P&T Committee Meeting Minutes
Medicaid
May 17, 2022

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

Call to Order:
Kim Clark called the meeting to order at 1:03 p.m., Tuesday, May 17, 2022.

Review and Approval of Minutes, Reviews, Fast Facts, and Updates: Kimberly Clark asked for a motion or approval to accept the March 15, 2022 minutes as written. Minutes approved unanimously. None were opposed.

DRUG REVIEWS

Opdualag (nivolumab and relatlimab-rmbw)

Review: Opdualag is a fixed-dose combination of Opdivo (nivolumab), a programmed death receptor-1 (PD-1) blocking antibody, and relatlimab, a lymphocyte activation gene-3 (LAG-3) blocking antibody. It is indicated for the treatment of adult and pediatric patients 12 years and older with unresectable or metastatic melanoma. Opdualag is a first-in-class combination PD-1 inhibitor/LAG-3 inhibitor and the first LAG-3 inhibitor to demonstrate benefit in a Phase 3 study. NCCN added recommendations for Opdualag as a preferred first-line systemic therapy option for metastatic or unresectable disease (Category 2A; Figure 1). It is also being studied in several other cancer types, including hepatocellular carcinoma, soft tissue sarcoma, lymphoma, head and neck cancer, non-small cell lung cancer, and ovarian cancer. The efficacy of Opdualag was investigated in RELATIVITY-047, a randomized, double-blind trial in 714 patients with previously untreated metastatic or unresectable Stage III or IV melanoma. Patients were randomized to receive Opdualag (480 mg-160 mg) by intravenous infusion every four weeks or Opdivo (nivolumab alone) 480 mg intravenous infusion every 4 weeks until disease progression or unacceptable toxicity. The major efficacy outcome evaluating progression-free survival showed that patients treated with Opdualag had a statistically significant improvement in PFS compared to nivolumab alone. A secondary endpoint evaluating overall survival was not statistically significant. There are no black box warnings for Opdualag. Warnings and precautions are consistent with Opdivo monotherapy and include the risk of severe or fatal immune-mediated adverse reactions (IMARS), infusion related reactions, complications of allogeneic HSCT, and embryo-fetal toxicity. In the RELATIVITY-047 trial, serious adverse reactions occurred in 36% of patients treated with Opdualag, most frequently adrenal insufficiency, anemia, colitis, pneumonia, acute myocardial infarction, back pain, diarrhea, myocarditis, and pneumonitis. The most common adverse reactions that occurred were musculoskeletal pain, fatigue, rash, pruritis, and diarrhea. The most common laboratory abnormalities were decreased hemoglobin, lymphocytes, and sodium and increased AST and ALT.

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

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

Outcome: Opdualag is a medical benefit that will be managed by GHP and will require a prior authorization. The following prior authorization criteria should apply:
Medical record documentation that Opdualag is written by a hematologist or oncologist AND
Medical record documentation that patients is greater than or equal to 12 years of age AND
For patients greater ≥ 12 years and 18 years:
Medical record documentation of weight greater than or equal to 40 kg
AND
Medical record documentation of a diagnosis of unresectable or metastatic melanoma

Authorization Duration: Initial approval will be for 12 months. Subsequent approvals will be for an additional 12 months and will require medical record documentation of continued disease improvement or lack of disease progression. The medication will no longer be covered if patient experiences toxicity or worsening of disease.

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

Carvykti (ciltacabtagene autoleucel)

Review: Carvykti is a B-cell maturation antigen (BCMA)-directed genetically modified autologous T-cell immunotherapy indicated for the treatment of adult patients with relapsed or refractory multiple myeloma after four or more prior lines of therapy, including a proteasome inhibitor, an immunomodulatory agent, and an anti-CD38 monoclonal antibody. Carvykti is an intravenous infusion supplied as a suspension of chimeric antigen receptor (CAR)-positive viable T-cells prepared from the patient's own peripheral blood mononuclear cells obtained via standard leukapheresis. The anti-BCMA CAR-T cells are infused back into the patient where they promote T cell activation, expansion and elimination of BCMA-expressing target cells. In addition to T cells, Carvykti may contain Natural Killer (NK) cells. The efficacy of Carvykti was evaluated in CARTITUDE-1, an open-label, single-arm trial in adult patients with relapsed or refractory multiple myeloma, who previously received at least prior lines of therapy including a proteasome inhibitor, an immunomodulatory agent, and an anti-C38 monoclonal antibody. The median number of prior lines of therapy was 6, with 82% of patients receiving 4 or more prior lines of therapy, 90% had received prior autologous stem cell transplantation. Ninety-nine percent were refractor to their last line of prior therapy and 88% were refractory to a proteasome inhibitor, immunomodulatory agent, and an anti-CD38 antibody. Ninety-seven patients were in the efficacy evaluable population, including 17 patients with manufacturing failures. Efficacy was based on overall response rate, complete response rate, and duration of response assessed by Independent Review Committee (IRC) using International Myeloma Working Group (IMWG) criteria. The median time to first response was 1 month. Ninety-five (97.9) patients demonstrated a response following Carvykti administration, with 76% of patients having a stringent complete response. The median duration of response was 21.8 months. Like other CAR-T therapies, Carvykti has black box warnings for Cytokine release syndrome, neurologic toxicities, Hemophagocytic lymphohistiocytosis/Macrophage Activation Syndrome (HLH/MAS), and prolonged and recurrent cytopenias. Cytokine release syndrome occurred in 95% of patients treated with Carvykti. Grade 3 or higher CRS occurred in 5% of patients with Grade 5 CRS reported in 1 patient. The median time to CRS onset was 7 days and median duration of CRS was 4 days in all but one patient who had a duration of CRS of 97 days and a subsequent fatal outcome (HLH). The most common manifestations of CRS included pyrexia, hypotension, increased AST and ALT, chills, and sinus tachycardia. During clinical trials, the most common Grade 3 or 4 reactions included infections, pneumonia, febrile neutropenia, and hypotension. The most common all Grade adverse reactions were pyrexia, cytokine release syndrome, hypogammaglobulinemia, hypotension, musculoskeletal pain, fatigue, infections of unspecified pathogen, cough, chills, diarrhea, nausea, encephalopathy, decreased appetite, upper respiratory tract infection, headache, tachycardia, dizziness, dyspnea, edema, viral infections, coagulopathy, constipation, and vomiting. Serious adverse reactions occurred in 55% of patients, most commonly CRS, sepsis, encephalopathy, and pneumonia. Fatal adverse reactions occurred in 9% of patients.

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

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

Outcome: Carvykti is a medical benefit and will require a prior authorization. The following prior authorization criteria should apply.

- Medical record documentation that Carvykti is prescribed by a hematologist/oncologist AND
- Medical record documentation of age greater than or equal to 18 years AND
- Medical record documentation of relapsed or refractory multiple myeloma AND

- Medical record documentation of at least four prior lines of therapy, including an immunomodulatory agent, a proteasome inhibitor, and an anti-CD38 monoclonal antibody AND
- Medical record documentation that the member has not received prior treatment with CAR-T cell therapy or other genetically modified T cell therapy

Authorization duration: One-time authorization for one administration of Carvykti

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

Pemfexy (pemetrexed)

Review: Pemfexy is a folate analog metabolic inhibitor indicated:

- In combination with cisplatin for the initial treatment of patients with locally advanced or metastatic non-squamous, non-small cell lung cancer (NSCLC)

- As a single agent for the maintenance treatment of patients with locally advanced or metastatic non-squamous NSCLC whose disease has not progressed after four cycles of platinum-based first-line chemotherapy

- As a single agent for the treatment of patients with recurrent, metastatic, non-squamous NSCLC after prior chemotherapy

Limitations of Use: Pemfexy is not indicated for the treatment of patients with squamous cell non-small cell lung cancer.

- In combination with cisplatin for the initial treatment of patients with malignant pleural mesothelioma whose disease is unresectable or who are otherwise not candidates for curative surgery.

The recommended dosage of Pemfexy is 500 mg/m2 intravenous infusion over 10 minutes on Day 1 of each 21 day cycle. When administered with cisplatin for initial treatment of locally advanced or metastatic NSCLC, this is continued for up to 6 cycles, disease progression, or unacceptable toxicity. For maintenance treatment of NSCLC, Pemfexy is initiated after four cycles of platinum-based first-line chemotherapy and is continued until disease progression or unacceptable toxicity. For patients with recurrent NSCLC and patients with mesothelioma, Pemfexy is continued until disease progression or unacceptable toxicity. All Pemfexy dosing recommendations are for patients with a creatinine clearance of 45 mL/min or greater. There is no recommended dose for patients with a CrCl less than 45 mL/min. Patients should also receive folic acid, vitamin B12, and corticosteroids to mitigate toxicity. Pemfexy is supplied as a single dose vial containing 500 mg pemetrexed per 20 mL (25 mg/mL).

Pemfexy efficacy is based on results of clinical trials from the reference product Alimta and in vivo bioavailability studies that demonstrated bioequivalence. The therapeutic active moiety and route of administration are the same, but the products differ in salt form (disodium vs. diacid), excipients, dosage form, and solution for dilution. Prior to administration, Pemfexy is diluted in 5% Dextrose in Water while Alimta is diluted with 0.9% Sodium Chloride. No new clinical safety or efficacy trials were conducted. Pemfexy was approved for the same indications as Alimta intravenous.

The use in specific populations is also based on the previous submitted clinical trial information for Alimta. The safety and efficacy have not been established in pediatric patients. For geriatric patients, there were no overall differences observed for efficacy between older and younger patients. In Alimta clinical trials, the incidences of

Grade 3-4 anemia, fatigue, thrombocytopenia, hypertension, and neutropenia were higher in patients 65 years and older compared to younger patients.

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

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

Outcome: Pemfexy is a medical benefit and will not require a prior authorization.

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

Recorlev (levoketoconazole)

Review: - Recorlev is indicated for the treatment of endogenous hypercortisolemia in adult patients with Cushing's syndrome (CS) for whom surgery is not an option or has not been curative. Recorlev is not indicated for the treatment of fungal infections. The safety and effectiveness of Recorlev for the treatment of fungal infections have not been established.

- Initiate dosage at 150mg orally twice daily, with or without food. Titrate dosage by 150mg daily, no more frequently than every 2-3 weeks. Maximum recommended dosage is 1200mg daily, administered as 600mg twice daily. The dosage of Recorlev may be reduced to 150mg once daily if needed for reasons of tolerability

- Recorlev was evaluated in 2 studies, Study 1 and Study 2. In Study 1, the number and percent of patients who had normal mUFC at the end of the randomized withdrawal phase was 11/21 (52.4%) in Recorlev group and 1/18 (5.6%) in placebo group, and the treatment difference (CI) was 46.8% (16.5%, 70.2%). In Study 2, the primary efficacy endpoint was the proportion of patients with normalization of mUFC, defined as mUFC at or below the ULN without requiring a dose increase during the maintenance phase, at the end of the 6-month maintenance phase. 29 of 94 patients [30.9%, 95% CI (21.7%, 41.2%)] met the primary endpoint.

- Recorlev has a black box warning for hepatotoxicity and QT prolongation. Recorlev is contraindicated in patients: With cirrhosis, acute liver disease or poorly controlled chronic liver disease, baseline AST or ALT greater than 3 times the upper limit of normal, recurrent symptomatic cholelithiasis, a prior history of drug induced liver injury due to ketoconazole or any azole antifungal therapy that required discontinuation of treatment, or extensive metastatic liver disease; Taking drugs that cause QT prolongation associated with ventricular arrhythmias, including torsades de pointes; With a prolonged QTcF interval of greater than 470 msec at baseline, history of torsades de pointes, ventricular tachycardia, ventricular fibrillation, or long QT syndrome (including first-degree family history); With known hypersensitivity to levoketoconazole, ketoconazole, or any excipient in Recorlev; Taking certain drugs that are sensitive substrates of CYP3A4 or CYP3A4 and P-gP

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

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

Outcome: Recorlev is a pharmacy benefit and should not be added to the GHP Family pharmacy formulary. The following prior authorization criteria should apply:
- Medical record documentation of endogenous hypercortisolemia associated with Cushing's syndrome AND

- Medical record documentation of age 18 years or older AND

- Medical record documentation that Recorlev is being prescribed by or in consultation with an endocrinologist AND

- Medical record documentation that pituitary surgery is not an option or has not been curative AND

- Medical record documentation of therapeutic failure on, intolerance to, or contraindication to two (2) of the following: ketoconazole, Metopirone, Signifor, Signifor LAR

Reauthorization Info: Subsequent approvals will be for an additional 12 months or less if the reviewing provider feels it is medically appropriate. Reauthorization requires medical record documentation of improvement in urinary free cortisol levels compared to baseline.

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

Ryplazim (plasminogen, human-tvmh)

Review: Ryplazim is a human-derived plasminogen indicated for the treatment of patients with plasminogen deficiency type 1 (hypoplasminogenemia). Ryplazim treatment temporarily increases plasminogen levels in the blood leading to a reduction or resolution of extravascular fibrinous lesions. Ryplazim is the first and only therapy approved for PLGD Type I.

The efficacy of Ryplazim was evaluated in RYPLAZIM Trial 2, an open-label, single-arm clinical trial in 15 pediatric and adult patients with PLGD Type 1. All patients enrolled had a baseline plasminogen activity level between < 5% and 45% of normal, and biallelic mutations in the plasminogen (PLG) gene. Patients received Ryplazim 6.6 mg/kg every 2 to 4 days for 48 weeks to achieve at least a 10% increase above baseline in individual trough plasminogen activity and to treat clinical manifestations of the disease.

Efficacy was based on overall rate of clinical success at 48 weeks, defined as 50% with visible or other measurable non-visible lesions achieving at least 50% improvement in lesion number or size, or functionality impact from baseline. Results showed that all patients with any lesion at baseline had at least 50% improvement in the number/size of their lesions. Twenty-five of 32 external lesions were resolved by the end of Week 48. Nine of 12 internal lesions were resolved by Week 48. No recurrent or new internal or external lesions occurred in any patient through Week 48. Spirometry was the only organ function test used during the trial. One patient with a history of ligneous airway disease had abnormal spirometry at baseline (FEV1 46.7% of predicted normal) prior to treatment that corrected to normal after 12 weeks of treatment (FEV1 89.3% of predicted normal).

There are no black box warnings for Ryplazim. Warnings include increased risk of bleeding from active mucosal disease-related lesions and worsening of active bleeding not related to disease lesions, tissue sloughing at mucosal sights, including those in the respiratory, gastrointestinal, and genitourinary systems, risk of transmission of infections agents, and hypersensitivity reactions, including anaphylaxis. During clinical trials, the most frequent reported adverse reactions were abdominal pain, bloating, nausea, fatigue, extremity pain, hemorrhage, constipation, dry mouth, headache, dizziness, arthralgia, and back pain.

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

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

Outcome: Ryplazim is a medical benefit and will be managed by GHP. The following prior authorization criteria will apply:

- Medical record documentation of a diagnosis of plasminogen deficiency type 1 (hypoplasminogenemia) confirmed by medical record documentation of all of the following:
    - Documentation of a plasminogen activity level less than or equal to 45% AND
    - Documentation of a history of external and/or internal lesions and symptoms consistent with a diagnosis of congenital plasminogen deficiency type 1 (PLGD) AND
    - Documentation of the presence of biallelic mutations in the plasminogen (PLG) gene

Authorization Duration: Approval will be given for an **initial duration of three (3) months** or less if the reviewing provider feels it is medically appropriate. After the initial three (3) month approval, subsequent approvals will be for a **duration of six (6) months** or less if the reviewing provider feels it is medically appropriate, requiring medical record documentation of:

- Medical record documentation of resolution or improvement in documented lesions AND medical record documentation of no new or recurrent lesions OR
- Medical record documentation of trough plasminogen level greater than or equal to 10% above baseline trough plasminogen level

Ongoing subsequent approvals will be for a **duration of six (6) months** or less if the reviewing provider feels it is medically appropriate, requiring medical record documentation of:

- Medical record documentation of continued positive response to Ryplazim therapy including no new or recurrent lesions OR
- Medical record documentation of trough plasminogen level greater than or equal to 10% above baseline trough plasminogen level

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

Sooanz (torsemide)

Review: Soaanz is a loop diuretic indicated in adults for the treatment of edema associated with heart failure or renal disease.

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

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

Outcome: Soaanz is a pharmacy benefit and should not be added to formulary.
Soaanz will require prior authorization with the following criteria:

- Medical record documentation of age greater than or equal to 18 years AND
- Medical record documentation that Soaanz will be used for the treatment of edema associated with heart failure OR renal disease AND
- Medical record documentation of therapeutic failure on, intolerance to, or contraindication to three (3) formulary alternatives, one of which must be generic Torsemide

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

Voxzogo (vosoritide)

Review: Voxzogo is a C type natriuretic peptide (CNP) analog indicated to increase linear growth in pediatric patients with achondroplasia who are 5 years of age and older with open epiphyses. It is the only FDA approved treatment for improving growth in patients with achondroplasia. Achondroplasia is the most common bone dysplasia in humans, occurring in approximately 1 in 20,00- live births, and is caused by a gain of function mutation in FGFR3. FGFR3 belongs to a family of proteins that plays a role in many cellular processes, such as regulation of cell grown and division, determination or cell type, formation of blood vessels, wound healing, and embryo development. The most noticeable clinical features in a patient with achondroplasia include disproportioned short stature (adult height is approximately 4 feet), long-bone shortening predominantly in the proximal upper and lower extremities and macrocephaly.

Voxzogo is a once daily, subcutaneous injection, that is dosed based on patient's actual body weight. The efficacy of Voxzogo was demonstrated in a multi-center, randomized, double-blind, placebo-controlled, phase 3 study in which 121 patients aged 5.1-14.9 years with a confirmed diagnosis of achondroplasia, were randomized to Voxzogo 15mcg/kg daily or placebo. Voxzogo resulted in a treatment difference in the change from baseline in AGV of 1.57cm/year after 52 weeks of treatment.

The most notable adverse event seen with Voxzogo is a transient decrease in blood pressure, therefore patients should be well hydrated and have adequate food intake prior to administration to decrease this risk. Voxzogo is not recommended for patients with eGFR < 60ml/min/1.73m2.

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

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

Outcome: Voxogo is a pharmacy benefit and should be added to the GHP Family formulary at the Brand Tier. The following prior authorization criteria should apply:

- Medical record documentation of a diagnosis of achondroplasia with genetic testing confirming a mutation of FGFR3 AND
- Medical record documentation that Voxzogo is prescribed by a pediatric endocrinologist AND
- Medical record documentation that member is 5 to 18 years of age AND
- Medical record documentation of evidence that patient has open epiphyses AND
- Medical record patient has not received (within the past 18 months) or plans to receive limb-lengthening surgery AND
- Medical record documentation that Voxzogo will not be used in combination with human growth hormone products AND
- Medical record documentation of GFR > 60ml/min/1.73m2 AND
- Medical record documentation of patient's current weight AND
- Medical record documentation that prescribed dose is appropriate for patient's current weight AND
- Medical record documentation of baseline annualized growth velocity (AGV), calculated based on standing height measured over the course of 6 months prior to request

Authorization Duration: 6 months
Reauthorization will require the following documentation:

- Medical record documentation of positive response to Voxzogo, as evidenced by improvement in annualized growth velocity (AGV) from baseline AND
- Medical record documentation of evidence that patient continues to have open epiphyses AND
- Medical record patient has not received (within the past 18 months) or plans to receive limb-lengthening surgery AND
- Medical record documentation that Voxzogo will not be used in combination with human growth hormone products AND
- Medical record documentation of GFR > 60ml/min/1.73m2 AND
- Medical record documentation of patient's current weight AND
- Medical record documentation that prescribed dose is appropriate for patient's current weight

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

Vyvgart (efgartigimod alfa-fcab)

Review: Myasthenia Gravis is a chronic autoimmune disease While most patients with MG initially present with the ocular form of MG which is limited to the eyelids and extraocular muscles, up to 85% of patients will progress to the generalized form of MG, which causes weakness in ocular muscles and bulbar, limb, and respiratory muscles. Muscle weakness associated with MG is due to an antibody-mediated immunologic attacks directed at 3 postsynaptic proteins in the neuromuscular junction membrane: acetylcholine receptor (AChR), muscle-specific kinase (MuSK), and low-density lipoprotein receptor-related protein 4 (LRP4).

Vyvgart is a human immunoglobulin G1 (IgG1)-derived Fc fragment indicated for the treatment of adult patients with anti-acetylcholine receptor antibody positive gMG. It binds to the neonatal Fc receptor, resulting in the reduction of circulating IgG, including abnormal AChR antibodies that are present in about 85% of patients with gMG. It is administered

There is no cure for gMG, but there are treatments available for symptom management. Acetylcholinesterase inhibitors such as pyridostigmine increase acetylcholine at the neuromuscular junction and are usually started as initial therapy in patients with mild or moderate gMG. Chronic immunosuppressive therapies such as glucocorticoids or non-steroidal immunosuppressants may also be used. For patients with severe disease or myasthenic crisis, rapid immunomodulatory therapies such as IVIG or plasma exchange may be necessary. Surgical removal of the thymus gland may be used as treatment but would typically be reserved for patients with a thymoma (10-15%) or patients over 60 years of age without thymoma with AChR antibodies. Around 10 to 30% of patients will not respond to conventional immunosuppressive therapy and may require management with Soliris or off-label rituximab.

Prior to the approval of Vyvgart, Soliris was the only FDA-approved treatment of gMG. Vyvgart offers a more flexible dosing schedule as well as a less expensive treatment option compared to Soliris. There are some additional pipeline agents that are likely to be approved for gMG over the next few years, including some subcutaneous products as well as additional intravenous products.

Vyvgart is also being evaluated for the treatment of primary immune thrombocytopenia, pemphigus vulgaris, and chronic inflammatory demyelinating polyneuropathy.

The efficacy and safety of Vyvgart in gMG was evaluated in the ADAPT trial, a 26-week randomized, double-blind, placebo-controlled study conducted in adult patients with Class II to IV gMG. The trial included patients

with a Myasthenia Gravis Activities of Daily Living (MG-ADL) score (assesses the impact of gMG on daily functions) of at least 5 (50% non-ocular) who were on a stable dose of at least one treatment for gMG (including acetylcholinesterase (AChE) inhibitors, steroids, or non-steroidal immunosuppressive therapies (NSISTs), either in combination or alone). The modified intent-to-treat population included AChR antibody-positive patients who had a valid MG-ADL assessment and at least 1 post-baseline MG-ADL assessment. Patients were randomized 1:1 to Vyvgart (10 mg/kg) or matching placebo administered as 4 infusions per cycle (1 per week), repeated as needed depending on clinical response and no sooner than 8 weeks after initiation of the previous cycle.

The primary efficacy endpoint was the percentage of MG-ADL responders (at least a 2 point reduction in the MG-ADL score compared to baseline for at least 4 consecutive weeks) during the first treatment cycle between treatment groups in the AChR-Ab positive population. Results showed a statistically significant difference favoring Vyvgart during the first treatment cycle (67.7% responder rate for Vyvgart vs. 29.7% for placebo). A secondary endpoint measured the percentage of responders using the Quantitative Myasthenia Gravis (QMG) total score which assesses muscle weakness. There was a statistically significant difference favoring Vyvgart compared to placebo during the first treatment cycle in the percentage of responders (3-point or greater reduction in QMG for at least 4 consecutive weeks) (63.1% responder rate for Vyvgart vs. 14.1% for placebo).

There are no black box warnings for Vyvgart. Safety concerns for Vyvgart include risk of infection, most commonly urinary tract infections and respiratory infections. Hematologic abnormalities were also reported during trials, with decreases in white blood cells, lymphocytes, and neutrophils. The majority of infections and hematologic abnormalities were mild to moderate in severity. Hypersensitivity reactions, including rash, angioedema, and dyspnea have also been observed in Vyvgart-treated patients. Reactions were mostly mild to moderate in severity, occurred within 1 to 3 hours after administration, and did not lead to treatment discontinuation.

The safety of Vyvgart with live or live-attenuated vaccines and the response to immunizations with any vaccine are unknown. Because Vyvgart reduces IgG levels, vaccination with live-attenuated or live-vaccines are not recommended during treatment with Vyvgart. Patients should be evaluated for age-appropriate vaccines before initiation of a new treatment cycle with Vyvgart.

During clinical trials, the most common adverse reactions reported were respiratory tract infection, headache, and urinary tract infection. Paresthesia and myalgia were also reported in a higher percentage of patients treated with Vyvgart compared to placebo. There is also potential for immunogenicity. During the clinical trial, 6 out of 83 patients developed neutralizing antibodies and due to the small number, the data is too limited to draw definitive conclusions regarding immunogenicity and the effect on pharmacokinetics, safety, or efficacy

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

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

Outcome: Vyvgart will be a medical benefit. The following additional prior authorization criteria should apply.

- Medical record documentation of age greater than or equal to 18 years AND
- Medical record documentation that Vyvgart is prescribed by or in consultation with a neurologist AND
- Medical record documentation of a diagnosis of generalized myasthenia gravis (gMG) that is anti-acetylcholine receptor (AChR) antibody positive AND
- Medical record documentation of Myasthenia Gravis Foundation of America Clinical Classification (MGFA) Class II to IV AND *
- Medical record documentation of a baseline Myasthenia Gravis-Activities of Daily Living (MG-ADL) score of 5 or more AND**

- Medical record documentation of therapeutic failure on, intolerance to, or contraindication to corticosteroids AND
- Medical record documentation of therapeutic failure on, intolerance to, or contraindication to cholinesterase inhibitors AND
- Medical record documentation of therapeutic failure on intolerance to, or contraindication to at least two (2) non-steroidal immunosuppressive therapies OR has failed at least one (1) immunosuppressive therapy and required chronic plasmapheresis or plasma exchange (PE) AND
- Medical record documentation of failure on intolerance to, or contraindication to rituximab or rituximab biosimilar AND
- Medical record documentation of failure on intolerance to, or contraindication to intravenous immunoglobulin (IVIG)

Authorization Duration (All LOB): Initial approval will be for 6 months. Subsequent approvals will be for 6 months and will require:
- Medical record documentation of continued disease improvement or lack of disease progression AND
- Medical record documentation that the member is responding positively to therapy as evidenced by a 3-point reduction from baseline in Myasthenia Gravis-Activities of Daily Living (MG-ADL) total score**

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

*Note: Class I Myasthenia gravis is indicated by any eye muscle weakness, possible ptosis (drooping or falling of the upper eyelid) and no other evidence of muscle weakness elsewhere, Class II to IV include muscle weakness in areas of the body beyond the eye.

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

MG Activities of Daily Living (MG-ADL)**

Grade	0	1	2	3	Score
Talking	Normal	Intermittent slurring or nasal speech	Constant slurring or nasal, but can be understood	Difficult to understand speech	
Chewing	Normal	Fatigue with solid food	Fatigue with soft food	Gastric tube	
Swallowing	Normal	Rare episode of choking	Frequent choking necessitating changes in diet	Gastric tube	
Breathing	Normal	Shortness of breath with exertion	Shortness of breath at rest	Ventilator dependence	
Impairment of ability to brush teeth or comb hair	None	Extra effort, but no rest periods needed	Rest periods needed	Cannot do one of these functions	
Impairment of ability to arise from a chair	None	Mild, sometimes uses arms	Moderate, always uses arms	Severe, requires assistance	
Double vision	None	Occurs, but not daily	Daily, but not constant	Constant	
Eyelid droop	None	Occurs, but not daily	Daily, but not constant	Constant	

Total score _____

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

FAST FACTS

Keytruda

Updated Indication: Keytruda has two changes recently approved by the FDA. The first is the withdrawal of the third line gastric cancer indication, which was previously approved under accelerated approval. The second change is a new indication, as a single agent, for the treatment of patients with advanced endometrial carcinoma that is MSI-H or dMMR, as determined by an FDA approved test, who have disease progression following prior systemic therapy in any setting and are not candidates for curative surgery or radiation.

Recommendation: No changes are recommended to the formulary placement or authorization duration of Keytruda. The following changes are recommended to Medical Benefit Policy 119.0:

7. Gastric Cancer
- Prescription written by a hematologist/oncologist AND
- ~~Medical record documentation of one of the following:~~
  - ~~Medical record documentation of a diagnosis of recurrent locally advanced or metastatic gastric or gastroesophageal junction adenocarcinoma AND~~
  - ~~Medical record documentation that tumors express PD-L1 (combined positive score [CPS] greater than or equal to 1) as determined by an FDA-approved test AND \~~
  - ~~Medical record documentation of disease progression on or after two or more prior lines of therapy (including fluoropyrimidine- and platinum-containing chemotherapy)* AND~~
  - ~~If patient has HER2-positive disease, medical record documentation of disease progression on or after HER2/neu-targeted therapy (including but not limited to trastuzumab (Herceptin)*~~

~~OR~~

  - Medical record documentation of a diagnosis of locally advanced unresectable or metastatic HER-2 positive gastric or gastroesophageal junction adenocarcinoma AND
  - Medical record documentation that Keytruda will be used as first-line treatment AND
  - Medical record documentation that Keytruda will be used in combination with trastuzumab, fluoropyrimidine- and platinum-containing chemotherapy

~~*Note to reviewer: Current recommendations intend Keytruda to be used as third-line treatment (i.e. patient is to have 2 prior lines of therapy, one of which must include HER2/neu-targeted therapy if the patient has HER-2 positive disease)~~

14. Endometrial Carcinoma
- Prescription written by a hematologist/oncologist AND
- Medical record documentation of a diagnosis of advanced endometrial carcinoma AND
- Medical record documentation of disease progression following at least one prior systemic therapy AND
- Medical record documentation that patient is not a candidate for curative surgery or radiation AND
- Medical record documentation of one of the following:
  - Medical record documentation that tumors are not microsatellite instability-high (MSI-H) or mismatch repair deficient (dMMR) AND

- Medical record documentation that Keytruda will be given in combination with lenvatinib (Lenvima)

OR

- Medical record documentation that Keytruda will be used as a single agent for treatment of tumors that are microsatellite instability-high (MSI-H) or mismatch repair deficient (dMMR)

Outcome: The committee unanimously voted to accept the recommendations.

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

Opdivo

Updated Indication: Opdivo is now indicated in combination with platinum-doublet chemotherapy, for neoadjuvant treatment of adult patients with resectable (tumors ≥ 4 cm or node positive) non-small cell lung cancer. The dosing for the new indications is 360 mg intravenously every 3 weeks with platinum-doublet chemotherapy on the same day every 3 weeks. Treatment is continued for 3 cycles.

Recommendation: No changes are recommended to the formulary placement of Opdivo. It is recommended that the following prior authorization criteria and auth duration criteria be added to Medical Benefit Policy 126.0:

2. *Non-Small Cell Lung Cancer (NSCLC)*

If the request is for metastatic NSCLC with progression after platinum-based chemotherapy:

- Medical record documentation of a diagnosis of metastatic non-small cell lung cancer (NSCLC) with disease progression while on or after platinum-based chemotherapy **AND**
- Medical record documentation that Opdivo is not being used in combination with any other agents for the treatment of metastatic non-small cell lung cancer (NSCLC)

OR

If the request is for first-line treatment of metastatic NSCLC expressing PD-L1 (≥ 1%):

- Medical record documentation of a diagnosis of metastatic non-small cell lung cancer (NSCLC) **AND**
- Medical record documentation of PD-L1 ≥ 1% as determined by an FDA-approved test **AND**
- Medical record documentation of no EGFR or ALK genomic tumor aberrations **AND**
- Medical record documentation that Opdivo will be used for first-line treatment in combination with Yervoy

OR

If the request is for first-line treatment metastatic or recurrent NSCLC:

- Medical record documentation of a diagnosis of metastatic or recurrent non-small cell lung cancer (NSCLC) **AND**

- Medical record documentation of no EGFR or ALK genomic tumor aberrations **AND**
- Medical record documentation that Opdivo will be used for first-line treatment in combination with Yervoy and 2 cycles of platinum-doublet chemotherapy

OR

If the request is for neoadjuvant treatment of resectable NSCLC:

1. Medical record documentation of resectable (tumor size greater than or equal to 4 centimeters or node-positive) non-small cell lung cancer (NSCLC) AND
2. Medical record documentation that Opdivo will be used for neoadjuvant treatment in combination with platinum-doublet chemotherapy.

AUTHORIZATION DURATION:

Neoadjuvant NSCLC: One approval will be given for up to 3 cycles for a total duration of 6 months.

Authorization of Opdivo for the neoadjuvant treatment of NSCLC should not exceed the FDA-approved treatment duration of 3 cycles. For requests exceeding the above limit, medical record documentation of the following is required:

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

Outcome: The committee unanimously voted to accept the recommendations.

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

Yescarta

Updated Indication: Yescarta is a CD19-directed genetically modified autologous T cell immunotherapy now indicated for the treatment of adult patients with large B-cell lymphoma that is refractory to first-line chemoimmunotherapy or that relapses within 12 months of first-line chemoimmunotherapy.

Recommendation: There are no changes recommended to the formulary placement or authorization duration of Yescarta. It is recommended that the following prior authorization criteria be changed to the Medical Benefit Policy 162.0 to incorporate the new indication:

Large B-Cell Lymphoma (second-line)

- Prescription written by a hematologist/oncologist **AND**
- Medical record documentation that patient is 18 years of age or older **AND**
- Medical record documentation of large B-cell lymphoma that is refractory to first-line chemoimmunotherapy **OR** that relapses within 12 months of first-line chemoimmunotherapy **AND**
- Medical record documentation that the member has not received prior treatment with CAR-T cell therapy or other genetically modified T cell therapy

Large B-Cell Lymphoma (third-line or beyond)

- Prescription written by a hematologist/oncologist **AND**
- Medical record documentation that patient is 18 years of age or older **AND**
- Medical record documentation of one of the following diagnoses:
    - Relapsed or refractory diffuse large B-cell lymphoma (DLBCL) not otherwise specified **OR**
    - Relapsed or refractory primary mediastinal large B-cell lymphoma **OR**
    - Relapsed or refractory high-grade B-cell lymphoma **OR**
    - Relapsed or refractory diffuse large B-cell lymphoma (DLBCL) arising from follicular lymphoma

AND

- Medical record documentation of a therapeutic failure on two or more previous lines of therapy **AND**
- Medical record documentation that the member has not received prior treatment with CAR-T cell therapy or other genetically modified T cell therapy

Note: Yescarta is not indicated for the treatment of patients with primary central nervous system lymphoma.

Outcome: The committee unanimously voted to accept the recommendations.

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

Updates

IVIG

Recommendation: It is recommended to update the prior authorization criteria for Intravenous Immune Globulin (IVIG) (Medical Benefit Policy 4.0) for the indication of Catastrophic Antiphospholipid Syndrome (CAPS) to reflect classification criteria as outlined by the Catastrophic antiphospholipid syndrome international consensus statement on classification criteria and treatment guidelines:

- **Catastrophic Antiphospholipid Syndrome (CAPS) (III/C)**

All of the following criteria must be met:

1. Documentation of patient with antiphospholipid syndrome (APS) with multiorgan failure (evidence of involvement of three or more organs, systems, and/or tissues AND
2. Development of manifestations simultaneously or in less than one week AND
3. Confirmation by histopathology of small vessel occlusion in at least one organ or tissue AND
4. Laboratory confirmation of the presence of antiphospholipid antibodies (lupus anticoagulant, anticardiolipin antibodies, and/or anti-beta2-glycoprotein I antibodies)

    OR

    - All four criteria are met, except for only two organs, systems and/or sites of tissues involvement OR
    - ~~All four criteria are met, except for laboratory confirmation OR~~
    - Criteria 1, 2, and 4 are met OR
    - Criteria 1,3, and 4 and the development of a third event in more than a week but less than a month, despite anticoagulation

    AND

5. Medical record documentation Intravenous Immunoglobulin (IVIG) will be used in combination with conventional therapies (eg. anticoagulation and corticosteroids)

Rationale: UpToDate references classification criteria for catastrophic antiphospholipid antibody syndrome (CAPS) adopted from Asherson, RA, Cervera, R, de Groot, PG, et al. Lupus 2003; 12:530. The four criteria are as listed within the policy. Definite CAPS requires all 4 criteria, and probable CAPS requires criteria be met as outlined within the policy. If all 4 criteria are met except for the laboratory confirmation at least six weeks apart due to the early death of a patient never tested for antiphospholipid (aPL) antibodies before the catastrophic APS, then patient classifies as probable CAPS. Due to the early death of a patient, this criteria is not applicable for purposes of prior authorization review.

It is recommended to rearrange the existing prior authorization criteria to accurately depict the clinical situations in which approval and denial would be recommended in accordance with the classification criteria for definite and probable CAPS as outlined by the Catastrophic antiphospholipid syndrome international consensus statement on classification criteria and treatment guidelines. The rearrangement of the existing prior authorization criteria is expected to result in consistency across all reviews. No clinical recommendations apply at this time.

Recommendations (continued):

- **Catastrophic Antiphospholipid Syndrome (CAPS) (III/C)**
  All of the following criteria must be met:

1. Documentation of patient with antiphospholipid syndrome (APS) with multiorgan failure (evidence of involvement of <u>two</u> or more organs, systems, and/or tissues) **AND**
2. Development of manifestations simultaneously or in less than one week **AND**
3. Confirmation by histopathology of small vessel occlusion in at least one organ or tissue **AND**
4. Laboratory confirmation of the presence of antiphospholipid antibodies (lupus anticoagulant, anticardiolipin antibodies, and/or anti-beta2-glycoprotein I antibodies) **AND**
5. Medical record documentation Intravenous Immunoglobulin (IVIG) will be used in combination with conventional therapies (eg. anticoagulation and corticosteroids).

OR

1. Documentation of patient with antiphospholipid syndrome (APS) with multiorgan failure (evidence of involvement of <u>three</u> or more organs, systems, and/or tissues **AND**
2. Development of manifestations simultaneously or in less than one week **AND**
3. Laboratory confirmation of the presence of antiphospholipid antibodies (lupus anticoagulant, anticardiolipin antibodies, and/or anti-beta2-glycoprotein I antibodies) **AND**
4. Medical record documentation Intravenous Immunoglobulin (IVIG) will be used in combination with conventional therapies (eg. anticoagulation and corticosteroids).

OR

1. Documentation of patient with antiphospholipid syndrome (APS) with multiorgan failure (evidence of involvement of <u>three</u> or more organs, systems, and/or tissues **AND**
2. Confirmation by histopathology of small vessel occlusion in at least one organ or tissue **AND**
3. Laboratory confirmation of the presence of antiphospholipid antibodies (lupus anticoagulant, anticardiolipin antibodies, and/or anti-beta2-glycoprotein I antibodies) **AND**
4. Development of a third event in more than a week but less than a month, despite anticoagulation **AND**

5. Medical record documentation Intravenous Immunoglobulin (IVIG) will be used in combination with conventional therapies (eg. anticoagulation and corticosteroids).

Outcome: The committee unanimously voted to accept the recommendation

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

DUR Updates

The following report was presented to the Committee for review:

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.
    - **1,468 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.
  - Letters were mailed out on 4/20/2022
  - We will re-run this data round 7/31/2022 to analyze the impact of the letter
- Use of Opioids from Multiple Providers (UOP) DUE
  - This is our 2021 3rd quarter Geisinger Health Plan DUE for Medicare, Medicaid, and 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 days or greater based on claims from 1/1/2021 through 9/27/2021:
    - **49 members** were identified who were seeing 4 or more providers from different offices for their opioid prescriptions
    - **11 members** were identified who were seeing 4 or more providers within the same office for their opioid prescriptions
    - 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
  - 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 60 members initially addressed, 54 members were still active. Of those members, **52 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 **1909 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 1909 members initially addressed, **1,827** are still active. Of those members, **217** now have a claim for a statin medication. This equates to about **12%** of the targeted members.

In Progress

- **No reports at this time.**

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 MANE in 2022, we sent **15 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 **176 members** who saw GHS pulmonologists and were sent to the CF coordinators for follow up
- Medicaid A-B-A Therapeutic Duplication Paid Claims Report
  - We get this report **daily** from PerformRX and it includes PAID pharmacy claims that have processed successfully. We have built out logic for this report to flag members who have two or more approved claims for two or more medications within the same market basket within the past 90 days. This only includes medications included within a market basket were the TD edit applies. This report was created to ensure that medications are approving as intended and serves as a way for us to monitor the edit.
- 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 MANE in 2022, we reviewed **16 members** and have made interventions for **2 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 MANE 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 MANE in 2022, we have reviewed **6 members** and **1 member** was 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 MANE in 2022, we have reviewed **32 new members**, and **9 members** were referred to MDs for discussion
- 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 MANE in 2022, we sent **5 members** a letter notifying them of the end of their opioid authorization(s).
- 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 MANE in 2022, we have reviewed **1 patient**, referred **0 patients** to MDs, and did not send any prescriber letters.
- 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 MANE in 2022, we have reviewed cases and corrected claims, resulting in a potential **cost savings/avoidance of $952.53**
- 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 MANE in 2022, letters have been sent to MI attributed providers of **453 GHP Family members**
- 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 MANE in 2022, we sent **31 letters** to encourage members to quit and provided resources for tobacco cessation.
- Antipsychotic with Opioid Report
    - We get this report **quarterly** to identify **Medicaid** 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 MANE in 2022, we have sent **185 letters** to **opioid prescribers** and **170 letters** to antipsychotic prescribers regarding a total of **207 members**
- 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 MANE in 2022, we have sent letters encouraging adherence to:
            - **101 members for Antiplatelet**
            - **177 members for Beta-blocker**
            - **198 members for Statin**
        - *member may flag for more than one measure and are included in the count for each measure
    - For MANE in 2022, we have attempted telephonic outreach to **14 members** non-adherent in all 3 measures and reached **5 members** to encourage adherence.

- **HEDIS Initiatives: *Using proactive HEDIS data***
- Asthma Medication Ratio (AMR) Member Letters
    - 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 MANE in 2022, we have sent letters to **6 members** to encourage adherence.
- Asthma Medication Ratio (AMR) Member Calls
    - Adam Kelchner runs this report **weekly** based off of proactive HEDIS reporting. we send Medicaid members 30 years of age and under 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 MANE in 2022, we have referred **55 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 MANE in 2022, we have sent letters to **0 members** in the **Effective Acute Phase** and letters to **354 members** in the **Effective Continuation Phase** to encourage adherence.
- Adherence to Antipsychotics for Individuals with Schizophrenia (SAA)
    - Jesse Barsh runs this proactive HEDIS report **monthly,** and we send letters to the flagged members who appear non-adherent to their antipsychotic medications.
        - For MANE in 2022, we have sent letters to **0 members** to encourage adherence**.**
- 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 MANE in 2022, we have sent letters to **50 providers** to encourage statin therapy
        - For MANE in 2022, we have sent letters to **11 members** to encourage statin adherence.
- 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 MANE in 2022, we have sent letters to **410 providers** to encourage statin therapy
        - For MANE in 2022, we have sent letters to **12 members** to encourage statin adherence.
- 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 MANE in 2022, we have sent letters to **3 members** to encourage beta-blocker therapy adherence.

- 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
        - For MANE in 2022, **30 members** were identified who were seeing 4 or more providers from different offices for their opioid prescriptions
        - For MANE in 2022, **9 members** were identified who were seeing 4 or more providers within the same office for their opioid prescriptions
        - 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
            - *One letter every 6 months*

Fliers/Letters

- Medicaid DUR/FWA Program Internal Fliers
    - Last updated 2/2022 next update 8/2022
- Current Provider Letters
    - Cystic Fibrosis Adherence Letter
    - Congestive Heart Failure DUE
    - Coronary Artery Disease DUE
    - Statin Use in Persons with Diabetes DUE
    - Opioid Overutilization
    - Severity Report
    - Antipsychotic with Opioid 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)
- Current Member Letters
    - Cystic Fibrosis Adherence 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)

Outcome: No questions or concerns

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

Xyrem

Recommendation: Based on feedback from DHS and Dr. Sreelatha Naik that amphetamines/stimulants should be avoided for treatment of narcolepsy it is recommended that the following update to the Xyrem policy be approved:

Medical record documentation of one of the following:

- For cataplexy with narcolepsy, medical record documentation of failure on, intolerance to, or contraindication to one of the following: venlafaxine XR or fluoxetine **OR**
- For excessive daytime sleepiness with narcolepsy: medical record documentation of failure on, intolerance to, or contraindication to modafinil
  - For patients 18 years and older, medical record documentation of failure on, intolerance to, or contraindication to one of the following: modafinil AND methylphenidate immediate release or amphetamine/dextroamphetamine immediate release **OR**
  - For patient 7-17 years, medical record documentation of failure on, intolerance to methylphenidate immediate release or amphetamine/dextroamphetamine immediate release

Outcome: The committee unanimously voted to accept the recommendation

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

Meeting adjourned at 5:15 pm

Future Scheduled Meetings
The next bi-monthly scheduled meeting will be held on July 19h, 2022 at 1:00 p.m.

Meetings will be held virtually via phone/Microsoft Teams