

P&T Committee Meeting Minutes
GHP Family
November 20, 2018

<p>Present: Bret Yarczower, MD, MBA – Chair Kristen Bender, PharmD – via phone Rajneel Chohan Pharm.D. Alyssa Cilia, RPh – via phone Kimberly Clark, PharmD Kristi Clarke, PharmD, MHA – via phone Tricia Heitzman, PharmD. Jason Howay, PharmD. – via phone Keith Hunsicker, PharmD. Kelli Hunsicker, PharmD. – via phone Steven Kheloussi, PharmD – via phone Phillip Krebs, R.EEG T. – via phone Perry Meadows, MD Jamie Miller, RPh – via phone Aubrielle Prater PharmD. Ginnetta Reed Kristen Scheib, PharmD. – via phone Richard Silbert, MD – via phone Michael Spishock, RPh – via phone Todd Sponenberg, PharmD. Jill Stone, Pharm.D. – via phone Kevin Szczecina, RPh Kelly Yelenic PharmD.</p>	<p>Absent: Kenneth Bertka, MD Beverly Blaisure, MD Holly Bones, PharmD Kim Castelnovo, RPh Dean Christian, MD Michael Evans, RPh Patrick Ferguson, RPh, MBA Sandra Garrett, RPh, MBA Stephen Moscello, RPh Jonas Pearson, RPh William Seavey, PharmD.</p>
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Call to Order:

Dr. Bret Yarczower called the meeting to order at 1:02 p.m., Tuesday, November 20, 2018.

Review and Approval of Minutes:

Dr. Bret Yarczower asked for a motion or approval to accept the September 18, 2018 minutes as written. Keith Hunsicker accepted the motion and Todd Sponenberg seconded the motion. None were opposed.

DRUG REVIEWS

LYRICA CR (pregabalin)

Review: Lyrica CR is available as extended release tablets and is indicated for the management of neuropathic pain associated with diabetic peripheral neuropathy (DPN) and postherpetic neuralgia (PHN). Unlike Lyrica which is indicated for neuropathic pain associated with DPN, PHN, adjunctive therapy for the treatment of partial onset seizures in patients 4 years of age and older, fibromyalgia, and neuropathic pain associated with spinal cord injury. Lyrica CR is administered once daily and should be initiated at 165 mg once daily and may be titrated to the maximum recommended dose of 330 mg (DPN) or 660 mg (PHN) daily for pain control, if tolerating. Lyrica CR is available as 82.5 mg, 165 mg, and 330 mg extended-release tablets. Unlike immediate-release Lyrica, Lyrica CR should not be used in patients who have a creatine clearance less than 30 mL/min or those undergoing hemodialysis. There are dose adjustments for patients that have creatine clearance from 30-60 mL/min. The efficacy of Lyrica CR for the management of PHN and DPN was based on the efficacy of Lyrica for these indications along with a well-controlled study in adults with PHN. Lyrica CR was studied in a 19-week randomized withdrawal study in adults with PHN, which compared daily doses of Lyrica CR 82.5 mg, 165 mg, 247.5 mg, 330 mg, 495 mg, or 660 mg with placebo. Lyrica CR demonstrated statistically significant improvement in the endpoint change in the mean pain score from baseline compared to placebo. In double-blind, placebo-controlled, randomized withdrawal trials in adults with fibromyalgia and as adjunctive therapy in adults with partial onset seizures, Lyrica CR failed to demonstrate efficacy. Lyrica CR shares the same contraindications and warnings/precautions as Lyrica. Lyrica CR also has similar special population considerations as Lyrica, except for renal dose adjustments. According to the American Academy of Neurology (AAN), pregabalin is established as effective and should be offered for relief of DPN (level A). For patients with DPN, UpToDate recommends using one of the antidepressants (e.g. amitriptyline, duloxetine, venlafaxine) or anticonvulsants (e.g. pregabalin) as initial therapy. UpToDate recommends treatment with gabapentin or pregabalin as initial treatment for most patients with moderate to severe PHN.

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 questions or comments. Kevin Szczecina made a motion to accept the criteria as written. Todd Sponenberg seconded the motion. None were opposed.

Financial Discussion: No questions or comments. Tricia Heitzman made a motion to accept the criteria as written. Keith Hunsicker seconded the motion. None were opposed.

Outcome: For Medicaid, Lyrica CR will be a pharmacy benefit and will not be added to the GHP Family formulary. The following prior authorization criteria should apply:

Neuropathic Pain Associated with Diabetic Peripheral Neuropathy:

- Medical record documentation of neuropathic pain associated with diabetic peripheral neuropathy AND
- Medical record documentation of failure on, intolerance to, or contraindication to Lyrica*

Postherpetic Neuralgia:

- Medical record documentation of postherpetic neuralgia AND
- Medical record documentation of failure on intolerance to, or contraindication to Lyrica*

Quantity Limit (enter by GPID):

82.5 mg tablets: 3 tablets per day
165 mg tablets: 3 tablets per day
330 mg tablets: 2 tablets per day

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

OLUMIANT (baricitinib)

Review: Olumiant is FDA approved for the treatment of adult patients with moderate to severe rheumatoid arthritis who have an inadequate response to one or more TNF antagonist therapies. Olumiant should not be given in combination with other JAK inhibitors, biologic disease-modifying antirheumatic drugs (DMARDs), or with potent immunosuppressants such as azathioprine and cyclosporine. It is the second oral JAK inhibitor on the market with this indication. It is available as a 2mg tablet and the recommended dose is 2mg once daily. Clinical trials (RA-BUILD and RA-BEACON) have shown that patients treated with Olumiant had higher rates of ACR response (as evidenced by greater improvement from baseline in the physical component score and the physical function, role physical, bodily pain, vitality, and general health domains) and DAS28-CRP <2.6 versus placebo-treated patients at Week 12. Olumiant 4 mg once daily was evaluated in the pivotal clinical trials and although the higher dose was associated with better efficacy, it was not approved by the FDA following recommendation by the FDA Arthritis Advisory Committee which found the safety and benefit-risk profile data of the 4mg dose to be inadequate. The warnings and precautions associated with Olumiant are similar to that of Xeljanz, with an additional black box warning for thrombosis. The 2015 American College of Rheumatology guidelines do not recommend use of one TNFi or nonTNFi biologic over another. Input from the Geisinger Health System AIMFARTHER2 ProvenCare team support Humira as a first line biologic agent and the providers currently favor use of Xeljanz over Olumiant.

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 questions or comments. Todd Sponenberg made a motion to accept the recommendations as presented. Kevin Szczecina seconded the motion. None were opposed.

Financial Discussion: No questions or comments. Tricia Heitzman made a motion to accept the recommendations as presented. Kelly Yelenic seconded the motion. None were opposed.

Outcome: For Medicaid, Olumiant will be a pharmacy benefit and will not be added to the GHP Family formulary. The following criteria should apply:

- Prescription is written by a rheumatologist **AND**
- Medical record documentation of age greater than or equal to 18 years **AND**
- Medical record documentation of a diagnosis of moderate to severe rheumatoid arthritis made in accordance with the American College of Rheumatology Criteria for the Classification and Diagnosis of RA **AND**
- Medical record documentation that Olumiant is not being used concurrently with a TNF blocker or other biologic agent **AND**
- Medical record documentation of therapeutic failure on, intolerance to, or contraindication to Humira*

Quantity Limit: 1 tablet per day

Authorization Duration: Approval will be given for an initial duration of six (6) months. For continuation of coverage, medical record documentation of clinical improvement or lack of progression in signs and symptoms of rheumatoid arthritis on six (6) months of baricitinib therapy is required.

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

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

RETACRIT (epoetin alfa-epbx)

Review: Retacrit is the only biosimilar to the commercially available epoetin alfa products, Procrit and Epogen. Retacrit carries the same indications as Procrit and Epogen: 1) treatment of anemia due to CKD on and not on dialysis, 2) anemia due to zidovudine in patients with HIV-infection, 3) anemia due to concomitant myelosuppressive chemotherapy, and 4) the reduction of allogenic red blood cell transfusions in patients undergoing elective, noncardiac, nonvascular surgery. The first indication listed was approved through comparative efficacy and safety trials to Epogen and Procrit, and the other three indications listed were approved via indication extrapolation. The dosing of Retacrit is consistent with that of Procrit and Epogen. Retacrit carries the same black box warning for increased risk of death, myocardial infarction, stroke, venous thromboembolism, thrombosis of vascular access and tumor progression or recurrence as well as the same warnings and precautions as Procrit and Epogen. In clinical trials, Retacrit was found to be “equivalent” to Epogen in patients with anemia of CKD requiring dialysis. Extension trials found Retacrit to be safe and effective for extended use. Retacrit is approved for use in patients aged as low as 1 month, and epoetin alfa products have proven to have similar efficacy and safety profiles between the elderly (65+ years) and younger populations.

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. Rajneel Chohan made a motion to accept the recommendations as written. Kevin Szczecina seconded the motion. None were opposed

Financial Discussion: No comments or questions. Tricia Heitzman made a motion to accept the recommendations as written. Kevin Szczecina seconded the motion. None were opposed.

Outcome: Retacrit will be a pharmacy or medical benefit. It is recommended that Retacrit be added to the GHP Family pharmacy formulary on the Brand tier. Prior authorization should apply. It is recommended that Retacrit be added to the existing policies, MBP 49.0 and Policy 901.0F, as listed below.

1. Treatment of symptomatic anemia of chronic renal insufficiency, chronic renal failure, including end stage renal disease either requiring or not requiring dialysis when all of the following criteria are met:
 - For New starts: Hgb less than or equal to 10 g/dL OR
 - For Continuation of therapy: Hgb less than 11 g/dL OR medical record documentation that the dose will be reduced or interrupted if Hgb is greater than or equal to 11g/d
 - AND

- Ferritin greater than or equal to 100 ng/mL or transferrin saturation level greater than or equal to 20%, or a history of chelation therapy for iron

2. Treatment of symptomatic anemia in zidovudine-treated HIV infected insured individuals when all of the following criteria are met:

- Endogenous erythropoietin levels of 500 MU/mL or less; AND
- Ferritin greater than or equal to 100 ng/mL or transferrin level saturation greater than or equal to 20% or a history of chelation therapy for iron; AND
- Zidovudine doses of 4200 mg or less per week; AND
- Hgb less than or equal to 10 g/dL for new starts OR Hgb less than 12 g/dL for continuation of therapy

Treatment should not last longer than 3 months following the discontinuation of zidovudine

3. Treatment of anemia secondary to myelosuppressive chemotherapy in *non-myeloid malignancies when all of the following criteria are met:

- Hgb less than or equal to 10 g/dL for new starts OR Hgb less than 12 g/dL for continuation of therapy AND
- Insured individual is currently on anemia-inducing chemotherapy and there is a minimum of two additional months of planned chemotherapy; AND
- Ferritin greater than or equal to 100 ng/mL or transferrin level saturation greater than or equal to 20% or a history of chelation therapy for iron

*Non-myeloid malignancies include all types of carcinoma, sarcoma, melanoma, multiple myeloma, lymphoma and lymphocytic leukemia

4. Treatment of symptomatic anemia secondary to myelodysplastic syndrome (MDS) when all of the following criteria are met:

- Hgb less than or equal to 10 g/dL for new starts OR Hgb less than 12 g/dL for continuation of therapy AND
- Ferritin greater than or equal to 100ng/dL or transferrin level saturation greater than or equal to 20% OR a history of chelation therapy for iron; AND
- Baseline endogenous erythropoietin levels of 500 MU/mL or less (NCCN Clinical Practice Guidelines in Oncology – Myelodysplastic Syndromes v2.2010)

5. Treatment of symptomatic anemia of chronic disease (rheumatoid arthritis, inflammatory bowel disease, systemic lupus erythematosus, and hepatitis C undergoing treatment) when all of the following criteria are met:

- Hgb less than or equal to 10g/dL for new starts OR less than 12g/dL for continuation of therapy AND
- Ferritin greater than or equal to 100ng/dL or transferrin level saturation greater than or equal to 20% or a history of chelation therapy for iron; AND
- Insured individual has a severe comorbidity (e.g. severe angina, pulmonary disease, heart failure, cerebrovascular disease causing transient ischemic attacks, lymphoma, myeloma, etc.); AND
- Insured individual's anemia is manifested by impairments such as, but not limited to, exercise intolerance, tachycardia or shortness of breath with minimal activity, or inability to perform activities of daily living

6. Reduction of allogeneic blood transfusion in anemic insured individuals undergoing surgery when all of the following criteria are met:

- Hgb less than 13 g/dL AND
- Ferritin greater than or equal to 100ng/dL or transferrin level saturation greater than or equal to 20% or a history of chelation therapy for iron; AND
- Anemia is related to chronic disease state (limited to rheumatoid arthritis, inflammatory bowel disease, systemic lupus erythematosus, and hepatitis C undergoing treatment); AND
- Insured individual is scheduled to undergo elective, non-cardiac, non-vascular surgery in which anticipated blood loss is greater than 2 units and the need for allogeneic blood transfusion is anticipated.

Note: Authorization will be for a duration of 1 month. Request for use beyond 4 weeks will require medical record documentation indicating medical necessity.

Note: Erythropoietin therapy (epoetin alfa) is not indicated for anemic patients who are able and willing to donate autologous blood.

AUTHORIZATION DURATION: Except for the indication of use in anemic surgical patients, approval for Epogen, Procrit or Aranesp therapy will be given for an initial duration of 12 months. Subsequent authorizations will be considered based on the stated criteria.

GENERAL GUIDANCE:

- For continuation of therapy, a repeat Hgb should be submitted after 3-12 months of therapy.
- In individuals whose Hgb is greater than or equal to 12gm/dL or rises by 1 gm/dl in any two-week period, additional doses should be withheld. (In insured individuals with Hgb of greater than or equal to 12 gm/dL Erythropoietin or Darbepoetin therapy will not be covered according to FDA recommendations, except when being used for reduction of allogeneic blood transfusion in anemic insured individuals undergoing surgery).
- For initiation or continuation of therapy, a ferritin level no greater than 3 months old and/ or transferrin saturation level no greater than 6 months old should be submitted.
- The member should receive supplemental iron if serum ferritin is less than 100ng/ml and transferrin saturation is less than 20 percent.

EXCLUSIONS:

Erythropoietin and Darbepoetin therapy is not covered for the following conditions because current clinical data indicates that erythropoietin stimulating agents have been shown to impart either a deleterious effect on the underlying disease, or that the underlying disease increases the risk of adverse effects related to use of erythropoietin stimulating agents. These conditions include but are not limited to:

- Anemia of cancer not related to cancer treatment;
- Anemia related to myelosuppressive chemotherapy when the cancer treatment goal is cure (e.g. early stage breast cancer, Hodgkin lymphoma, non-Hodgkin's lymphoma, testicular cancer, Early stage non-small cell lung cancer, small cell lung cancer)
- Anemia associated only with radiotherapy;
- Anemia due to cancer treatment in insured individuals with uncontrolled hypertension;
- Anemia associated with the treatment of acute and/or chronic myelogenous leukemias (CML or AML), or erythroid cancers;
- Anemia in cancer or in cancer treatment due to folate deficiency, iron deficiency, vitamin B-12 deficiency, bleeding, hemolysis, or bone marrow fibrosis;
- Prophylactic use of erythropoietin stimulating agents to prevent chemotherapy-induced anemia;
- Prophylactic use of erythropoietin stimulating agents to reduce tumor hypoxia;
- Erythropoietin-type resistance due to neutralizing antibodies

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

COPIKTRA (duvelisib)

Review: Copiktra is a dual PI3K inhibitor (PI3K- δ and PI3K- γ) indicated for use in adult patients with refractory chronic lymphocytic leukemia/small lymphocytic lymphoma (CLL/SLL) or follicular lymphoma (FL). Copiktra is dosed as one 25 mg oral capsule twice daily with or without food for both indications. Copiktra can be used as

monotherapy in refractory CLL/SLL. This provides an advantage over the other agent in its class indicated for refractory CLL/SLL, Zydelig (idelalisib), which must be used in combination with rituximab. Copiktra has been shown to significantly improve progression free survival when compared to ofatumumab in patients with CLL/SLL; however, there was a higher incidence of death due to serious side effects with Copiktra. Overall response was also improved in patients with FL who were treated with Copiktra. Copiktra has four major adverse events covered in its black box warning: risk of fatal infections, diarrhea or colitis, cutaneous reactions, and pneumonitis. Copiktra has multiple different drug interactions since it is metabolized through CYP 3A4. Copiktra has recently been added to the NCCN guidelines as a preferred regimen for relapsed/refractory CLL/SLL with or without del(17p)/TP53 mutation and as an “Other recommended regimen” for FL in patients who have relapsed or are refractory to at least 2 prior therapies.

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

Clinical Discussion: No comments or questions. Tricia Heitzman made a motion to accept the recommendations as written. Kevin Szczecina seconded the motion. None were opposed

Financial Discussion: No comments or questions. Keith Hunsicker made a motion to accept the recommendations as written. Kelly Yelenic seconded the motion. None were opposed

Outcome: Copiktra is a pharmacy benefit and should be added to the brand tier of the GHP Family formulary requiring prior authorization. The following criteria should apply:

- Prescription written by a hematologist/oncologist **AND**
- Medical record documentation of a diagnosis of either
 - o Relapsed or refractory chronic lymphocytic leukemia (CLL) or small lymphocytic lymphoma (SLL)**OR**
 - o Relapsed or refractory follicular lymphoma (FL) **AND**
- Medical record documentation of a therapeutic failure on, intolerance to, or contraindication to at least two prior therapies **AND**
- Documentation that the patient is at least 18 years of age or older

Authorization duration: Initial approval will be for 12 months or less if the reviewing provider feels it is medically appropriate. Subsequent approvals will be for an additional 12 months or less if the reviewing provider feels it is medically appropriate and will require medical record documentation of continued disease improvement or lack of disease progression. The medication will no longer be covered if the member experiences unacceptable toxicity or worsening of disease.

Quantity Limit: 60 tablets per 30 days

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

AZEDRA (iobenguane I 131)

Review: Azedra is a radioactive therapeutic agent indicated for the treatment of adult and pediatric patients 12 years and older with iobenguane scan positive, unresectable, locally advanced or metastatic pheochromocytoma or paraganglioma who require systemic anticancer therapy. Metastatic pheochromocytoma and paraganglioma may

result in unresectable disease with a poor prognosis, including a five-year survival rate as low as 12%. Before Azedra's approval, there were no FDA-approved anti-tumor therapeutics for these cancers. Azedra is given intravenously as a dosimetric dose followed by two therapeutic doses administered 90 days apart.

Pheochromocytoma and paraganglioma (PPGL) are rare neuroendocrine cancers that arise from cells in and around the adrenal glands. The combined estimated annual incidence of PPGL is approximately 0.8 per 100,000 person years. PPGL tumors frequently secrete high levels of hormones that can lead to life-threatening high blood pressure, heart failure, and stroke in these patients. In the clinical study that led to its approval, Azedra was effective in achieving a 50% reduction, lasting six months or longer, in the use of drugs that 17 of the 68 trial participants needed to control blood pressure. Azedra also decreased tumor size for 15 (22%) of patients who received it. Cancer worsened for only 4.7% of patients over the year after treatment. Azedra can cause serious side effects including risk from radiation exposure, bone marrow problems and other cancers (myelosuppression and secondary malignancies), thyroid problems (hypothyroidism), elevations in blood pressure, kidney problems (renal toxicity), respiratory problems (pneumonitis), pregnancy warning (embryo-fetal toxicity), and fertility problems. NCCN Guidelines recommend use as primary treatment for locally unresectable disease or distant metastases if prior positive MIBG scan. Surgical resection is the recommended treatment for patients with resectable tumors.

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

Clinical Discussion: No comments or questions. Keith Hunsicker made a motion to accept the recommendations as written. Kelly Yelenic seconded the motion. None were opposed.

Financial Discussion: No Comments or questions. Kim Clark make a motion to accept the recommendations as written. Rajneel Chohan seconded the motion. None were opposed.

Outcome: Azedra will be a medical benefit for GHP Family members and should not be added to the respective pharmacy formulary at this time. To ensure appropriate utilization, it is recommended that a prior authorization with the following criteria apply:

Pheochromocytoma/Paraganglioma

- Prescription is written by a hematologist/oncologist **AND**
- Medical record documentation that patient is 12 years of age or older **AND**
- Medical record documentation of a diagnosis of unresectable, locally advanced or metastatic pheochromocytoma or paraganglioma **AND**
- Medical record documentation of a positive iobenguane scan (ex. MIBG (metaiodobenzylguanidine) scan, iobenguane I 131) **AND**

Authorization Duration: Azedra will be approved for a one time authorization of three (3) total doses (one dosimetric dose and two therapeutic doses).

Dosing Note: After the member receives the initial dosimetric dose, a dosimetry and biodistribution assessment should occur to determine if a dose adjustment is needed prior to giving the therapeutic doses as follows:

- Acquire anterior/posterior whole body gamma camera images within 1 hour of the AZEDRA dosimetric dose and prior to patient voiding (Day 0; Scan 1).
- Acquire additional images on Day 1 or 2 following patient voiding (Scan 2).
- Acquire additional images between Days 2-5 following patient voiding (Scan 3).

For each individual patient, calculate the radiation dose estimates to normal organs and tissues per unit activity [D (organ)] of administered dose using data extracted from these 3 images. Calculate in accordance with the Medical

Internal Radiation Dose (MIRD) schema or related methodology. Whenever possible, use patient-specific organ masses (e.g., estimated from imaging).

Based on dosimetry assessment determine if a dose adjustment is needed for therapeutic dose. Administer a total of 2 therapeutic doses intravenously a minimum of 90 days apart.

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

AJOVY (fremanezumab-vfrm)

Review: Ajovy is a calcitonin gene-related peptide (CGRP) antagonist indicated for the preventive treatment of migraine in adults. Ajovy (fremanezumab-vfrm) joins Aimovig (erenumab-aooe) as the second calcitonin gene-related peptide (CGRP) receptor antagonist approved for the preventive treatment of migraine in adults. Ajovy is a humanized monoclonal antibody that binds to the CGRP ligand and blocks its binding to the receptor. CGRP is a 37 amino acid neuropeptide that is expressed in trigeminal ganglia nerves and is a potent vasodilator of cerebral and dural vessels. Stimulation of the trigeminal ganglion induces the release of CGRP and CGRP infusion can trigger a migraine attack.

CGRP antagonists are all administered via monthly subcutaneous injections. Ajovy is available as a 225 mg/1.5 mL single-dose prefilled syringe for subcutaneous administration. It may be administered by healthcare professionals, caregivers, or self-administered by patients. The recommended dosage is either 225 mg monthly, or 675 mg every 3 months (quarterly), which is administered as three consecutive subcutaneous injections of 225 mg each.

CGRP antagonists have comparable efficacy and safety profiles. The safety and efficacy of Ajovy for the preventive treatment of episodic or chronic migraine was evaluated in two multicenter, randomized, 3-month, double-blind, placebo-controlled studies. The trials excluded patients who used onabotulinumtoxinA during the 4 months before screening and those with history of cardiovascular disease/events and cerebrovascular events.

Study 1 included adults with a history of episodic migraine. All patients were randomized (1:1:1) to receive subcutaneous injections of either Ajovy 675 mg quarterly, Ajovy 225 mg monthly, or placebo monthly, over a 3-month treatment period. The primary efficacy endpoint was the mean change from baseline in the monthly average number of migraine days. Secondary endpoints included the proportion of patients reaching at least a 50% reduction in monthly average number of migraine days from baseline, the mean change from baseline in the monthly average number of days of use of any acute headache medications, the mean change from baseline to week 4 in the number of migraine days, mean the change from baseline to week 12 in monthly average number of migraine days in patients not receiving concomitant migraine preventive medication, and the mean change in the Migraine Disability Assessment score. Both monthly and quarterly dosing regimens of Ajovy demonstrated statistically significant improvements for efficacy endpoints compared to placebo over the 3-month period. There was a sub-analysis of the Phase 3 study in patients who previously used topiramate or onabotulinumtoxinA for episodic migraine. In patients who used prior topiramate, Ajovy significantly reduced the number of headache days of at least moderate severity. For patients with prior onabotulinumtoxinA use, there were nonsignificant reductions versus placebo in monthly migraine days and headache days. The sample size for Botox was too small to detect any significant difference.

Study 2 included adults with a history of chronic migraine. All patients were randomized (1:1:1) to receive subcutaneous injections of either Ajovy 675 mg starting dose followed by 225 mg monthly, 675 mg every 3 months, or placebo monthly, over a 3-month treatment period. The primary efficacy endpoint was the mean change from baseline in the monthly average number of headache days of at least moderate severity. The secondary endpoints were the mean change from baseline in the monthly average number of migraine days, the proportion of patients reaching at least 50% reduction in the monthly average number of headache days of at least moderate severity, the mean change from baseline in the monthly average number of days of use of any acute headache medication, the mean change from baseline in the number of headache days of at least moderate severity during the first month of

treatment, and the mean change in HIT-6 score (disability measure) from baseline to 4 weeks after administration. Both monthly and quarterly dosing regimens of Ajovy treatment demonstrated statistically significant improvement for key efficacy outcomes compared to placebo.

Similar to the other CGRP antagonists, there are no boxed warnings. It is contraindicated in patients with serious hypersensitivity to Ajovy or to any of the excipients and it has warnings and precautions for hypersensitivity reactions. Safety and effectiveness of Ajovy in pediatric patients have not been established.

In addition to Aimovig, Ajovy, and Emgality, the following agents are FDA-approved for migraine prevention: propranolol, timolol, valproic acid/divalproex sodium, topiramate and onabotulinumtoxinA (Botox). Botox is indicated for the preventive treatment of chronic migraines only, whereas Aimovig, Ajovy, and Emgality have been shown to decrease the frequency of both chronic and episodic migraine headaches.

According to American Academy of Neurology the following is recommended for episodic migraine prevention in adults:

- Established as effective (level A):
 - Divalproex sodium/sodium valproate
 - Topiramate
 - Metoprolol
 - Propranolol
 - Timolol
- Probably effective (level B)
 - Amitriptyline
 - Venlafaxine
 - Atenolol
 - Nadolol
- Possibly effective (Level C)
 - Candesartan
 - Lisinopril
 - Clonidine
 - Guanfacine
 - Carbamazepine
 - Nebivolol

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

Clinical Discussion: Kim Clark made a motion to accept the recommendations as written. Kevin Szczecina seconded the motion. None were opposed

Financial Discussion: No comments or questions. Kevin Szczecina made a motion to accept the recommendations as written. Keith Hunsicker seconded the motion. None were opposed

Outcome: Ajovy will be a pharmacy benefit. It is recommended that Ajovy not be added to the GHP Family formulary. Ajovy will require a prior authorization with the following criteria.:

- Prescription written by or in consultation with a neurologist or headache specialist AND
- Medical record documentation of patient age greater than or equal to 18 years AND
- Medical record documentation of a diagnosis of migraine with or without aura, based on the ICHD-III diagnostic criteria AND
- Medical record documentation of number of baseline migraine or headache days per month AND
- Medical record documentation that Ajovy will not be used in combination with botulinum toxin AND

- Medical record documentation of therapeutic failure on, intolerance to, or contraindication to at least three (3) of the following:
 - One (1) beta blocker (metoprolol, propranolol, timolol, atenolol, nadolol)
 - Topiramate
 - Divalproex/Sodium Valproate
 - Amitriptyline
 - Venlafaxine

ICHD-III Diagnostic Criteria³	
Migraine without Aura:	Migraine with Aura:
A) At least five (5) attacks fulfilling criteria B through D below:	A) At least two (2) attacks fulfilling criteria B through C below:
B) Headache lasting 4 to 72 hours (untreated or unsuccessfully treated)	B) One (1) or more of the following fully reversible aura symptoms: <ul style="list-style-type: none"> ○ Visual ○ Sensory ○ Speech and/or language ○ Motor ○ Brainstem ○ Retinal
C) Headache with at least two (2) of the following characteristics: <ul style="list-style-type: none"> ○ unilateral location ○ pulsating quality ○ moderate to severe pain intensity ○ aggravation by or causing avoidance of routine physical activity (e.g. walking or climbing stairs) 	C) At least three (3) of the following: <ul style="list-style-type: none"> ○ at least one (1) aura symptom spreads over 5 or more minutes ○ two (2) or more aura symptoms occur in succession ○ each individual aura symptom lasts 5 to 60 minutes¹ ○ at least one (1) aura symptom is unilateral² ○ at least one (1) aura symptom is positive³ ○ the aura is accompanied, or followed within 60 minutes, by a headache
D) At least one of the following during the headache: <ul style="list-style-type: none"> ○ nausea and/or vomiting ○ photophobia and phonophobia 	D) Not better accounted for by another ICHD-3 diagnosis
E) Not better accounted for by another ICHD-3 diagnosis	

1. Example, if three symptoms occur during an aura, the acceptable maximal duration is 3 x 60 minutes. Motor symptoms may last up to 72 hours.
2. Aphasia (impairment of language) is always a unilateral symptom; dysarthria (slurred or slowed speech) may or may not be.
3. Scintillations (flash of light) and pins and needles are positive symptoms of aura

Authorization Duration: Initial approval will be for six (6) months and subsequent approvals will be for twelve (12) months.

Reauthorization Criteria:

- Medical record documentation of continued or sustained reduction in migraine or headache frequency AND
- Medical record documentation that Ajovy is not being used concurrently with botulinum toxin.

Quantity Limit: 4.5 mL per 90 days

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

EMGALITY (galcanezumab-gnlm)

Review: Emgality is a calcitonin-gene related peptide (CGRP) antagonist indicated for the preventive treatment of migraine in adults. Emgality (galcanezumab-gnlm) joins Aimovig (erenumab-aooe) and Ajovy

(fremanezumab-vfrm) as the third calcitonin gene-related peptide (CGRP) receptor antagonist approved for the preventive treatment of migraine in adults. Similar to Ajovy, Emgality is a humanized monoclonal antibody that binds to the CGRP ligand and blocks its binding to the receptor. CGRP is a 37 amino acid neuropeptide that is expressed in trigeminal ganglia nerves and is a potent vasodilator of cerebral and dural vessels. Stimulation of the trigeminal ganglion induces the release of CGRP and CGRP infusion can trigger a migraine attack.

Aimovig, Ajovy, and Emgality are all administered via monthly subcutaneous injections (Ajovy provides an additional quarterly dosing option). The recommended dose of Emgality is 240 mg (two consecutive injections of 120 mg each) once as a loading dose, followed by monthly doses of 120 mg. Emgality is available as 120 mg/mL single-dose prefilled pen.

Aimovig, Ajovy, and Emgality have comparable efficacy and safety profiles. The safety and efficacy of Emgality for the preventive treatment of episodic or chronic migraine was evaluated in three multicenter, randomized, double-blind, placebo-controlled studies: two 6-month studies in patients with episodic migraine (Studies 1 and 2) and one 3-month study in patients with chronic migraine (Study 3). Patients were not allowed to use Botox in any of the clinical trials. Patients were also excluded if they had a history of cardiovascular or cerebrovascular events.

Studies 1 and 2 included adults with a history of episodic migraine. All patients were randomized in a 1:1:2 ratio to receive once-monthly subcutaneous injections of Emgality 120 mg (with 240 mg loading dose), Emgality 240 mg, or placebo. The primary efficacy endpoint was the mean change from baseline in the number of monthly migraine headache days over the 6-month treatment period. Key secondary endpoints included the mean percentages of patients reaching at least 50%, 75%, and 100% reduction from baseline in the number of monthly migraine headache days, the mean change from baseline in the number of monthly migraine headache days with use of any acute headache medication, and the impact of migraine on daily activities. Emgality 120 mg demonstrated statistically significant improvements for efficacy endpoints compared to placebo over a 6 month period. The 240 mg dose showed no additional benefit.

Study 3 included adults with a history of chronic migraine. All patients were randomized in a 1:1:2 ratio to receive once-monthly subcutaneous injections of Emgality 120 mg (with 240 mg loading dose), Emgality 240 mg, or placebo over a 3-month treatment period. Emgality 120 mg demonstrated statistically significant improvement for the mean change from baseline in the number of monthly migraine headache days and in the mean percentage of patients reaching at least 50% reduction from baseline in the number of monthly migraine headache days. Emgality treatment with the 240 mg once-monthly dose showed no additional benefit. Emgality 120 mg was not significantly better than placebo for the proportion of patients with $\geq 75\%$ or 100% reduction in migraine headache days. Patients treated with Emgality 120 mg showed a nominally greater reduction in the number of monthly migraine headache days that acute medication was taken and the mean change from baseline in the MSQ Role Function-Restrictive Domain score (function score).

Similar to the other CGRP antagonists, there are no boxed warnings. It is contraindicated in patients with serious hypersensitivity to Emgality or to any of the excipients and it has warnings and precautions for hypersensitivity reactions, similar to Ajovy. CGRP is recognized as a potent microvascular vasodilator and hypothesized to play a protective role in CV health. Observational studies have reported increased relative risks for CV events in the migraine population compared to the non-migraine population. These events included ischemic stroke, TIA, ischemic heart disease, and MI. The cardiovascular safety of Emgality was evaluated in phase 3 randomized, double blind, placebo-controlled studies in adult patients for the prevention of episodic and chronic migraine. The studies showed no increase in mean blood pressure, heart rate, or clinically important changes in ECG parameters. Safety and effectiveness of Emgality in pediatric patients have not been established.

In addition to Aimovig, Ajovy, and Emgality, the following agents are FDA-approved for migraine prevention: propranolol, timolol, valproic acid/divalproex sodium, topiramate and onabotulinumtoxinA (Botox). Botox is indicated for the preventive treatment of chronic migraines only, whereas Aimovig, Ajovy, and Emgality have been shown to decrease the frequency of both chronic and episodic migraine headaches.

According to American Academy of Neurology the following is recommended for episodic migraine prevention in adults:

- Established as effective (level A):

- Divalproex sodium/sodium valproate
- Topiramate
- Metoprolol
- Propranolol
- Timolol
- Probably effective (level B)
 - Amitriptyline
 - Venlafaxine
 - Atenolol
 - Nadolol
- Possibly effective (Level C)
 - Candesartan
 - Lisinopril
 - Clonidine
 - Guanfacine
 - Carbamazepine
 - Nebivolol
 - Pindolol

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

Clinical Discussion: Kim Clark made a motion to accept the recommendations as written. Rajneel Chohan seconded the motion. None were opposed.

Financial Discussion: No comments or questions. Kevin Szczecina made a motion to accept the recommendations as written. Kim Clark seconded the motion. None were opposed.

Outcome: Emgality will be a pharmacy benefit. It is recommended that Emgality not be added to the GHP Family formulary. Emgality will require a prior authorization with the following criteria.

- Prescription written by or in consultation with a neurologist or headache specialist AND
- Medical record documentation of patient age greater than or equal to 18 years AND
- Medical record documentation of a diagnosis of migraine with or without aura, based on the ICHD-III diagnostic criteria AND
- Medical record documentation of number of baseline migraine or headache days per month AND
- Medical record documentation that Emgality will not be used in combination with botulinum toxin AND
- Medical record documentation of therapeutic failure on, intolerance to, or contraindication to at least three (3) of the following:
 - One (1) beta blocker (metoprolol, propranolol, timolol, atenolol, nadolol)
 - Topiramate
 - Divalproex/Sodium Valproate
 - Amitriptyline
 - Venlafaxine

ICHD-III Diagnostic Criteria ³	
Migraine without Aura:	Migraine with Aura:

B) At least five (5) attacks fulfilling criteria B through D below:	C) At least two (2) attacks fulfilling criteria B through C below:
D) Headache lasting 4 to 72 hours (untreated or unsuccessfully treated)	D) One (1) or more of the following fully reversible aura symptoms: <ul style="list-style-type: none"> ○ Visual ○ Sensory ○ Speech and/or language ○ Motor ○ Brainstem ○ Retinal
E) Headache with at least two (2) of the following characteristics: <ul style="list-style-type: none"> ○ unilateral location ○ pulsating quality ○ moderate to severe pain intensity ○ aggravation by or causing avoidance of routine physical activity (e.g. walking or climbing stairs) 	E) At least three (3) of the following: <ul style="list-style-type: none"> ○ at least one (1) aura symptom spreads over 5 or more minutes ○ two (2) or more aura symptoms occur in succession ○ each individual aura symptom lasts 5 to 60 minutes¹ ○ at least one (1) aura symptom is unilateral² ○ at least one (1) aura symptom is positive³ ○ the aura is accompanied, or followed within 60 minutes, by a headache
F) At least one of the following during the headache: <ul style="list-style-type: none"> ○ nausea and/or vomiting ○ photophobia and phonophobia 	F) Not better accounted for by another ICHD-3 diagnosis
G) Not better accounted for by another ICHD-3 diagnosis	

4. Example, if three symptoms occur during an aura, the acceptable maximal duration is 3 x 60 minutes. Motor symptoms may last up to 72 hours.
5. Aphasia (impairment of language) is always a unilateral symptom; dysarthria (slurred or slowed speech) may or may not be.
6. Scintillations (flash of light) and pins and needles are positive symptoms of aura

Authorization Duration: Initial approval will be for six (6) months and subsequent approvals will be for twelve (12) months.

Reauthorization Criteria:

- Medical record documentation of continued or sustained reduction in migraine or headache frequency AND
- Medical record documentation that Emgality is not being used concurrently with botulinum toxin.

Quantity Limit: One-time 1-week authorization for a QL of 2 mL per 30 days. For the remainder of the 6 month authorization, QL 1 mL per 30 days should apply.

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

SYM TUZA (darunavir/cobicistat/emtricitabine/tenofovir alafenamide)

Review: Patients with HIV will require life-long treatment with ART; thus, research and new drug therapies which improve toxicity, delay the onset of resistance, and improve adherence potential is critical. Treatment guidelines for the use of ART in patients living with HIV released by the Department of Health and Human Services (DHHS) in 2017 streamlined its recommendations on when to initiate ART, the preferred regimens when ART is initiated, and recommendations for switching regimens in the setting of virologic suppression. An initial ART regimen for a treatment-naïve patient generally consists of two NRTI's in combination with a third active antiretroviral (ARV) drug from one of three drug classes: an integrase strand transfer inhibitor (INSTI), a non-nucleoside reverse transcriptase inhibitor (NNRTI), or a protease inhibitor (PI) with a pharmacokinetic booster (either ritonavir or cobicistat). DHHS prefers INSTI based regimens for most people living with HIV, and only recommends a boosted PI based regimen in certain clinical situations, as detailed in Tables 1 and 2. INSTI-based regimens have gained their place as initial recommended therapy based on a large database of large clinical trials showing high rates of

virologic suppression, greater tolerability compared to other regimens, and high barrier to resistance. Boosted PI based regimens, such as those containing darunavir/ritonavir, are recommended in combination with two NRTI's only in certain clinical situations. These clinical scenarios include the following:

- ART must be started before HIV drug resistance results are available
- A one-pill, once-daily regimen is desired (Symtuza would now qualify as this)
- HIV-associated dementia
- Patients with history of poor adherence to ARV or inconsistent engagement in care

Symtuza is a complete four-drug combination single-tablet regimen (STR) containing darunavir, a protease inhibitor (PI), cobicistat, a protease enhancer, and two nucleoside analog reverse transcriptase inhibitors (NRTI) as the backbone, emtricitabine (FTC) and tenofovir alafenamide (TAF). Symtuza is the first branded boosted PI- based STR and is the fourth STR utilizing FTC/TAF as the NNRTI backbone. Additionally, Symtuza is the ninth STR approved for use in both treatment-naïve and treatment-experienced patients. The AMBER trial was a phase 3, randomized, double-blind, active-controlled trial evaluating the efficacy of Symtuza versus Prezcoibix (darunavir/cobicistat) with emtricitabine/tenofovir (FTC/TDF). The primary endpoint was non-inferiority of Symtuza versus the control regimen for the proportion of patients that achieved virologic suppression (viral load of less than 50 copies per mL) at 48 weeks. Symtuza was found to be non-inferior to the combination of Prezcoibix with FTC/TDF. The EMERALD trial was a Phase 3, randomized, double-blind trial evaluating the efficacy of Symtuza in virologically suppressed patients who switched from a boosted protease inhibitor regimen combined with emtricitabine and TDF. Prior to enrollment, subjects were on a stable antiretroviral regimen with HIV-1 RNA less than 50 copies per mL for at least 6 months prior to trial entry and had no history of treatment failure. The primary endpoint in the trial evaluated the proportion of patients with virologic rebound, defined as HIV-1 RNA \geq 50 copies/mL or premature discontinuation with last HIV-1 RNA \geq 50 copies/mL, at week 48. Switching to Symtuza was found to be non-inferior to the control arm in the EMERALD trial. There were no observed resistance associated mutations to darunavir, TAF or TDF.

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

Clinical Discussion: No comments or questions. Kim Clark made a motion to accept the recommendations as written. Aubrielle Prater seconded the motion. None were opposed.

Financial Discussion: No comments or questions. Kevin Szczecina made a motion to accept the recommendations as written. Tricia Heitzman seconded the motion. None were opposed.

Outcome: For Medicaid, Symtuza is a pharmacy benefit and should be added to the brand tier of GHP Family formulary.

Quantity Limit: one tablet daily

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

FULPHILA (pegfilgrastim-jmdb)

Review: Fulphila, pegfilgrastim-jmdb, is the first biosimilar agent available on the market for Neulasta. It is indicated to decrease the incidence of infection, as manifested by febrile neutropenia, in patients with non-myeloid malignancies receiving myelosuppressive anti-cancer drugs associated with a clinically significant incidence of febrile neutropenia. Fulphila is not indicated for the mobilization of peripheral blood progenitor cells for

hematopoietic stem cell transplantation and has also not been studied for treatment of radiation injury syndrome. Fulphila is available as a 6mg/0.6ml single-dose prefilled syringe and should be given at a dose of 6mg subcutaneously once per chemotherapy cycle. Weight based dosing is available for pediatric patients weighing less than 45kg. Fulphila should not be given between 14 days before and 24 hours after administration of cytotoxic chemotherapy. Pegfilgrastim was evaluated in three clinical trials. Studies 1 and 2 evaluated patients with cancer who were receiving myelosuppressive chemotherapy. Both studies compared a single dose of pegfilgrastim to daily filgrastim. Both studies met the major efficacy outcome measure of demonstrating that the mean days of severe neutropenia of pegfilgrastim-treated patients did not exceed that of filgrastim-treated patients by more than 1 day in cycle 1 of chemotherapy. In Study 3, pegfilgrastim was compared to placebo and the trial met the outcome measure of demonstrating that the incidence of febrile neutropenia was lower for pegfilgrastim-treated patients as compared to placebo treated patients. The incidence of hospitalizations and IV anti-infective use for the treatment of febrile neutropenia was also lower in the pegfilgrastim-treated patients compared to the placebo-treated patients. One additional study was completed in pediatric patients with sarcoma who were receiving chemotherapy to evaluate efficacy and safety in this population. Patients were treated with either a single dose of pegfilgrastim or daily filgrastim. Recovery of neutrophil counts was similar in the pegfilgrastim and filgrastim groups and the most common adverse event was bone pain. No studies specifically evaluating Fulphila (pegfilgrastim-jmdb) were available at the time of this review. All clinical trials included in the package insert were also included in the FDA approved package labeling for Neulasta. Warnings and precautions associated with Fulphila are similar to other pegfilgrastim products, including include risk of splenic rupture, acute respiratory distress syndrome, serious allergic reactions (including anaphylaxis), risk of serious/fatal sickle cell crisis in patients with sickle cell disorder, glomerulonephritis, leukocytosis, capillary leak syndrome, potential for tumor growth stimulation on malignant cells, aortitis, and positive bone image changes seen on nuclear imagine due to increased hematopoietic activity of bone marrow. The most common adverse events were bone pain and pain in extremities.

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

Clinical Discussion: No comments or questions. Todd Sponenberg made a motion to accept the recommendations as written. Tricia Heitzman seconded the motion. None were opposed.

Financial Discussion: No comments or questions. Kevin Szczecina made a motion to accept the recommendations as written. Todd Sponenberg seconded the motion. None were opposed.

Outcome: Fulphila is a pharmacy or medical benefit and should be added to the Brand Tier of the GHP Family formulary. It is recommended that Fulphila be added the existing policies for Neulasta with the same quantity limit and authorization duration as the reference product. Prior authorization criteria for Fulphila will be as follows, noting Fulphila is not indicated for PBPC mobilization & radiation injury syndrome.

Medical record documentation of a diagnosis of cancer, and when any of the following FDA labeled indications or uses supported by clinical guidelines are present:

Primary Prophylaxis: For the prevention of febrile neutropenia (FN) when the risk of FN due to the myelosuppressive chemotherapy regimen is 20% or greater. Those regimens include but are not limited to:

- TC (paclitaxel/cisplatin, or cyclophosphamide/docetaxel or docetaxel/cisplatin or paclitaxel/carboplatin)
- MVAC (methotrexate, vinblastine, doxorubicin, cisplatin)
- AC (doxorubicin, cyclophosphamide, docetaxel)
- AT (doxorubicin, paclitaxel)
- TIC (paclitaxel, ifosfamide, mesna, cisplatin)

- VAPEC-B (vincristine, doxorubicin, prednisolone, etoposide, cyclophosphamide, bleomycin)
- A(N)CVB (doxorubicin or mitoxantrone, cyclophosphamide, vindesine, bleomycin)
- DHAP (dexamethasone, cisplatin, cytarabine)

NOTE: Regimens not specified in this document must be listed on a nationally recognized guideline stating risk of FN of greater than 20%.

OR

For the prevention of FN when the risk of developing FN is less than 20%, but **any** other risk factor listed below is present:

- Age 65 years or greater
- Poor performance status
- Previous history of FN
- Extensive prior radiation or chemotherapy treatment
- Poor nutritional status
- Recent surgery or open wounds or active infection
- Advanced cancer
- Persistent neutropenia
- Bone marrow involvement by tumor
- Liver dysfunction (bilirubin >2.0)
- Renal dysfunction (CrCl <50)

Secondary Prophylaxis – prevention of FN when a previous cycle of chemotherapy resulted in a neutropenic complication and for which primary prophylaxis was not received, and a dose reduction will compromise disease-free or overall survival or treatment outcome.

Treatment of Febrile Neutropenia - as an adjunct to antibiotics in high-risk individuals with FN who are at high risk for infection related complications or when **any** of the following prognostic factors are documented:

- Age 65 years or greater
- Anticipated prolonged and profound neutropenia
- Uncontrolled primary disease
- Pneumonia
- Invasive fungal infection
- Hypotension
- Multi-organ dysfunction
- Hospitalized at the time of development of the fever

Dose Dense Therapy – specifically in the treatment of node positive breast cancer, small cell lung cancer, and diffuse aggressive non-Hodgkin's lymphoma.

Leukemia or Myelodysplastic Syndromes – insured individuals with:

- Acute myeloid leukemia (AML) receiving induction or consolidation chemotherapy
- Acute lymphoblastic leukemia (ALL) after completion of the first few days of chemotherapy of the initial induction or the first post-remission course

- Myelodysplastic syndrome with less than 15% blasts in the bone marrow, or recurrent neutropenic infections are experienced.

Lymphoma – Age 65 years or greater treated with curative chemotherapy, e.g., CHOP (cyclophosphamide, doxorubicin, vincristine, prednisone)

Note: Fulphila is not indicated for PBPC mobilization & Radiation Injury Syndrome

EXCLUSIONS: There is insufficient evidence in the published, peer reviewed medical literature to clearly establish that the use of colony stimulating factors (CSF) improves the health outcomes in any of the following indications. The use of CSF's for the following indications is considered not medically necessary and are **NOT COVERED:**

- Routine use as prophylaxis on most chemotherapy regimens; or
- Use as prophylaxis during chemotherapy regimens with a febrile neutropenia risk of less than 20% and no high risk for complications; or
- Use in insured members who are neutropenic but afebrile and not meeting any of the above criteria; or
- Use as an adjunct to antibiotics in uncomplicated febrile neutropenia; or use in relapsed or refractory myeloid leukemia; or
- Use in chemo-sensitization of myeloid leukemias; or
- Use prior to or concurrent with chemotherapy for acute myeloid leukemia; or
- Use prior to or concurrently with chemotherapy for “priming” effect; or
- Use to allow an increase in the dose-intensity of cytotoxic chemotherapy beyond the established dose ranges for these regimens; or
- Use during concomitant chemotherapy and radiation therapy; or
- Continued use if no response is seen within 45 days.

Quantity Limits: One 6mg dose per chemotherapy cycle

Authorization Duration: 6 months

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

PALYNZIQ (pegvaliase-pqpz)

Review: Palynziq is a phenylalanine-metabolizing enzyme indicated to reduce blood phenylalanine concentrations in adult patients with phenylketonuria who have uncontrolled blood phenylalanine concentrations greater than 600 micromol/L on existing management. Pegvaliase-pqpz is a PEGylated phenylalanine ammonia lyase (PAL) enzyme and it is a substitute for the deficient PAH enzyme activity. Dietary restriction of phenylalanine (Phe) intake is the mainstay of PKU management. Palynziq joins Kuvan (sapropterin), a synthetic cofactor for PAH, in the pharmacologic space for adjunctive PKU treatment. In contrast to Kuvan, which relies upon residual PAH activity and is thus more effective in patients with milder forms of PKU, Palynziq provides an alternative pathway for Phe metabolism (independent of PAH activity) and thereby offers a different adjunctive pharmacologic option for patients with PKU whose Phe levels remain uncontrolled despite existing therapy.

Palynziq therapy should be managed by a healthcare provider with experience in PKU management. Prior to initiating treatment, baseline blood Phe concentrations should be obtained. After initiating treatment, blood Phe concentrations should be obtained every 4 weeks until a maintenance dose is established, and then periodically thereafter. Patient tolerability, blood Phe concentrations, and dietary protein/Phe intake should be assessed throughout Palynziq therapy. Premedication with an H1-receptor antagonist, H2-receptor antagonist, and/or

antipyretic may be considered prior to Palynziq administration based upon patient tolerability. Auto-injectable epinephrine should be prescribed with Palynziq. The first dose should be administered by a healthcare provider. The dose should be titrated to achieve a dose of 20 mg once daily, see Table 1. The maximum dose is 40 mg once daily and may be considered in patients who have been maintained continuously on 20 mg once daily for at least 24 weeks and who have not achieved either a 20% reduction in blood Phe concentrations compared to pre-Palynziq baseline levels or blood Phe concentrations ≤ 600 micromol/L. If patients still have not achieved this on 40 mg/day for 16 weeks, Palynziq should be discontinued. If patients experience blood Phe concentrations below 30 micromol/L during the titration and maintenance phases of treatment, the dose of Palynziq may be reduced and/or dietary protein/Phe intake may be modified to maintain serum Phe concentrations above 30 micromol/L and within a clinically acceptable range. If Palynziq is readministered after an anaphylaxis episode, the first dose should be administered under the supervision of a healthcare provider and the patient should be observed for at least 60 minutes following the dose.

The Palynziq clinical program has been ongoing in the US since 2008, which consists of 7 clinical trials in more than 350 subjects exposed with more than 800 person-years of drug exposure. It included a Phase 1, 4 Phase 2 studies leading into long term extension study, and 2 Phase 3 studies (PRISM-1 and PRISM-2). The inclusion criteria included patients 18-70 years old, however, early in the clinical trial patients aged 16 years and older were included, but there was an amendment to the protocol that increased the age to 18 years for enrollment, to minimize exposing a sensitive population to hypersensitivity risks. Patients had to have a Phe concentration > 600 micromol/L and willing to maintain protein intake within 10% of baseline levels during the study. If patients were taking Kuvan, it had to be discontinued at least 14 days prior to first dose. Patients taking medication for a psychiatric disorder had to maintain a stable dose prior to enrollment and throughout the study.

Study 301 was an open-label, randomized, parallel-group, multicenter study of two Palynziq doses (20 and 40 mg/day) administered as induction, titration, and maintenance regimen up to 36 weeks. Palynziq treatment reduced mean blood Phe concentrations in both 20 and 40 mg/day randomized groups. The mean reduction from baseline in all subjects was 479.4 (566.53) micromol/L at week 28 (n=133) and 432.1 (608.17) micromol/L at week 36 (n=80). There was a statistically significant difference in treatment effect comparisons in subjects completing the Maintenance phase favoring the 40 mg/day group (p=0.0068). There was a significant positive correlation observed between blood Phe declines from baseline and neurocognitive and neuropsychiatric symptom scores. The study notes that increasing protein intake from intact food would increase blood Phe levels and potentially decrease the observed Phe-reducing effect of Palynziq.

Study 302 was a four-part, clinical trial that included a randomized, double blind, placebo controlled, discontinuation study and an ongoing, long term, open-label extension with Palynziq dosed at 5-60 mg/day. At week 8 of the randomized withdrawal period, Palynziq-treated patients (20 mg once daily or 40 mg once daily) maintained their reduced blood Phe concentrations as compared to baseline levels, whereas patients randomized to placebo returned to their pretreatment baseline blood Phe concentrations. Palynziq did not demonstrate a difference in inattention and mood assessment scores vs placebo at 8 weeks from randomized withdrawal baseline. However, there were trends toward improvement of attention and mood with greater blood Phe reduction overtime. In patients taking Palynziq (20-40 mg/day), the mean Phe concentration was 1232.7 (386.4) micromol/L at baseline and reduced to 779.1 (523.6) micromol/L at 6 months, 574.1 (536.8) micromol/L at 12 months, and 490.8 (537.1) micromol/L at 24 months. Sixty percent of patients reached a blood Phe concentration of ≤ 600 micromol/L, 51% reached a blood Phe concentration of ≤ 360 micromol/L, and 41% achieved a blood Phe concentration of ≤ 120 micromol/L by 24 months.

Palynziq has a black box warning specifically for anaphylaxis, for which Palynziq's use is restricted under a Risk Evaluation and Mitigation Strategy (REMS) program. Anaphylaxis is also listed as a warning and precaution. Because of this risk of anaphylaxis, the initial dose of Palynziq must be administered under the supervision of a healthcare provider equipped to manage anaphylaxis (with close observation for at least 60 minutes following injection), and all patients treated with Palynziq must be prescribed epinephrine autoinjectors (and counseled on their use). In clinical trials with Palynziq, 9% of patients experienced a total of 37 anaphylactic episodes, a majority of which occurred within 1 hour after injection and within the first year of dosing. More than half of the patients who experienced anaphylaxis were rechallenged with Palynziq, and 28% who were rechallenged had recurrence of

anaphylaxis. Based on animal studies without PKU, Palynziq may cause fetal harm when administered to a pregnant woman. However, there are limited data with pegvaliase-pqpz use in pregnant women to inform a drug-associated risk. There is a pregnancy surveillance program for Palynziq to report exposure of Palynziq during pregnancy or those conceiving within one month following the last dose.

Palynziq will possibly be studied at doses >40 mg/day, as long-term therapy, during pregnancy, and in patients < 18 years of age.

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

Clinical Discussion: Tricia Heitzman made a motion to accept the recommendations as written. Todd Sponenberg seconded the motion. None were opposed.

Financial Discussion: No comments or questions. Kevin Szczecina made a motion to accept the recommendations as written. Kelly Yelenic seconded the motion. None were opposed.

Outcome: Palynziq will be a pharmacy benefit. It is recommended that Palynziq be added to the GHP Family formulary at the Brand Tier. Palynziq will require a prior authorization with the following criteria:

- Medical record documentation that Palynziq is prescribed by a metabolic specialist AND
- Medical record documentation of diagnosis of phenylketonuria (PKU) AND
- Medical record documentation of the member being ≥ 18 years AND
- Medical record documentation of phenylalanine (Phe) concentrations greater than 600 micromol/L on existing management (e.g. dietary restriction of Phe and protein intake/ use of medical foods and/or Kuvan) AND
- Medical record documentation that the member has (or will receive) a prescription for epinephrine auto-injector AND
- Medical record documentation of therapeutic failure on, intolerance to, or contraindication to Kuvan* AND
- Medical record documentation that Palynziq will not be used in combination with Kuvan

Authorization Duration: Initial approval will be for twelve (12) months and subsequent approvals will be for twelve (12) months.

Reauthorization Criteria:

- Medical record documentation of a 20% reduction in Phe concentration from baseline or a blood Phe concentration ≤ 600 micromol/L OR
- Medical record documentation of improvement in neuropsychiatric symptoms or an increase in Phe tolerance.

Quantity Limit: *Pharmacist note to CSR: Authorization should be entered by HICL and only checking the Formulary PA required box (no QLS need to be entered within the authorization).*

2.5 mg/0.5 mL syringe: 0.15 mL per day

10 mg/0.5 mL syringe: 0.5 mL per day

20 mg/mL syringe: 2 mL per day

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

ORILISSA (elagolix)

Review: Orilissa (elagolix) is the first FDA approved oral GnRH antagonist used for the treatment of endometriosis-associated pain. It is available as a 150 mg tablet to be taken once daily or a 200 mg tablet to be taken twice daily. Orilissa 150 mg once daily could be used up to 24 months. In patients with dyspareunia, Orilissa could be initiated at 200 mg twice daily for a maximum duration of 6 months. In patients with moderate hepatic impairment, Orilissa 200 mg twice daily should not be used and Orilissa 150 mg once daily should have a maximum duration of 6 months. Orilissa is contraindicated in pregnant patients due to the risk of early pregnancy loss in those exposed to Orilissa early in pregnancy; in patients with osteoporosis due to the risk of further bone loss; in patients with severe hepatic impairment due to the risk of bone loss; and in patients currently using strong OATP1B1 inhibitors due to the risk of increasing elagolix plasma concentrations, which increases the risk of bone loss. Though not currently included in treatment guidelines, Orilissa likely has a similar role to other GnRH analogues and could potentially be used after failure to high-dose NSAIDs and extended-cycle contraceptives.

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

Clinical Discussion: Changes to the proposed authorization and reauthorization duration criteria were discussed. Kevin Szczecina made a motion to accept the recommendations as amended. Kelly Yelenic seconded the motion. None were opposed.

Financial Discussion: No comments or questions. Kevin Szczecina made a motion to accept the recommendations as written. Todd Spenberg seconded the motion. None were opposed.

Outcome: Orilissa is a pharmacy benefit and should be added to the GHP Family formulary on the brand tier. The following additional criteria should apply:

- Prescription written by a gynecologist **AND**
- Documentation that the patient is at least 18 years of age **AND**
- Medical record documentation of a diagnosis of moderate to severe pain associated with endometriosis **AND**
- *For requests for the 200 mg strength:* Medical record documentation of a diagnosis of dyspareunia **AND**
- Medical record documentation of a therapeutic failure on, intolerance to, or contraindication to one formulary extended-cycle contraceptive **AND**
- Medical record documentation of a therapeutic failure on, intolerance to, or contraindication to **two** formulary NSAIDs

Quantity Limit: 30 tablets per 30 days for Orilissa 150 mg. 60 tablets per 30 days for Orilissa 200 mg.

Authorization Duration: Initial approval will be for 6 months (or less, if there is medical record documentation of a previous incomplete course of therapy with Orilissa) for either the 150 mg or the 200 mg tablets. One subsequent approval for Orilissa 150 mg for a period of 18 months (or less, if there is medical record documentation of a previous incomplete course of therapy with Orilissa) may be approved if the criteria below to be met. No subsequent approvals for the 200 mg strength will be allowed.

Reauthorization info:

- Medical record documentation that the correct FDA approved strength/dosing is being prescribed (150 mg once daily) **AND**
- Medical record documentation that the patient has not been treated for more than a total of 24 months with Orilissa 150 mg once daily **OR** more than a total of 6 months with Orilissa 200 mg twice daily **OR**

documentation of medical or scientific literature to support the use of this agent beyond the FDA-approved treatment duration

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

DOPTELET (avatrombopag)

Review: Doptelet (avatrombopag) is the first oral thrombopoietin receptor agonist (TPO-RA) approved specifically for use in broadly-defined chronic liver disease (CLD) patients with thrombocytopenia anticipating an invasive procedure. Promacta (eltrombopag) is another oral TPO-RA for treatment of thrombocytopenia; however, it is indicated to allow initiation and maintenance of interferon treatment in hepatitis C virus (HCV) patients. It can be anticipated that Doptelet will not share the same place in therapy as Promacta, as the platelet threshold ($<50 \times 10^9/L$) for using both TPO-RAs and triggering interferon therapy modification are the same. Thus, it is appropriate for patients who are thrombocytopenic due to HCV interferon therapy to be already receiving Promacta, in advance of planned procedures. HCV patients who have not yet undergone (or are not candidates for) interferon therapy, however, remain viable candidates for procedure-prophylaxis Doptelet. Additionally, Doptelet may be used in CLD patients who are receiving splenic surgical interventions (e.g., splenectomy or embolization) for the management of thrombocytopenia. Doptelet is dosed for 5 days, beginning 10-13 days before a scheduled procedure, at levels dictated by the patient's baseline platelet count. Those at or above $40 \times 10^9/L$ (but less than 50) receive 40 mg once daily, while those below 40 will receive 60 mg once daily. It is provided in 20 mg tablets, in packages of 10 or 15 tablets (one full regimen at either dosing). Doptelet's dosing is based upon the clinical observation that platelet levels tend to peak 8-13 days after dosing begins when administered as a short course and return to approximately baseline levels around day 35. The efficacy of Doptelet was evaluated in ADAPT-1 and 2, two identical multi-center double-blind, randomized placebo-controlled clinical trials. To be included in the trial, patients had to have thrombocytopenia (defined as $<50 \times 10^9$ platelets per liter) and an underlying diagnosis of chronic liver disease, with a scheduled upcoming procedure. The primary endpoint was successful prevention of the need for bleeding rescue treatment after randomization and through 7 days following the scheduled procedure. In both baseline platelet count cohorts, patients in the DOPTELET treatment groups had a greater proportion of responders than the corresponding placebo treatment groups that was both clinically meaningful and statistically significant. There are no black box warnings or contraindications associated with the use of Doptelet. Safety and effectiveness in pediatric patients have not been established. Clinical studies of DOPTELET did not include sufficient numbers of subjects aged 65 and over to determine whether they respond differently from younger subjects. Other reported clinical experience has not identified differences in responses between the elderly and younger patients. There are no dosage adjustments due to renal or hepatic insufficiency provided in the manufacturer's labeling. Sandeep Khurana, MD, a board-certified gastroenterologist at Geisinger Medical Center was consulted. He believes that the use of Doptelet should be restricted to the need for elective surgery or endoscopy in the decompensated cirrhotic population and should only be prescribed by hematologists/oncologists, gastroenterologists/hepatologists and transplant surgeons. He does not believe that the product will be used often, but it should be restricted.

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

Clinical Discussion: No comments or questions. Todd Sponenberg made a motion to accept the recommendations as written. Keith Hunsicker seconded the motion. None were opposed.

Financial Discussion: A suggestion was made to add an Rx count of 1 to the authorization criteria. Kim Clark made a motion to accept the recommendations as amended. Tricia Heitzman seconded the motion. None were opposed.

Outcome: For Medicaid, Doptelet will be a pharmacy benefit. It is recommended that Doptelet not be added to the GHP Family formulary. The following prior authorization criteria should apply.

- Medical record documentation of thrombocytopenia in adult patients with chronic liver disease **AND**
- Medical record documentation of member's age being ≥ 18 years old **AND**
- Medical record documentation of a platelet count of $< 50 \times 10^9/L$ measured within the past 30 days **AND**
- Medical record documentation of a planned invasive procedure to be performed 10-13 days after initiation date for Doptelet treatment **AND**
- Medical record documentation that the prescription for Doptelet is written by or in consultation with a hematologist, gastroenterologist, hepatologist, immunologist, transplant specialist, or endocrinologist **AND**
- Medical record documentation that the member is not receiving other TPO-RAs (Nplate/romiplostim, Promacta/eltrombopag) **AND**
- Medical record documentation of the correct dose being used (Platelet count 40 to $<50 \times 10^9/L$ - 40 mg once daily for 5 consecutive days OR for platelet count $<40 \times 10^9/L$ - 60 mg once daily for 5 consecutive days)

Authorization Duration: 30 days

Quantity Limit: For platelet count 40 to $<50 \times 10^9/L$ – 10 tablets per fill, for platelet count $<40 \times 10^9/L$ – 15 tablets per fill. One fill per Rx.

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

ARISTADA INITIO (aripiprazole lauroxil)

Review: Aristada Initio is a second-generation antipsychotic indicated, in combination with oral aripiprazole, for the initiation of Aristada when used for the treatment of schizophrenia in adults. The FDA approved dosing regimen of Aristada Initio is one dose of 30mg of oral aripiprazole, one dose of 675mg of Aristada Initio, and the first dose of Aristada (given within 10 days of the oral aripiprazole and Aristada Initio). Traditionally, induction consisted of 21 days of oral aripiprazole overlap given with the first dose of Aristada. Aristada Initio, contains the same active ingredient as Aristada; however, the release mechanism of the Aristada Initio is faster than that of Aristada. Because of this, the two drugs are not interchangeable. Aristada Initio is only indicated for the induction or re-induction into Aristada treatment and is not for repeat dosing beyond induction. The prescribing information for Aristada Initio does not include any new clinical trials to support the approval of the medication. The approval of Aristada Initio was dependent on the trials presented in the oral Abilify and Aristada prescribing information and a pharmacokinetic bridging analysis. The safety of Aristada Initio closely resembles that of Aristada; however, Aristada Initio has the added warning/precaution of potential for dosing and medication errors. Aristada Initio maintains the black box warning of increased mortality in elderly patients with dementia-related psychosis, which is demonstrated in other aripiprazole products as well. Although Aristada Initio has not been shown to have any efficacy or safety advantages over the traditional 21-day oral aripiprazole overlap initiation regimen, Aristada Initio may fill an unmet need in patients who are unable to initiate treatment utilizing an oral product due to adherence or other factors.

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

Clinical Discussion: No comments or questions. Todd Sponenberg made a motion to accept the recommendations as written. Aubrielle Prater seconded the motion. None were opposed.

Financial Discussion: No comments or questions. Kevin Szczecina made a motion to accept the recommendations as written. Todd Sponenberg seconded the motion. None were opposed.

Outcome: Aristada Initio will be a medical benefit for GHP Family members. It is not recommended to add Aristada Initio to the formulary at this time. Aristada Initio should require prior authorization as outlined below

- Medical record documentation that the patient is 18 years of age or older **AND**
- Medical record documentation of a history of poor adherence to oral medications and documentation that education to improve adherence has been attempted **AND**
- Medical record documentation of use for an FDA approved indication:
 - Abilify Maintena – Schizophrenia or maintenance monotherapy treatment of Bipolar I Disorder
 - Aristada – Schizophrenia
 - Aristada Initio – Initiation of Aristada (in combination with oral aripiprazole) to treat schizophrenia
 - Invega Sustenna – Schizophrenia or Schizoaffective disorders as monotherapy and as an adjunct to mood stabilizers or antidepressants
 - Invega Trinza – Schizophrenia
 - Risperdal Consta – Schizophrenia or Bipolar I Disorder as monotherapy or as adjunctive therapy to lithium or valproate
 - Zyprexa Relprevv – Schizophrenia
- In addition: The following criteria should apply to Invega Trinza:
 - Medical record documentation that the patient has been adequately treated with Invega Sustenna for at least 4 months.

GRANDFATHER PROVISION – Geisinger Health Plan will grandfather prescriptions for non-formulary medications or those formulary medications requiring prior authorization within quantity limits when there is an on-line prescription drug claim history showing 30 days use of the requested medication within the previous 90 days. If there is no on-line claim, the prescribing provider should request a prior authorization. Medical record documentation showing the member receiving the requested medication for at least 30 days within the previous 90 days must be provided.

LIMITATIONS:

The following quantity limits should apply (please enter claims payment note, when entering authorization)

- Abilify Maintena – One syringe or vial per 28 days
- Aristada – One syringe per 28 days (441mg/1.6ml, 662mg/2.4ml, 882mg/3.2ml strength), one syringe per 56 days (1064mg/3.9ml strength)
- Aristada Initio – Enter claims payment note as follows:
 - Aristada Initio – Rx Count of 1, quantity limit of 2.4mL (one syringe) per 28 days
 - Aristada – Open-ended authorization with quantity limit: One syringe per 28 days (441mg/1.6ml, 662mg/2.4ml, 882mg/3.2ml strength), one syringe per 56 days (1064mg/3.9ml strength)
- Invega Sustenna –two syringes per 1 week, then one syringe per 28 days thereafter
 - Enter claims payment note as follows to account for loading dose in the first week:
 - Rx Count of 1 approved by GPID for 234 mg, quantity limit 1
 - Rx Count of 1 approved by GPID for 156 mg, quantity limit 1
 - Open-ended authorization for quantity limit 1 syringe per month, request to be approved by GPID for the prescribed strength.
- Invega Trinza – One syringe per 84 days (3 months)

- Risperdal Consta – Two vials per 28 days
- Zyprexa Relprevv – Two vials per 28 days

Note: PA is not required for inpatient or ER use for any of these medications.

Note: Only members with documented adherence issues will be eligible for medications delivered via injection

Note: The FDA approved dosing of induction into treatment with Aristada includes oral aripiprazole, Aristada Initio and Aristada (outlined below) and it is appropriate for the member to receive all the mentioned products over the course of one month for treatment initiation.

- One 30mg dose of oral aripiprazole (given on Day 1)
- One 675mg dose of Aristada Initio (given on Day 1)
- One (first) dose of Aristada (441mg, 662mg, 882mg, or 1064mg) (given on Day 1 or up to 10 days after the dose of Aristada Initio)

AUTHORIZATION DURATION:

For Aristada Initio: Approval will be for a one-time fill/visit (authorization duration of 1 month) of Aristada Initio AND a lifetime authorization of the specific approved injectable of Aristada.

All other approvals will be made for a lifetime authorization of the specific approved injectable.

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

EPIDIOLEX (cannabidiol)

Review: Epidiolex is the first cannabinoid to be FDA approved for the treatment of seizures in patients 2 years of age and older with Lennox-Gastaut syndrome and Dravet syndrome. Though it is approved for monotherapy use per the FDA labeling, it has only been studied as adjunct therapy at this time. Its mechanism of action is unknown but is thought to be independent of its interaction with cannabinoid receptors. Epidiolex is dosed twice daily, which is similar to the dosing schedule of other adjunct drug therapy options. Epidiolex has been shown to be effective in reducing the frequency of seizures in patients, however there are currently no head-to-head trials with other therapy options. The most common adverse events seen with Epidiolex were somnolence, decreased appetite, diarrhea, transaminase elevations, fatigue, rash, insomnia, sleep disorders, and infections. Epidiolex has also been shown to cause hepatocellular injury, suicidal thoughts and ideation, and withdrawal seizures, as well as have numerous drug interactions including interactions requiring additional monitoring and dose adjustments with valproate and clobazam (two possible first-line options). Epidiolex is a highly refined substance that does not contain tetrahydrocannabinol (THC), the chemical responsible for marijuana's psychoactive effects, but it is still a C-V controlled substance. Currently it is unknown where Epidiolex will fall into therapy; however, it will most likely become a viable therapeutic option to reduce seizure activity in both Lennox-Gastaut syndrome and Dravet syndrome, and possibly in patients with other intractable seizure types in the future.

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

Clinical Discussion: No comments or questions. Todd Sponenberg made a motion to accept the recommendations as written. Kelly Yelenic seconded the motion. None were opposed.

Financial Discussion: No comments or questions. Rajneel Chohan made a motion to accept the recommendations as written. Todd Sponenberg seconded the motion. None were opposed.

Outcome: Epidiolex should be added to the GHP Family formulary on the brand tier with a prior authorization. The following additional criteria should apply.

- Medical record documentation that Epidiolex is prescribed by a neurologist **AND**
- Documentation that the patient is at least 2 years of age **AND**
- Medical record documentation of a diagnosis of either Lennox-Gastaut syndrome or Dravet syndrome
- *For Lennox-Gastaut Syndrome:* Medical record documentation of a therapeutic failure on, intolerance to, or contraindication to two generic formulary alternatives.

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

POLELIGEO (mogamulizumab-kpke)

Review: Poteligeo is an injectable CC chemokine receptor type 4 (CCR4)- directed monoclonal antibody indicated for the treatment of adults with a rare form of hard-to-treat subtypes of cutaneous T-cell lymphomas called mycosis fungoides or Sézary syndrome after at least one prior failed systemic therapy. The efficacy of Poteligeo was evaluated against vorinostat in a randomized, open-label, multicenter trial in 372 adult patients with MF or SS after at least one prior systemic therapy. The trial demonstrated that Poteligeo significantly prolonged PFS compared to vorinostat (7.6 months versus 3.1 months, respectively). Poteligeo also demonstrated an improvement in overall response rate compared to vorinostat. Warnings and precautions include dermatologic toxicity, infusion related reaction, infections, autoimmune complications and complications of allogeneic stem cell transplant after treatment with Poteligeo therapy. The most common adverse reactions (reported in $\geq 20\%$ of patients) were rash, infusion related reactions, fatigue, diarrhea, musculoskeletal pain, and upper respiratory tract infection.

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

Clinical Discussion: No comments or questions. Tricia Heitzman made a motion to accept the recommendations as written. Kevin Szczecina seconded the motion. None were opposed.

Financial Discussion: No comments or questions. Kim Clark made a motion to accept the recommendations as written. Kelly Yelenic seconded the motion. None were opposed.

Outcome: For GHP Family Poleligio will be covered under the medical benefit and will not be added to the formulary. The following additional criteria should apply.

- Medical record documentation of use of Poteligeo for the treatment of relapsed or refractory mycosis fungoides or Sézary syndrome **AND**
- Member is 18 years of age or older **AND**
- Medical record documentation of resistance or intolerance to one prior therapy **AND**
- Medical record documentation that Poteligeo is prescribed by a hematologist or oncologist

Authorization Duration: Initial approval will be for 12 months or less if the reviewing provider feels it is medically appropriate.

Reauthorization Info: 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.

DELSTRIGO (doravirine/lamivudine/tenofovir disoproxil fumarate)

Review: Delstrigo is a complete three-drug combination, single-tablet regimen (STR) containing Pifeltro (doravirine), a new non-nucleoside reverse transcriptase inhibitor (NNRTI), and two nucleoside analog reverse transcriptase inhibitors (NRTI) as the backbone, lamivudine (3TC) and tenofovir disoproxil fumarate (TDF). Delstrigo is similar to branded Atripla (efavirenz/emtricitabine/TDF) but substitutes lamivudine (3TC) for emtricitabine (FTC) in the dual-NRTI backbone and incorporates a new NNRTI, Pifeltro. An initial ART regimen for a treatment-naïve patient generally consists of two NRTIs in combination with a third active antiretroviral (ARV) drug from one of three drug classes: an integrase strand transfer inhibitor (INSTI), a non-nucleoside reverse transcriptase inhibitor (NNRTI), or a protease inhibitor (PI) with a pharmacokinetic booster (either ritonavir or cobicistat). DHHS prefers INSTI-based regimens for most people living with HIV, and only recommends NNRTI-based or PI-based regimens in certain clinical situations. INSTI-based regimens have gained their place as initial recommended therapy based on a robust database of large clinical trials showing high rates of virologic suppression, greater tolerability compared to other regimens, and high barrier to resistance. NNRTI-based regimens (which include Delstrigo) are recommended in combination with two NRTIs only in certain clinical situations. These clinical scenarios include the following:

- A one-pill, once-daily regimen is desired (Delstrigo would qualify as this)
- Patients with history of poor adherence to ARV or inconsistent engagement in care
- Patients requiring concurrent treatment for tuberculosis

The recommended dosage of Delstrigo is one tablet taken orally once daily. If the patient is using rifabutin, a dose adjustment is required; the patient should take one Delstrigo tablet daily, followed by one tablet (100 mg) of Pifeltro (doravirine) 12 hours after the daily dose of Delstrigo for the duration of rifabutin co-administration. The overall efficacy of Pifeltro/Delstrigo was evaluated in two phase 3, 48-week, randomized, double-blind, active-controlled trials. The DRIVE-FORWARD trial compared Pifeltro combined with 2 NRTIs, emtricitabine/tenofovir disoproxil fumarate (FTC/TDF) or abacavir/lamivudine (ABC/3TC), to active control darunavir/ritonavir (DRV/r) combined with either FTC/TDF or ABC/3TC. The DRIVE-AHEAD trial compared Delstrigo to efavirenz/emtricitabine/tenofovir (EFV/FTC/TDF). Both trials were completed in patients with no antiretroviral treatment history. The primary endpoints were the proportions of patients that achieved virologic suppression (viral load of less than 50 copies per mL) at 48 weeks. Pifeltro/Delstrigo was found to be non-inferior to the respective active-control. The most common adverse reactions (all grades) reported in at least 2% of subjects in the Delstrigo or Pifeltro groups were dizziness, headache, fatigue, nausea, abdominal pain, abnormal dreams, insomnia, diarrhea, somnolence, and rash. The majority (72%) of adverse reactions associated with doravirine occurred as Grade 1 (mild). When utilizing Delstrigo, it is recommended to closely monitor hepatic function with both clinical and laboratory follow-up for at least several months in patients who are co-infected with HIV-1 and HBV and have stopped treatment with Delstrigo. Additionally, Delstrigo is contraindicated in 1) patients with a previous hypersensitivity reaction to lamivudine and 2) when co-administered with drugs that are strong cytochrome P450

3A enzyme inducers, as significant decreases in doravirine plasma concentrations may occur (may decrease effectiveness of Delstrigo). There are a number of warnings and precautions noted with Delstrigo therapy including:

- New onset or worsening renal impairment: prior to or when initiating and during Delstrigo, assess serum creatinine, estimated creatinine clearance, urine glucose, and urine protein in all patients. Avoid administering Delstrigo with concurrent or recent use of nephrotoxic drugs.
- Bone loss and mineralization defects: consider monitoring bone mineral density (BMD) in patients with a history of pathologic fracture or other risk factors of osteoporosis or bone loss.
- Monitor for Immune Reconstitution Syndrome.

The warnings and precautions noted are class-related effects and shared with other NNRTI regimens. The most common adverse events noted in the trials include dizziness, nausea, and abnormal dreams.

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

Clinical Discussion: No comments or questions. Kevin Szczecina made a motion to accept the recommendations as written. Aubrielle Prater seconded the motion. None were opposed.

Financial Discussion: No comments or questions. Kim Clark made a motion to accept the recommendations as written. Kevin Szczecina seconded the motion. None were opposed.

Outcome: Delstrigo will be a pharmacy benefit. It is recommended that Delstrigo be added to the formulary on the Brand Tier.

Quantity Limit: One (1) tablet per day

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

PIFELTRO (doravirine)

Review: Pifeltro is a single drug non-nucleoside reverse transcriptase inhibitor (NNRTI). Indicated for use in combination with other antiretroviral agents for the treatment of HIV-1 infection in adult patients with no prior antiretroviral treatment history. Pifeltro is dosed as one 100 mg tablet taken once daily in combination with other antiretroviral agents. If patient is on Rifabutin therapy the Pifeltro will need to be increased to one tablet twice daily (~12 hours apart) for the duration of rifabutin co-administration. An initial ART regimen for a treatment-naïve patient generally consists of two NRTIs in combination with a third active antiretroviral (ARV) drug from one of three drug classes: an integrase strand transfer inhibitor (INSTI), a non-nucleoside reverse transcriptase inhibitor (NNRTI), or a protease inhibitor (PI) with a pharmacokinetic booster (either ritonavir or cobicistat). DHHS prefers INSTI-based regimens for most people living with HIV, and only recommends NNRTI-based or PI-based regimens in certain clinical situations. INSTI-based regimens have gained their place as initial recommended therapy based on a robust database of large clinical trials showing high rates of virologic suppression, greater tolerability compared to other regimens, and high barrier to resistance. NNRTI-based regimens (which include Delstrigo) are recommended in combination with two NRTIs only in certain clinical situations. These clinical scenarios include the following:

- A one-pill, once-daily regimen is desired (Delstrigo would qualify as this)
- Patients with history of poor adherence to ARV or inconsistent engagement in care
- Patients requiring concurrent treatment for tuberculosis

The overall efficacy of Pifeltro/Delstrigo was evaluated in two phase 3, 48-week, randomized, double-blind, active-controlled trials. The DRIVE-FORWARD trial compared Pifeltro combined with 2 NRTIs, emtricitabine/tenofovir disoproxil fumarate (FTC/TDF) or abacavir/lamivudine (ABC/3TC), to active control darunavir/ritonavir (DRV/r) combined with either FTC/TDF or ABC/3TC. The DRIVE-AHEAD trial compared Delstrigo to efavirenz/emtricitabine/tenofovir (EFV/FTC/TDF). Both trials were completed in patients with no antiretroviral treatment history. The primary endpoints were the proportions of patients that achieved virologic suppression (viral load of less than 50 copies per mL) at 48 weeks. Pifeltro/Delstrigo was found to be non-inferior to the respective active-control. The most common adverse reactions (all grades) reported in at least 2% of subjects in the Delstrigo or Pifeltro groups were dizziness, headache, fatigue, nausea, abdominal pain, abnormal dreams, insomnia, diarrhea, somnolence, and rash. The majority (72%) of adverse reactions associated with doravirine occurred as Grade 1 (mild).

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

Clinical Discussion: No comments or questions. Tricia Heitzman made a motion to accept the recommendations as written. Kevin Szczecina seconded the motion. None were opposed.

Financial Discussion: No comments or questions. Todd Sponenberg made a motion to accept the recommendations as written. Tricia Heitzman seconded the motion. None were opposed.

Outcome: Pifeltro will be a pharmacy benefit. It is recommended that Pifeltro be added to the formulary on the Brand Tier.

Quantity Limit: Two (2) tablets per day

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

VIZIMPRO (dacomitinib)

Review: Vizimpro is indicated for the first-line treatment of patients with metastatic non-small cell lung cancer (NSCLC) with epidermal growth factor receptor (EGFR) exon 19 deletion or exon 21 L858R substitution mutations as detected by an FDA-approved test. Vizimpro is a new second generation tyrosine kinase inhibitor (TKI). It is the fifth once daily, oral TKI to market, joining Tarceva (erlotinib), Gilotrif (afatinib), Iressa (gefitinib), and Tagrisso (osimertinib). All products are on Geisinger formularies with the exception of Iressa for GHP Family. Vizimpro is supplied as 15, 30 and 45 mg film-coated tablets. The recommended dosage is 45mg orally once daily, until disease progression or unacceptable toxicity occurs. The approval of Vizimpro is based on results from the randomized, open-label, multinational, phase 3 ARCHER 1050 study. Participants had unresectable, metastatic NSCLC with EGFR exon 19 deletion or exon 21 L858R substitution mutation and with no prior therapy for metastatic disease or recurrent disease with a minimum of 12 disease-free months after completion of systemic therapy. Patients with metastases in the central nervous system were ineligible to participate. A total of 452 patients were randomized to receive Vizimpro 45mg (N=227) or Iressa 250mg once daily until disease progression or unacceptable toxicity. A blinded independent review evaluated progression-free survival (PFS) as the major efficacy outcome in ARCHER 1050. Other efficacy outcomes included overall response rate (ORR), duration of response (DoR), and overall survival (OS). In the ARCHER 1050 study Vizimpro demonstrated a significant improvement in PFS. At 24 months, 30.6% of patients on Vizimpro were progression-free, versus 9.6% of those on Iressa. The duration of response was also significantly longer for those on Vizimpro (14.8 months versus 8.3 months for Iressa). The

overall response rate was not significantly different between the two groups, although survival data were not mature at the time of the analysis. In the ARCHER 1050 trial, more adverse events occurred in patients on Vizimpro compared to those on Iressa. Gastrointestinal and dermatologic toxicities affect a significant number of patients taking Vizimpro, although they can often be managed by dosage interruptions and/or reductions. Warnings and precautions include interstitial lung disease (ILD), diarrhea, dermatologic reactions, and embryo-fetal toxicity. Serious adverse reactions were reported in 27% of those taking Vizimpro; the most common serious reactions were diarrhea (2.2%) and interstitial lung disease (1.3%). Two deaths due to adverse effects occurred, one due to diarrhea and one due to liver disease. Dose interruptions occurred in 57% of patients and dose reductions occurred in 66% of patients. Do not use Vizimpro with proton pump inhibitors (PPIs). Patients may use locally-acting antacids or H₂-receptor antagonists while on Vizimpro, but Vizimpro should be administered at least 6 hours before or 10 hours after a H₂ receptor antagonist. Vizimpro increases the concentration of drugs that are CYP2D6 substrates; avoid concomitant use of Vizimpro with agents where minimal increases in the CYP2D6 substrate may lead to serious or life-threatening toxicities. The safety and effectiveness in pediatrics have not been established. Geriatric members may be at higher risk for adverse events compared to younger subjects.

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

Clinical Discussion: No comments or questions. Kelly Yelenic made a motion to accept the recommendations as written. Kevin Szczecina seconded the motion. None were opposed.

Financial Discussion: No comments or questions. Kevin Szczecina made a motion to accept the recommendations as written. Keith Hunsicker seconded the motion. None were opposed.

Outcome: Vizimpro will be a pharmacy benefit. Vizimpro will be added to the GHP Family formulary on the Brand Tier. The following prior authorization criteria should apply.

- Prescription written by a hematologist/oncologist **AND**
- Medical record documentation of the member being ≥ 18 years **AND**
- Medical record documentation of metastatic non-small cell lung cancer (NSCLC) with epidermal growth factor receptor (EGFR) exon 19 deletion or exon 21 L858R substitution mutations as detected by an FDA-approved test

Authorization Duration: Initial approval will be for 12 months or less if the reviewing provider feels it is medically appropriate. Subsequent approvals will be for an additional 12 months or less if the reviewing provider feels it is medically appropriate and will require medical record documentation of continued disease improvement or lack of disease progression. The medication will no longer be covered if the member experiences unacceptable toxicity or worsening of disease.

Quantity limit: 1 tablet per day, 30-day supply per fill

Additional formulary recommendations: It is recommended to add Iressa to the Brand tier of GHP Family Formulary.

Discussion: No comments or questions. Kevin Szczecina made a motion to accept the recommendations as written. Tricia Heitzman seconded the motion. None were opposed.

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

LIBTAYO (cemiplimab-rwlc)

Review: Libtayo is a programmed death receptor-1 (PD-1) blocking antibody that is indicated for the treatment of metastatic cutaneous squamous cell carcinoma (cSCC) or locally advanced cSCC in patients who are not candidates for surgery or radiation. It is the only PD-L1 inhibitor approved for this indication, with 5 others, including Keytruda and Opdivo, approved for other indications. Libtayo comes as a 350 mg/7 mL solution in a single dose vial and is dosed as a 350 mg IV infusion over 30 minutes every 3 weeks. It is the only FDA approved medication for metastatic and locally advanced cSCC and does not carry any black box warnings. Still there are numerous warnings/precautions for immune-mediated adverse events. The most common adverse events with Libtayo include fatigue, rash, and diarrhea. NCCN states that Libtayo may be considered as an option for patients with metastatic or locally advanced cSCC who are not candidates for curative surgery or radiation. Libtayo is only currently available from one specialty pharmacy, Onco360 Specialty Pharmacy.

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

Clinical Discussion: No comments or questions. Tricia Heitzman made a motion to accept the recommendations as written. Todd Sponenberg seconded the motion. None were opposed.

Financial Discussion: No comments or questions. Todd Sponenberg made a motion to accept the recommendations as written. Kelly Yelenic seconded the motion. None were opposed.

Outcome: Libtayo will be covered under the medical benefit and will not be added to the GHP Family formulary. The following criteria will apply:

- Prescription written by a hematologist or oncologist **AND**
- Documentation that the patient is 18 years of age or greater **AND**
- Medical record documentation of a diagnosis of metastatic cutaneous squamous cell carcinoma (cSCC) or locally advanced cSCC **AND**
- Medical record documentation that the patient is not a candidate for curative surgery or curative radiation

Authorization duration: Initial approval will be for 12 months or less if the reviewing provider feels it is medically appropriate. Subsequent approvals will be for an additional 12 months or less if the reviewing provider feels it is medically appropriate and will require medical record documentation of continued disease improvement or lack of disease progression. The medication will no longer be covered if the member experiences unacceptable toxicity or worsening of disease.

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

FAST FACTS

SIGNIFOR LAR (pasireotide)

Updated Indication: Signifor LAR is indicated for the treatment of:

- Patients with acromegaly who have had an inadequate response to surgery and/or for whom surgery is not an option.
- Patients with Cushing's disease for whom pituitary surgery is not an option or has not been curative.

Recommendations: There is no change recommended to formulary placement at this time. However, it is recommended to add the following prior authorization criteria to the existing policy to reflect the new indication.

Prior Authorization Criteria:

Cushing's Disease

- Medical record documentation of a diagnosis of Cushing's disease AND
- Prescription written by 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 ketoconazole AND Metopirone*

Authorization Duration (for Cushing's Disease): If approved, approval will be given for a period of six (6) months. Re-authorization will require medical record documentation that urinary free cortisol levels are within normal limits.

There will be no updates to the current quantity limits

Discussion: No comments or questions

Outcome: Kelly Yelenic made a motion to accept the recommendations as written. Kevin Szczecina seconded the motion. None were opposed.

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

XELJANZ (tofacitinib)

Updated Indication: Treatment of adult patients with moderate to severely active ulcerative colitis (UC)

Recommendation: Xeljanz is currently non-formulary for the GHP Family formulary. There are no formulary changes recommended at this time. However it is recommended that the following prior authorization criteria be added to the Xeljanz policy.

Ulcerative Colitis

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

- Medical record documentation of a diagnosis of moderate to severe ulcerative colitis **AND**
- Medical record documentation that request is for Xeljanz (NOTE: Xeljanz XR is not FDA approved for this indication) **AND**
- Medical record documentation that Xeljanz is prescribed by a gastroenterologist **AND**
- Medical record documentation of age greater than or equal to 18 years **AND**
- Medical record documentation of a therapeutic failure on, intolerance to, or contraindication to Humira **AND**
- Medical record documentation that Xeljanz is not being used concurrently with a TNF blocker or other biologic agent.

QUANTITY LIMIT: 2 tablets per day, 30 day supply per fill (GPID)

AUTHORIZATION DURATION: Approval will be given for an initial duration of six (6) months. For continuation of coverage, medical record documentation of clinical improvement or lack of progression in the signs and symptoms of ulcerative colitis at six (6) months of Xeljanz therapy is required. After the initial six (6) month approval, subsequent approvals for coverage will be for a duration of one (1) year requiring medical record documentation of continued or sustained improvement in the signs and symptoms of ulcerative colitis while on Xeljanz therapy.

Discussion: No comments or questions.

Outcome: Kevin Szczecina made a motion to accept the recommendations as written. Keith Hunsicker seconded the motion. None were opposed.

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

XEOMIN (incobotulinumtoxin A)

Updated Indication: Xeomin is now indicated for the treatment of chronic sialorrhea in adult patients

Recommendation: No changes are recommended to the formulary placement of Xeomin. It is recommended that the prior authorization criteria be updated as outlined below to account for Xeomin's new indication.

Geisinger Health Plan approved FDA labeled indications for Botulinum Toxin Type A (**Xeomin** only) are:

1. Sialorrhea

- Documentation that patient is at least 18 years of age **AND**
- Medical record documentation of a diagnosis of chronic sialorrhea resulting from Parkinson's disease, atypical parkinsonism, stroke, or traumatic brain injury

Discussion: No comments or questions.

Outcome: Todd Sponenberg made a motion to accept the recommendations as written. Kelly Yelenic seconded the motion. None were opposed.

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

KISQALI (ribociclib)

Updated Indication: Kisqali is a kinase inhibitor indicated in combination with:

- An aromatase inhibitor for the treatment of pre/perimenopausal or postmenopausal women with hormone receptor (HR)-positive, human epidermal growth factor receptor 2 (HER2)-negative advanced or metastatic breast cancer, as initial endocrine-based therapy; or
- fulvestrant for the treatment of postmenopausal women with HR-positive, HER2-negative advanced or metastatic breast cancer, as initial endocrine-based therapy or following disease progression on endocrine therapy.

Recommendation: There is no change recommended to formulary placement at this time. However, it is recommended to update the prior authorization criteria to the following.

Prior Authorization Criteria:

Kisqali as Initial Endocrine Therapy

- Prescription is written by an oncologist AND
- Medical record documentation of diagnosis of hormone-receptor (HR) positive, HER2-negative, advanced or metastatic breast cancer AND
- Medical record documentation that Kisqali is being prescribed as initial endocrine therapy AND
- Medical record documentation of one of the following:
 - Medical record documentation of postmenopausal status OR
 - Medical record documentation of pre/perimenopausal status AND that member will be treated with ovarian ablation or suppression with a luteinizing hormone-releasing hormone (LHRH) agonist AND
- Medical record documentation that Kisqali will be used in combination with an aromatase inhibitor or fulvestrant

Kisqali Following Disease Progression on Endocrine Therapy

- Prescription is written by an oncologist AND
- Medical record documentation of diagnosis of hormone-receptor (HR) positive, HER2-negative, advanced or metastatic breast cancer AND
- Medical record documentation that Kisqali is being prescribed after disease progression following endocrine therapy AND
- Medical record documentation of one of the following:
 - Medical record documentation of postmenopausal status OR
 - Medical record documentation of pre/perimenopausal status AND that member will be treated with ovarian ablation or suppression with a luteinizing hormone-releasing hormone (LHRH) agonist AND
- Medical record documentation that Kisqali will be used in combination with fulvestrant

Discussion: It was recommended that the following “note to reviewer” be added: Kisqali Femara Co-Pack is supplied with letrozole, an aromatase inhibitor. The Co-Pack is **not** indicated in combination with fulvestrant for the treatment of postmenopausal women with HR-positive, HER2-negative advanced or metastatic breast cancer, as initial endocrine-based therapy or following disease progression on endocrine therapy.

Outcome: Todd Sponenberg made a motion to accept the recommendations as amended. Keith Hunsicker seconded the motion. None were opposed.

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

FYCOMPA (perampanel)

Updated Indication: Treatment of partial-onset seizures with or without secondarily generalized seizures in patients with epilepsy 4 years of age and older

Recommendation: No formulary changes are recommended at this time. No change to the quantity limit is recommended at this time. The following prior authorization criteria change should be made to reflect the updated indication:

- Medical record documentation of a diagnosis of partial onset seizures **AND**
- Patient is at least 4 years of age **AND**
- Medical record documentation of therapeutic failure on, intolerance to, or contraindication to three (3) formulary alternatives

OR

- Medical record documentation of a diagnosis of primary generalized tonic-clonic seizures **AND**
- Fycompa is being used concomitantly with at least one (1) other formulary antiepileptic drug **AND**
- Patient is at least 12 years of age **AND**
- Medical record documentation of therapeutic failure on, intolerance to, or contraindication to three (3) formulary alternatives

Discussion: No comments or questions.

Outcome: Rajneel Chohan made a motion to accept the recommendations as written. Kevin Szczecina seconded the motion. None were opposed.

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

CIMZIA (certolizumab)

Updated Indication: Cimzia is now indicated for the treatment of adults with moderate to severe plaque psoriasis who are candidates for systemic therapy or phototherapy

Recommendation: No change is recommended to the formulary placement of Cimzia. It is recommended that the policy be updated to account for the new indication. It is recommended that the current quantity limits are clarified to ensure appropriate authorization entry.

Plaque Psoriasis

- Prescription written by a dermatologist **AND**
- Medical record documentation of age greater than 18 years **AND**
- Medical record documentation of a diagnosis of moderate to severe plaque psoriasis characterized by greater than or equal to 5% of body surface area involved or disease involving crucial body areas such as the hands, feet, face, or genitals **AND**
- Medical record documentation that Cimzia is not being used concurrently with a TNF blocker or other biologic agent **AND**
- Medical record documentation of a therapeutic failure of, contraindication to, or intolerance of a minimum 3-month trial of Humira* **AND** Cosentyx*

Quantity Limit (FOR PLAQUE PSORIASIS ONLY): 2 kits per 28 days

Note: This product is billed per kit. Each kit contains two 200mg syringes.

Authorization Duration:

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

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

Additional Recommendation:

Quantity Limits:

New starts: One-week authorization for QL of 3 kits per 28 days, Remainder of the 6-month authorization duration QL of 1 kit per 28 days

Continued maintenance: QL of 1 kit per 28 days

Note: This product is billed per kit. Each kit contains two 200 mg syringes.

Discussion: No comments or questions.

Outcome: Kim Clark made a motion to accept the recommendations as written. Kevin Szczecina seconded the motion. None were opposed.

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

RUBRACA (rucaparib)

Updated Indication: Rubraca is indicated:

- for the maintenance treatment of adult patients with recurrent epithelial ovarian, fallopian tube, or primary peritoneal cancer who are in a complete or partial response to platinum-based chemotherapy
- for the treatment of adult patients with deleterious BRCA mutation (germline and/or somatic)-associated epithelial ovarian, fallopian tube, or primary peritoneal cancer who have been treated with two or more chemotherapies. Patients should be selected for therapy based on an FDA-approved companion diagnostic for Rubraca (<http://www.fda.gov/CompanionDiagnostics>).

Recommendation: There is no change recommended to formulary placement however, it is recommended to update the prior authorization criteria to the following.

Prior Authorization Criteria

- Prescription must be written by an oncologist/hematologist AND
- Medical record documentation of the member being ≥ 18 years AND
- Medical record documentation of a diagnosis of recurrent epithelial ovarian, fallopian tube, or primary peritoneal cancer AND medical record documentation of Rubraca being used as maintenance treatment after a complete or partial response to platinum-based chemotherapy OR
- Medical record documentation of deleterious BRCA mutation (germline and/or somatic)-associated epithelial ovarian, fallopian tube, or primary peritoneal cancer (as verified by an FDA-approved test) who have been treated with two or more chemotherapies

Note: The Food and Drug Administration approved test is BRACAnalysis CDx, FoundationOne CDx, FoundationFocus CDxBRCA Assay (see <http://www.fda.gov/CompanionDiagnostics>)

There are no changes to quantity limits or authorization duration at this time.

Discussion: No comments or questions.

Outcome: Kevin Szczecina made a motion to accept the recommendations as written. Rajneel Chohan seconded the motion. None were opposed.

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

LENVIMA (lenvatinib)

Updated Indication: Lenvima is now indicated as first-line treatment for patients with unresectable hepatocellular carcinoma (HCC).

Recommendations: No formulary changes are recommended at this time. The following prior authorization criteria should be added to the existing policy:

Unresectable Hepatocellular Carcinoma

1. Medical record documentation that Lenvima is prescribed by a hematologist or oncologist **AND**
2. Medical record documentation that Lenvima is being used for the treatment of unresectable hepatocellular carcinoma (HCC) **AND**
3. Medical record documentation that patient has Child-Pugh Class A liver disease **AND**
4. Medical record documentation that patient has not received prior therapy for unresectable hepatocellular carcinoma **AND**
5. Medical record documentation that appropriate dose of Lenvima is prescribed based on patient's body weight (≥ 60 kg: Lenvima 12mg once daily, < 60 kg: Lenvima 8mg once daily)

QUANTITY LIMIT:

Patient weight ≥ 60 kg: 12 mg blister pack – 3 capsules per day (GPID), 30 day supply per fill

Patient weight < 60 kg: 8mg blister pack – 2 capsules per day (GPID), 30 day supply per fill

AUTHORIZATION DURATION: Initial approval will be for 12 months or less if the reviewing provider feels it is medically appropriate. Subsequent approvals will be for an additional 12 months or less if the reviewing provider feels it is medically appropriate and will require medical record documentation of continued disease improvement or lack of disease progression. The medication will no longer be covered if the member experiences unacceptable toxicity or worsening of disease.

Discussion: No comments or questions.

Outcome: Kevin Szczecina made a motion to accept the recommendations as written. Tricia Heitzman seconded the motion. None were opposed.

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

MIRCERA (methoxy polyethylele glycol-epoetin beta)

Updated Indication: Mircera is now indicated for the treatment of anemia associated with chronic kidney disease in pediatric patients 5 to 17 years of age on hemodialysis who are converting from another erythropoiesis-stimulating agent (ESA) after their hemoglobin level was stabilized with an ESA.

Recommendation: No changes are recommended to the formulary placement of Mircera at this time. It is recommended that the current Mircera criteria are updated to include the new indication as outlined below.

For initial authorization in adult patients:

- Medical record documentation of age 18 years or greater AND
- Medical record documentation of use for the treatment of anemia associated with chronic kidney disease (CKD) in patients on dialysis and patients not on dialysis AND
- Hemoglobin (Hgb) less than 10 g/dL for new starts AND
- Ferritin greater than or equal to 100 ng/mL or transferrin level saturation greater than or equal to 20%

For initial authorization in pediatric patients:

- Medical record documentation of age 5 years or greater AND
- Medical record documentation of use for the treatment of anemia associated with chronic kidney disease in patients on dialysis AND
- Medical record documentation that patient's hemoglobin has stabilized on and is converting to Mircera from another erythropoiesis-stimulating agent AND
- Hemoglobin (Hgb) less than 11 g/dL for new starts AND
- Ferritin greater than or equal to 100 ng/mL or transferrin level saturation greater than or equal to 20%

For continuation of therapy, a repeat Hgb should be submitted after 12 months of therapy.

For continuation of therapy in adult patients:

- Medical record documentation of age 18 years or greater AND
- Medical record documentation of use for the treatment of anemia associated with chronic kidney disease (CKD) in patients on dialysis and patients not on dialysis AND
- Hemoglobin (Hgb) less than 11 g/dL for continuation of therapy AND
- Ferritin greater than or equal to 100 ng/mL or transferrin level saturation greater than or equal to 20%

For continuation of therapy in pediatric patients:

- Medical record documentation of age 5 years or greater AND
- Medical record documentation of use for the treatment of anemia associated with chronic kidney disease in patients on dialysis AND
- Hemoglobin (Hgb) less than 11 g/dL for new starts AND
- Ferritin greater than or equal to 100 ng/mL or transferrin level saturation greater than or equal to 20%

In individuals whose Hgb is greater than or equal to 12gm/dL or rises by 1gm/dl in any two-week period, additional doses should be withheld.

AUTHORIZATION DURATION: Each authorization period (initial and re-authorization) will be defined as a period of 12 months. Re-authorization will be considered based on continuation of therapy criteria listed above.

Discussion: No comments or questions.

Outcome: Kevin Szczecina made a motion to accept the recommendations as written. Tricia Heitzman seconded the motion. None were opposed.

UPDATES

Rhopressa

Discussion: A recent rebate opportunity has revealed an opportunity to configure the current formulary placement of Rhopressa to improve access and decrease costs to the plan and members by expanding our formulary agents. Dr. Herbert Ingraham the Chairman, Department of Ophthalmology stated that our current “policy is reasonable. There are several meds which can be tried before this newer, more expensive agent. I simply want to make sure that, in those settings where this agent may keep a patient from needing surgery when other agents have failed, it will be available to your members and our patients. My other comment is that there are some instances (for example, a history of iritis, uvetis or other ocular inflammation) where the use of a prostaglandin agent would NOT be the first-line choice. But other agents (timolol, cosopt, brimonidine, etc) would certainly be acceptable before going to this new agent.”

Recommendations: There are no formulary changes based on the information presented above. However, it is recommended that the following note be added to the current Rhopressa policies:

Note to reviewing Pharmacist: There are certain ocular inflammatory conditions including iritis and uveitis which do not warrant the use of Prostaglandin eye drops as first line therapy

Discussion: No comments or questions.

Outcome: Aubrielle Prater made a motion to accept the recommendations as presented. Keith Hunsicker seconded the motion. None were opposed.

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

Aimovig

Discussion:

Current Quantity Limits for GHP Family:

2 mL per 30 days

Dosing Schedule:

Recommended dose: 70 mg or 140 mg (2, 70 mg injections) subcutaneously once monthly

How Supplied: Aimovig is supplied as a 70 mg/1 mL autoinjector, available as a single-pack or 2-pack.

Recommendations:

Quantity Limit Recommendations: It is recommended to update the quantity limits in the Aimovig policies for GHP Family to reflect the following:

If requesting a dose of:	Approve only this NDC:	With a QL of:
70 mg per month	55513-0841-02	2 mL per 60 days
140 mg per month	55513-0841-02	2 mL per 30 days

Policy Recommendations (all lines of business):

The current Aimovig policies require the prescription to be written by a neurologist. It is recommended to update the prescriber requirement in the Aimovig policies for all lines of business to the following:

- *Prescription written by or in consultation with a neurologist or headache specialist*

Discussion: No questions or comments

Outcome: Kevin Szczecina made a motion to accept the recommendations as presented. Keith Hunsicker seconded the motion. None were opposed

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

Hepatitis C Policy Updates

Discussion: Geisinger Health System will begin transplanting livers from donors infected with Hepatitis C

Recommendations: It is recommended that “OR Medical record documentation of a hepatitis C negative recipient receiving a transplant from a hepatitis C positive donor” be added to all policies for medications used to treat Hepatitis C.

Discussion: It was suggested that documentation as to why the prescriber is not using the preferred treatment be required for requests for all medications other than Mavyret

Outcome: Keith Hunsicker made a motion to accept the recommendations as amended. Tricia Heitzman seconded the motion. None were opposed.

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

Humira

Discussion:

Ulcerative Colitis/Crohn’s Disease Criteria Update: The FDA approved dosing regimen of Humira for the treatment of Ulcerative Colitis & Crohn’s disease is 40mg every other week. While many patients achieve disease control on this dose, patients with continued symptoms may benefit from increasing to weekly dosing, per the American Gastroenterological Association Guidelines for Inflammatory Bowel Disease.

For Rheumatoid Arthritis Indication: To ensure member has received the most benefit from biweekly Humira, prior to increase to weekly, it is important to ensure member has been complaint with current regimen

Authorization Duration Update:

Currently, Geisinger Health Plan’s policy for Humira states that members will be granted an initial authorization for a duration of 6 months and continued authorization will be for a period of 1 year. Often, patients are switched from biweekly to weekly dosing, and the current policy does not clearly state the authorization duration for members who have their dose increased.

Recommendations:

For Ulcerative Colitis:

An exception for coverage of **WEEKLY administration** of Humira (which is self-administered) may be made for members who meet the following criteria:

- Medical record documentation of a diagnosis of moderate to severe ulcerative colitis **AND**
- Medical record documentation that Humira is prescribed by a gastroenterologist **AND**
- Medical record documentation of age greater than or equal to 18 years **AND**
- Medical record documentation of a therapeutic failure on, intolerance to, or contraindication to azathioprine or 6-mercaptopurine (6-MP) **OR** medical record documentation of a therapeutic failure on or intolerance to prior biologic therapy **AND**
- Medical record documentation that Humira is not being used concurrently with a TNF blocker or other biologic agent **AND**
- Medical record documentation of a contraindication to, intolerance to, or therapeutic failure on BIWEEKLY (every other week) administration of Humira **AND**
- Medical record documentation that the member has been compliant with BIWEEKLY administration of Humira **AND**
- Medical record documentation of inadequate drug trough level ($\leq 7.5\text{mcg/mL}$) to support weekly dosing, per AGA guidelines.

AUTHORIZATION DURATION: 6 months initial, 1 year on reauthorization

QUANTITY LIMIT: 4 syringes per 28 days

NOTE TO REVIEWER:

- For patients with an adequate drug trough, AGA does not recommend antibody levels to guide therapy. Patients should be switched to another agent.
- For patients with an inadequate drug trough & undetectable antibodies, a dose increase may be warranted.
- For patients with an inadequate drug trough & detectable antibodies, a switch to another agent is recommended. However, patients with low antibody levels may be considered for a dose increase, in hopes of overcoming antibody level and achieving response.

For Crohn's Disease:

An exception for coverage of **WEEKLY administration** of Humira (which is self-administered) may be made for members who meet the following criteria:

- Medical record documentation that Humira is prescribed by a gastroenterologist **AND**
- Medical record documentation of age greater than or equal to 6 years **AND**
- Medical record documentation of a diagnosis of moderately or severely active Crohn's disease **AND**
- Medical record documentation of one of the following:
 - Medical record documentation of therapeutic failure on, intolerance to, or contraindication to corticosteroids **AND** immunomodulators (e.g. azathioprine and 6-mercaptopurine) **OR** medical record documentation of a therapeutic failure on or intolerance to prior biologic therapy **OR**
 - Medical record documentation of moderate/high risk patient as defined by age at initial diagnosis < 30 years, extensive anatomic involvement, perianal and/or severe rectal disease, deep ulcers, prior surgical resection, and structuring and/or penetrating behavior **AND**
- Medical record documentation that Humira is not being used concurrently with a TNF blocker or other biologic agent **AND**

- Medical record documentation of a contraindication to, intolerance to, or therapeutic failure on BIWEEKLY (every other week) administration of Humira **AND**
- Medical record documentation that the member has been compliant with BIWEEKLY administration of Humira **AND**
- Medical record documentation of inadequate drug trough level ($\leq 7.5\text{mcg/mL}$) to support weekly dosing, per AGA guidelines.

AUTHORIZATION DURATION: 6 months initial, 1 year on reauthorization

QUANTITY LIMIT: 4 syringes per 28 days

NOTE TO REVIEWER:

- For patients with an adequate drug trough, AGA does not recommend antibody levels to guide therapy. Patients should be switched to another agent.
- For patients with an inadequate drug trough & undetectable antibodies, a dose increase may be warranted.
- For patients with an inadequate drug trough & detectable antibodies, a switch to another agent is recommended. However, patients with low antibody levels may be considered for a dose increase, in hopes of overcoming antibody level and achieving response.

For Rheumatoid Arthritis:

Recommend addition of the following criteria to the RA weekly dosing criteria:

- Medical record documentation that the member has been compliant with BIWEEKLY administration of Humira

Authorization Duration Update:

To ensure consistency among reviewers, it is recommended that the current authorization duration and wording be updated to reflect that members who receive a dose increase for Humira, will be granted an initial authorization for a period of 6 months. Recommend the following revisions to current policy authorization durations:

Current Initial Authorization Duration Wording:

Approval will be given for an initial duration of six (6) months. For continuation of coverage, medical record documentation of clinical improvement or lack of progression in signs and symptoms of [disease] on six (6) months of adalimumab therapy is required.

Revised Initial Authorization Duration Wording:

Approval for new starts and dose increases (biweekly to weekly), adalimumab will be given for an initial duration of six (6) months. For continuation of coverage, medical record documentation of clinical improvement or lack of progression in signs and symptoms of [disease] on six (6) months of adalimumab therapy is required.

Discussion: No comments or questions.

Outcome: Keith Hunsicker made a motion to accept the recommendations as presented. Todd Sponenberg seconded the motion. None were opposed.

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

Discussion: During the review of Jynarque at September's P&T there were questions as to how to determine if a member is at high risk for rapidly progressing ADPKD.

Recommendations from National Agencies or Organizations:

Per the practical guide for the treatment of ADPKD by the Mayo clinic, the first step to consider before prescribing tolvaptan is confirming the diagnosis. When there is a family history of ADKPKD, diagnosis relies on imaging. When there is no family history or when the appearance and function of the kidneys are not consistent with ADPKD, genetic testing may be helpful to detect rare forms of ADPKD and other cystic diseases.

The next step is to confirm the diagnosis of rapidly progressive disease. Physicians prescribing tolvaptan should consider the patient's age, height-adjusted total kidney volume (htTKV) and eGFR to identify individuals at the highest risk of rapid progression. The Mayo imaging classification is a tool that uses htTKV and age to identify patients at the highest risk for progression independent of renal function. There are 5 classes stratified in the basis of growth rates. There is also a model that uses this classification plus eGFR. Mayo classes 1C, 1D, 1E are considered to be at higher risk for rapid progression to ESRD. Other risk factors for progressive disease include Propko score of 7 to 9 and kidney length > 16.5 cm by ultrasound.

In the REPRISÉ trial patients > 55 years did not benefit from tolvaptan, which may have been due to the slow disease progression, as suggested by their lower rate of eGFR decline on placebo.

Specialist Feedback:

Dr. Alexander Chang, Dr. Evan Norfolk, and Dr. Gurmukteshwar Singh (nephrology at Geisinger) created the following criteria for tolvaptan use:

- Established diagnosis of ADPKD by nephrologist
 - Suggest genetic testing or modified Pei-Ravine criteria
 - With family history: several cysts per kidney (3 if by sonography; 5 if by CT or MRI)
 - Without family history: 10 cysts per kidney (by any radiologic method, above) and exclusion of other cystic kidney diseases.
- Age: 18-55 years
- EGFR: >25
- Labs in the previous 2 months: Renal and hepatic function panel, urinalysis and protein/creat ratio, hemoglobin A1C if diabetic. Pregnancy test in women of childbearing potential
- Physician and patient enrolled in REMS (can be dropped once FDA stops the REMS requirement)
- Measurement of total kidney volume by CT or MRI (US is not accurate/ reproducible and should be accepted only with documented contra-indication to CT AND MRI)
- Documentation by nephrologist that patient is at risk of progressions of ADPKD: Physician must document one of the following:
 - Mayo classification class 1C, 1D or 1E
 - Total Kidney Volume >750 mL
 - PROPKD score >6
 - Contra-indication to CT and MRI and ultrasound-measured kidney length >16.5 cm
- Absence of exclusion criteria below

Exclusion Criteria:

- Uncontrolled diabetes (HbA1C>7.5%) or significant diabetic kidney disease (Proteinuria >3000 mg/day, proliferative retinopathy)
- Acute kidney injury
- Evidence of additional kidney disease like glomerulonephritis
- Renal cell cancer or recent kidney surgery
- Liver function abnormalities unless deemed as expected for ADPKD by gastroenterologist

- Women of childbearing potential who do not agree to practice effective birth control
- Women who are breastfeeding and/or have a positive pregnancy test
- Chronic diuretic use

Recommendations: It is recommended that prior authorization criteria be updated to:

- Prescription written by a nephrologist AND
- Medical record documentation of the member being ≥ 18 years AND
- Medical record documentation of a diagnosis of Autosomal Dominant Polycystic Kidney Disease (ADPKD) as confirmed by cysts and family history or genetic testing* AND
- Medical record documentation of a GFR ≥ 25 mL/min AND
- Medical record documentation the member is at risk for rapidly progressing ADPKD as documented by one of the following:
 - Mayo classification class 1C, 1D, or 1E
 - Total Kidney Volume > 750 mL
 - PROPKD score > 6
 - Kidney length > 16.5 cm as measured by ultrasound (if CT and MRI contraindicated)

*Note to reviewer: Per nephrology at Geisinger, the diagnosis of ADPKD should be established through genetic testing or modified Pei-Ravine criteria:

- With family history: several cysts per kidney (3 if by sonography; 5 if by CT or MRI)
- Without family history: 10 cysts per kidney (by any radiologic method, above) and exclusion of other cystic kidney diseases.

There will be no changes to quantity limits, authorization durations, and re-authorization criteria

Discussion: No comments or questions.

Outcome: Kim Clark made a motion to accept the recommendations as presented. Tricia Heitzman seconded the motion. None were opposed.

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

Medical Benefit Policy Updates

Discussion: DHS requested the following updates be made

Recommendations:

MBP 55.0 Myozyme (alglucosidase alfa) – medication is no longer available, policy retired

MBP 182.0 Crysvita: In patients with X-linked hypophosphatemia the normal physiologic response to hypophosphatemia of an elevation of $1,25(\text{OH})_2$ vitamin D is absent therefore serum concentrations may be low or inappropriately normal (in view of the ambient hypophosphatemia). The policy was updated as follows to better reflect this.

Crysvita (burosumab-twza) will be considered medically necessary when ALL of the following criteria are met:

- Medical record documentation that the patient is at least 1 year of age or older **AND**

- Medical record documentation that Crys vita is being prescribed by, or in consultation with, an endocrinologist, geneticist, or nephrologist **AND**
- Medical record documentation of a diagnosis of X-linked hypophosphatemia as evidenced by one of the following:
 - Reduced TmP/GFR ratio **AND** Reduced or normal plasma concentration of 1,25-dihydroxycholecalciferol (1,25-DHCC) or 25-hydroxyvitamin D [25(OH)D] **OR**
 - Genetic testing confirming a mutation in the PHEX (Phosphate regulating Endopeptidase on the X chromosome) gene

AND

- Medical record documentation that the patient is not concurrently using vitamin D analogs or phosphate supplements.

Discussion: No comments or questions.

Outcome: Kim Clarke made a motion to accept the recommendations as presented. Kevin Szczecina seconded the motion. None were opposed.

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

Formulary Updates

Discussion: To increase access to medication assisted opioid addiction treatment and to decrease prior authorization requests, several changes to the formulary were made.

Recommendations:

In an effort to increase access to Medication Assisted Treatment for opioid addiction it is recommended that the prior authorization requirement be removed from the following medications. There will be no changes to the tiering/formulary placement of the medications:

- Suboxone Film
- Probuphine
- Sublocade

It is also recommended the following formulary addition be made:

Medication	Tier/UM	Rationale
Colchicine capsules	Generic w/QL of 3 per day	Lower MAC price than tablets

Discussion: No comments or questions.

Outcome: Tricia Heitzman made a motion to accept the recommendations as presented. Kim Clark seconded the motion. None were opposed.

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

Praluent

Discussion: Per UpToDate, statins, ezetimibe, and PCSK9 inhibitors have been shown to reduce the risk of adverse cardiovascular events and statins have been well studied. In patients with CV disease, lifestyle interventions should be recommended. In patients at a high risk for CVD events and whose LDL-C remains > 70 mg/dL despite the use of a statin, ezetimibe and/or PCSK9 inhibitor may be added. In those at high-risk (average, high, or very high) that cannot tolerate any statin, either a PCSK9 inhibitor or ezetimibe is recommended. Bile acid sequestrants are rarely used for elevated LDL-C. There is no CV outcomes data for bile acid sequestrants. Per UpToDate, fibrates are not recommended for the treatment of hyperlipidemia in the absence of hypertriglyceridemia. Unlike statins, which have demonstrated clinical efficacy across a broad range of LDL-C levels, fibrates may reduce CV events in a subset of patients with high triglycerides, or low HDL, and metabolic syndrome only.

ODYSSEY Clinical Trial: The ODYSSEY Outcomes study compared the safety and efficacy of Praluent compared with placebo among patients with recent acute coronary syndrome already on intensive or maximum-tolerated statin therapy. Patients who had an ACS event 1-12 months ago were randomized, after a run-in phase of 2-16 weeks on high-intensity statin therapy, to Praluent (n=9,462) or placebo (9,462). The duration of follow-up was 2.8 years. The primary outcome was major adverse cardiac events (coronary heart disease death, MI, ischemic stroke, unstable angina). There was significantly less MACE in the Praluent group compared to placebo. However, there was no difference in coronary heart disease deaths when comparing Praluent to placebo

Recommendations: It is recommended to remove the following criteria from the current Praluent policy:

- *“Medical record documentation of a therapeutic failure on, intolerance to, or contraindication to a bile acid sequestrant or fibrate OR medical record documentation of a low-density lipoprotein (LDL) greater than or equal to 100 AND...”*

Discussion: No comments or questions.

Outcome: Kevin Szczecina made a motion to accept the recommendations as presented. Kim Clark seconded the motion. None were opposed.

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

Intranasal Corticosteroids

Discussion: At the September 2018 P&T Committee meeting, a prior authorization for Xhance was created requiring the following criteria for GHP Family:

- Medical record documentation that member is at least 18 years of age **AND**
- Medical record documentation of diagnosis of nasal polyps **AND**
- Medical record documentation of failure on, contraindication to, or intolerance to mometasone furoate

Additional information:

Drug	AWP/MAC per unit (\$)	AWP/MAC per 28 day supply (\$)	1 package will last how many days?
Xhance 93 mcg	\$33.47 per mL	\$535.52	30 to 60 days
Beconase AQ	\$14.08 per gm	\$352.00	45 to 90 days

Mometasone	\$3.59 per gm	\$61.03	30 to 60 days
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Recommendations: It is recommended that Beconase AQ be added to the Brand tier of the Medicaid formulary. No policy changes are recommended for Beconase AQ at this time.

It is also recommended that the GHP Family policy for Xhance be updated to require failure on, intolerance to, or contraindication to Beconase AQ.

Therefore, the Xhance policies should read as follows:

- Medical record documentation that member is at least 18 years of age **AND**
- Medical record documentation of diagnosis of nasal polyps **AND**
- Medical record documentation of failure on, contraindication to, or intolerance to mometasone furoate **AND**
Beconase AQ

Discussion: No comments or questions.

Outcome: Aubrielle Prater made a motion to accept the recommendations as presented. Tricia Heitzman seconded the motion. None were opposed.

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

GHP Family Policy Updates

Discussion:

Policy 4.0F Formulary Exception/Prior Authorization: during DHS' annual review of Policy 4.0F it was noted that several additional classes of medications should be grandfathered

Policy 1462.0F Nasal Steroid Step: The Committee decided to require a step through fluticasone propionate and triamcinolone acetonide for Omnaris, Qnasl, Budesonide, or Zentonna to be approved. However, many pharmacies state they have a difficult time processing triamcinolone acetonide for GHP Family

Recommendations:

Policy 4.0F Formulary Exception/Prior Authorization– It is recommended the following drug classes be grandfathered:

- A. HAE Agents
- B. HCV Agents
- C. Pancreatic Enzymes
- D. Ulcerative Colitis Agents
- E. Cytokine and CAM Antagonists and Related Agents
- F. Enzyme Replacement/Gaucher's Disease
- G. IPF Agents
- H. Thalidomide and Derivatives
- I. Antiparkinson's Agents
- J. PAH Agents

Policy 1462.0F Nasal Steroid Step –It is recommended that the step be changed to:

- Medical record documentation of current utilization, intolerance to, or contraindication to fluticasone propionate AND mometasone furoate

Discussion: No comments or questions.

Outcome: Kim Clark made a motion to accept the recommendations as presented. Aubrielle Prater seconded the motion. 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 5:41 pm.

Future Scheduled Meetings

Tuesday, January 15, 2019 at 1:00 HCN3A & 3B Conference room

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