Geisinger

P&T Committee Meeting Minutes
Commercial/Marketplace/GHP Kids
September 20, 2022

Present (via Teams):	**Absent:**
Bret Yarczower, MD, MBA – Chair	Kristen Bender, Pharm.D.
Amir Antonius, Pharm.D.	Holly Bones, Pharm.D.
Emily Antosh, Pharm.D.	Alyssa Cilia, RPh
Jeremy Bennett, MD	Michael Evans, RPh
Kim Castelnovo	Tricia Heitzman, Pharm.D.
Kimberly Clark, Pharm.D.	Nichole Hossler, MD
Rajneel Farley, Pharm.D.	Jason Howay, Pharm.D.
Kelly Faust Pharm.D.	Jamie Miller, RPh
Emily Hughes, Pharm.D.	Jonas Pearson, RPh
Keith Hunsicker, Pharm.D.	Michael Shepherd, MD
Kelli Hunsicker, Pharm.D.	Richard Silbert, MD
Derek Hunt, Pharm.D.	Todd Sponenberg, Pharm.D.
Kerry Ann Kilkenny, MD	
Philip Krebs, R.EEG T	
Briana LeBeau, Pharm.D.	
Ted Marines, Pharm.D.	
Lisa Mazonkey, RPh	
Tyreese McCrea, Pharm.D.	
Perry Meadows, MD	
Mark Mowery, Pharm.D.	
Austin Paisley, Pharm.D.	
Kimberly Reichard, Pharm.D.	
Melissa Renn, Pharm.D.	
Melissa Sartori, Pharm.D.	
Angela Scarantino	
Kristen Scheib, Pharm.D.	
William Seavey, Pharm.D.	
Leslie Shumlas, Pharm.D.	
Aubrielle Smith Pharm.D.	
Kirsten Smith, Pharm.D.	
Michael Spishock, RPh	
Jill Stone, Pharm.D.	
Robert Strony, MD MBA	
Luke Sullivan, DO	

Kevin Szczecina, RPh Amanda Taylor, MD Ariana Wendoloski, Pharm.D. Brandon Whiteash, Pharm.D. Margaret Whiteash, Pharm.D. Jeremy Garris (non-voting participant) Mallory Ellis, Pharm.D. (Pharmacy Resident) Kiara Mendez (Pharmacy Student) Jemimah Royer (Pharmacy Student)	

Call to Order:
Dr. Bret Yarczower called the meeting to order at 1:02 p.m., Tuesday, September 20, 2022.

Review and Approval of Minutes:
Dr. Bret Yarczower asked for a motion or approval to accept the July 19, 2022 and August 2022 e-vote minutes as written. Minutes approved unanimously. None were opposed.

DRUG REVIEWS

DARTISLA ODT (glycopyrrolate)

Review: Dartisla ODT is an orally-disintegrating formulation of glycopyrrolate indicated in adults to reduce symptoms of a peptic ulcer as an adjunct to treatment of peptic ulcer. It is not indicated as monotherapy for the treatment of peptic ulcer because effectiveness in peptic ulcer healing has not been established. It works by inhibiting the action of acetylcholine on parietal cells in the stomach and decreasing the volume and acidity of gastric secretions. It must be used in combination with other treatments which treat the underlying etiology of the condition (e.g., proton pump inhibitors, antimicrobial agents, H2-receptor antagonists, avoidance of NSAID use).

The recommended dosage of Dartisla ODT is 1.7 mg given two or three times daily administered on top of the tongue. The tablet should be allowed to disintegrate then swallowed without water. Patients receiving the 2 mg dosage strength of another oral tablet dosage of glycopyrrolate may be switched to the 1.7 mg dosage of Dartisla ODT. Dartisla ODT is not recommended for patients in whom a lower strength of glycopyrrolate (e.g., 1 mg tablet) is appropriate for initial or maintenance treatment because the dosage of Dartisla ODT may exceed the initial or maintenance dosage of other glycopyrrolate products. The maximum recommended dosage of Dartisla ODT is 6.8 mg.

There were no new clinical trials conducted for the approval of Dartisla ODT. Instead, approval is based on safety and effectiveness of Robinul Forte (glycopyrrolate) tablets and a relative bioavailability study which demonstrated comparable systemic exposure between Dartisla ODT 1.7 mg and Robinul Forte 2 mg tablets.

Dartisla ODT is contraindicated in patients at risk of anticholinergic toxicity due to an underlying medical condition including glaucoma, obstructive uropathies, mechanical obstructive diseases of the gastrointestinal tract, gastrointestinal motility disorders, bleeding gastrointestinal ulcer, active inflammatory or infectious colitis, history of toxic megacolon, and myasthenia gravis. The safety profile of Dartisla is based on published literature and post-marketing pharmacovigilance reports and is expected to be similar to glycopyrrolate tablets.

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

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

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

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

- Medical record documentation that Dartisla ODT will be given as an adjunct to treatment of peptic ulcer disease **AND**
- Medical record documentation of age greater than or equal to 18 years

AND

- Medical record documentation of difficulty swallowing **OR**
- Medical record documentation of a therapeutic failure on, intolerance to, or contraindication to glycopyrrolate tablets.

QUANTITY LIMIT: 4 tablets per day

MEDISPAN AUTHORIZATION LEVEL: GPI-12

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

SOOLANTRA (ivermectin 1% cream)

Review: Soolantra (ivermectin 1%) cream is a topical product indicated for the treatment of inflammatory lesions of rosacea in adult patients. Soolantra should be applied to the affected areas of the face one daily, using a pea sized amount and avoiding the eyes and lips. The efficacy of Soolantra was demonstrated in two randomized, double-blind vehicle-controlled trials with a total of 1371 subjects aged 18 years and older who were treated once daily for 12 weeks with either SOOLANTRA cream or vehicle cream. SOOLANTRA cream was more effective than vehicle cream based on the Investigator Global Assessment (IGA) scale looking at patients scored as “clear” or “almost clear” and in the absolute change from baseline in inflammatory lesion counts at Week 12. Soolantra was also demonstrated to be superior to twice daily metronidazole during an investigator blinded study of 962 patients with severe PPR Ivermectin showed a significantly higher percentage of patients with improvement in IGA score at week 16 to ‘clear’ or ‘almost clear’. The most commonly noted adverse effects with Soolantra include localized reactions such as burning and skin irritation.

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: Kristen clarified that generic ivermectin 1% cream would be added to the generic non-preferred tier of the Marketplace formulary. No additional comments or questions. The committee unanimously voted to accept the recommendations as amended. None were opposed.

Outcome: Ivermectin 1% cream is a pharmacy benefit and will be added to the Commercial, Marketplace, and GHP Kids formularies at the generic or generic non-preferred tier.

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

RADICAVA ORS (edaravone)

Review: Radicava and Radicava ORS are indicated for the treatment of amyotrophic lateral sclerosis (ALS). Radicava is available as a 30 mg/100 mL intravenous solution. Radicava ORS is available as a 105 mg/5mL oral suspension. The recommended dose of Radicava ORS is 105 mg (5 mL) taken orally or via feeding tube in the morning after overnight fasting. For both the oral suspension and IV infusion, Radicava is administered as an initial treatment cycle with daily dosing for 14 days, followed by a 14-day drug-free period. Subsequent cycles are daily dosing for 10 days out of 14-day periods, followed by a 14-day drug-free period. Food should not be consumed for 1 hour after administration except for water. If patients consume a high-fat meal (800-1,000 calories), they must fast 8 hours before administration of Radicava ORS. If patients consume a low-fat meal (400-500 calories), they must fast 4 hours before administration of Radicava ORS. If patients consume caloric supplement (250 calories), they must fast 2 hours before administration. Radicava ORS should be disposed after 15 days from opening the bottle or within 30 days from the shipment date on the pharmacy label, which ever happens first. When patients switch from Radicava to Radicava ORS, they should use the same dosing frequency. Once they switch to ORS, patients need to follow Radicava dosing recommendations with regards to food consumption.

ALS is a fatal, progressive neurodegenerative disorder that affects upper and lower neurons. The loss of neurons in the brain and spinal cord initially leads to focal weakness, with muscle weakness spreading over time. Most patients die of respiratory failure within 2 to 5 years. There are no treatments to stop or significantly slow progression of ALS, therefore the management is largely supportive (e.g. respiratory management, nutritional support). Riluzole and Radicava are the only two drugs approved to treat the disease, but only provide a modest benefit. Riluzole has been shown to prolong survival by 2 to 3 months on average. There was a recent study published in August 2022 evaluating the overall survival in patients treated with Radicava IV compared to those not treated with Radicava in the real-world setting of 636 patients. In the data, 65.4% of patients had a history of riluzole prescription. The median overall survival was 29.5 months with edaravone compared to 23.5 months without and the risk of death was 27% lower in cases than in controls (HR, 0.73; 95% CI, 0.51-0.91; p= 0.005). However, data from adequately powered RCTs are needed to support this finding. The oral suspension of Radicava was approved based on bioequivalence with the IV formulation. Oral administration will overcome many of concerns associated with IV administration. There is a new oral agent that is currently being reviewed by the FDA, AMX0035 (taurursodiol and sodium phenylbutyrate). The American Academy of Neurology guidelines in 2009 (reaffirmed in 2020) recommend that riluzole should be offered to slow disease progression but does not mention the use of edaravone.
The efficacy of Radicava ORS is based on bioavailability study comparing Radicava and Radicava ORS. The efficacy of Radicava was established in a 6-month, randomized, placebo-controlled, double-blind study conducted in Japanese patients with ALS who were living independently, with functionality retained most activities of daily living, normal respiratory function, and definite or probable ALS, and disease duration of 2 years or less. Radicava was compared to placebo and 90% of patients in both groups were being treated with riluzole. The primary endpoint was the change in ALSFRS-R total score from baseline to Week 24. The ALSFRS-R scale consists of 12 questions that evaluate the fine motor, gross motor, bulbar, and respiratory function of patients with ALS (speech, salivation, swallowing, handwriting, cutting food, dressing/hygiene, turning in bed, walking, climbing stairs, dyspnea, orthopnea, and respiratory insufficiency). Higher score represents greater functional ability. The decline in ALSFRS-R scores from baseline was significantly less in Radicava treated patients compared to placebo.

Radicava and Radicava ORS are contraindicated in patients with a history of hypersensitivity to edaravone or any of the inactive ingredients in this product. Hypersensitivity reactions and cases of anaphylaxis have been reported in spontaneous postmarketing reports with Radicava. Radicava and Radicava ORS contain sodium bisulfite which may cause allergic reactions including anaphylactic symptoms and life-threatening or less severe asthmatic episodes in susceptible people. The most common adverse reactions that occurred in ≥ 10% of Radicava-treated patients were contusion, gait disturbance, and headache. There are no adequate data on the developmental risk associated with the use of Radicava or Radicava ORS in pregnant women but based on animal data it may cause fetal harm. There are no data on the presence of edaravone in human milk, the effects on the breastfed infant, or the effects on milk production. Edaravone and its metabolites are excreted in the milk of lactating rats. The safety and effectiveness of Radicava or Radicava ORS in pediatric patients have not been established. No overall differences in safety or effectiveness were observed between geriatric patients and younger patients, but greater sensitivity of some older individuals cannot be ruled out.

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

Clinical Discussion: Phil Krebs questioned whether the benefit was regardless of disease course or only effective for new starts – 90% of patients included in trials were already taking riluzole so unsure how to tell. The trial was looking at historical and we don't currently have randomized controlled trials to definitively say whether or not there is clear survival benefit. 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: Radicava ORS is a pharmacy benefit that will be added to the Commercial/Exchange/CHIP formularies at the Specialty tier or the Brand Non-Preferred tier for those with a three-tier benefit. Radicava ORS will require a prior authorization with the following criteria to match the criteria for the IV formulation:

- Prescription written by or in consultation with a neurologist **AND**
- Medical record documentation of a diagnosis of ALS (amyotrophic lateral sclerosis) **AND**
- Medical record documentation of baseline functional status (as evidenced by a scoring system such as ALSFRS-R, or by physician documentation of subjective reports on speech, motor function, pulmonary function, etc.) **AND**
- Medical record documentation that Radicava is being given in combination with riluzole OR intolerance or contraindication to riluzole

QUANTITY LIMIT: 50 mL per 28 days (coded in the extract), when approving the initial auth we will enter a one-time, two week OQL override with 70 mL per 28 days to allow for the loading dose.

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

- Medical record documentation that member is tolerating and compliant with prescribed edaravone regimen **AND**

- Medical record documentation of regular physician follow-up

MEDISPAN AUTHORIZATION LEVEL: GPI-12

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

NORLIQVA (amlodipine)

Review: Norliqva is indicated for the treatment of hypertension in adults and children 6 years of age and older, to lower blood pressure. Lowering pressure reduces the risk of fatal and nonfatal cardiovascular events, primarily strokes and myocardial infarctions. Norliqva is also indicated for the symptomatic treatment of chronic stable angina and the treatment of confirmed or suspected vasospastic angina. Norliqva may be used alone or in combination with other antianginal agents. In patients with recently documented coronary artery disease (CAD) by angiography and without heart failure or an ejection fraction <40%, Norliqva is indicated to reduce the risk of hospitalization for angina and to reduce the risk of coronary revascularization procedure.

The usual initial antihypertensive oral dose of Norliqva is 5mg orally once daily, and the maximum dose is 10mg orally once daily. Small, fragile, or elderly patients, or patients with hepatic insufficiency may be started on 2.5mg orally once daily and this dose may be used when adding Norliqva to other antihypertensive therapy. The recommended dose for chronic stable or vasospastic angina is 5mg to 10mg orally once daily, with the lower dosage suggested in the elderly and in patients with hepatic insufficiency. Most patients with require 10mg orally once daily for adequate effect. The recommended dose range for patients with CAD is 5mg to 10mg orally once daily. In clinical studies, the majority of patients required 10mg. Norliqva is available as a 1mg/mL clear, pale straw-colored solution with a peppermint flavor supplied in 150mL amber glass bottles with a child-resistant closure.

According to the 2017 ACC/AHA Hypertension Treatment Guidelines, pharmacological agents used in addition to lifestyle modifications provide the primary treatment for hypertension. Agents that have been shown to reduce clinical events should be used preferentially, so the primary agents used for hypertension include thiazide diuretics, ACE inhibitors, ARBs, and CCBs. Many patients can be started on a single anti-hypertensive, but consideration for 2 drugs of different classes should be given to patients with stage 2 hypertension. Therapy selection should also take into account patient-specific factors such as age, concurrent medications, costs, and comorbidities.

Approval of Norliqva is based upon previous clinical trials of amlodipine. No new clinical trials were completed. Norliqva is contraindicated in patients with a sensitivity to amlodipine. Norliqva has warnings and precautions for hypotension, increased angina or myocardial infarction, and patients with hepatic failure. The most common adverse reactions to amlodipine were edema, dizziness, flushing, and palpitation which occurred in a dose-related manner. Other adverse reactions not clearly dose-related but reported with an incidence > 1% are fatigue and nausea.

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

Clinical Discussion: Dr. Yarczower questioned anticipated utilization of product, which is expected to be low. 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: Norliqva is a pharmacy benefit and will not be added to the Commercial, Marketplace, or GHP Kids formulary. The following prior authorization criteria will apply:

- Medical record documentation of use for an FDA approved indication **AND**
- Medical record documentation of difficulty swallowing **OR**
- Medical record documentation of therapeutic failure on, intolerance to, or contraindication to three (3) generic formulary calcium channel blockers, one of which must be amlodipine tablets

GPI LEVEL: GPI-12

FORMULARY ALTERNATIVES: amlodipine oral tablets, amlodipine/benazepril, Cartia XT, diltiazem, diltiazem extended release, felodipine extended release, nifedipine, Taztia XT, Tiadylt extended release, nifedipine extended release, verapamil, verapamil extended release

QUANTITY LIMIT: 300 mL per 30 days (10 mL/day)

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

JELMYTO (mitomycin)

Review: Jelmyto is an alkylating drug indicated for the treatment of adult patients with low-grade upper tract urothelial cancer.

Jelmyto is the first drug approved to treat cancer that grows in the upper portion of the urinary system known as upper tract urothelial cancer. Most urothelial cancers start in the bladder, but upper tract cancers start in the lining of the kidney or the ureter (the tube that connects the kidney to the bladder). In some people, upper tract cancers can block the ureter or kidney and cause problems including swelling, infection, and decrease in kidney effectiveness. These problems could lead to kidney and ureter removal.

Dr. Heinric Williams, urology physician, stated that endoscopic management is the primary treatment that is used for LG-UTUC. Due to a single primary treatment, there is a high rate of recurrence. For this reason, there is significant interest in developing adjuvant therapies that can be delivered to the upper tract. LG-UTUC is not rare, but it is a frustrating disease to manage due to limitations in medical instruments to access the upper tract.

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

Clinical Discussion: Is there a time frame for when we need to have Part D recommendations? No stipulations for when the review must be completed. 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: Jelmyto will be a medical benefit. Jelmyto will be added to the medical benefit cost share list when processed on the medical benefit. If processed at a specialty pharmacy, Jelmyto will process at the Specialty tier or the Brand Non-preferred tier for members with a three-tier benefit. The following prior authorization criteria will apply:

- Documentation of age greater than or equal to 18 years **AND**
- Medical record documentation that Jelmyto is prescribed by or in consultation with a hematologist, oncologist or urologist **AND**
- Medical record documentation of a diagnosis of low-grade Upper Tract Urothelial Cancer (LG-UTUC) **AND**
- Medical record documentation of a prescribed dose and administration that is consistent with FDA-approved package labeling, nationally recognized compendia, or peer-reviewed medical literature

AUTHORIZATION DURATION: Initial approval will be for 3 months or less if the reviewing provider feels it is medically appropriate. Subsequent approvals will be for an additional 12 months or less of the reviewing provider feels it is medically appropriate and will require medical record documentation of a complete response 3 months after Jelmyto initiation as evidenced by urine cytology and ureteroscopy. The medication will no longer be covered if patient experiences toxicity, worsening of disease, experiences a perforation of the bladder or upper urinary tract or if the patient has received 17 total instillations (maximum number of instillations per FDA approved labeling).

QUANTITY LIMIT:

- Initial authorization: 3 month duration with quantity limit of 6 doses
- Re-authorization: 12 month duration with a quantity limit of 11 doses (not to exceed 17 total doses)

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

CAMZYOS (mavacamten)

Review: Camzyos is a first in its class cardiac myosin inhibitor indicated for the treatment of adults with symptomatic New York Heart Association (NYHA) class II-III obstructive hypertrophic cardiomyopathy (oHCM). By inhibiting myosin, mavacamten limits myosin's interaction with actin, resulting in limited cross-bridge formation and enhancing heart muscle relaxation. Mavacamten provides effective symptom relief and improves functional capacity in oHCM patients.

Hypertrophic cardiomyopathy (HCM) is a genetic condition with an estimated prevalence of 1 in every 500 people within the United States. The disease causes the heart muscles to uncontrollably contract and as a result, thicken, potentially leading to an array of symptoms and complications. Patients with HCM can be asymptomatic, especially early in the disease. However, HCM may cause shortness of breath, chest pain, fatigue, swollen ankles, legs, feet, abdomen, and neck veins, dizziness, lightheadedness, and syncope. Serious complications of HCM include fatal arrythmias or sudden cardiac death. HCM can be divided into two types: obstructive and nonobstructive. Obstructive HCM is more common, affecting two-thirds of HCM patients, and is denoted by left ventricular outflow obstruction. Nonobstructive HCM similarly has cardiac hypertrophy present but does not cause left ventricle obstruction.

Current therapies for oHCM provide symptom relief. They do not treat the underlying cause of oHCM. First-line therapies include beta-blockers and non-dihydropyridine calcium channel blockers. Disopyramide and septal reduction therapy are second-line options if the patient continues to have symptoms despite use of first-line agents.

Camzyos is available as an oral capsule in 2.5 mg, 5 mg, 10 mg, and 15 mg strengths with the recommended starting dosage being 5 mg once daily. Once stabilized on this dose, dosage adjustments are made based on the patient's clinical status and electrocardiogram (ECG) results.

Camzyos causes reduced left ventricular ejection fraction (LVEF) and has a boxed warning for risk of heart failure. Because of this boxed warning, mavacamten is only available through a REMS program. Patients must have an ECG performed before initiation of mavacamten and at weeks 4, 8, 12, and every 12 weeks thereafter during treatment. Initiation of mavacamten in patients with a LVEF less than 55% is not recommended. The Camzyos REMS Program requires that prescribers, patients, and pharmacies be registered with the program for the patient to receive the drug. Contraindications to the use of mavacamten include the use of moderate to strong CYP2C19 inhibitors and inducers, moderate to strong CYP3A4 inducers, and strong CYP3A4 inhibitors due to the increased risk of heart failure when combined with mavacamten.

The most notable clinical trial for Camzyos is the EXPLORER-HCM trial, a double-blind, randomized, placebo-controlled, multicenter, international, parallel group trial. Patients enrolled in the trial had to be ≥18 years old and weigh ≥45 kg, have diagnosed oHCM according to ACC/AHA and ESC guidelines with LVEF ≥55% and NYHA class II or III oHCM, and an oxygen saturation ≥90% at screening. The study included 251 patients randomized 1:1 to receive mavacamten 5 mg daily or placebo.
The primary endpoint was either improvement of mixed peak oxygen consumption (pVO2) by ≥1.5 mL/kg/min and ≥1 NYHA class reduction or a ≥3.0 mL/kg/min pVO2 increase and no worsening of NYHA class. A significantly greater number of patients in the Camzyos arm achieved the primary endpoint at week 30 compared to placebo (37% vs. 17%, p=0.0005). Baseline LVEF and LVEF at week 38 after an eight-week drug washout period were compared and were similar among the groups. Syncope and dizziness were the most common adverse effects and occurred more frequently in the mavacamten group.

The safety and efficacy of Camzyos in certain populations and for extended time periods have not been evaluated. The safety and efficacy of Camzyos in pediatric patients has not been established. However, completed clinical trials have included patients who are 65 and older and have demonstrated similar safety and efficacy within this population. Trials regarding the long-term (≥1 year) safety and efficacy of Camzyos are currently lacking. The MAVA-LTE and DISCOVER-HCM trials plan to study mavacamten's long-term safety and efficacy.

Proposed criteria were presented to Geisinger Cardiology MTDM and the providers we consulted were in favor of decreasing the number of required alternatives.

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

Clinical Discussion: Dr. Yarczower questioned the drug interactions and if we were promoting pharmacogenomic testing to check for poor/rapid metabolizers of those drugs. We are just including a note to reviewer since the member should not be taking the medication in combination with those agents to ensure the patient is not at a greater risk of heart failure due to the DDI. No comments or questions. The committee unanimously voted to accept the recommendations as presented. None were opposed.

Financial Discussion: No comments or questions. Thirty-one committee members voted to accept the recommendations as presented. Two members voted to reject the recommendations

Outcome: Camzyos will be added to the Commercial, Marketplace, and GHP Kids formularies at the Specialty Tier or Brand Non-Preferred Tier for member with a 3 tier benefit. The following prior authorization criteria will apply:

- Medical record documentation that Camzyos is prescribed by a cardiologist **AND**
- Medical record documentation of age ≥18 years old **AND**
- Medical record documentation of diagnosis of NYHA class II-III obstructive hypertrophic cardiomyopathy **AND**
- Medical record documentation of left ventricular ejection fraction (LVEF) ≥55% **AND**
- Medical record documentation of therapeutic failure on, intolerance to, or contraindication to two of the following: beta-blockers, non-dihydropyridine calcium channel blockers, or disopyramide

NOTE: Medical record documentation that patient is not currently prescribed moderate to

strong CYP2C19 inhibitors or inducers, moderate to strong CYP3A4 inducers, or strong CYP3A4 inhibitors

GPI LEVEL: GPI-12

FORMULARY ALTERNATIVES: Beta-blockers (acebutolol, atenolol, betaxolol, bisoprolol, carvedilol, labetalol, metoprolol succinate, metoprolol tartrate, nadolol, pindolol, propranolol, timolol), nondihydropyridine calcium channel blockers (diltiazem, verapamil), disopyramide

QUANTITY LIMIT: 30 tablets per 30 days

AUTHORIZATION DURATION: Initial approval will be for 6 months. Subsequent approvals are dependent upon the criteria listed below and will be allotted for 12 months.

REAUTHORIZATION CRITERIA:
- Medical record documentation of LVEF ≥50% **AND**
- Medical record documentation of clinical improvement or maintenance of condition.

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

ALKINDI SPRINKLE (hydrocortisone)

Review: Alkindi Sprinkle is FDA approved for the use in pediatric patients for replacement therapy of adrenocortical insufficiency.

Alkindi Sprinkles comes in oral granules contained in capsules of 0.5 mg, 1 mg, 2 mg, and 5 mg strengths. The capsule should not be swallowed, and the granules should not be chewed or crushed. After opening the capsule, the granules should be poured directly onto the patient's tongue, poured onto a spoon and placed in the patient's mouth, or poured onto a spoonful of cold or room temperature soft food. Once the granules are in the patient's mouth, they should be swallowed within 5 minutes so there is no bitter taste. Fluids should be given immediately after the dose is given to ensure all granules were swallowed. Dosing is dependent on the individual, where the lowest possible dose should be used first. It is recommended to start the dose between 8-10 mg/m2 daily and rounding the dose to the nearest 0.5 or 1 mg. Depending on the patient's age and disease symptoms, a higher dose might be needed. The total daily dose should be divided into 3 doses and given three times daily, but older patients could have their daily doses divided into two doses and given twice daily. Alkindi Sprinkle can cause tube blockage, so should not be given in nasogastric or gastric tubes.

Glucocorticoids are the ideal choice for adrenal insufficiency replacement therapy as they have little variability in metabolism between patients, can be easily dose titrated and monitored, and mimic the endogenous cortisol rhythm. Hydrocortisone is the drug of choice for a short acting glucocorticoid, taken in two or three divided doses.

An open-label, uncontrolled, single-arm clinical study was done to evaluate Alkindi Sprinkle in 18 pediatric patients with adrenocortical insufficiency. At least one dose of Alkindi Sprinkle was given to all patients who ranged from 36 days to 5.7 years of age. Adverse reactions from most prevalent to least included pyrexia, gastroenteritis, viral upper respiratory tract infection,

vomiting, viral infection, conjunctivitis, otitis media viral, tonsillitis, body temperature increase, bronchitis, dental caries, diarrhea,

Alkindi Sprinkle's safety and efficacy have not been established in geriatric patients. As discussed previously, safety and efficacy of Alkindi Sprinkle has been established for the use of adrenocortical insufficiency replacement therapy.

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: Alkindi Sprinkle is a pharmacy benefit that will be added to the Commercial, Marketplace, and GHP Kids formularies at 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 of age less than or equal to 17 years **AND**
- Medical record documentation of a diagnosis of adrenocortical insufficiency **AND**
- Medical record documentation of difficulty swallowing **OR**
- Medical record documentation of a therapeutic failure on, intolerance to, or contraindication to two (2) generic formulary corticosteroid, one of which must be hydrocortisone

GPI LEVEL: GPI-12

FORMULARY ALTERNATIVES: hydrocortisone, cortisone, dexamethasone, fludrocortisone, methylprednisolone, prednisone, prednisolone

AUTHORIZATION DURATION: Approval will be for 12 months, and patients will need to be reassessed yearly for age appropriateness and need for the sprinkle formulation.

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

ARAZLO (tazarotene)

Review: Arazlo is a retinoid indicated for the topical treatment of acne vulgaris in patients 9 years of age and older. Arazlo is available as a 0.045% lotion in a 45-gram tube and should be applied as a thin layer to the affected areas once daily. Arazlo is the first tazarotene formulation available in lotion form. It is important to avoid concomitant use with oxidizing agents, such as benzoyl peroxide. If the concomitant use of Arazlo with oxidizing agents is required, apply each at different times of the day (ex. One in the morning and the other in the evening).

Common side effects with Arazlo include application site pain, dryness, exfoliation, photosensitivity, erythema, and pruritis. Utilizing a moisturizer, sunscreen, decreasing frequency

of application or discontinued use will help mitigate these side effects. Patients tend to become more tolerant to the medication with continued use.

The safety and efficacy of once daily use of Arazlo for the treatment of acne vulgaris was assessed in two multicenter, randomized, double-blind clinical trials in subjects 9 years and older with facial acne vulgaris compared to placebo. Enrolled subjects had a score of moderate (3) or severe (4) acne on the evaluators global severity score (EGSS), 20 to 50 inflammatory lesions (papules, pustules, and nodules), 25 to 100 non-inflammatory lesions (open and closed comedones) and two or fewer facial nodules.

The efficacy endpoints of success on the EGSS, absolute change in noninflammatory lesion count, and absolute change in inflammatory lesion count were assessed at Week 12. Success on the EGSS was defined as at least a 2-grade improvement from Baseline and an EGSS score of clear (0) or almost clear. In both studies all primary efficacy endpoints were met with statistical significance.

Additionally, there was a phase 2 head-to-head study that compared Arazlo to Tazarotene 0.1% cream and both medications showed similar treatment success measured by reductions in inflammatory and non-inflammatory lesions over 12 weeks. However, Arazlo did show fewer patients experiencing adverse events believed to be due to the lower strength and lotion formulation of tazarotene.

Arazlo is contraindicated in pregnancy as it may cause fetal harm when administered to a pregnant patient. Clinical trials of Arazlo did not include sufficient numbers of subjects aged 65 years and older to determine whether they respond different from younger subjects.

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: Arazlo is a pharmacy benefit and will be added to the Brand Non-Preferred tier of the Commercial, Marketplace, and CHIP Formularies. Arazlo will be added to policy 313.0 Fabior Foam as a separate section as follows:

For Arazlo:

- Medical record documentation of a diagnosis of acne, acne vulgaris, or adult-onset acne **AND**
- Medical record documentation of age greater than or equal to 9 years **AND**
- For members 12 years of age and older: Medical record documentation of therapeutic failure on, intolerance to, or contraindication to three (3) formulary alternatives, two of which must be adapalene and tretinoin

GPI LEVEL: GPI-12

FORMULARY ALTERNATIVES: adapalene, benzoyl peroxide, topical clindamycin, clindamycin/benzoyl peroxide, oral doxycycline, topical erythromycin, erythromycin/benzoyl peroxide, isotretinoin, oral minocycline, sulfacetamide/sulfur, topical tretinoin*

(*Prior authorization required over the age of 30)

RPH SIGNOFF: not required

Additional Recommendations:

- Recommend adding a PA to Tazorac 0.1%, 0.05% gel and Tazorac 0.05% cream for Commercial for new starts ONLY
- Recommend updating the current Fabior Foam policy (policy 313.0) to be renamed Fabior Foam, Tazarotene Foam, Tazorac gel, Tazorac cream and Arazlo policy
    - I recommend updating policy 313.0 to read:

For Acne Vulgaris (All except Arazlo):

- Medical record documentation of a diagnosis of acne, acne vulgaris, or adult-onset acne **AND**
- Medical record documentation of age greater than or equal to 12 years **AND**
- Medical record documentation of therapeutic failure on, intolerance to, or contraindication to three formulary alternatives, two of which must be adapalene and tretinoin

For Arazlo:

- Medical record documentation of a diagnosis of acne, acne vulgaris, or adult-onset acne **AND**
- Medical record documentation of age greater than or equal to 9 years **AND**
- For members 12 years of age and older: Medical record documentation of therapeutic failure on, intolerance to, or contraindication to three (3) formulary alternatives, two of which must be adapalene and tretinoin

For Psoriasis (Tazorac 0.05% cream, Tazorac 0.05% gel and Tazorac 0.1% gel):

- Medical record documentation of a diagnosis of plaque psoriasis **AND**
- Medical record documentation of therapeutic failure on, intolerance to, or contraindication to a topical corticosteroid **OR**
- Medical record documentation of disease involving crucial body areas such as the hands, feet, or genitals **AND**
- Medical record documentation of therapeutic failure on, intolerance to, or contraindication to one formulary alternatives **AND** at least 2 to 3 months of methotrexate or phototherapy

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

QUTENZA (capsaicin)

Review: Qutenza (capsaicin) topical system is a topical analgesic FDA approved for the treatment of neuropathic pain associated with postherpetic neuralgia and neuropathic pain associated with diabetic peripheral neuropathy of the feet.

For diabetic peripheral neuropathy, if a patient requires pharmacologic intervention, it is recommended that first-line therapy includes pregabalin, gabapentin, amitriptyline, or duloxetine. Second-line therapy includes venlafaxine, desvenlafaxine, tramadol, tapentadol, lidocaine transdermal patch, or topical capsaicin (cream or transdermal patch). Third-line treatment includes citalopram, paroxetine, escitalopram, or opioids.

For postherpetic neuralgia, if a patient requires pharmacologic intervention, it is recommended that first-line therapy includes pregabalin, gabapentin, and amitriptyline. Second-line treatments include lidocaine transdermal patch, topical capsaicin (cream or transdermal patch), antiseizure medications (valproic acid, carbamazepine, oxcarbazepine, or lamotrigine), duloxetine, venlafaxine, or opioids.

Qutenza can only be administered by physicians or health care professionals under the close supervision of a physician. Qutenza should be administered in a well-ventilated area while wearing nitrile gloves.

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

Clinical Discussion: Dr. Strony questioned if there were any head to head studies between lidocaine and Qutenza, there were not. No additional comments or questions. The committee unanimously voted to accept the recommendations as presented. None were opposed.

Financial Discussion: Dr. Yarczower asked if it was possible to remove the prior authorization for lidocaine for only FDA approved indications. If we lift the PA it would process freely for any indication. No additional comments or questions. The committee unanimously voted to accept the recommendations as presented. None were opposed.

Outcome: Qutenza will be a medical benefit. Qutenza will be added to the medical benefit cost share list when processed on the medical benefit. If processed at a specialty pharmacy, Qutenza will process at the Specialty tier or the Brand Non-preferred tier for members with a three-tier benefit. Qutenza will require prior authorization with the following criteria:

- Medical record documentation of age greater than or equal to 18 years **AND**
- Medical record documentation of postherpetic neuralgia **OR** diabetic peripheral neuropathy **AND**
- Medical record documentation of a prescribed dose and administration that is consistent with FDA-approved package labeling, nationally recognized compendia, or peer-reviewed medical literature **AND**
- Medical record documentation of an intolerance to, contraindication to, or therapeutic failure on pregabalin **AND**
- For diabetic peripheral neuropathy: Medical record documentation of therapeutic failure on, intolerance to, or contraindication to two (2) of the following: gabapentin, tricyclic antidepressant (amitriptyline, nortriptyline, desipramine), duloxetine, venlafaxine, valproate sodium, capsaicin cream **OR**
- For postherpetic neuralgia: Medical record documentation of therapeutic failure on, intolerance to, or contraindication to two (2) of the following: gabapentin, tricyclic antidepressant (amitriptyline, nortriptyline, desipramine), capsaicin cream, lidocaine patch

QUANTITY LIMIT: 4 patches every 90 days, Darwin Rx Count 16 (for 12 months)

AUTHORIZATION DURATION: 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.

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

VERKAZIA (cyclosporine ophthalmic)

Review: Verkazia is FDA approved for the treatment of Vernal keratoconjunctivitis (VKC) in children and adults. It is a type of ocular allergy that tends to occur in males in a warm, dry tropical environment such as the Mediterranean, Middle East, Africa, Central America, and India. The cause of VKC is unknown, but it tends to be seasonal (or may progress to chronic) and is mediated by an IgE response. Although this disease is rare, it can lead to corneal ulcers and vision loss, so treatment is necessary.

Verkazia's approval was based on 2 randomized, multicentered, double-masked, vehicle-controlled clinical trials (VEKTIS and NOVATIVE studies). In the VEKTIS trial, the primary endpoint of mean composite score that reflected corneal fluorescein statin (CFS) was statistically significant in both treatment groups using high dose (qid dosing) and low dose (bid dosing) cyclosporine emulsion. The NOTATIVE trial further showed improvements in inflammation of the cornea (keratitis score) and ocular itching. The most common adverse events were eye pain (12%) and eye pruritus (8%). These usually were short lived and occurred during instillation.

The treatment of VKC is similar to the treatment of allergic conjunctivitis. Treatment is usually initiated with a topical ophthalmic antihistamine with mast cell stabilizing properties such as olopatadine, epinastine, azelastine, or ketotifen. Alternatively topical mast cell stabilizers, such as cromolyn, in combination with oral antihistamines can be used. Disease that is refractory to this initial treatment can be treated with topical corticosteroids or cyclosporine.

The use of Restasis for the treatment of VKC is considered off-label but recognized in certain pharmaceutical compendia. There are some clinical trials that evaluated the use of Restasis in the treatment of VKC that have shown to be successful. Verkazia is the first approved drug specifically for Vernal keratoconjunctivitis.

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: Verkazia is a pharmacy benefit and will not be added to the Commerical/Exchange/CHIP formularies. The following prior authorization criteria will apply:

- Medical record documentation of age ≥ 4 years old AND
- Medical record documentation of a diagnosis of vernal keratoconjunctivitis in children and adults AND
- Medical record documentation of therapeutic failure, intolerance to, or contraindication of at least one mast cell stabilizer/topical antihistamine (i.e., olopatadine, azelastine, epinastine)

GPI LEVEL: GPI-12

QUANTITY LIMIT: 120 each

FORMULARY ALTERNATIVES: olopatadine 0.1% ophthalmic, olopatadine 0.2% ophthalmic, azelastine 0.05% ophthalmic, epinastine 0.05% ophthalmic, cyclosporine 0.05% ophthalmic emulsion, Restasis 0.05% ophthalmic emulsion, Restasis 0.05% Multidose emulsion, cromolyn 4% ophthalmic

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

XYOSTED (testosterone enanthate)

Review: Xyosted is a testosterone subcutaneous injection indicated for testosterone replacement therapy in adult males for conditions associated with a deficiency or absence of endogenous testosterone. This includes both primary hypogonadism (low serum testosterone, FSH and LH above the normal range) and hypogonadotropic hypogonadism (low testosterone, FSH and LH in normal to low range).

Prior to initiating Xyosted, the hypogonadism diagnosis should be confirmed by measuring morning serum testosterone levels on at least two separate days. Xyosted is administered with a starting dose of 75 mg subcutaneous injection administered once weekly. Total testosterone trough concentrations should be measured following 6 weeks of dosing, following 6 weeks after dose adjustment, and periodically while on treatment. Trough concentrations between 350 ng/dL and 650 ng/dL correlate with testosterone exposures in the normal ranged during the entire dosing intervals. Trough concentrations above 650 ng/dL require a dose decrease by 25 mg and concentrations below 350 ng/dL require a dose increase by 25 mg. Xyosted is supplied as a 0.5 mL single-dose syringe autoinjector in three strengths: 50 mg/0.5 mL, 75 mg/0.5 mL, and 100 mg/0.5 mL.

The efficacy of Xyosted was evaluated in a 52-week, open-label study to evaluated efficacy and safety in 150 adult males with hypogonadism. Patients self-administered the initial dose of 75 mg once weekly on the same day of the week. At week 7, doses were adjusted or maintained according to the serum testosterone concentrations drawn at the end of the dosing interval of Week 6. The primary endpoint measuring percentage of patients with time-averaged serum total testosterone concentration within normal range at Week 12 showed that 135 (90%) of patients treated with Xyosted had a serum total testosterone concentration within the normal range. Secondary endpoints measuring percentage of patients with maximum total testosterone

concentrations over 3 predetermined limits (>1500 ng/dL, 1800-2500 ng/dL and >2500 ng/dL) showed that no patients had a Cmax > 1500 ng/dL at Week 12.

The safety profile of Xyosted was consistent with the known safety profile of testosterone replacement therapy, except for increases in blood pressure and four cases of depression and suicidal ideation and behavior (including one completed suicide reported during the long-term Xyosted study).
Xyosted includes a black box warning for hypertension that may increase the risk for major adverse cardiovascular events (MACE), including non-fatal myocardial infarction, non-fatal stroke and cardiovascular death, with greater risk for MACE in patients with cardiovascular risk factors or established cardiovascular disease. Patients should be monitored after initiating therapy for new or worsening hypertension and re-evaluated for risk vs. benefit in patients who develop cardiovascular risk factors or disease while on treatment.

Xyosted includes a warning for risk of depression and suicide and advises that patients should be monitored for new or worsening depression, anxiety or other mood changes. Depression and suicide have been reported with other studies and post marketing reports for testosterone replacement therapies and at this time, it is unclear if Xyosted presents an increased risk of suicidality and depression compared to other treatments. For the first three years of Xyosted marketing, depression and suicide case reports will be monitored with the quarterly NDA Periodic Adverse Event Report (PADER) and changes may be proposed to the Xyosted labeling based on the findings of these reports.

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: Xyosted is pharmacy benefit and will not be added to the Commercial, Exchange, and CHIP pharmacy formularies. The following prior authorization criteria will apply:

- Medical record documentation of use for testosterone replacement therapy in adult males for conditions associated with a deficiency or absence of endogenous testosterone:
    - Primary hypogonadism (congenital or acquired) **OR**
    - Hypogonadotropic hypogonadism (congenital or acquired)

OR

- Medical record documentation of a diagnosis of gender dysphoria, as defined by the current version of the Diagnostic and Statistical Manual of Mental Disorders (DSM)

AND

- Medical record documentation of therapeutic failure on, intolerance to, or contraindication to three formulary alternatives

MEDISPAN AUTHORIZATION LEVEL: GPI-12

FORMULARY ALTERNTATIVES: testosterone cypionate, testosterone enanthate, Androderm, Aveed*

RPH SIGNOFF REQUIRED: no

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

JATENZO (testosterone undecanoate)

Review: Jatenzo is an oral capsule formulation of testosterone undecanoate indicated for testosterone replacement therapy in adult males for conditions associated with a deficiency or absence of endogenous testosterone. This includes both primary hypogonadism (low serum testosterone, FSH and LH above the normal range) and hypogonadotropic hypogonadism (low testosterone, FSH and LH in normal to low range). Jatenzo and Tlando are two new testosterone formulations that offer the advantage of oral dosing.

Prior to initiation treatment with Jatenzo, the diagnosis is confirmed by measuring serum testosterone levels in the morning on at least two separate days. The recommended starting dosage of Jatenzo is 237 mg taken orally twice daily, in the morning and evening with food. Seven days after starting treatment, the dosage can be adjusted according to the schedule in Table 1, based on serum testosterone measurements.

Table 1: JATENZO Dose Adjustment Scheme

Testosterone Concentration in Serum From Plain Tube Drawn 6 hours After Morning Dose	Current JATENZO Dose (mg, twice daily)	New JATENZO Dose (mg, twice daily)
Less than 425 ng/dL	158	198
	198	237
	237	316 (two 158 mg capsules)
	316 (two 158 mg capsules)	396 (two 198 mg capsules)
425 ng/dL – 970 ng/dL	No Dose Change	
More than 970 ng/dL	396 (two 198 mg capsules)	316 (two 158 mg capsules)
	316 (two 158 mg capsules)	237
	237	198
	198	158
	158	Discontinue Treatment

The efficacy and safety of Jatenzo was studied in 166 adult hypogonadal males in an open-label 4 month study. Al patients received Jatenzo at a starting dose of 237 mg twice daily with meals and was adjusted on Days 21 and 56 according to labeling based on average testosterone concentration. The primary endpoint measuring mean plasma total testosterone concentration (Cavg) over 24-hours within the normal eugonadal range on the final PK visit of the study showed that 145 (87%) men treated with Jatenzo had a mean total testosterone concentration withing the normal range at the end of treatment.
Secondary endpoints measuring percentage of patients with maximum total testosterone concentrations at three predetermined levels showed that 83% had C_{max} less or equal to 1500 ng/dL, and 3% each had levels 1800 ng/dL- 2500 ng/dL, and greater than 2500 ng/dL.

The safety profile of Jatenzo is consistent with the known safety profile of other testosterone, except for the risk of increased blood pressure. During clinical trials of Jatenzo, systolic blood pressure in increased during 4 months of treatment by an average of 4.9 mmHG based on ambulatory blood pressure monitoring and 2.8 mmHg based on blood pressure cuff

measurements. These can increase the risk of MACE, with greater risk in patients with established cardiovascular disease or risk factors. Jatenzo carries a black box warning for these risks.

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

Clinical Discussion: Kim updated the quantity limit to 4 capsules per day for the 158mg capsules and 198mg capsules. 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: Jatenzo is a pharmacy benefit and will be added to the Brand Non-Preferred tier of the Commercial, Marketplace, and CHIP formularies. The following prior authorization criteria will apply:

- Medical record documentation of use for testosterone replacement therapy in adult males for conditions associated with a deficiency or absence of endogenous testosterone:
    - Primary hypogonadism (congenital or acquired) **OR**
    - Hypogonadotropic hypogonadism (congenital or acquired)

  AND
- Medical record documentation of therapeutic failure on, intolerance to, or contraindication to three formulary alternatives

MEDISPAN AUTHORIZATION LEVEL: GPI-12

QUANTITY LIMIT:

- 158mg and 198mg capsules: 4 capsules/day
- 237mg capsules: 2 capsules/day

FORMULARY ALTERNTATIVES: testosterone gel, testosterone transdermal gel, testosterone transdermal solution, testosterone cypionate, testosterone enanthate, Androderm, Aveed*

RPH SIGNOFF REQUIRED: no

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

Tlando (testosterone undecanoate)

Review: Tlando is an oral capsule formulation of testosterone undecanoate indicated for testosterone replacement therapy in adult males for conditions associated with a deficiency or absence of endogenous testosterone. This includes both primary hypogonadism (low serum testosterone, FSH and LH above the normal range) and hypogonadotropic hypogonadism (low testosterone, FSH and LH in normal to low range). Jatenzo and Tlando are two new testosterone formulations that offer the advantage of oral dosing.

Prior to initiating Tlando, the diagnosis of hypogonadism is confirmed by measuring serum testosterone concentration in the morning on at least two separate days. The recommended dosage of Tlando is 225 mg (two 112.5 mg capsules) twice daily, once in the morning and evening with food. Serum testosterone should be checked three to four weeks after initiating Tlando, and periodically thereafter. The dose of Tlando should be continued or discontinued based on the serum testosterone measurements:

- Serum testosterone 300 - 1080 ng/dL: continue TLANDO
- Serum testosterone < 300 ng/dL: discontinue TLANDO
- Serum testosterone > 1080 ng/dL: discontinue TLANDO

The efficacy and safety of Tlando was evaluated in Study 16-002, an open-label, single-arm study in adult hypogonadal male patients. A total of 95 patients received Tlando 225 mg twice daily with food for approximately 24 days. The primary endpoint evaluation demonstrated that 80% of patients treatd with Tlando had a 24-hour average serum testosterone concentration (Cavg0-24h) within the normal range (300 – 1800 ng/dL).

The safety profile of Tlando is consistent with Jatenzo, another oral testosterone agent, and contains a black box warning for increased blood pressure which may in turn increase the risk of MACE, including non-fatal MI, non-fatal stroke, and cardiovascular death. During one clinical trial, Tlando increased systolic blood pressure after 4 months of treatment by an average of 4.3 mmHg based on ambulatory blood pressure monitoring and 4.8 mmHg from baseline based on blood pressure cuff measurements. Other warnings and precautions are consistent with Jatenzo and other testosterone replacement therapy products.

Tlando is not approved for the treatment of pediatric patients, as this has note been studied and improper use of testosterone may result in acceleration of bone age and premature closure of epiphyses. There have not been sufficient numbers of geriatric patients in controlled studies to determine if efficacy and safety differs between older and younger patients. Geriatric patients treated with androgens may be at risk for worsening signs and symptoms of BPH and hypertension.
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: Tlando is a pharmacy benefit and will be added to the Brand Non-Preferred tier of the Commercial, Marketplace, and CHIP formularies. The following prior authorization criteria will apply:

- Medical record documentation of use for testosterone replacement therapy in adult males for conditions associated with a deficiency or absence of endogenous testosterone:
    - Primary hypogonadism (congenital or acquired) **OR**
    - Hypogonadotropic hypogonadism (congenital or acquired)

  AND
- Medical record documentation of therapeutic failure on, intolerance to, or contraindication to three formulary alternatives

MEDISPAN AUTHORIZATION LEVEL: GPI-12

QUANTITY LIMIT: 2 capsules per day

FORMULARY ALTERNTATIVES: testosterone gel, testosterone transdermal gel, testosterone transdermal solution, testosterone cypionate, testosterone enanthate, Androderm, Aveed*

RPH SIGNOFF REQUIRED:

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

CLASS REVIEWS

COVID-19

Novavax Clinical Review:
The Novavax COVID-19 Vaccine is an adjuvanted vaccine which contains the SARS-CoV-2 Spike Protein and Matrix M adjuvant (to enhance the immune response of the vaccinated individual). The spike protein in this vaccine is produced in insect cells and the Matrix-M adjuvant contains saponin extracts from the bark of the Soapbark tree that is native to Chile. It is authorized under an EUA for administration to prevent COVID-19 in individuals 12 years of age and older as a two-dose primary series.

Novavax COVID-19 Vaccine is administered intramuscularly as a primary series of two doses (0.5 mL each) three weeks apart in individuals 12 years and older.

Support for the emergency use authorization comes from Study 1, an ongoing phase 3 trial in which participants 18 years of age and older were randomized 2:1 to receive two doses of Novavax COVID-19 adjuvanted or placebo, 3 weeks apart. Efficacy analysis which included data from 25,657 participants 18 years of age and older who did not have evidence of COVID-19 through 6 days after the second dose and had a median follow up of 2.5 months after Dose 2 showed that the vaccine was 90.4% effective in preventing PCR-confirmed symptomatic mild, moderate, or severe COVID-19 occurring at least 7 days after Dose 2.

On August 19th, 2022, the EUA of Novavax was updated to include patients 12 years of age through 17 years of age and older based on safety and efficacy data from the adolescent primary series expansion of Study 1. In the expansion, 2,232 individuals 12 to 17 years of age received at least one dose of Novavax COVID-19 vaccine or saline placebo. Effectiveness was based on comparison of SARS-CoV-2 neutralizing antibody titers 14 days after dose 2 in adolescents compared to adults and noninferiority of immune responses was demonstrated by geometric mean titers and seroconversion rates. In the adolescent group, the evaluation of 1,799 patients showed that the vaccine was 78.29% effective in preventing PCR-confirmed symptomatic mild, moderate, or severe COVID-19 occurring at least 7 days after Dose 2.

Warnings, Precautions, and adverse reactions are consistent with other COVID-19 vaccines. The most commonly reported adverse reactions by vaccine recipients included pain/tenderness, redness, and swelling at the injection site, fatigue, muscle pain, headache, joint pain, nausea/vomiting, and fever. Safety of the vaccine in the adolescent population did not identify any safety concerns that would preclude issuance of the EUA.

Recommendations: Novavax COVID-19 Vaccine, Adjuvanted will be covered as a medical or pharmacy benefit and will not require a prior authorization. It will be covered as a preventive vaccine for a $0 copay.

Comirnaty Update:
Comirnaty full FDA approval has been expanded to include adolescent patients 12 to 17 years of age in addition to those 18 years and older for two-dose primary series for prevention of COVID-19. In addition, it has emergency use authorizations for a third primary series dose to individuals 12 years of age and older with certain kinds of immunocompromise, for a single booster dose in patients 12 years and older, primary series doses for pediatric patients 6 months to 4 years and primary and booster doses for pediatric patients 5 to 12 years of age.

Recommendations: Comirnaty is covered as a medical or pharmacy benefit and does not require a prior authorization. It is covered as a preventive vaccine for a $0 copay.

Bebtelovimab Update:
Bebtelovimab is the only monoclonal antibody that is currently authorized for the treatment of COVID-19 in adult s and pediatric patients (12 years and older, weighing at least 40 kg). Recently, the purchasing of Bebtelovimab has shifted to the private market after the depletion of 150,000 doses purchased by the US government in June 2022.

Recommendations: Bebtelovimab will be covered as a medical benefit and will be free to patients who qualify under the Emergency Use Authorization parameters issued by the FDA. It will not require a prior authorization.

Olumiant Update:
Olumiant received the full FDA approval for the treatment of COVID-19 in hospitalized adults requiring supplemental oxygen, non-invasive, or invasive mechanical ventilation, or ECMO. It previously had an EUA in place for this indication and efficacy is based on findings of the previously submitted trials. No new clinical trials were included in the information submitted for approval. Olumiant is still available through the Emergency Use Authorization for treatment of COVID-19 in hospitalized pediatric patients 2 years to less than 18 years of age.

Recommendations: The EUA for Olumiant is limited to inpatient use and Olumiant for the treatment of COVID-19 will be provided to inpatient pharmacies only by Lilly Authorized Specialty Distributors. Olumiant for the treatment of COVID-19 will not be available at retail pharmacies and is not authorized for outpatient use. The following change is recommended to the note for the reviewer for Commercial Policy 530.0 Olumiant:

> Note to Reviewer* If Olumiant is being prescribed for COVID-19, see the FDA website for the Olumiant Prescribing Information and Emergency Use Authorizations at https://www.fda.gov/emergency-preparedness-and-response/mcm-legal-regulatory-and-policy-framework/emergency-use-authorization#coviddrugs for current FDA approved and EUA authorized use. At this time, Olumiant is authorized for inpatient use only for COVID-19 and would not be covered for outpatient use.

Lagevrio Update:
Molnupiravir, a prodrug that inhibits the replication of multiple RNA viruses, including SARS-CoV-2, was previously evaluated by the P&T Committee. Emergency Use Authorization was reauthorized in August 2022 under the brand name Lagevrio (molnupiravir). No changes are recommended to the current formulary placement of Lagevrio.

Recommendations: Lagevrio is a pharmacy benefit and is free to patients who qualify under the Emergency Use Authorization parameters issued by the FDA. It does not require a prior authorization and is currently on formulary to cover the cost of administration.

Sotrovimab Update:
Due to high frequency of Omicron BA.2 subvariant, not currently authorized in the US. Currently not available in Darwin which is consistent with the EUA status. No changes are needed at this time.

Bamlanivimab/Etesevimab Update:

Due to high frequency of Omicron variant, not currently authorized in the US. Currently not available in Darwin which is consistent with the EUA status. No changes are needed at this time.

REGEN-COV, Casirivimab/Imdevimab Update:
Due to high frequency of Omicron variant, not currently authorized in the US. Currently not available in Darwin which is consistent with the EUA status. No changes are needed at this time.

Clinical Discussion: No comments or questions. 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.

FAST FACTS

DIACOMIT (stiripentol)

Clinical Summary: Diacomit is now indicated for the treatment of Dravet syndrome in patients taking clobazam who are 6 months of age and older and weigh 7 kg or more. Previously Diacomit was indicated in patients 2 years of age and older with Dravet syndrome. The dosage for patients is 50 mg/kg/day administered in 2 or 3 divided doses, depending on patient's age and body weight (Table 1).

The efficacy of Diacomit in the new patient population is supported by pharmacokinetic and safety studies and extrapolation of the efficacy demonstrated in two clinical studies in pediatric patients 3 years to less than 18 years of age. The safety of Diacomit in patients 6 months to less than 2 years of age with Dravet syndrome was studied in a total of 106 patients in 5 open label studies. The adverse reactions observed were consistent with those seen in clinical studies in patients 2 years of age and older.

Current formulary status: Specialty/Brand NP tier, requires a PA

Recommendation: No changes are recommended to the formulary placement of Diacomit. The following changes are recommended for Commercial Policy 565.0 to incorporate the new indications:

- Medical record documentation that Diacomit is prescribed by a neurologist **AND**
- Medical record documentation of age greater than or equal to ~~2 years~~ 6 months of age **AND**
- Medical record documentation of weight greater than or equal to 7 kg **AND**
- Medical record documentation of a diagnosis of Dravet syndrome **AND**
- Medical record documentation that Diacomit is to be used in combination with clobazam

MEDISPAN AUTHORIZATION LEVEL: GPI-10

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

RUBRACA (rucaparib)

Background: AstraZeneca has voluntarily withdrawn the indication for Lynparza for the treatment of adult patients with deleterious or suspected deleterious germline BRCA-mutated (BRCAm) advanced ovarian cancer who have been treated with three or more lines of chemotherapy.

Recommendation: It is recommended that the Commercial Policy 362.0 for Lynparza be updated to remove the withdrawn indication.

For Ovarian Cancer

- 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: o 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 ovarian 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 recurrent 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: Was this included in the policy due to FDA approval. Yes, likely included as part of an accelerated approval and after confirmatory trials were completed, there was no benefit. 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.

CABENUVA QL UPDATE

BACKGROUND: Every 2-month dosing was recently approved for Cabenuva. Recommended Every-2-Month Dosing Schedule: Initiate injections of Cabenuva (600 mg of cabotegravir and 900 mg of rilpivirine) on the last day of current antiretroviral therapy or oral lead-in for 2 consecutive months and continue with injections of Cabenuva every 2 months thereafter. When a dose is missed by more than three months, patients need to re-initiate with the initial injections for 2 consecutive months then resume every 2 month dosing.

Current quantity limit for Cabenuva 600mg/900mg is 6mL every 180 days.

Recommendation: It is recommended to update the quantity limits for the 600mg/900mg strength to:

- 6mL per 28 day

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.

RITUXIMAB UPDATE

Background: It is recommended to update the limitations under Rheumatoid Arthritis (RA) and the authorization duration under Chronic Immunothrombocytopenia (ITP) for Rituxan, Truxima, Ruxience and Riabni's policy (MBP 48.0) to accurately reflect dosing recommendations of the prescribing information and to align authorization durations across all indications for chronic use for rituximab.

It is also recommended to update the alternatives section under Chronic Immunothrombocytopenia (ITP) for Rituxan, Truxima, Ruxience and Riabni's policy (MBP 48.0) for the Medicaid/Commercial/ Exchange/CHIP lines of business. Lastly it is recommended to update the alternatives section under Chronic Immunothrombocytopenia (ITP) for Rituxan as listed in the Medicare 2022 Part B Step Therapy policy to closely align with the American Society of Hematology guidelines for immune thrombocytopenia.

Recommendation:

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

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/mm3 with active bleeding; or platelet count < 30,000/mm3 and a documented history of significant bleeding; or platelet count < 20,000/mm3 **AND**
- Medical record documentation of therapeutic failure on, intolerance to, or contraindication to corticosteroids and/or 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.~~

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 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 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).

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.

ORENCIA UPDATE

Background: It is recommended to update the limitation of use for Orencia (MBP 40.0) to more accurately reflect the limitation of use documented on the FDA approved prescribing information.

Recommendation: MBP 40.0 Orencia IV (abatacept)
LIMITATIONS: ~~Abatacept should not be administered concomitantly with TNF antagonists and is not recommended for use concomitantly with anakinra.~~ The concomitant use of Orencia with other potent immunosuppressants [e.g. biologic disease-modifying antirheumatic drugs (bDMARDS), Janus kinase (JAK) inhibitors] is not 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.

MEDICAL ADMINISTRATIVE POLICY UPDATE

Background: It is recommended to update the Administrative Medical Drug Policy (MBP 1.0) to adequately address policy and procedure pertaining to the medical benefit.

Recommendation:

MBP 1.0 Administrative Medical Drug Policy

I. Policy:

Administrative Medical Drug Policy

II. Purpose/Objective:

1. To define the processes and procedures followed by Geisinger Health Plan for coverage determinations.
2. To provide a policy of coverage regarding medical benefit drugs without specific coverage criteria.
3. To provide a policy of coverage regarding medical benefit drugs with quantity limits.
4. To provide a policy of coverage regarding medical benefit drugs with claims edits.
5. To provide reference to a policy of coverage regarding medical benefit drugs with site of care requirements.

III. Responsibility:

A. Medical Directors
B. Medical Management
C. Pharmacy Department

IV. Required Definitions

1. Attachment – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. Exhibit – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. Devised – the date the policy was implemented.
4. Revised – the date of every revision to the policy, including typographical and grammatical changes.
5. Reviewed – the date documenting the annual review if the policy has no revisions necessary.

V. Additional Definitions

1. FDA – Food and Drug Administration.
2. Prescribing healthcare professional – a person who writes, gives or orders medical drugs and is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
3. Providing healthcare provider – a person or entity who administers and/or dispenses medications and is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
4. GHP – Geisinger Health Plan or “Plan”
5. Medical Necessity or Medically Necessary means Covered Services rendered by a Health Care Provider that the Plan determines are:
    a. appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
    b. provided for the diagnosis and the direct care and treatment of the Member's condition, illness disease or injury;
    c. in accordance with current standards good medical treatment practiced by the general medical community;
    d. not primarily for the convenience of the Member, or the Member's Health Care Provider; and

e. the most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient

6. Coverage Determination – A decision of coverage for a medication (approval/denial)
7. Member – Individual who has enlisted in the benefit
8. CPhT – Certified pharmacy technician
9. LPN – Licensed practical nurse
10. Off-label drug use - use of a drug that has been approved by the Food and Drug Administration (FDA) for other indications, treatment regimens or in patient populations that are not specifically included in the approved labeling.
11. Orphan-drug - a designation granted by the FDA under the Orphan Drug Act of 1983. This designation is granted to a drug or biologic agent intended to treat or prevent a rare disease or condition, defined in the Rare Diseases Act of 2002 as one which affects less than 200,000 people in the United States and for which there is no reasonable expectation that the cost of developing the drug would be recovered from the sale of the drug in the United States

Medicaid Business Segment

Medical Necessity shall mean a service or benefit that is compensable under the Medical Assistance

Program and if it meets any one of the following standards:

(i) the service or benefit will, or is reasonably expected to, prevent the onset of an illness, condition or disability.

(ii) the service or benefit will, or is reasonably expected to, reduce or ameliorate the physical, mental or development effects of an illness, condition, injury or disability.

(iii) the service or benefit will assist the Member to achieve or maintain maximum functional capacity in performing daily activities, taking into account both the functional capacity of the Member and those functional capacities that are appropriate for members of the same age

DESCRIPTION:

This policy explains how coverage decisions are determined for GHP members who have medical drug benefits, including Commercial, Affordable Care Act (ACA), GHP Kids, Self-Insured plans, Medicare and Medicaid, unless a specific limitation or exception exists. Coverage exceptions include decisions about the medical necessity of a specific drug, decisions about drugs exceeding quantity limits, and decisions whether a member has satisfied prior authorization requirements, site of care requirements, or claims edit requirements.

CRITERIA FOR USE: Requires Prior Authorization by Medical Director or Designee

A) Coverage Determination Procedure
   1) A request may be initiated for an exception in accordance with the following:
      i) Requests should be directed to the Department of Pharmacy Services
      ii) Information needed for a determination include, but is not limited to, the following:
         (1) Caller’s name and telephone number;
         (2) Member’s medical record number and insurance identification number;
         (3) Prescribing and providing healthcare provider's name and telephone number;
         (4) The product and exception requested;
         (5) Clinical rationale including medical records, laboratory data, past treatment history and other documentation, as determined by the Plan to be relevant.

2) Requests for exception will be reviewed as follows:
    i) A Certified Pharmacy Technician (CPhT) or License Practical Nurse (LPN), under the supervision of a Health Plan Pharmacist, will perform an initial review of medical record documentation and treatment history to recommend approval or denial of requests where there are explicit utilization management criteria and no clinical judgement is required.
        (1) If the request for exception is approved, no further action will be required on the part of the Health Plan Pharmacist or the Licensed Physician (dependent upon the exception requested).
        (2) If the CPhT or LPN recommends denial upon initial review, the requests will be forwarded to a Health Plan Pharmacist for review.
    ii) For all requests where clinical judgement is required, explicit utilization management criteria do not exist, or those which a CPhT or LPN recommends denial (or approval, dependent upon the determination requested), a Health Plan Pharmacist will perform an initial review of medical record documentation and treatment history to recommend approval or denial. The request will be approved if, in the professional judgment of the pharmacist reviewer, the services are medically necessary to meet the medical needs of the member of the request.
        (1) If the request for exception is approved, no further action will be required on the part of the Licensed Physician.
        (2) If the Health Plan Pharmacist recommends denial upon initial review, the request will be forwarded to a Licensed Physician for review.
    iii) A Licensed Physician shall make the final decision in all instances where a Health Plan Pharmacist recommends denial. The request will be approved if, in the professional judgment of the physician reviewer, the services are medically necessary to meet the medical needs of the member of the request.
3) Documentation of the determination of coverage and the notifications will take place within GHP coverage determination decision making or customer service documentation tool(s).

B) Off-Label Requests
1) Off-label drug use for a medical drug is considered to be medically necessary when **all** of the following criteria are met:
    i) The drug has been approved by the FDA for at least one indication; **AND**
    ii) The drug is being prescribed to treat a condition not listed in the product labeling, but for which treatment is medically necessary; **AND**
    iii) Conventional therapies have been tried and failed, are contraindicated, or do not exist; **AND**
    iv) The proposed drug use is supported by any one or more of the following:
        (1) The National Comprehensive Cancer Network Practice Guidelines™ in Oncology category 1, 2A, or 2B recommendation; **OR**
        (2) The National Comprehensive Cancer Network Drug & Biologics Compendium™ category of Evidence and consensus 1, 2A, or 2B; **OR**
        (3) The American Hospital Formulary Service – Drug Information; **OR**
        (4) Thompson Micromedex DrugDex Compendium (DrugDex®) class I, IIa, or IIb indication; **OR**
        (5) Elsevier Gold Standard's Clinical Pharmacology Compendium (Clinical Pharmacology®) **OR**
        (6) Indication is listed in Lexi-Drugs as "Use: Off-Label" and rated as "Evidence Level A"
2) If a medical policy exists for a specific drug, reference should be made to that document for information regarding the FDA approved use(s) of that drug. When a clinical trial is

open for accrual that provides the drug under consideration for the indication requested, and when the insured individual meets the eligibility requirements of that trial, providers are encouraged to consider that option.

C) Quantity Limit Exceptions
   1) A quantity limit exception may be made for members who meet the following criteria:
      i) Medical record documentation that requested dose cannot be achieved by using a formulary alternative (e.g. use of one 90mg syringe in place of two 45mg syringes) **AND**
      ii) Medical record documentation that prescribed dosage does not exceed those approved by the Food and Drug Administration (FDA) or accepted standards of care **AND**
      iii) If request is for dose that exceeds Food and Drug Administration (FDA) approved labeling, medical record documentation of peer-reviewed literature citing well-designed clinical trials to indicate that the member's healthcare outcome will be improved by dosing that exceeds FDA approved labeling **AND**
      iv) Medical record documentation that current quantity limit has been ineffective in management of member's condition or is likely to be ineffective or adversely affect the patient's compliance based on clinical evidence & the known physical and mental characteristics of the member

D) Claims Editing Process
   1) A claim edit is developed to ensure the drug is:
      i) Used for industry accepted indications – both on- and off-label.
      ii) Dosed appropriately based on the specific diagnosis.
      iii) Administered at a frequency that is appropriate for the diagnosis.
      iv) Given in accordance with any lifetime maximum units, visits and/or administrations.
      v) Administered to the appropriate age group.
      vi) Administered by an appropriate route.
      vii) Given in conjunction with appropriate laboratory studies and/or monitoring.
      viii) Not given in conjunction with other drugs that might cause adverse drug interactions.
      ix) Reported with an appropriate amount if billed as drug wastage.
      x) Reported with the appropriate National Drug Code (NDC).
   2) A review for the medical necessity of a claim not having met requirements set forth by a claim edit shall have the use supported by one or more of the following:
      i) Manufacturer's prescribing information
      ii) Elsevier Gold Standard's Clinical Pharmacology
      iii) Thomson MICROMEDEX® (DRUGDEX®, DrugPoints®)
      iv) American Hospital Formulary System (AHFS) DI
      v) National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium

E) Site of Care
   1) Medical benefit policy (MBP) 181.0 provides 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 for participating lines of business. See MBP 181.0 for information regarding the medical necessity of site of care.

Discussion: No comments or questions.

Outcome: Twenty-seven committee members voted to accept the recommendations as presented. One member voted to reject the recommendations

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

GLP-1 UPDATE

Background: Pharmacy trends have seen a significant spike in utilization of GLP-1 agonists. The most significant increase is in Ozempic, a GLP-1 agonist indicated for the treatment of diabetes. A review of orders written by Geisinger physicians demonstrates that a high percentage of that utilization appears to be for off label indications.

Recommendation: It is recommended that a prior authorization with the following criteria is implemented for Ozempic, Rybelsus, Trulicity, and Victoza in order to ensure utilization for a Food and Drug Administration (FDA) approved indication:

- Medical record documentation of a diagnosis of type 2 diabetes mellitus

The implementation date for Commercial and Self-Insured plans will be 1/1/2023.

The implementation date for Medicare Part D and Marketplace plans will be 1/1/2024.

Prior authorization will be proactively placed for those members identified with a diagnosis of type 2 diabetes on medical claims.

As a self-insured client, the Geisinger employer group may continue to allow certain Ozempic products to process without a prior authorization.

Discussion: There was discussion regarding the benefit allowances for weight loss medications. Clarified that weight loss medications are excluded per most plans benefit documents. Coverage of these agents would require a decision from BRT to add the benefit. No additional comments or questions.

Outcome: Twenty-nine committee members voted to accept the recommendations as presented. Two members voted to reject the recommendations

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

MULTISOURCE BRAND CONTRACEPTIVE UPDATE

Background: Current contraceptive coverage includes all single source brands and generics for $0 member cost sharing. Multisource brands are currently available on the brand non-preferred tier. An exceptions process exists which allows members to request $0 coverage of a multisource brand after the following criteria are met:

- Medical record documentation of therapeutic failure on, or intolerance to the generic formulary agent(s) and/or the preferred brand agent(s) **OR**
- Medical record documentation of therapeutic failure on, intolerance to, or contraindication to the inactive ingredients of the generic formulary agent(s) and/or the preferred brand agent(s)

AND

- Medical record documentation of therapeutic failure on, intolerance to, or contraindication to up to three formulary alternatives, if available

On January 10, 2022, the Department of Health and Human Services released a set of frequently asked questions which clarified what the department considers to be reasonable medical management as it relates to the coverage of contraceptive products. After reviewing this guidance with the GHP legal team it was determined that a change in policy is necessary.

Recommendation: To ensure compliance with Affordable Care Act regulations, it is recommended that all multisource brand contraceptives are moved to the $0 ACA preventative tier. Member refunds will be generated back to the date of the published FAQs, 1/10/2022.

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.

CIBINQO AND RINVOQ UPDATE

Background: Cibinqo and Rinvoq's indication includes a limitation in use that it is not recommended for use in combination with other Janus kinase (JAK) inhibitors, biologic immunomodulators, or with other immunosuppressants such as azathioprine and cyclosporine.

Recommendation: It is recommended that the following criterion be added to the atopic dermatitis section of the Cibinqo and Rinvoq policies to ensure it is used as monotherapy:

Cibinqo
- Medical record documentation that Cibinqo will not be used in combination with another Janus kinase (JAK) inhibitor, biologic immunomodulator, or with other immunosuppressants including but not limited to azathioprine and cyclosporine

Rinvoq
- Medical record documentation that Rinvoq will not be used in combination with another Janus kinase (JAK) inhibitor, biologic immunomodulator, or with other immunosuppressants including but not limited to azathioprine and cyclosporine

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.

2023 COMMERCIAL & CHIP FORMULARY UPDATES

Recommendation: The following changes are recommended for the 2023 Commercial/CHIP Formulary. Unless otherwise specified, members will not be grandfathered.

Formulary Removals:

Drug Name	Recommendation	Rationale
Absorica Oral Capsule 10 MG, 20 MG, 30 MG, 40 MG	Move to Non-Formulary 1/1/2023	Multi-source brand, generic on formulary
Bydureon BCise Subcutaneous Auto-injector 2 MG/0.85ML	Move to Non-Formulary 1/1/2023	Improved rebate opportunity for formulary GLP-1 agonists if moved to NF. 7 active members currently utilizing will be grandfathered.
Bydureon Subcutaneous Pen-injector 2 MG	Move to Non-Formulary 1/1/2023	Product Discontinued
Eurax External Lotion 10 %	Move to Non-Formulary Immediately	Product Discontinued
Ferriprox Oral Tablet 1000 MG	Move to Non-Formulary 1/1/2023	Multi-source brand, generic on formulary
Ferriprox Oral Tablet 1000 MG	Move to Non-Formulary 1/1/2023	Multi-source brand, generic on formulary
Ferriprox Twice-A-Day Oral Tablet 1000 MG	Move to Non-Formulary 1/1/2023	Multi-source brand, generic on formulary
Ilumya Subcutaneous Solution Prefilled Syringe 100 MG/ML	Move to Non-Formulary 1/1/2023	Improved rebate opportunity for formulary psoriasis agents if moved to NF. No current utilization.
Ilumya Subcutaneous Solution Prefilled Syringe 100 MG/ML	Move to Non-Formulary 1/1/2023	Improved rebate opportunity for formulary psoriasis agents if moved to NF. No current utilization.
Jynarque Oral Tablet 15 MG	Move to Non-Formulary 1/1/2023	Multi-source brand, generic on formulary
Jynarque Oral Tablet 30 MG	Move to Non-Formulary 1/1/2023	Multi-source brand, generic on formulary

Jynarque Oral Tablet Therapy Pack 15 MG	Move to Non-Formulary 1/1/2023	Multi-source brand, generic on formulary
Jynarque Oral Tablet Therapy Pack 15 MG	Move to Non-Formulary 1/1/2023	Multi-source brand, generic on formulary
Pradaxa Oral Capsule 110 MG	Move to Non-Formulary 1/1/2023	Improved rebate opportunity for formulary anticoagulants if moved to NF. No current utilization.
Pradaxa Oral Capsule 150 MG, 75 MG	Move to Non-Formulary 1/1/2023	Improved rebate opportunity for formulary anticoagulants if moved to NF. 11 active members currently utilizing will be grandfathered.
Pradaxa Oral Capsule 75 MG	Move to Non-Formulary 1/1/2023	Improved rebate opportunity for formulary anticoagulants if moved to NF. 1 active member currently utilizing will be grandfathered.
Taltz Subcutaneous Solution Auto-injector 80 MG/ML	Move to Non-Formulary 1/1/2023	Improved rebate opportunity for formulary psoriasis agents if moved to NF. 22 active members currently utilizing will be grandfathered.
Taltz Subcutaneous Solution Prefilled Syringe 80 MG/ML	Move to Non-Formulary 1/1/2023	Improved rebate opportunity for formulary psoriasis agents if moved to NF. 1 active member currently utilizing will be grandfathered.
Vimpat Oral Tablet 100 MG, 150 MG, 200 MG, 50 MG	Move to Non-Formulary 1/1/2023	Multi-source brand, generic on 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.

QUARTERLY CASE AUDIT

Background: The Quarterly Case Audit for 2nd quarter 2022 was held on September 1st, 2022. There were no formulary changes proposed at this meeting. We will continue to look for opportunities to create more drug specific policies at future quarterly case audit meetings.

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

DUR UPDATE

Commercial/Exchange/TPAs (COMM, D6)

Drug Use Evaluations (DUEs)

- Use of Opioids at High Dosage
  - This is our 2022 2nd quarter Geisinger Health Plan DUE for Commercial, Exchange, TPA, Medicaid, Medicare
  - From this report, we identified members 18 years and older with 15+ opioid covered days and had an MME of 90 or greater per day based on claims from 1/1/2022 through 7/27/2022
  - We hope to send out letters at the beginning of 9/2022
- Asthma Medication Ratio
  - This is our 2022 1st quarter Geisinger Health Plan DUE for Commercial, Exchange, Medicaid, CHIP
  - From this report, we used proactive HEDIS data and identified members aged 5-64 with an AMR<0.5. Pharmacy claims from the prior 6 months (9/2021-3/2022) were pulled into the report.
    - See below for the number of members that were identified with an AMR<0.5
      - For **COMM:** 6
      - For **D6: 6**
    - Letters were sent to the MI attributed PCP of each member with the respective medication fill history to encourage conversation around the importance of controller medications.
  - Letters were mailed out on 4/20/2022
  - Adam K. re-ran this data on 8/29/2022 to analyze the effectiveness of the letter. Of the 12 members initially identified, 9 members were still active. Of those members, **4 members** showed an AMR increase compared to 4/2022.
- 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: **15**
        - For D6: 5
    - 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
  - Adam K. re-ran this data on 3/10/2022 to analyze the effectiveness of the letter. Of the 20 members initially addressed, 13 members were still active. Of those members, **all 13 members** showed a decrease in the number of prescribers they were seeing compared to 10/2021
- 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**

In Progress

- For Exchange: HEDIS PQA Adherence Reports for the following measures:
    - Renin Angiotensin System Antagonists (PDC-RASA)
    - Diabetes All Class (PDC-DR)
    - Statins (PDC-STA)
- For Exchange: HEDIS PQA INR report
    - International Normalized Ratio Monitoring for Individuals on Warfarin (INR)
- For Exchange: HEDIS PQA Long term Opioid use report
    - Annual Monitoring for Persons on Long-Term Opioid Therapy (AMO)

Ongoing

- TNF and Oral Oncology Agent Report
    - We get this report monthly for the Commercial/Exchange, TPA, and CHIP LOBs from Adam Kelchner.
    - This report was generated in response to removing the renewal prior authorization requirement for these agents.
    - This report identifies members who are on a TNF or Oral Oncology agent and may not have been seen by their applicable specialist in the last 15 months.
    - We research these members and reach out to the offices/members as necessary to ensure the member has been seen within the last 15 months, an appointment has been scheduled or will be scheduled with the member to ensure the member continues to be able to receive their medication.
- Cystic Fibrosis Adherence Report
    - 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 2022, please see below for the number of **members** an adherence letter was sent to:
            - Letters are only sent to members every 6 months
                - For COMM: **5**
                - For D6: **6**
                - For TP48: **14**
                - For WF89: **4**
        - There were no letters sent to non-GHS pulmonologists
        - Please see below for the number of members referred to the CF coordinators:
            - For COMM: **16**
            - For D6: **17**
            - For TP48: **32**
            - For WF89: **8**

- 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 2022:
        - For COMM (Commercial): **7 members** reviewed and **2 interventions** made
        - For D6 (Exchange): **6 members** reviewed and **0 interventions** made
        - For TG48/GH51: **5 members** reviewed and **0 interventions** made
        - For TP45: **0 members** reviewed and **0 interventions** made
        - For TP56: **0 members** reviewed and **0 interventions** made
        - For EMYD: **0 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: 0 **member** reviewed and **0 interventions** made
        - For SASF: 0 **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 2022, we reviewed all 2022 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 Commercial/Exchange, TPAs in 2022, we have reviewed **0 members** and **0 members** were referred to Dr. Meadows
- 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 2022, see below for the new members reviewed and those referred to the MDs:
        - For COMM: we have reviewed **0 new members** and **0 members** were referred to MDs
        - For D6: we have reviewed **4 new members** and **2 members** were referred to MDs
        - For EMYD: we have reviewed **0 new members** and **0 members** were referred to MDs
        - For TG48: we have reviewed **1 new member** and **0 members** was referred to MDs

        - For SASE: we have reviewed **0 new members** and **0 members** was referred to MDs
        - For TPI2: we have reviewed **1 new member** and **1 member** 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 2022, 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: **0**
        - For TG48/TG51: **1**
- 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 2022, see below for the number of reviewed cases.
        - For COMM: we have reviewed **1 member** and sent **1 case** to MDs for review
        - For EMYD: we have reviewed **1 member** and sent **0 cases** to MDs for review
        - For TG48: we have reviewed **0 member** 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 2022, we have reviewed cases and corrected claims, resulting in a potential **cost savings/avoidance of $2,547.58**
        - For D6 in 2022, we have reviewed cases and corrected claims, resulting in a potential **cost savings/avoidance of $927.30**
        - For TPJ0 in 2022, we have reviewed cases and corrected claims, resulting in a potential **cost savings/avoidance of $29.99**
        - For TPE0 in 2022, we have reviewed cases and corrected claims, resulting in a potential **cost savings/avoidance of $17.19**
        - For TPN2 in 2022, we have reviewed cases and corrected claims, resulting in a potential **cost savings/avoidance of $156.32**
        - For EMYD in 2022, we have reviewed cases and corrected claims, resulting in a potential **cost savings/avoidance of $1,802.48**
        - For TG48, TG51 in 2022, we reviewed cases and corrected claims, resulting in a potential **cost savings/avoidance of $2,742.74**

        - For SASN in 2022, we reviewed cases and corrected claims, resulting in a potential **cost savings/avoidance of $820.91**
        - For SASK in 2022, we reviewed cases and corrected claims, resulting in a potential **cost savings/avoidance of $7.81**
        - For TP45 in 2022, we reviewed cases and corrected claims, resulting in a potential **cost savings/avoidance of $163.09**

- Duplicate Antipsychotics
    - We get this report **quarterly**, and we send letters to the PCPs to address potential duplicate therapy issues.
        - We have not sent any provider letters in 2022

- 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 2022 see below for the number of members identified and had sent letters to their MI attributed PCP:
            - For COMM: **57**
            - For D6: **56**
            - For EMYD: **0**
            - For SASF: **1**
            - For SASN: **5**
            - For SASE: **0**
            - For TG48, TG51: **56**
            - For TPB3: **0**
            - For TPE0: **1**
            - For TPH2: **1**
            - For TPM2: **1**
            - For TP23: **0**
            - For TP45: **2**
            - For TP46: **1**
            - For TP50: **3**
            - For TP51: **3**
            - For TP56: **0**
            - For TP88: **0**
            - For TPU1: **2**
            - For TPA6: **0**
            - For WF89: **2**
- 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 2022, we sent letters to the below number of members:
        - For COMM: **5**

        - For D6: **4**
        - For EMYD: **6**
        - For SASN: **1**
        - For SASE: **1**
        - For TG48, TG51: **8**
        - For TPB3: **0**
        - For TP23: **0**
        - For TP33: **1**
        - For TP45: **0**
        - For TP46: **1**
        - For TP50: **2**
        - 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 2022, we have sent letters encouraging adherence to the below number of members:
        - **Members for Antiplatelet:**
            - COMM: **64**
            - D6: **46**
            - EMYD: **4**
            - SASN: **6**
            - TG48, TG51: **12**
            - TP41: **0**
            - TP23: **0**
            - TP45: **3**
            - TP46: **1**
            - TP50: **1**
            - TP56: **0**
            - TP64: **1**
            - TP74: **0**
            - PM71: **1**
            - TP88: **0**
            - TPA6: **0**
            - WF89: **2**
            - TPD2: **0**
            - SASE: **2**
            - SASF: **1**
            - TPB3: **1**
            - TPF2: **0**
            - TPI0: **0**
            - TPL0: **0**
            - TPM2: **0**
            - **P**M70: **1**
            - PM71: **1**
        - **Members for Beta-Blocker:**
            - COMM: **61**
            - D6: **87**
            - EMYD: **11**
            - SASN: **9**
            - TG48, TG51: **29**
            - TP23: **3**
            - TP45: **1**
            - TP46: **1**
            - TP50: **0**
            - TP56: **1**
            - TP88: **0**
            - TPA6: **0**
            - WF89: **1**
            - TPI0: **4**
            - SASK: **0**
            - TPB3: **1**
            - TPR1: **1**
            - TPU1: **1**
            - SASE: **1**

        - **Members for Statin:**
            - COMM: **83**
            - D6: **70**
            - EMYD: **11**
            - SASN: **11**
            - SASF: **1**
            - TG48, TG51: **34**
            - TP23: **1**
            - TP45: **2**
            - TP46: **2**
            - TP56: **0**
            - PM71: **0**
            - SASK: **0**
            - SAQ2: **1**
            - TPI0: **0**
            - TPM2: **0**
            - TPR1: **0**
            - TP88: **0**
            - TPA6: **0**
            - TPU1: **1**
            - WF89: **2**
            - TP50: **1**
            - TP64: **2**
            - PM70: **0**
            - TP74: **2**
            - SASE: **1**
            - TPB3: **2**
            - TP41: **1**
        - *member may flag for more than one measure and are included in the count for each measure
    - In 2022, we have attempted telephonic outreach to the below number of members non-adherent in all 3 measures and reached the below members to encourage adherence.
        - COMM:
            - Attempted: **2**
            - Reached: **1**
        - D6:
            - Attempted: **2**
            - Reached: **1**
        - SASN:
            - Attempted: **1**
            - Reached: **0**

- **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 2022, see below for the number of letters sent to members:
            - COMM: **2**
            - D6: **1**
- Asthma Medication Ratio (AMR) Member Calls
    - Adam Kelchner runs this report **weekly** based off of proactive HEDIS reporting. The RPHs call Commercial/Exchange members who have had a controller or reliever medication filled in the past 3 months AND are past due for their controller medication.
    - For Commercial/Exchange in 2022, see below for the number of members we have outreached to and the number of members that have been reached:
        - COMM:
            - Outreached to: **21**

        - Reached: **9**
    - D6:
        - Outreached to: **13**
        - Reached: **8**
- 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 2022, see below for the number of letters sent to members:
            - Effective Acute Phase:
                - COMM: **0**
                - D6: **2**
            - Effective Continuation Phase:
                - COMM: **53**
                - D6: **46**
- 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 2022, see below for the number of letters sent to members:
            - COMM: **1**
            - 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 2022, see below for the number of letters sent to **providers** to encourage statin therapy initiation**:**
            - COMM: **18**
            - D6: **17**
        - For Commercial/Exchange in 2022, see below for the number of letters sent to **members** to promote statin adherence:
            - COMM: **11**
            - D6: **2**
- 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 2022, see below for the number of letters sent to **providers** to encourage statin therapy initiation**:**
            - COMM: **116**
            - D6: **57**
        - For Commercial/Exchange in 2022, see below for the number of letters sent to **members** to promote statin adherence:
            - COMM: **18**
            - D6: **8**
- Persistence of Beta-Blocker Treatment After a Heart Attack (PBH)

- We get this report **monthly** 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 2022, see below for the number of letters sent to **members:**
        - COMM: **1**
        - D6: **0**

- Use of Opioids from Multiple Providers (UOP)
    - We get this report quarterly to identify members 18 years of age and older with a total day supply of all opioid claims to be 15 days or greater
        - See below for the number of members that were identified who were seeing 4 or more providers from different offices for their opioid prescriptions
            - **COMM: 10**
            - **D6: 1**
        - See below for the number of members that were identified who were seeing 4 or more providers within the same office for their opioid prescriptions
            - **COMM: 2**
            - **D6: 1**
        - We sent letters to the MI attributed PCP of each member with the respective medication fill history to encourage medication evaluation of the opioid medications

Fliers/Letters

- Commercial/Exchange DUR/FWA Program internal Fliers
    - Last updated 02/2022 next update 11/2022
- Current Provider Letters
    - Cystic Fibrosis Adherence Letter
    - TNF/Oral Oncology Letter
    - Congestive Heart Failure DUE
    - Coronary Artery Disease DUE
    - Statin Use in Persons with Diabetes DUE
    - Opioid Overutilization
    - Duplicate Antipsychotic medication
    - Severity Report
    - HEDIS: Statin Therapy for Patients with Cardiovascular Disease (SPC)
    - HEDIS: Statin Therapy for Patients with Diabetes (SPD)
    - HEDIS: Asthma Medication Ratio (AMR)
    - HEDIS: Use of Opioids from multiple providers (UOP)
    - HEDIS: Use of Opioids at High Dosage (HDO)
- Current Member Letters
    - Cystic Fibrosis Adherence Letter
    - TNF/Oral Oncology Letter
    - Ending Opioid Authorizations
    - Tobacco Cessation Letter
    - STENT Adherence Report

- 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)

CHIP (CHBQ)

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

Drug Use Evaluations (DUEs)

- Asthma Medication Ratio
  - This is our 2022 1st quarter Geisinger Health Plan DUE for Commercial, Exchange, Medicaid, CHIP
  - From this report, we used proactive HEDIS data and identified members aged 5-64 with an AMR<0.5. Pharmacy claims from the prior 6 months (9/2021-3/2022) were pulled into the report.
    - **0 members** were identified with an AMR<0.5
    - Letters were sent to the MI attributed PCP of each member with the respective medication fill history to encourage conversation around the importance of controller medications.
- 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.

Ongoing

- Cystic Fibrosis Adherence Report
  - 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 with the member
    - 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
    - For CHBQ in 2022, we sent **0 members** an adherence letter
      - Letters are only sent to members every 6 months
      - There were **0 members** who saw a non-GHS pulmonologist and a letter was sent to that pulmonologist
      - There were **0 members** who saw GHS pulmonologists and were sent to the CF coordinators for follow up
- 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 2022, 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 2022, we reviewed all 2022 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 2022, 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 2022, 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 2022, we sent **0 members** a letter notifying them of the end of their opioid authorization(s).
- Severity Report
    - This is a **monthly** report 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 CHBQ in 2022, letters have been sent to MI attributed providers of **1 CHIP member**
- 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 2022, we have reviewed cases and corrected claims, resulting in a potential **cost savings/avoidance of $1,105.50**
- 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 2022, 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 2022, 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 2022, 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 2022, we have sent letters to **0 providers**

- **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 2022, we sent **1 letter** to members
- Asthma Medication Ratio (AMR) Member Calls
    - Adam Kelchner runs this report **weekly** based off of proactive HEDIS reporting. we send CHIP members who have had a controller or reliever medication filled in the past 3 months AND are past due for their controller medication to the Respiratory Therapists for direct telephonic outreach.
        - For CHBQ in 2022, we have referred **4 members** to the Respiratory Therapists for outreach.
- 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 2022, we sent **0 letters** to members in the **Effective Acute Phase**, and **0 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 2022, 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 2022, we have sent **0 letters** to providers
        - For CHBQ in 2022, 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 2022, we have sent **0 letters** to providers
        - For CHBQ in 2022, 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 2022, we have sent **0 letters** to members

Fliers/Letters

- Current Provider Letters
    - Cystic Fibrosis Adherence Letter
    - TNF/Oral Oncology Letter
    - Duplicate Antipsychotic medication
    - Severity Report
    - HEDIS: Statin Therapy for Patients with Cardiovascular Disease (SPC)
    - HEDIS: Statin Therapy for Patients with Diabetes (SPD)
    - HEDIS: Asthma Medication Ratio (AMR)
- Current Member Letters
    - Cystic Fibrosis Adherence Letter
    - TNF/Oral Oncology Letter
    - Ending Opioid Authorizations
    - Tobacco Cessation Letter
    - STENT Adherence Report
    - 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)

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 3:28 pm

Future Scheduled Meetings

The next bi-monthly scheduled meeting will be held on November 15th, 2022 at 1:00 p.m.

Meeting will be held virtually via phone/Microsoft Teams.