of 600 mg (two 300 mg injections), followed by 300 mg given every other week (Q2W). (2.3)

Dosage in Pediatric Patients (6 to 17 Years of Age)

Body Weight	Initial Loading Dose	Subsequent Doses[a]
15 to less than 30 kg	600 mg (two 300 mg injections)	300 mg Q4W
30 to less than 60 kg	400 mg (two 200 mg injections)	200 mg Q2W
60 kg or more	600 mg (two 300 mg injections)	300 mg Q2W

[a] Q2W – every other week; Q4W – every 4 weeks

Asthma

Dosage in Adult and Pediatric Patients 12 Years and Older

Initial Loading Dose	Subsequent Dose
400 mg (two 200 mg injections)	200 mg every 2 weeks (Q2W)
or	
600 mg (two 300 mg injections)	300 mg every 2 weeks (Q2W)
Dosage for patients with oral corticosteroid-dependent asthma or with co-morbid moderate-to-severe atopic dermatitis or adults with co-morbid chronic rhinosinusitis with nasal polyposis	
600 mg (two 300 mg injections)	300 mg every 2 weeks (Q2W)

Dosage in Pediatric Patients 6 to 11 Years of Age

Body Weight	Initial Dose and Subsequent Doses
15 to less than 30 kg	100 mg every other week (Q2W) or 300 mg every four weeks (Q4W)
≥30 kg	200 mg every other week (Q2W)

Recommendation: It is recommended to update the quantity limits for all indications. Also, it is recommended to add the following criteria for all indications to the initial and re-authorization criteria in the Dupixent policy:

…. "Medical record documentation that the member is receiving an appropriate dose* based on patient's age and weight"

*Note to the reviewing pharmacists: See the chart below for the Dupixent dose recommendations.

Atopic Dermatitis

Dosage in Adults

- Recommended dosage is an initial dose of 600 mg (two 300 mg injections), followed by 300 mg given every other week (Q2W). (2.3)

Dosage in Pediatric Patients (6 to 17 Years of Age)

Body Weight	Initial Loading Dose	Subsequent Doses[a]
15 to less than 30 kg	600 mg (two 300 mg injections)	300 mg Q4W
30 to less than 60 kg	400 mg (two 200 mg injections)	200 mg Q2W
60 kg or more	600 mg (two 300 mg injections)	300 mg Q2W

[a] Q2W – every other week; Q4W – every 4 weeks

Asthma

Dosage in Adult and Pediatric Patients 12 Years and Older

Initial Loading Dose	Subsequent Dose
400 mg (two 200 mg injections)	200 mg every 2 weeks (Q2W)
or	
600 mg (two 300 mg injections)	300 mg every 2 weeks (Q2W)
Dosage for patients with oral corticosteroid-dependent asthma or with co-morbid moderate-to-severe atopic dermatitis or adults with co-morbid chronic rhinosinusitis with nasal polyposis	
600 mg (two 300 mg injections)	300 mg every 2 weeks (Q2W)

Dosage in Pediatric Patients 6 to 11 Years of Age

Body Weight	Initial Dose and Subsequent Doses
15 to less than 30 kg	100 mg every other week (Q2W) or 300 mg every four weeks (Q4W)
≥30 kg	200 mg every other week (Q2W)

The following changes are recommended to the Dupixent quantity limits:

All authorizations will be entered by GPI-10.

Atopic Dermatitis:

- Adults: 600 mg followed by 300 mg given every other week (Q2W)
  - Loading Dose Quantity Limit: 8 mL per 42 days (max quantity 8, min/max day supply 42) with a duration of two-week. (Enter Min day supply manually in Darwin after adding DS override); QL for letter: Loading dose: 8 mL per 42 days
  - Maintenance Quantity Limit: 4 mL per 28 day (max qty of 4, min/max day supply of 28) (Enter Min day supply manually in Darwin after adding DS override); QL for the letter: 4 mL per 28 days
- Pediatric Patients 6 to 17 years:
  - 15 to less than 30 kg: 600 mg (two 300 mg injections) and 300 mg given every 4 weeks (Q4W)
    - Loading Dose Quantity Limit: 8 mL per 42 days (max quantity 8, min/max day supply 42) with a duration of two-week. (Enter Min day supply manually in Darwin after adding DS override); QL for letter: Loading dose: 8 mL per 42 days
    - Maintenance Quantity Limit: 2 mL per 28 days (max qty of 2, min/max day supply of 28) (Enter Min day supply manually in Darwin after adding DS override); QL for the letter: 2 per 28 days
  - 30 kg to less than 60 kg: 400 mg (two 200 mg injections) and 200 mg every 2 weeks (Q2W)
    - Loading Dose Quantity Limit: 4.56 mL per 42 days (max quantity 4.56, min/max day supply 42) with a duration of two-week. (Enter Min day supply manually in Darwin after adding DS override); QL for letter: Loading dose: 4.56 mL per 42 days

        - Maintenance Quantity Limit: 2.28 mL per 28 days (max qty of 2.28, min/max day supply 28) (Enter Min day supply manually in Darwin after adding DS override); QL for the letter: 2.28 mL per 28 days
    - 60 kg or more: 600 mg (two 300 mg injections) and 300 mg every 2 weeks (Q2W):
        - Loading Dose Quantity Limit: 8 mL per 42 days (max quantity 8, min/max day supply 42) with a duration of two-week. (Enter Min day supply manually in Darwin after adding DS override); QL for letter: Loading dose: 8 mL per 42 days
        - Maintenance Quantity Limit: 4 mL per 28 day (max qty of 4, min/max day supply of 28) (Enter Min day supply manually in Darwin after adding DS override); QL for the letter: 4 mL per 28 days

Asthma:

- Adults and Pediatric 12 years and older:
    - 400 mg (two 200 mg injections) and 200 mg every 2 weeks (Q2W)
        - Loading Dose Quantity Limit: 4.56 mL per 42 days (max quantity 4.56, min/max day supply 42) with a duration of two-week. (Enter Min day supply manually in Darwin after adding DS override); QL for letter: Loading dose: 4.56 mL per 42 days
        - Maintenance Quantity Limit: 2.28 mL per 28 days (max qty of 2.28, min/max day supply 28) (Enter Min day supply manually in Darwin after adding DS override); QL for the letter: 2.28 mL per 28 days
    - 600 mg (two 300 mg injections) and 300 mg every 2 weeks (Q2W)
        - Loading Dose Quantity Limit: 8 mL per 42 days (max quantity 8, min/max day supply 42) with a duration of two-week. (Enter Min day supply manually in Darwin after adding DS override); QL for letter: Loading dose: 8 mL per 42 days
        - Maintenance Quantity Limit: 4 mL per 28 day (max qty of 4, min/max day supply of 28) (Enter Min day supply manually in Darwin after adding DS override); QL for the letter: 4 mL per 28 days
- Pediatric patients 6 to 11 years of age:
    - 15 to less than 30 kg:
        - 100 mg every other week (Q2W)
            - Quantity Limit:1.34 mL per 28 days (max qty of 1.34, min/max day supply 28) (Enter Min day supply manually in Darwin after adding DS override); QL for the letter; 1.34 mL per 28 days
        - 300 mg every 4 weeks (Q4W)
            - Quantity Limit: 2 mL per 28 days (max qty of 2, min/max day supply of 28) (Enter Min day supply manually in Darwin after adding DS override); QL for the letter: 2 per 28 days
    - Greater than or equal to 30 kg:
        - 200 mg every other week (Q2W)
            - Quantity Limit: 2.28 mL per 28 days (max qty of 2.28, min/max day supply 28) (Enter Min day supply manually in Darwin after adding DS override); QL for the letter: 2.28 mL per 28 days

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

Background: In order to be eligible for a rebate, we needed to remove the NDC requirement in our Cosentyx commercial policies. Also, the quantity limit for 75 mg syringe for Plaque Psoriasis in pediatric patients needs to be updated since it is billed per mL and not per syringe.

Recommendation: There are no changes to the current prior authorization criteria. However, it is recommended to update the MediSpan authorization level for all indications to GPI-10. Also, it is recommended to update the QL for the 75 mg syringe for Plaque Psoriasis to the following:

- 75 mg every 4 weeks
    1. In PA Hub: Add PA, OQL, number of claims authorized 1, max quantity dispensed 2 with a duration of one-month.
        - QL FOR LETTER: Loading dose: 2 mL per 28 days;
        - Maintenance dose: 0.5 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.

LYNPARZA

Background: The following correction is recommended for Lynparza Commercial Policy 362.0 to be consistent with the FDA approved indications for Lynparza.

Recommendation:
<u>Ovarian Cancer</u>

- Medical record documentation that Lynparza is prescribed by an oncologist or hematologist **AND**
- Medical record documentation of age greater than or equal to 18 years **AND**

If the member is in complete/partial response to first-line platinum based chemotherapy:

- Medical record documentation of advanced epithelial ovarian, fallopian tube or primary peritoneal cancer **AND**
- Medical record documentation member has had a complete or partial response to first-line platinum based chemotherapy **AND**
- Medical record documentation that Lynparza will be used as maintenance treatment **AND**
- Medical record documentation of one of the following:
    - Medical record documentation of deleterious or suspected deleterious germline or somatic BRCA-mutation (*gBRCA*m or *sBRCAm*) **OR**
    - Medical record documentation of both of the following:
        - Documentation of homologous recombination deficiency (HRD)-positive status with a deleterious or suspected deleterious *BRCA* mutation **AND**

- Documentation that Lynparza will be prescribed in combination with bevacizumab

OR

If the member has failed three or more prior lines of chemotherapy:

- Medical record documentation of advanced ~~epithelial~~ ovarian~~, fallopian tube or primary peritoneal~~ cancer **AND**
- Medical record documentation of deleterious or suspected deleterious germline *BRCA*-mutated advanced ovarian cancer as verified by a Food and Drug Administration (FDA) approved test **AND**
- Medical record documentation of therapeutic failure on, intolerance to, or contraindication to three or more prior lines of chemotherapy

OR

If the member has platinum-sensitive recurrent disease and has completed two or more lines of platinum-based chemotherapy:

- Medical record documentation of <u>recurrent</u> epithelial ovarian, primary peritoneal, or fallopian tube cancer **AND**
- Medical record documentation of Lynparza being used as maintenance therapy after a complete or partial response to platinum-based chemotherapy **AND**
- Medical record documentation that Lynparza will be used as maintenance 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.

RETIRED MBP UPDATE

Background:

MBP 147.0 Lartruvo (olaratumab), *Eli Lilly and Company* (All LOBs):

Upon annual review of MBP 147.0, it was discovered that Lartruvo was withdrawn from the market and the BLA was revoked as of 2/25/20 per the 7/17/20 federal register. Because Lartruvo was withdrawn from the market, MBP 147.0 was retired effective 8/26/21.

MBP 131.0 Cosentyx (secukinumab) Vials, *Novartis Pharmaceuticals Corporation*, (All LOBs except GHP Family):

Upon annual review of MBP 131.0 it was noted that Cosentyx vials are not currently being marketed. After further review it was discovered that the vials for provider administration, while listed within the prescribing information, have never been marketed by the manufacturer. The manufacturer was contacted and questioned to the plans (or lack of plans) for marketing Cosentyx vials. The manufacturer stated that there are no current or future plans at this time for bringing Cosentyx vials to market. As such, MBP 131.0 was retired effective 12/23/21.

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

Background: FreeStyle Libre via the pharmacy benefit and Continuous Glucose Monitors in general via the medical benefit have been identified as products with a high approval percentage:

FreeStyle Libre (12/2020-12/2021)	79%
Continuous Glucose Monitors (12/2020-11/2021)	99.8%

Current Formulary Status:

	Commercial/Marketplace/GHP Kids	Medicaid
FreeStyle Libre 14 Day Reader	Brand Preferred Tier, PA, QL 1/730 days	Brand Preferred Tier, PA
FreeStyle Libre 14 Day Sensor	Brand Preferred Tier, PA, QL 2/28 days	Brand Preferred Tier, PA, QL 4.5/30 days
FreeStyle Libre 2 Reader	Brand Preferred Tier, PA, QL 1/730 days	Brand Preferred Tier, PA
FreeStyle Libre 2 Sensor	Brand Preferred Tier, PA, QL 2/28 days	Brand Preferred Tier, PA, QL 4.5/30 days
FreeStyle Libre Reader	Brand Preferred Tier, PA, QL 1/730 days	Brand Preferred Tier, PA
FreeStyle Libre Sensor	Brand Preferred Tier, PA, QL 3/30 days	Brand Preferred Tier, PA, QL 4.5/30 days
Dexcom G6 Sensor/Transmitter/Receiver	Medical benefit, PA	Medical benefit, PA

Recommendation: Due to the high approval percentage and a recently identified rebate which would make it advisable to cover Dexcom continuous glucose monitors via the pharmacy benefit, the following changes are recommended when claims are processed at an in network pharmacy:

- FreeStyle Libre 14 Day Reader/FreeStyle Libre 2 Reader/FreeStyle Libre Reader
    - Recommend removal of PA, add QL by time to GHP Family of 1 Reader per 730 days
- FreeStyle Libre 14 Day Sensor/FreeStyle Libre 2 Sensor
    - Recommend removal of PA, add QL by ratio to GHP Family of 2 Sensors per 28 days
- FreeStyle Libre Sensor
    - Recommend removal of PA, add QL by ratio to GHP Family of 3 Sensors per 30 days
- Dexcom G6 Transmitter Miscellaneous (GPI 97202012066300, DDID 202418, NDC 08627001601)
    - A single Dexcom G6 transmitter lasts for three months (90 days), starting from the first time you snap it into a sensor--provided that it is used within five months of its shipping date.
    - Recommended addition to brand preferred tier with no PA, add QL by time of 1 transmitter per 90 days
- Dexcom G6 Sensor Miscellaneous (GPI 97202012046300, DDID 202419, NDC 08627005303)

    - Dexcom G6 sensors are designed to last for a maximum of 10 days, after which time the Dexcom G6 will require the insertion of a new sensor.
    - Recommended addition to brand preferred tier with no PA, add QL by time of 1 sensor per 10 days
- Dexcom G6 Receiver Device (GPI 97202012026200, DDID 202420, NDC 08627009111)
    - Recommended addition to brand preferred tier with no PA, add QL by time of 1 receiver per 730 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.

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 10 drugs (Soliris, Ultomiris, Uplizna, Onpattro). 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. Eculizumab (Soliris)
13. Edaravone (Radicava)
14. Eptinezumab (Vyepti)
15. Eteplirsen (Exondys 51)
16. Galsulfase (Naglazyme)
17. Golodirsen (Vyondys 53)
18. Golimumab (Simponi Aria)
19. Immune Globulin (IVIG)
20. Imiglucerase (Cerezyme)
21. Inebilizumab (Uplizna)
22. Infliximab & infliximab biosimilar products
23. Laronidase (Aldurazyme)
24. Mepolizumab (Nucala)
25. Omalizumab (Xolair)
26. Patisiran (Onpattro)
27. Ravulizumab (Ultomiris)
28. Tildrakizumab (Ilumya)
29. Tocilizumab (Actemra IV)
30. Ustekinumab (Stelara)
31. Vedolizumab (Entyvio)
32. Viltolarsen (Viltepso)

Discussion: Things have seemed to go smoothly with site of care, relatively positive feedback. 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.

JANUARY 2022 P&T DUR/ADHERENCE UPDATE

Background: This report includes data for all of 2021

Commercial/Exchange/TPAs

Drug Use Evaluations (DUEs)

- Use of Opioids from Multiple Providers (UOP) DUE
    - This is our 2021 3rd quarter Geisinger Health Plan DUE for Medicare, Medicaid, Commercial
    - From this report, we identified members 18 years of age and older with a total day supply of all opioid claims to be 15 day or greater based on claims from 1/1/2021 through 9/27/2021:
        - See below for the number of **members** who were identified who were seeing 4 or more providers from different offices for their opioid prescriptions
            - For COMM: **14**
            - For D6: **4**
        - See below for the number of **members** who were identified who were seeing 4 or more providers within the same office for their opioid prescriptions
            - For COMM: **0**
            - For D6: **0**
        - We sent letters to the member's MI attributed PCP with the respective medication fill history to encourage medication evaluation of the opioid medications
    - Mitch Kocen completed the mail merge via Quadient on 10/14/2021 and the print shop sent out the letters on 10/18/2021
    - We will re-run this data around 2/2022 to analyze the impact of the letter
- Statin Use in Persons with Diabetes DUE
    - This is our 2021 2nd quarter Geisinger Health Plan DUE for all LOBs
    - From this report, we identified **1,564 members** age 40 to 75 with at least 2 distinct fills of any diabetic medication(s) without a statin claim. We sent an educational letter to providers to encourage prescribing of a statin to members, if medically appropriate.
    - The Print Shop completed the mail merge and sent out letters to the member's providers on 8/2/2021.

- Adam K. re-ran this data on 11/19/2021 to analyze the effectiveness of the letter. Of the **1564 members** initially addressed, **1430** are still active. Of those members, **128** now have a claim for a statin medication. This equates to about **9%** of the targeted members.
- See below for the number of letters sent:
  - For COMM: **613**
  - For D6: **372**
  - For TP23: **4**
  - For TP33: **2**
  - For TP41: **2**
  - For TP45: **34**
  - For TP46: **11**
  - For TP49: **2**
  - For TP50: **11**
  - For TP56: **2**
  - For TP64: **3**
  - For TPA6: **2**
  - For TPA7: **3**
  - For TPB3: **1**
  - For TPD2: **1**
  - For TPE0: **4**
  - For TPF0: **1**
  - For TPF2: **2**
  - For TPH2: **0**
  - For TPI0: **4**
  - For TPI2: **4**
  - For TPL0: **0**
  - For TPM2: **2**
  - For TPN1: **1**
  - For TPU1: **2**
  - For TPW1: **2**
  - For WF89: **11**
  - For EMYD: **0**
  - For SASE: **6**
  - For SAI1: **1**
  - For SASF: **1**
  - For SASN: **55**
  - For SASX: **5**
  - For PM70: **2**
  - For PM71: **1**
  - For TG48/TG51: **397**

- <u>Asthma DUE</u>
  - This is our 2021 1st quarter Geisinger Health Plan DUE for all LOBs
  - From this report, we identified **209 members** who received 4 or more prescriptions for an asthma medication within the past 6 months but did not receive an asthma controller medication in that same 6-month period. We sent letters to providers which included fill history for rescue medications.
  - The Print Shop completed the mail merge and sent out letters to the members' providers on 6/18/2021.
  - Adam K. re-ran this data on 10/7/2021 to analyze the effectiveness of the letter. Of the **209 members** initially addressed, **189 members** are still active. Of those members, **25** now have a claim for a controller medication. This equates to about **13%** of the targeted members.
  - See below for the number of letters sent:
    - For COMM: **79**
    - For D6: **61**
    - For TP23: **1**
    - For TP33: **0**
    - For TP41: **0**
    - For TP45: **3**
    - For TP46: **1**
    - For TP49: **0**
    - For TP50: **1**
    - For TP56: **0**
    - For TP64: **0**
    - For TPA6: **1**
    - For TPI0: **0**
    - For TPI2: **0**
    - For TPL0: **1**
    - For TPM2: **2**
    - For TPN1: **0**
    - For TPU1: **0**
    - For TPW1: **0**
    - For WF89: **5**
    - For EMYD: **17**
    - For SASE: **1**
    - For SAI1: **1**
    - For SASF: **0**

- For TPA7: **0**
- For TPB3: **0**
- For TPD2: **0**
- For TPE0: **2**
- For TPF0: **0**
- For TPF2: **0**
- For TPH2: **1**
- For SASN: **6**
- For SASX: **0**
- For PM70: **0**
- For PM71: **0**
- For TG48/TG51: **26**

In Progress

- We are working on building a report to monitor members on an Immunomodulator or Oral Oncology medication as we have taken off the renewal prior authorization requirement for select medications in these classes
    - We hope to identify members who have not been seen in the last 12 months by the specialist prescribing one of these medications and outreach to the provider to notify them to set up an appointment with the member.
- Working with GHP's Respiratory therapists to improve controller medication adherence (AMR HEDIS measure)
    - We are looking to implement weekly referrals of 10 members to the two respiratory therapists

Ongoing

- <u>Cystic Fibrosis Adherence Report</u>
    - We get this report monthly for all LOBs from Adam Kelchner. The report identifies patients who have a specific diagnosis of Cystic Fibrosis & outpatient/office visits within the past 2 years. Further the report calls out medication fill history for specific CF medications and the corresponding PDC.
        - For those members who are seen by a GHS provider we send their information to the CF coordinators to discuss their medication adherence
        - We send letters to non-GHS providers with the CF medication fill history for those members with a PDC less than 80%
        - And for all members we send a letter discussing the importance of medication adherence
        - In 2021, please see below for the number of **members** an adherence letter was sent to:
            - For COMM: 3
            - For D6: 3
            - For TP48: 4
            - For WF89: 1
        - There were no letters sent to Non-GHS pulmonologists
        - Please see below for the number of members referred to the CF coordinators:
            - For COMM: 3
            - For D6: 3
            - For TP48: 4
            - For WF89: 1

- Duplicate Anticoagulant Report
    - We get this report **weekly** for **all LOBs** flagging members filling duplicate anticoagulant medications. We personally reach out to the providers/members of the flagged members to confirm proper medication therapy.
    - For 2021:
        - For COMM (Commercial): **10 members** reviewed and **2 interventions** made
        - For D6 (Exchange): **7 members** reviewed and **2 interventions** made
        - For TG48/GH51: **7 members** reviewed and **2 interventions** made
        - For TP45: **0 members** reviewed and **0 interventions** made
        - For TP56: **0 members** reviewed and **0 interventions** made
        - For EMYD: **2 members** reviewed and **0 interventions** made
        - For MT38: **0 members** reviewed and **0 interventions** made
        - For TP74: **0 members** reviewed and **0 interventions** made
        - For SASN: **1 member** reviewed and **0 interventions** made
        - For SASF: **1 member** reviewed and **0 interventions** made
- Duplicate Specialty Therapy
    - We run an in-house retrospective report **quarterly** for **all LOBs** with help from Adam Kelchner and Aubrielle Smith. These members are identified and written up and sent to a medical director if follow up is needed.
        - For Commercial/Exchange/TPA in 2021, we reviewed all 2021 data and **0 members** were referred to Dr. Yarczower for additional follow-up.
- Suboxone with an Opioid Report
    - We get this report **weekly** for **all LOBs** from Adam Kelchner and we are writing up each new member that flags on the report. These members are being discussed at our weekly meeting with Dr. Meadows and Dr. Hossler. Both medical directors look into whether it is appropriate to end the opioid authorizations still in place or if further intervention is required.
    - For Commercial/Exchange/TPA in 2021, see below for the new members reviewed and those referred to the MDs:
        - For COMM: we have reviewed **10 new members** and **4 members** were referred to MDs
        - For D6: we have reviewed **9 new members** and **2 members** were referred to MDs
        - For EMYD: we have reviewed **4 new members** and **2 members** were referred to MDs
        - For TG48: we have reviewed **3 new members** and **1 member** was referred to MDs
        - For SASE: we have reviewed **1 new member** and **0 members** was referred to MDs
- Ending Opioid Authorizations
    - We are working on identifying members who have active opioid authorizations in place but have since started Buprenorphine therapy. The letter is sent to the members notifying them the opioid authorization has been ended due to the start of buprenorphine therapy.
    - For Commercial/Exchange/TPA in 2021, see below for the number of letters we sent to members notifying them that we are ending their opioid authorization(s):
        - For D6: **1**
        - For COMM: **1**

        - For TG48/TG51: **2**
- Opioid Overutilization Report
    - We get this report **monthly** from PerformRx and we write up each member that flags on the report. We have been monitoring the members that are continuously showing up on the report by any change in their MED. For those members we deem appropriate we will send a letter to their PCP.
    - For Commercial/Exchange/TPA in 2021, see below for the number of reviewed cases.
        - For COMM: we have reviewed **2 patients** and sent **1 case** to MDs for review
        - For EMYD: we have reviewed **3 patients** and sent **0 cases** to MDs for review
        - For TG48: we have reviewed **2 patients** and sent **0 cases** to MDs for review
- FWA Reports
    - We get this report **weekly** for **all LOBs** from Jeremy Baker. We prepare this report by determining which claims need to be verified, and our GHP technician makes calls to pharmacies to correct/verify claims.
    - We review claims for anti-hypertensives, statins, 1-day supply, and inhalers
        - For COMM in 2021, we have reviewed cases and corrected claims, resulting in a potential **cost savings/avoidance of $1,822.69**
        - For D6 in 2021, we have reviewed cases and corrected claims, resulting in a potential **cost savings/avoidance of $410.19**
        - For TP45 in 2021, we have reviewed cases and corrected claims, resulting in a potential **cost savings/avoidance of $19.33**
        - For TG48, TG51 in 2021, we reviewed cases and corrected claims, resulting in a potential **cost savings/avoidance of $1,141.17**
        - For SASN in 2021, we reviewed cases and corrected claims, resulting in a potential **cost savings/avoidance of $1,331.97**
- Severity Report
    - We get this report **monthly** for **all LOBs** on members who have filled a medication that has a level one interaction with another medication they have a claim for
        - For Commercial/Exchange/TPA in 2021:
            - *We are working with PerformRx on a revision to this report*
- Tobacco Cessation Program
    - We get this report **monthly** to identify members on prolonged tobacco cessation treatment. We send a letter and resource pamphlet to provide additional behavioral health support through Geisinger Health and Wellness.
    - For Commercial/Exchange/TPA in 2021, we sent letters to the below number of members:
        - For COMM: **13**
        - For D6: **13**
        - For EMYD: **23**
        - For SASN: **0**
        - For SASE: **2**
        - For TG48, TG51: **10**
        - For TPB3: **1**
        - For TP23: **0**
        - For TP45: **0**
        - For TP46: **0**
        - For TP56: **0**

        - For TP88: **0**
        - For TPA6: **0**
        - For WF89: **0**
- STENT Adherence Report
    - We get this report **monthly** to identify members on an antiplatelet medication and then flag for betablocker and statin medication claims.
    - In 2021, we have sent letters encouraging adherence to the below number of members:
        - **Members for Antiplatelet:**
            - COMM: **125**
            - D6: **93**
            - EMYD: **5**
            - SASN: **8**
            - TG48, TG51: **25**
            - TP41: **1**
            - TP23: **0**
            - TP45: **4**
            - TP46: **1**
            - TP50: **1**
            - TP56: **1**
            - TP74: **1**
            - TP88: **2**
            - TPA6: **0**
            - WF89: **5**
            - TPD2: **1**
            - SASE: **4**
            - SASF: **1**
            - TPB3: **0**
            - TPF2: **1**
            - TPI0: **1**
            - TPL0: **1**
            - TPM2: **1**
        - **Members for Beta-Blocker:**
            - COMM: **103**
            - D6: **78**
            - EMYD: **7**
            - SASN: **5**
            - TG48, TG51: **45**
            - TP23: **1**
            - TP45: **1**
            - TP46: **0**
            - TP50: **1**
            - TP56: **0**
            - TP88: **1**
            - TPA6: **0**
            - WF89: **1**
            - TPI0: **1**
            - SASE: **1**
        - **Members for Statin:**
            - COMM: **130**
            - D6: **86**
            - EMYD: **17**
            - SASN: **4**
            - TG48, TG51: **31**
            - TP23: **2**
            - TP45: **4**
            - TP46: **2**
            - TP56: **0**
            - TP88: **1**
            - TPA6: **2**
            - WF89: **1**
            - TP50: **2**
            - PM70: **1**
            - TP74: **1**
            - SASE: **4**
            - TPB3: **1**
            - TP41: **1**
        - *member may flag for more than one measure and are included in the count for each measure

- **HEDIS Initiatives: *Using proactive HEDIS data***
- Asthma Medication Ratio (AMR)

    - Jesse Barsh runs this report **monthly,** and we send letters to the flagged members who have a ratio of controller to total asthma medications of < 0.5.
        - For Commercial/Exchange in 2021, see below for the number of letters sent to members:
            - COMM: **19**
            - D6: **17**
- Antidepressant Medication Management (AMM)
    - Jesse Barsh runs this report **monthly,** and we send letters to the flagged members who appear non-adherent to their antidepressant medications.
        - For Commercial/Exchange in 2021, see below for the number of letters sent to members:
            - Effective Acute Phase:
                - COMM: **1**
                - D6: **0**
            - Effective Continuation Phase:
                - COMM: **85**
                - D6: **70**
- Adherence to Antipsychotics for Individuals with Schizophrenia (SAA)
    - Jesse Barsh runs this report **monthly,** and we send letters to the flagged members who appear non-adherent to their antipsychotic medications.
        - For Commercial/Exchange in 2021, see below for the number of letters sent to members:
            - COMM: **2**
            - D6: **1**
- Statin Therapy for Patients with Cardiovascular Disease (SPC)
    - We get this report **monthly** to identify members with cardiovascular disease and who have not received a statin medication or who are non-adherent to statin therapy
        - For Commercial/Exchange in 2021, see below for the number of letters sent to **providers** to encourage statin therapy initiation**:**
            - COMM: **27**
            - D6: **20**
        - For Commercial/Exchange in 2021, see below for the number of letters sent to **members** to promote statin adherence:
            - COMM: **41**
            - D6: **14**
- Statin Therapy for Patients with Diabetes (SPD)
    - We get this report **monthly** to identify members with cardiovascular disease and who have not received a statin medication or who are non-adherent to statin therapy
        - For Commercial/Exchange in 2021, see below for the number of letters sent to **providers** to encourage statin therapy initiation**:**
            - COMM: **246**
            - D6: **137**
        - For Commercial/Exchange in 2021, see below for the number of letters sent to **members** to promote statin adherence:
            - COMM: **41**
            - D6: **18**
- Persistence of Beta-Blocker Treatment After a Heart Attack (PBH)

- We get this report **<u>monthly</u>** to identify members with a diagnosis of AMI who received beta-blocker treatment for 6 months after discharge and who are non-adherent to beta-blocker therapy
    - For Commercial/Exchange in 2021, see below for the number of letters sent to **members:**
        - COMM: **0**
        - D6: **1**

Fliers/Letters

- <u>Commercial/Exchange DUR/FWA Program internal Fliers</u>
    - Last updated 08/2021 next update 02/2022
- <u>Current Provider Letters</u>
    - Cystic Fibrosis Adherence Letter
    - Use of Opioids from multiple providers DUE
    - Congestive Heart Failure DUE
    - Coronary Artery Disease DUE
    - Statin Use in Persons with Diabetes DUE
    - Asthma Med Ratio DUE
    - Opioid Overutilization
    - Severity Report
    - HEDIS: Statin Therapy for Patients with Cardiovascular Disease (SPC)
    - HEDIS: Statin Therapy for Patients with Diabetes (SPD)
- <u>Current Member Letters</u>
    - Cystic Fibrosis Adherence Letter
    - Ending Opioid Authorizations
    - Tobacco Cessation Letter
    - HEDIS: Asthma Medication Ratio (AMR)
    - HEDIS: Antidepressant Medication Management (AMM)
    - HEDIS: Adherence to Antipsychotics for Individuals with Schizophrenia (SAA)
    - HEDIS: Statin Therapy for Patients with Cardiovascular Disease (SPC)
    - HEDIS: Statin Therapy for Patients with Diabetes (SPD)
    - HEDIS: Persistence of Beta-Blocker Treatment After a Heart Attack (PBH)
    - STENT Adherence Report

CHIP (CHBQ)

- All of our Medicaid adherence/DUR reports include logic to identify the CHIP population

Drug Use Evaluations (DUEs)

- Statin Use in Persons with Diabetes DUE
  - This is our 2021 2nd quarter Geisinger Health Plan DUE for all LOBs
  - From this report, we identified **0 members** age 40 to 75 with at least 2 distinct fills of any diabetic medication(s) without a statin claim. We sent an educational letter to providers to encourage prescribing of a statin to members, if medically appropriate.
- Asthma DUE
  - This is our 2021 1st quarter Geisinger Health Plan DUE for all LOBs
  - From this report, we identified **8 members** who received 4 or more prescriptions for an asthma medication within the past 6 months but did not receive an asthma controller medication in that same 6-month period. We sent letters to providers which included fill history for rescue medications.
  - The Print Shop completed the mail merge and sent out letters to the members' providers on 6/18/2021.
  - Adam K. re-ran this data on 10/7/2021 to analyze the effectiveness of the letter. Of the **8 members** initially addressed, **8 members** are still active. Of those members, **0** now have a claim for a controller medication.

Ongoing

- Duplicate Anticoagulant Report
  - We get this report **weekly** for **all LOBs** flagging members filling duplicate anticoagulant medications. We personally reach out to the providers/members of the flagged members to confirm proper medication therapy.
    - For CHBQ in 2021, we have reviewed **0 members** and have made interventions for **0 members**
- Duplicate Specialty Therapy
  - We run an in-house retrospective report **quarterly** for **all LOBs** with help from Adam Kelchner and Aubrielle Smith. These members are identified and written up and sent to a medical director if follow up is needed.
    - For CHBQ in 2021, we reviewed all 2021 data and **0 members** were referred to Dr. Yarczower for additional follow-up.
- Duplicate Buprenorphine Therapy
  - We get this report **quarterly** with help from Adam Kelchner. The report works to identify members who have at least a 7 day overlap period of generic Buprenorphine and generic Buprenorphine/naloxone products. Members identified as being on both products are being forwarded to Dr. Meadows and Dr. Hossler for further outreach.
    - For CHBQ in 2021, we have reviewed **0 members** and **0 members** were referred to MDs
- Suboxone with an Opioid Report
  - We get this report **weekly** for **all LOBs** from Adam Kelchner and we are writing up each member that flags on the report. These members are being discussed at our weekly meeting with Dr. Meadows and Dr. Hossler. Both MDs look into whether it is

appropriate to end the opioid authorizations still in place or if further intervention is required.
    - For CHBQ in 2021, we have reviewed **0 new members**, and **0 members** were referred to MDs
- Ending Opioid Authorizations
    - We are working on identifying members who have active opioid authorizations in place but have since started Buprenorphine therapy. The letter is sent to the members notifying them the opioid authorization has been ended due to the start of buprenorphine therapy.
        - For CHBQ in 2021, we sent **0 members** a letter notifying them of the end of their opioid authorization(s).
- FWA Reports
    - We get this report **weekly** for **all LOBs** from Jeremy Baker. We prepare this report by determining which claims need to be verified, and our GHP technician makes calls to pharmacies to correct/verify claims.
    - We review claims for anti-hypertensives, statins, 1-day supply, and inhalers
        - For CHBQ in 2021, we have reviewed cases and corrected claims, resulting in a potential **cost savings/avoidance of $61.13**
- Tobacco Cessation Program
    - We get this report **monthly** to identify members on prolonged tobacco cessation treatment. We send a letter and resource pamphlet to provide additional behavioral health support through Geisinger Health and Wellness.
        - For CHBQ in 2021, we have not sent any letters
- STENT Adherence Report
    - We get this report **monthly** to identify members on an antiplatelet medication and then flag for betablocker and statin medication claims.
    - For CHBQ in 2021, we have sent letters encouraging adherence to:
        - Members for Antiplatelet:
            - CHBQ: **0**
        - Members for Beta-blocker:
            - CHBQ: **0**
        - Members for Statin:
            - CHBQ: **0**
        - *member may flag for more than one measure and are included in the count for each measure
- Antipsychotic with Opioid Report
    - We get this report **quarterly** to identify **CHIP** members with an overlap of 8 or more days between an opioid and antipsychotic medication.
    - We send a letter with claims data to both the opioid prescriber and the antipsychotic prescriber to encourage collaboration in medication management.
        - For CHBQ in 2021, we sent **0 letters** to **opioid prescribers** and **0 letters** to **antipsychotic prescribers**
- Duplicate Antipsychotics
    - We get this report **quarterly**, and we send letters to the PCPs to address potential duplicate therapy issues.
        - For CHBQ in 2021, we have sent letters to **1 provider**
- **HEDIS Initiatives: *Using proactive HEDIS data***
- Asthma Medication Ratio (AMR)

    - Jesse Barsh runs this proactive HEDIS report **monthly,** and we send letters to the flagged members who have a ratio of controller to total asthma medications of < 0.5.
        - For CHBQ in 2021, we sent **4 letters** to members
- Antidepressant Medication Management (AMM)
    - Jesse Barsh runs this proactive HEDIS report **monthly,** and we send letters to the flagged members who appear non-adherent to their antidepressant medications.
        - For CHBQ in 2021, we sent **0 letters** to members in the **Effective Acute Phase**, and **8 letters** to members in the **Effective Continuation Phase**
- Adherence to Antipsychotics for Individuals with Schizophrenia (SAA)
    - Jesse Barsh runs this report **monthly,** and we send letters to the flagged members who appear non-adherent to their antipsychotic medications.
        - For CHBQ in 2021, we have sent **0 letters** to members
- Statin Therapy for Patients with Cardiovascular Disease (SPC)
    - This is a **monthly** report to identify members with cardiovascular disease and who have not received a statin medication or who are non-adherent to statin therapy
        - For CHBQ in 2021, we have sent **0 letters** to providers
        - For CHBQ in 2021, we have sent **0 letters** to members
- Statin Therapy for Patients with Diabetes (SPD)
    - This is a **monthly** report to identify members with cardiovascular disease and who have not received a statin medication or who are non-adherent to statin therapy
        - For CHBQ in 2021, we have sent **0 letters** to providers
        - For CHBQ in 2021, we have sent **0 letters** to members
- Persistence of Beta-Blocker Treatment After a Heart Attack (PBH)
    - This is a **monthly** report to identify members with a diagnosis of AMI who received beta-blocker treatment for 6 months after discharge and who are non-adherent to beta-blocker therapy
        - For CHBQ in 2021, we have sent **0 letters** to members

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

2022 FORMULARIES FOR APPROVAL

Recommendation: Please review the attached PDF versions of the 2022 formularies for approval.

- AON Exchange Formulary
- Commercial 4 Tier Formulary
- Commercial Traditional Formulary
- Commercial Triple Choice Formulary
- GHP Kids Formulary
- Marketplace Formulary
- Northern Light Employee Formulary

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 3:48 pm

Future Scheduled Meetings

The next bi-monthly scheduled meeting will be held on March 15th, 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.