P&T Committee Meeting Minutes
Medicaid
May 21, 2019

Present:	**Absent:**
Bret Yarczower, MD, MBA – Chair	Kenneth Bertka, MD
Kristen Bender, PharmD – via phone	Beverly Blaisure, MD
Kim Castelnovo, RPh – via phone	Holly Bones, Pharm.D.
Rajneel Chohan Pharm.D.	Dean Christian, MD
Kimberly Clark, Pharm.D.	Alyssa Cilia, RPh
Tricia Heitzman, Pharm.D.	Michael Evans, RPh
Keith Hunsicker, Pharm.D.	Jason Howay, Pharm.D.
Kelli Hunsicker, Pharm.D. – via phone	Steven Kheloussi, Pharm.D.
Phillip Krebs, R.EEG T. – via phone	Perry Meadows, MD
Jamie Miller, RPh	Steven Moscola, RPh
Aubrielle Prater Pharm.D.	Jonas Pearson, RPh
Kimberly Reichard Pharm.D.	William Seavey, Pharm.D.
Angela Scarantino – via phone	Michael Spishock, RPh
Kristen Scheib, Pharm.D. – via phone	
Richard Silbert, MD – via phone	
Todd Sponenberg, Pharm.D.	
Jill Stone, Pharm.D. – via phone	
Kevin Szczecina, RPh	
Kelly Yelenic Pharm.D.	

Call to Order:
Dr. Bret Yarczower called the meeting to order at 1.03 p.m., Tuesday, May 21, 2019.

Review and Approval of Minutes:
Dr. Bret Yarczower asked for a motion or approval to accept the Feb 28, 2019 (electronic vote) and March 19, 2019 minutes as written. Keith Hunsicker accepted the motion and Kevin Szczecina seconded the motion. None were opposed.

DRUG REVIEWS

DOVATO (dolutegravir/lamivudine)

Review: Dovato is approved as a complete regimen, which means that it does not need to be used with any other drugs. Dovato contains only two active ingredients, which makes it the first two-drug FDA-approved fixed dose therapy for treatment naïve adults infected with HIV. These fixed dose combinations work to provide an advantage to the patient by decreasing the number and/or frequency of doses that they may need to be simplifying the dosage regimen. Each of the two Dovato components are currently commercially available separately as Epivir and Tivicay. The approximate cost of Dovato is $2,754, which is similar to the individual components combined.

Dovato is available as a tablet and taken by mouth once daily without regard to meals. Patient also taking certain other medications (carbamazepine, rifampin) require an additional dose of Tivicay (dolutegravir) 50 mg, taken 12 hours after Dovato. Both males and females of reproductive potential should use contraception or avoid using Dovato. The drug has been associated with neural tube defects in the fetus when used during the time of conception and/or during the first trimester.

Dovato was shown to be effective based upon data from the GEMINI 1 and 2 clinical trials. These were duplicate randomized, double-blind, multicenter, parallel group, non-inferiority studies in treatment naïve adults. Dovato was compared to the three-drug combination of Truvada (tenofovir disoproxil fumarate/emtricitabine) and Tivicay (dolutegravir). In GEMINI 1 90 percent of Dovato users achieved plasma HIV-1 RNA of less than 50 copies per mL vs 93 percent of users receiving the three-drug regimen after 48 weeks. In GEMINI 2 93 percent of Dovato users achieved plasma HIV-1 RNA of less than 50 copies per mL vs 94 percent of users receiving the three-drug regimen after 48 weeks. These results demonstrate non-inferiority in each study. The most common side effects observed in clinical trials included: headache, diarrhea, nausea, insomnia and fatigue.

Moving forward it is important to keep an eye on these agents as we study them longer we get a better idea of resistance. As we currently have open access to these agents it may be beneficial to manage this class as we gather additional information on safety, efficacy and resistance.

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

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

Outcome: Dovato will be a pharmacy benefit. It is recommended that Dovato be added to the GHP Family formulary on the Brand Tier. Dovato will <u>not</u> require prior authorization.

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.

FIRDAPSE (amifampridine)

Review: Firdapse is a broad-spectrum potassium channel blocker which prolongs presynaptic nerve depolarization, allowing more calcium to be transferred to the nerve ending and improving the central, autonomic, and neuromuscular presynaptic release of acetylcholine (Ach). Firdapse is considered first-line symptomatic treatment

of patients with both paraneoplastic and non-paraneoplastic Lambert-Eaton Myasthenic Syndrome (LEMS) with moderate to severe muscle weakness. LEMS, an autoimmune disorder of reduced Ach at the neuromuscular junction, can be diagnosed based on clinical signs and symptoms confirmed by post-exercise or post-activation increase in compound muscle action potential (CMAP) or anti-P/Q type VGCC antibody testing.

The safety and efficacy of Firdapse in the treatment of adult patients with LEMS were investigated in two double-blind, placebo-controlled, randomized discontinuation studies. Trial one was a four-phase trial during which patients were initially titrated to stable adequate doses of Firdapse, then randomized to continue Firdapse or receive a downward titration to placebo over 7 days. Treatment was continued for an additional 7 days before final assessments after which patients could continue or resume treatment with Firdapse for up to two years in an open-label long-term safety phase. Trial two evaluated patients who had been stabilized on a steady dose and frequency of Firdapse for at least one week, then randomized to either continue their current Firdapse dosage or switch to placebo for 4 days before final assessments. In both trials, the primary outcomes measuring change from baseline in Quantitative Myasthenia Gravis (QMG) score and Subject Global Impression (SGI) showed worsening scores in both the Firdapse and placebo treatment arms. The placebo treatment arms in each trial had a significantly greater change, indicating a greater degree of muscle weakness and lower perceived benefits of the treatment on their well-being. One secondary outcome measuring change from baseline in Clinical Global impression improvement (CGI-I) scores also showed a significantly greater change in each placebo treatment arm, indicating worsening clinical symptoms as perceived by the investigator. The functional mobility test assessed in trial 1 did not show a significant change from baseline in either treatment arm, while the functional mobility test in trial 2 found that a significantly greater number of patients had a decrease in functional mobility when compared to the Firdapse treatment group.

There are no black box warnings, but Firdapse is contraindicated in patients with a known hypersensitivity to amifampridine phosphate, aminopyridines, or any component of the formulation and in patients with a history of seizure. The most common adverse events (>10%) reported during clinical trials were paresthesia, upper respiratory infections, hypertension, elevated liver enzymes, abdominal pain, nausea, diarrhea, back pain, and muscle spasms. Other adverse reactions reported in at least 5% of all patients studied include muscle weakness, extremity pain, cataracts, falls, constipation, bronchitis, lymphadenopathy, dyspnea, urinary tract infection, gastroesophageal reflex, insomnia, peripheral edema, pyrexia, viral infection, depression, erythema, hypercholesterolemia, blood creatinine phosphokinase increase, and influenza. Seizures, which may be dose dependent, occurred in approximately 2% of patients and could occur at any time after initiation of treatment in patients regardless of seizure history, necessitating dose reduction or discontinuation in certain patients.

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

Clinical Discussion: It was asked if there were any comparative trials to IVIG. There were not. Todd Sponenberg made a motion to accept the recommendations as presented. Tricia Heitzman seconded the motion. None were opposed.

Financial Discussion: It was suggested that we require trial of pyridostigmine, and that reauthorization would be approved based on provider attestation as well, since members will ultimately progress, even with this medication. Kelly Yelenic made a motion to accept the recommendations as amended. Aubrielle Prater seconded the motion. None were opposed.

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

- Medical record documentation of age 18 or older AND
- Medical record documentation that Firdapse is being prescribed by a neurologist AND

- Medical record documentation of diagnosis of Lambert-Eaton myasthenic Syndrome confirmed by one of the following:
    - Medical record documentation of post-exercise facilitation test showing increase in compound muscle action potential (CMAP) amplitude of at least 60 percent compared to pre-exercise baseline value OR
    - Medical record documentation of high-frequency Repetitive Nerve Stimulation (RNS) showing increase in compound muscle action potential (CMAP) of at least 60 percent OR
    - Medical record documentation of positive anti-P/Q type voltage-gated calcium channel antibody test.

  AND
- Medical record documentation of intolerance, contraindication, or therapeutic failure to pyridostigmine

Quantity Limit: 8 tablets/day, maximum day supply of 30 days per fill

Authorization Duration:
Initial Approval will be for 6 months. Subsequent authorizations will be for 12 months and will require:

- Medical record documentation of clinical improvement or lack of progression in signs and symptoms of Lambert-Eaton Myasthenic Syndrome OR
- Medical record documentation of prescriber attestation that the member will benefit from continued therapy with Firdapse and that Firdapse treatment continues to be medically necessary.

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

SPRAVATO (esketamine)

Review: Spravato is approved for treatment-resistant depression (TRD) in adults, for use in conjunction with an oral antidepressant. The last labeled drug for TRD, Symbyax (fluoxetine/olanzapine) was approved more than a decade ago in 2003. Spravato (esketamine) nasal spray is an N-methyl-D-aspartate (NMDA) antagonist. Its effects via glutamate modulation are believed to help restore synaptic connections between neurons. Spravato's novel mechanism and rapid onset of action are expected to provide a therapeutic advantage early in treatment for some patients with treatment resistant depression. Traditional oral antidepressant medications often require one month or longer (4-8 weeks) for therapeutic effect, while the antidepressant effects of Spravato are often noted within hours of the first dose. Spravato will typically be started in combination with an oral antidepressant in patients with previous failure of two or more adequate trials of antidepressants. Spravato is self-administered; however, due to potential adverse effects, administration must occur in a certified doctor's office or clinic with observation by a healthcare professional required for a minimum of 2 hours post-dose.

Spravato should be initiated at 56mg (2 devices) intranasally for the first dose, then 56mg or 84mg (3 devices) twice weekly for the remainder of the four week induction phase. During the following 4 weeks patients should receive 56mg or 84mg once weekly. After week 8, patients will receive 56mg or 84mg administered every 2 weeks or once weekly; dosing frequency should be adjusted to the least frequent dosing to maintain remission/response. Each device delivers two sprays containing a total of 28 mg of esketamine. Patient will administer the first spray into one nostril and the second spray into the other nostril. Patients should rest for 5 minutes after delivery of each device in order to allow medication to absorb and should not blow nose after administration.

Four phase 3 trials evaluated the efficacy of Spravato. However, only two of the four efficacy studies met the primary endpoint. In patients ≥ 65 years there no statistically significant difference in the primary efficacy endpoint when comparing Spravato + newly initiated oral antidepressant (NIOA) versus placebo + NIOA.

Study 1 (TRANSFORM-2 study) was a short-term study that evaluated a four-week treatment of flexible Spravato dosing in adults 18 to <65 years old with treatment resistant depression. Enrolled patients met DSM-5 criteria for MDD and did not respond adequately to at least two different antidepressants of adequate dose and duration. Patients were required to discontinue prior antidepressant treatments prior to starting the study. Participants were then randomized to receive twice weekly doses of intranasal Spravato (flexible dose, 56mg or 84mg) or placebo. All patients receiving Spravato or placebo began the study drug treatment in combination with a newly initiated oral antidepressant (NIOA). The primary efficacy endpoint was measured as the change from baseline in the Montgomery-Asberg Depression Rating Scale (MADRS) score at the end of the 4-week induction phase. After four weeks, the patients receiving Spravato demonstrated significant improvement in the primary efficacy endpoint over patients receiving placebo.

Study 2 (SUSTAIN-1) was studied in adults 18 to <65 years old who had previously exhibited response or remission to Spravato in one of the short-term phase 3 trials or an open-label direct enrollment study with flexible dosing (Spravato 56mg or 84mg). Patients received Spravato with an oral antidepressant during the initial 16-week induction and optimization phase of the trial and then received Spravato or placebo with an oral antidepressant for the maintenance phase (variable time period). The primary efficacy endpoint of Study 2 was the time to relapse in the stable remitter group. Relapse was defined as a MADRS total score of 22 or greater for two consecutive weeks, hospitalization for worsening depression, or any other clinically relevant event that indicated relapse. Patients receiving Spravato experienced a statistically significant longer time to relapse than the patients receiving placebo. The time to relapse was also longer for those receiving Spravato in the stable responder population and was statistically significant compared to the time to relapse in the placebo group. A total of 27% of patients in stable remission on Spravato had a relapse during the maintenance treatment phase, while 45% of patients in stable remission on placebo had a relapse.

Spravato has a black box warning for sedation, dissociation, abuse and misuse, suicidal thoughts and behaviors. Due to the risks of serious adverse outcomes from sedation, dissociation, and abuse and misuse, Spravato is only available through a restricted program (Spravato REMS). Contraindications to Spravato include history of intracerebral hemorrhage, aneurysmal vascular disease or arteriovenous malformation, or hypersensitivity to esketamine or ketamine. Warnings and precautions include increases in blood pressure, cognitive impairment, sedation, dissociation, suicidal thoughts and behaviors, abuse and misuse of esketamine, impaired ability to drive and operate machinery, and embryo-fetal toxicity. The most common adverse reactions (incidence ≥ 5% and at least twice that of placebo plus oral antidepressant) are dissociation, dizziness, nausea, sedation, vertigo, hypoesthesia, anxiety, lethargy, increased blood pressure, vomiting, and feeling intoxicated. The safety and effectiveness have not been established in pediatric patients.

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

Clinical Discussion: Dr. Silbert stated that the provider community has concerns over long term use. It was asked if other therapies (i.e. ECT or psychotherapy) be considered before this. In Dr Silberts opinion, yes. It was discussed that there was no need to limit prescriber due to product REMS program. It was recommended to ament the criteria that to broaden the definition of treatment resistant depression by failure of antidepressants from multiple classes. It was also recommended to not have a upper age limit. 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. Tricia Heitzman made a motion to accept the recommendations as presented. Kevin Szczecina seconded the motion. None were opposed.

Outcome: Spravato will be covered as a medical benefit requiring prior authorization for GHP Family members. The following prior authorization criteria should apply.

- Medical record documentation of age ≥ 18 years AND
- Medical record documentation of diagnosis of major depression disorder (MDD) AND
- Medical record documentation of Spravato being used for treatment-resistant depression as defined by failure of at least two antidepressants from two different classes at an optimized dose for at least 6 weeks AND
- Medical record documentation that Spravato will be used in combination with a newly initiated antidepressant AND
- Medical record documentation of the patient's baseline depression status using an appropriate rating scale (e.g. PHQ-9, Clinically Useful Depression Outcome Scale, Quick Inventory of Depressive Symptomatology-Self Report 16 Item, MADRS, HAM-D) AND
- Medical record documentation of therapeutic failure on, intolerance to, or contraindication to olanzapine/fluoxetine capsules

Authorization Duration:
Initial approval will be for 1 month or less if the reviewing provider feels it is medically appropriate. For continued coverage, the following criteria is required.

- Medical record documentation of clinical improvement in depression symptoms as measured by an appropriate rating scale (compared to previous measurement).

Subsequent approvals will be for an additional 12 months or less if the reviewing provider feels it is medically appropriate. For continued coverage, the following criteria is required.

- Medical record documentation of clinical improvement or lack of progression in depression symptoms as measured by an appropriate rating scale (compared to previous measurement).

Quantity Limits:
23 devices per 28 days

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

YUPELRI (revefenacin)

Review: Yupelri is a long-acting antimuscarinic antagonist (LAMA) approved for use in the maintenance treatment of COPD. Current guidelines recommend the use of a LAMA or long-acting $beta_2$-agonist in cases of moderate to severe COPD, with a LAMA being the initial preferred agent in patients with a higher exacerbation rate. Yupelri is the seventh approved LAMA and the second available as a nebulization solution. It should not be initiated when patients are experiencing acute deteriorating or potentially life-threating episodes and should be reserved for patients who have difficulty with soft mist or dry powder formulation. It is available as a 175 mcg once daily nebulization solution via standard jet nebulizer.

The efficacy of Yupelri is shown through two 12-week randomized, double-blind, placebo controlled parallel group studies in adult patients (mean age 64 years) with COPD. Patients included in the trials had a mean post bronchodilator FEV_1 of 55% and 37 % were on concurrent therapy with a long-acting $beta_2$-agonist (LABA) or inhaled corticosteroid (ICS)/LABA. The two efficacy trials measured patient response as change from baseline in trough (pre-dose) FEV_1 at day 85 with the Yupelri treatment arm showing significant improvement in lung function over placebo. Other outcomes measured were overall treatment effect, the use of rescue medications, change from baseline to peak FEV_1, and responder rate for St. George's Respiratory Questionnaire. In both trials, there was a statistically significant change from baseline in trough FEV_1 overall treatment effect, but all other secondary

endpoints failed to reach statistical significance. The adverse reactions with the highest incidence in the trials were cough, nasopharyngitis, upper respiratory tract infection, headache, and back pain.

The safety of Yupelri was also studied in a 52-week open-label active control (tiotropium) trial where patients were randomized to receive Yupelri 88 mcg, Yupelri 175 mcg, or Spiriva 18 mcg daily. The demographic and baseline characteristics of the safety trial were similar to those of previous studies with the exception that 50% were on concurrent therapy (previously 37%). The adverse reactions reported in the safety trial were similar to those in the previous efficacy trials.

There are no black box warnings for Yupelri, but it should be avoided in patients with hypersensitivity to revefenacin or any other components, patients with narrow angle glaucoma, patients with prostatic hyperplasia or bladder neck obstruction, and patients with hepatic impairment. As with other bronchodilators, there is a risk of paradoxical bronchospasms and should be discontinued in these patients. Yupelri has limited systemic absorption (bioavailability <3%) and is relatively well tolerated with the most common adverse reactions being cough, nasopharyngitis and upper respiratory infection. Other adverse reactions include dizziness, headache, bronchitis, oropharyngeal pain, back pain, and hypertension.

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 presented. Todd Sponenberg seconded the motion. None were opposed

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

Outcome: Yupelri is a pharmacy benefit that should not be added to the GHP Family formulary. The following criteria should apply:

- Medical record documentation of intolerance, contraindication, or therapeutic failure to Spiriva OR
- Medical record documentation of inability to perform proper inhaler technique

Quantity Limit: 90 mL per 30 das

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

XIMINO (minocycline hydrochloride)

Review: Ximino (minocycline hydrochloride) is an extended-release minocycline capsule specifically indicated for the treatment of only inflammatory lesions of non-nodular moderate to severe acne vulgaris in patients 12 years of age or older. The tetracycline class of antibiotics is considered first-line therapy in moderate to severe acne that is resistant to topical treatments. Currently, doxycycline and minocycline are both used in the treatment of AV and are more effective than tetracycline, but neither is superior to each other. Solodyn is another extended-release formulation of minocycline. Solodyn is available as an extended release tablet and its generic is readily available. Ximino, along with Solodyn, allow for once daily dosing, while traditional minocycline must be dosed twice daily. To date, The American Academy of Dermatology has not preferred one formulation of oral minocycline over another in its treatment guideless for acne vulgaris.

Ximino is supplied as extended-release, hard-gelatin capsules containing minocycline hydrochloride, USP equivalent to 45 mg, 90 mg, or 135 mg. The recommended dosage of Ximino is approximately 1 mg/kg once daily for 12 weeks.

In two efficacy and safety trials, a total of 924 subjects with non-nodular moderate to severe acne vulgaris received minocycline hydrochloride or placebo for a total of 12 weeks. In trial 1, there was a 43.1% mean percent improvement in inflammatory lesions and 17.3% of patients were categorized as clear or almost clear on the EGSA scale. In trial 2, there was a 45.8% mean percent improvement in inflammatory lesions and 15.9% of patients were categorized as clear or almost clear on the EGSA scale.

There are no contraindications or black box warnings associated with the use of Ximino. There are various warnings and precautions with its use that align with those of the tetracycline drug class. Over 50% of people experienced at least 1 treatment-emergent event, the most common of which were headache, fatigue, and dizziness.

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 presented. Todd Sponenberg seconded the motion. None were opposed

Financial Discussion: No comments or questions. Aubrielle Prater made a motion to accept the recommendations as presented. Keith Hunsicker seconded the motion. None were opposed

Outcome: Ximino will be a pharmacy benefit for GHP Family members. It is recommended that Ximino **not** be added to the GHP Family pharmacy formulary.

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

UDENYCA (pegfilgrastim-cbqv)

Review: Udenyca is a biosimilar leukocyte colony-stimulating factor that is highly similar to the US-licensed reference product, Neulasta, 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. Udenyca is not indicated for the mobilization of peripheral blood progenitor cells for hematopoietic stem cell transplantation. Udenyca acts on hematopoietic cells by binding to cell surface receptors and stimulating proliferation, differentiation commitment, and end-cell functional activation. Udenyca is the second FDA approved pegfilgrastim biosimilar, the first being Fulphila (pefilgrastim-jmdb). Neither of the pegfilgrastim biosimilar products are interchangeable with Neulasta. Neulasta Onpro offers a "on-body" administration method and is unique to Neulasta. The on-body administration is not available with either biosimilar product.

No new clinical trials were included in the Udenyca prescribing information. The clinical trials in the prescribing information are consistent with those presented in the Neulasta prescribing information. Studies CHS-1701-05, CHS-1701-03, and CHS-1701-01 were crossover studies included in the clinical development program of Udenyca, intended to demonstrate pharmacokinetic (PK) bioequivalence (BE). Study CHS-1701-04, which was also part of Udenyca's clinical program, was designed as the confirmatory study intended to establish immunogenicity similarity Udenyca and Neulasta. Study CHS-1701-05 demonstrated similarity in PK, PD, and BE between Neulasta and Udenyca. Study CHS-1701-04 supported immunogenicity similarity between Udenyca and Neulasta. Study CHS-1701-04 had an unexplainable difference between Neulasta and Udenyca in one of the

treatment arms (second treatment arm proved to be superimposable). Because of this unexplainable difference, the study was not powered to demonstrate similarity in PK, PD, or BE. Study CHS-1701-01 had differences in the Udenyca material which was not representative of the commercial material, and for this reason was not powered to make any efficacy conclusions. Information from this study was included in the safety summary only.

The safety profile of Udenyca was similar to Neulasta in clinical trials and consistent with the known safety profile reported for Neulasta. There were no unexpected safety findings in healthy subjects in the clinical development program and there was no impact of ADA or Nab on safety. The most commonly reported treatment-emergent adverse events (≥2% incidence in any treatment group) in the clinical development program of Udenyca included back pain, headache, pain in extremity, arthralgia, pain, neck pain, nausea, musculoskeletal chest pain, dizziness, vomiting, myalgia, musculoskeletal pain, abdominal pain, muscle spasms, upper respiratory tract infection, non-cardiac chest pain, oropharyngeal pain, and pain in jaw. Reported warnings and precautions in the Udenyca prescribing information is equivalent to those presented in the Neulasta prescribing information.

The National Comprehensive Cancer Network (NCCN) Guidelines in Oncology maintain specific recommendations for the use of hematopoietic growth factors, including pegfilgrastim. Recommendations for the prevention of chemotherapy induced febrile neutropenia are similar between G-CSF products, and vary depending on the febrile neutropenia risk of the chemotherapy regimen given.

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 presented. Aubrielle Prater seconded the motion. None were opposed

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

Outcome: Udenyca will be a pharmacy or medical benefit requiring prior authorization. It is recommended that Udenyca be added to the Brand Tier to match the tiering of its reference product, Neulasta. Requests for coverage will require the following prior authorization:

<u>Neupogen, Neulasta, Fulphila, Udenyca, Nivestym, Zarxio, Granix and Leukine:</u>

- **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)
- 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)

Neupogen, Neulasta, Fulphila, Udenyca, Nivestym, Zarxio and Leukine: May also be considered medically necessary for any of the following:

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)

Radiation therapy –

- If prolonged delays secondary to neutropenia are anticipated.
- As treatment for radiation injury secondary to doses of 3-10 Grays (Gy) or greater

Note: Fulphila and Udenyca are not indicated for Radiation Injury Syndrome

Stem Cell Transplantation- when one of the following is met:

- Bone Marrow Transplant (BMT)-
    - Documentation of a non-myeloid malignancy undergoing myeloablative chemotherapy followed by autologous or allogenic bone marrow transplant (G-CSF is given after BMT)

OR

- Peripheral Blood Progenitor Cell (Mobilization)Transplant (PBPC)
    - Used for mobilization of autologous hematopoietic progenitor cells into the peripheral blood for collection by leukapheresis. (G-CSF is given prior to and throughout leukapheresis)

Note: Neulasta is considered off-label for PBPC mobilization
Note: Fulphila and Udenyca are not indicated for PBPC mobilization

Neupogen, Nivestym, and Zarxio: May also be considered medically necessary for the following:
Severe Chronic Neutropenia – when the following criteria are met

- Diagnosis of Congenital, Cyclic, or Idiopathic Neutropenia AND
- Documentation of an Absolute Neutrophil Count (ANC) <500 cells/mm3 on three separate occasions during a 6 month period (for Congenital or Idiopathic Neutropenia) OR five consecutive days of ANC <500 cells/mm3 per cycle (for Cyclic Neutropenia) AND
- Documentation that the member experienced a clinically significant infection, fever, or oropharyngeal ulcer during the past 12 months.

Leukine:
Delayed Neutrophil Recovery or Graft Failure -

- Medical record documentation that the member has had an allogeneic or autologous bone marrow transplant and neutrophil recovery* has not occurred.

*Note to reviewer: Neutrophil engraftment is defined as the first day of three consecutive days where the neutrophil count (ANC) is 500 cells/mm3 or greater.

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.

Treatment period will be defined as 6 months, re-review will be required after that time.

Neulasta/Fulphila/Udenyca Quantity Limit: One (1) 6 mg dose per chemotherapy cycle

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

TIGLUTIK (riluzole)

Review: Tiglutik is a thickened oral suspension of riluzole approved for treatment of amyotrophic lateral sclerosis (ALS) based on bioavailability studies. Riluzole is thought to slow the progression of ALS by reducing the neurotransmitter glutamate-induced excitotoxicity through various mechanisms including inhibition of glutamic acid release, blocking NMDA receptor mediated response, and interfering with glutamate release at voltage-dependent sodium channels.

There were no efficacy trials for Tiglutik, but the approval was based on the safety and efficacy shown in trials for Rilutek tablets and on data from a pharmacokinetic study comparing the bioavailability of Tiglutik oral suspension to Rilutek film coated tablets. In a single-center, open-label, single-dose, randomized, 3-period, 6-sequence, crossover study, patients were randomized to receive the same dosage of riluzole as either Tiglutik suspension or Rilutek tablets in fasting conditions. The study also included a food effect arm to determine if absorption of Tiglutik was decreased with a high fat meal. The study enrolled 36 patients who were non-smokers and met age and weight criteria and included 34 of these patients in the pharmacokinetic evaluation. Bioequivalence was concluded if the ratios of mean $AUC_{0\text{-}inf}$ and C_{max} of test medication to reference medication fall between 80-125%. The study concluded that in fasting conditions the ratios of test medication to reference medication $AUC_{0\text{-}t}$ and $AUC_{0\text{-}inf}$ were 95% and C_{max} was 108% and the primary endpoints for bioequivalence were satisfied. For the food effect arm, C_{max} decrease by approximately 55% while AUC was not significantly affected, and it was determined that the observed food effect on Tiglutik suspension was similar to riluzole tablets.

The bioavailability study showed an increased incidence of oral hypoesthesia in patients receiving Tiglutik suspension compared to Rilutek oral tablets. Other adverse events that occurred more often with Tiglutik suspension were soft feces, headache, and somnolence. The most common adverse events reported with riluzole tablets were nausea, pyrexia, asthenia, dyspnea, increased AST and ALT, fatigue, pneumonia, and dysphagia. Other adverse events reported in more than 10% of patients were weakness, decreased lung function, hypertension abdominal pain, and increased liver function tests. Throat and mouth paresthesia, pharyngeal hypothesia, numbness of tongue, swollen tongue, and mouth and throat swelling have been reported post marketing in Europe. Severe neutropenia (ANC $<500/mm^3$) has also been reported within the first two months of therapy. Interstitial lung disease has occurred and may require discontinuation of therapy. Mild to moderate hepatic impairment increases

AUC and is not recommended in patients with baseline elevations of serum aminotransferases greater than 5 times the upper limit of normal or evidence of hepatic dysfunction.

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 presented. Tricia Heitzman seconded the motion. None were opposed.

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

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

- Prescription written by or in consultation with neurologist AND
- Medical record documentation of age 18 years or older AND
- Medical record documentation of diagnosis of ALS AND
- Medical record documentation of therapeutic failure on, intolerance to, or contraindication to riluzole tablets OR
- Medical record documentation that the patient has dysphagia or is unable to swallow tablets

Quantity Limit: 600 milliliters/30 days

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

OXTELLAR XR (oxcarbazepin)

Review: Oxtellar XR (oxcarbazepine) is indicated for the treatment of partial-onset seizures in patients 6 years and older. Oxtellar XR is available as 150 mg, 300 mg, 600 mg extended-release tablets. It is initiated at 600 mg per day in adult patients and titrated up to 1200 mg/day to 2400 mg/day. For pediatric patients, Oxtellar XR is initiated at 8 mg/kg to 10 mg/kg once daily and titrated to 900, 1200, or 1800 mg/day based on body weight. It is dose adjusted for geriatric patients, those with severe renal impairment, and those using strong CYP3A4 inducers or UGT inducers.

The use of Oxtellar XR for the treatment of partial onset seizures in pediatric patients 6 years of age and older is based on adequate and well-controlled studies of Oxtellar XR in adults, along with clinical trials of immediate-release oxcarbazepine in pediatric patients, and on pharmacokinetic evaluations of the use of Oxtellar XR in pediatric patients. Study 1 included adult patients (n=366) with refractory partial-onset seizures (18 to 65 years of age). Subjects were randomized to 1 of 3 treatment groups either Oxtellar XR 1200 mg/day, Oxtellar XR 2400 mg/day, or placebo. Compared to placebo, both Oxtellar XR 1200 mg/day and Oxtellar XR 2400 mg/day had a reduction in the median percentage change from baseline in seizure frequency per 28 days during the treatment period relative to baseline. Although, the 2400 mg/day group was the only treatment arm to achieve statistical significance.

There are no black box warnings associated with the use of Oxtellar XR. Oxtellar XR is contraindicated in patients with a known hypersensitivity to oxcarbazepine, to any of the components of Oxtellar, or to eslicarbazepine acetate (Aptiom ©). Warnings and precautions include: hyponatremia, anaphylactic reactions and angioedema, cross hypersensitivity reaction to carbamazepine, serious dermatological reactions (SJS and TEN) with an increased risk in patients carrying HLA-B*1502 allele, suicidal behavior and ideation, withdrawal of antiepileptic drugs, drug reaction with eosinophilia and systemic symptoms (DRESS)/multi-organ hypersensitivity, hematologic reactions,

risk of seizures in pregnant women due to gradual decrease in plasma concentrations, and exacerbations of new onset primary generalized seizures has been reported with immediate-release oxcarbazepine. The most common adverse reactions (≥ 5%) in adults were dizziness, somnolence, headache, balance disorder, tremor, vomiting, diplopia, asthenia, and fatigue.

Due to the lack of comparative efficacy and tolerability data in clinical trials, providers must create treatment plans based on a combination of drug, seizure, and patient-specific factors. When selecting an antiepileptic, it is important to distinguish between focal (partial) and generalized epilepsy syndrome. Per UpToDate broad spectrum antiseizure medications used to treat both focal (partial) and generalized onset includes: Briviact, clobazam, felbamate, lamotrigine, levetiracetam, Fycompa, Banzel, topiramate, valproate, and zonisamide. Narrow spectrum antiseizure medications used to treatment focal-onset seizures: carbamazepine, Aptiom, gabapentin, Vimpat, oxcarbazepine, phenobarbital, phenytoin, Lyrica, tiagabine, and vigabatrin.

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 presented. Rajneel Chohan seconded the motion. None were opposed.

Financial Discussion: It was discussed to amend the criteria in that one of the required trials of medication be immediate release oxcarbazepine. Kim Clark made a motion to accept the recommendations as presented. Rajneel Chohan seconded the motion. None were opposed.

Outcome: Oxtellar XR will not be added to the GHP Family formulary. Oxtellar XR will require a prior authorization with the following criteria.

- Medical record documentation of a diagnosis of partial-onset seizures AND
- Medical record documentation of age greater than or equal to 6 years AND
- Medical record documentation of therapeutic failure on, intolerance to, or contraindication to three (3) formulary alternatives, one of which must be oxcarbazepine.

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

ULTOMIRIS (ravulizumab-cwvz)

Review: Paroxysmal nocturnal hemoglobinuria (PNH) is a rare, progressive, hematologic disorder originating from a genetic mutation in hematopoietic stem cells responsible for the formation of key components which protect the cell from destruction through complement activation. A deficiency in CD55 and CD59 complement inhibitor proteins leads to continuous activation of C3, C5, and the terminal complement pathway for all blood lines, particularly red blood cells, resulting in intravascular and extravascular hemolysis.

Ultomiris (ravulizumab) is the second complement inhibitor indicated for the treatment of adult patients with PNH. Ultomiris is a long acting monoclonal antibody that binds the C5 complement protein, inhibiting complement activation and preventing terminal complement-mediated intravascular hemolysis. Ultomiris is derived from the Soliris (eculizumab) with four amino acid substitutions in the eculizumab backbone resulting in a longer terminal half-life allowing for extended dosing interval. Maintenance dosing of Ultomiris is extended to every 8 weeks compared to Soliris maintenance dosing of every 2 weeks. The sustained efficacy of Ultomiris throughout the dosing interval may limit the risk of breakthrough hemolysis and thrombosis resulting from suboptimal C5 blockade, seen in some patients treated with Soliris particularly at the end of the biweekly dosing interval.

The efficacy of Ultomiris compared to Soliris was investigated in two open-label randomized, active-controlled, non-inferiority clinical trials. The first trial included 246 complement-inhibitor naïve patients diagnosed with PNH

confirmed with flow cytometry with LDH levels ≥ 1.5 x ULN and one or more signs and symptoms of PNH. Patients were stratified according to transfusion history and LDH screening level and randomized 1:1 to receive the recommended loading and maintenance dosing regimen of either Ultomiris or eculizumab. The key primary endpoints investigated were transfusion avoidance and hemolysis measured through LDH normalization and key secondary endpoints were percentage change from baseline to day 183 in LDH, change from baseline to day 183 in quality of life assessed on the Functional Assessment of Chronic Illness Therapy (FACIT)- Fatigue score, proportion of patients with breakthrough hemolysis, and proportion of patients with stabilized hemoglobin. Ultomiris achieved non-inferiority to eculizumab for all key primary and secondary endpoints. Superiority testing performed for breakthrough hemolysis did not show a statistical difference between patients treated with Ultomiris and eculizumab

The second trial included 195 adult patients who were clinically stable on eculizumab and had received treatment at the labeled dose for at least 6 months prior to study entry and had an LDH level ≤ 1.5 x ULN at screening. Patients were stratified by transfusion history and randomized 1:1 to receive the recommended loading and maintenance doses of Ultomiris or continue maintenance doses of eculizumab. The key primary endpoint for trial two was hemolysis measured as percentage change in LDH levels from baseline and key secondary endpoints were proportion of patients with breakthrough hemolysis, change from baseline in quality of life assessed with FACIT-Fatigue Scale, transfusion avoidance and proportion of patients with stabilized hemoglobin. Ultomiris achieved non-inferiority to eculizumab for all key primary and secondary endpoints. Superiority testing of percentage change in LDH did not show a statistical difference between patients treated with Ultomiris and eculizumab. In both trials, patients treated with Ultomiris achieved complete terminal compliment inhibition (serum free C5 < 0.5 mcg/mL) by the end of the first infusion and sustained it throughout the endpoint, which was a threshold not consistently met in patients receiving eculizumab.

Ultomiris has a black box warning for life threatening meningococcal infections/sepsis and patients should be vaccinated at least two weeks prior to initiation of Ultomiris. If immediate initiation of Ultomiris is required, patients should receive prophylactic antibiotics for two weeks from the times of vaccination administration to prevent meningococcal infections. Patients also have an increased susceptibility to encapsulated bacterial infections such as Neisseria meningitidis, Streptococcus pneumoniae, Haemophilus influenzae, or Neisseria gonorrhoeae and should be monitored for signs and symptoms of new or worsening infection. During clinical trials, it was found that the safety profile of Ultomiris was similar to that of eculizumab, with the most frequent adverse reactions of upper respiratory tract infection and headache. Other adverse reactions reported were hyperthermia, pyrexia, diarrhea, nausea, and abdominal pain, pain in extremity, arthralgia, and dizziness. Infusion reactions such as lower back pain, drop in blood pressure, or infusion related pain have also occurred but did not require discontinuation of Ultomiris.

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 presented. Keith Hunsicker 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: Ultomiris is a medical benefit and should not be added to the GHP Family pharmacy formulary. Requests for coverage will require the following:

- Prescription is written by a hematologist AND
- Medical record documentation of 18 years of age or older AND
- Medical record documentation of diagnosis of paroxysmal nocturnal hemoglobinuria (PNH) AND
- Medical record documentation of patient being vaccinated with the meningococcal vaccine
- Physician documentation of one of the following:

- member is transfusion-dependent (i.e., has at least 1 transfusion in the 24 months prior to initiation of ravulizumab due to documented hemoglobin less than 7 g/dL in persons without anemic symptoms or less than 9 g/dL in persons with symptoms from anemia) prior to initiation of ravulizumab treatment OR
- there is a significant adverse impact on the insured individual's health such as end organ damage or thrombosis without other cause.

Authorization Duration: Initial Approval will be for 6 months. Subsequent authorizations will be for 6 months and will require:

- Medical record documentation:
  - Hemolysis control measured by lactic acid dehydrogenase (LDH) level less than 1.5 times the upper limit of normal (ULN) AND
  - Reduced need or elimination of transfusion requirements OR
  - Stabilization of hemoglobin levels

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

NOCDURNA (desmopressin)

Review: Nocdurna (desmopressin) is indicated for the treatment of nocturia due to nocturnal polyuria in adults who awaken $\geq$ 2 times per night to void. Desmopressin, a synthetic analog of vasopressin (antidiuretic hormone), binds selectively to vasopressin 2 receptors in the kidney, increasing water reabsorption and reducing urine production. Noctiva is also a desmopressin analog with the same indication but has only been studied in patients 50 years of age and older. Noctiva and Nocdurna are the first two products to be approved in the US for this indication.

In a double-blind trial, 237 women 18 years of age and older with nocturnal polyuria and greater than or equal to 2 voids per night were randomized to receive sublingual desmopressin 27.7 mcg or placebo once daily for 3 months. In a second trial 230 men 18 years of age and older with nocturnal polyuria and great than or equal to 2 voids per night were randomized to receive sublingual desmopressin 55.3 mcg or placebo once daily for 3 months. In both trials, desmopressin significantly reduced the mean number of voids per night compared to placebo. Significantly more patients achieved a $\geq$33% reduction from baseline in mean voids per night with desmopressin than with placebo.

Nocdurna was generally well tolerated in clinical trials, but it can cause severe, potentially life-threatening hyponatremia-continuous monitoring after initiating Nocdurna is very important. Dry mouth, headache, and dizziness occurred with use of desmopressin sublingual tablets in clinical trials. Nocdurna has a black box warning for hyponatremia and is contraindicated for use in patients at increased risk of hyponatremia, such as those who take loop diuretics or corticosteroids or have polydipsia, an eGFR <50 mL/min/1.73 m^2, SIADH (syndrome of inappropriate antidiuretic hormone secretion) or other disorders that cause fluid or electrolyte imbalances or have heart failure or uncontrolled hypertension. The drug is also not recommended for patients at risk of increased intracranial pressure or with a history of urinary retention. The recommended dose for women is lower than that for men because women had a higher incidence of hyponatremia with the 55.3-mcg dose in clinical trials. Fluid intake should be limited from 1 hour before to 8 hours after taking the drug.

Nocdurna' s benefit is fairly small, with a minority of patients showing statistically significant improvement over placebo. However, it is typically well-tolerated, an may be more palatable than a nasal spray dosage form.

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

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

Outcome: Nocdurna should not be added to the GHP Family formulary. The following prior authorization criteria should apply:

- **For Noctiva:** Medical record documentation of age greater than or equal to 50 years

- **For Nocdurna:** Medical record documentation of age greater than or equal to 18 years

AND

- Medical record documentation of a diagnosis of nocturia due to nocturnal polyuria, as defined by a night-time urine production exceeding one-third of the 24-hour urine production confirmed with a 24-hour urine frequency/volume chart **AND**
- Medical record documentation that the patient is waking at least 2 times per night to void **AND**
- Medical record documentation that the patient is not currently hyponatremic (serum sodium < 135 meq/L) and does not have a history of hyponatremia **AND**
- Medical record documentation of an eGFR >50 ml/min/1.73m^2 **AND**
- Medical record documentation that the patient has no diagnosis of syndrome of inappropriate antidiuretic hormone (SIADH) secretion, New York Heart Association (NYHA) class II-IV congestive heart failure, or uncontrolled hypertension **AND**
- Medical record documentation that medication is not being used in combination with a loop diuretic or systemic or inhaled glucocorticoids.

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

- 0.13 gm/day

Nocdurna Quantity Limit: Enter authorizations for both strengths by GPID.

- 27.7 mcg tablet: 1 tablet per day
- 55.3 mcg tablet: 1 tablet per day

Authorization Duration: Initial authorizations will be for a period of **6 months.** Reauthorizations will also be for **6 months** and will require the following:

- Medical record documentation the individual is experiencing clinical benefit from the use of medication **AND**
- Medical record documentation that the patient is not currently hyponatremic (serum sodium < 135 meq/L) and does not have a history of hyponatremia **AND**
- Medical record documentation of an eGFR >50 ml/min/1.73m^2 **AND**
- Medical record documentation that the patient has no diagnosis of syndrome of inappropriate antidiuretic hormone (SIADH) secretion, New York Heart Association (NYHA) class II-IV congestive heart failure, or uncontrolled hypertension **AND**
- Medical record documentation that medication is not being used in combination with a loop diuretic or systemic or inhaled glucocorticoids.

Note: the usual dosage for Nocdurna

- Females: 27.7 mcg once daily sublingually, one hour before bedtime (lower dose for women due to the higher risk of hyponatremia)

- Males: 55.3 mcg once daily sublingually, one hour before bedtime

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

ELZONRIS (tagraxofusp-erzs)

Review: Elzonris, the only approved treatment for blastic plasmacytoid dendritic cell neoplasm (BPDCN) in adults and pediatric patients 2 years and older, is a cytotoxin which targets the immunohistochemical marker CD123 found on nearly all malignant plasmacytoid dendritic cells. Elzonris is a fusion protein of recombinant human interleukin-3 (IL-3) and truncated diphtheria toxin (DT) which inhibits protein synthesis and causes cell death in CD123-expressing cells. It is administered intravenously at a dosage of 12 mcg/kg over 15 minutes once daily on days 1 through 5 in a 21-day cycle. Treatment with Elzonris should continue until disease progression or unacceptable toxicity occurs.

One multi-stage, nonrandomized, open-label, multicenter study evaluated the dosing regimen and the safety and efficacy of Elzonris in patients with first-line and recurrent or refractory BPDCN or AML with an ECOG score of 2 or less and adequate organ function. The primary endpoint investigated during the third stage of the trial was complete response rate in patients with previously untreated BPDCN. Complete response rate included complete response (disappearance from each site of initial disease) and clinical complete response (complete response in which patients had residual skin abnormalities not indicative of active disease). In the 13 patients evaluated, complete response rate was 55% with 3 patients having complete response and 4 patients having a clinical complete response. An observed duration of response ranged from approximately 6.5 months to 12.5 months. A secondary endpoint evaluating complete response of 16 patients treated during Stage 1 and 2 of the trial, showed a complete response rate of 88%. At the time of analysis, two patients were ongoing in the study and a secondary endpoint evaluating duration of response was not reached. Another secondary endpoint measuring the data pooled from all patients with previously untreated BPDCN from the first 3 stages of the study showed a 90% overall response rate (partial response or better). Progression free survival rate and overall survival were not interpretable since it was a single arm study. The study noted that 13 out of the 29 previously untreated patients were successfully bridge to stem-cell transplant while in remission after Elzonris treatment. The survival probabilities in this group at 18 and 24 months were 59% and 52% respectively.

The trial also assessed 15 patients with recurrent or refractory previously treated patients diagnosed with BPDCN (median time since diagnosis 1 year). Only one patient in this population had a complete response and one patient had a clinical complete response, but overall response rate (partial response or better) was 67%. Only one patient was able to successfully bridge to stem cell transplant during disease remission. The median duration of survival in previously treated patients was 8.5 months.

The safety of Elzonris was studied in a total of 162 patients exposed to Elzonris during all stages of the clinical trial as well as three additional trials evaluating the efficacy of Elzonris in the treatment of other diseases. The safety population includes 94 patients who were treated with the recommended dosage (12 mcg/kg/day) for 5 days in a 21-day cycle. Elzonris has a black box warning for capillary leak syndrome with at least 55 % of patients experiencing two or more symptoms of CLS within a 7-day period. Most patients were managed by withholding Elzonris and administering albumin with or without diuretics and steroids, but more severe cases required more supportive measures (vasopressors, ventilator support, dialysis) and in 2 cases led to death. Hypersensitivity reactions were reported in 46% of patients and manifestations of hypersensitivity (rash, pruritis, stomatitis, or, wheezing) were reported in $\geq$ 5 % of patients. Elevations in liver enzymes occurred in 88% of treated patients and Elzonris should be held if ALT or AST rise to more than 5 times the upper limit of normal. No dosage adjustment is needed for mild to moderate renal or hepatic impairment but Elzonris doses should be held if renal or hepatic toxicity occur during treatment.

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 presented. Aubrielle Prater seconded the motion. None were opposed.

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

Outcome: Elzonris is considered a medical benefit requiring prior authorization for GHP Family. The following criteria should apply:

- Prescription being written by hematologist/oncologist AND
- Medical record documentation of age ≥ 2 years AND
- Medical record documentation of diagnosis of Blastic plasmacytoid dendritic cell neoplasm (BPDCN)

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.

GAMIFANT (emapalumab-lzsg)

Review: Gamifant is an interferon gamma (IFNγ) blocking antibody indicated for the treatment of adult and pediatric (newborn and older) patients with primary hemophagocytic lymphohistiocytosis (HLH) with refractory, recurrent or progressive disease or intolerance with conventional HLH therapy. Gamifant is a novel drug that addresses an unmet need for the treatment of primary HLH in patients awaiting HSCT.

The recommended starting dose of Gamifant is 1 mg/kg given as an intravenous infusion over 1 hour twice per week (every three to four days). Doses subsequent to the initial dose may be increased (up to 10 mg/kg, although max dose is not clearly defined) based on clinical and laboratory criteria that may be found in the full prescribing information. After the patient's condition is stabilized, the dose should be decreased to the previous level to maintain clinical response. Administer Gamifant until HSCT is performed or patient experiences unacceptable toxicity. Discontinue Gamifant when a patient no longer requires therapy for the treatment of HLH. Per IPD, most patients will be initiated in an inpatient setting, with potential for outpatient administration following stabilization.

The efficacy of Gamifant was evaluated in a multi-center, single-arm trial with a total of 27 pediatric patients with suspected or confirmed primary HLH with either refractory, recurrent, or progressive disease during conventional HLH therapy or who were intolerant of conventional HLH therapy. The inclusion criteria included: primary HLH based on a molecular diagnosis or family history consistent with primary HLH or 5 out of 8 criteria fulfilled: 1) fever, 2) splenomegaly, 3) cytopenias affecting 2 of 3 lineages in the peripheral blood (hemoglobin < 9, platelets < 100 x 109/L, neutrophils < 1 x 109/L), 4) hypertriglyceridemia (fasting triglycerides > 3 mmol/L or ≥ 265 mg/dL) and/or hypofibrinogenemia (≤ 1.5 g/L), 5) hemophagocytosis in bone marrow, spleen, or lymph nodes with no evidence of malignancy, 6) low or absent NK-cell activity, 7) ferritin ≥ 500 mcg/L, 8) soluble CD25 ≥ 2400 U/mL. Patients also had to have evidence of active disease assessed by treating physician. All patients had received previous HLH treatments. Patients received a median of 3 prior agents before enrollment into the trial. Prior regimens included combinations of the following agents: dexamethasone, etoposide, cyclosporine A, and anti-thymocyte globulin. All patients received dexamethasone as background HLH treatment with doses between 5 to 10

mg/m2/day. Cyclosporine A was continued if administered prior to screening. Patients receiving methotrexate and glucocorticoids administered intrathecally at baseline could continue these treatments. The primary efficacy endpoint of the study was overall response rate (ORR) at the end of Gamifant treatment. Overall response rate was defined as achievement of either a complete or partial response or HLH improvement. Complete response was defined as normalization of all HLH abnormalities. Partial response was defined as ≥ 3 HLH abnormalities and improvement was defined as ≥ 3 HLH abnormalities improved by at least 50% from baseline. The study achieved its efficacy endpoint, with 63% of patients demonstrating an overall response at the end of treatment. Twenty-six percent achieved a complete response, 30% a partial, and 7.4% achieved HLH improvement.

There are no black box warnings or contraindications associated with the use of Gamifant. There are warnings and precautions for infections, increased risk of infections associated with the use of live vaccines, and infusion–related reactions. The most common serious adverse reactions (≥ 3%) included infections, gastrointestinal hemorrhage, and multiple organ dysfunction. Fatal adverse reactions occurred in two (6%) of patients and included septic shock and gastrointestinal hemorrhage. The most commonly reported adverse reactions (≥ 20%) were infections, hypertension, infusion-related reactions, and pyrexia.

Per Amy Ellenburg, pediatric hematology/oncology pharmacist at Geisinger, there are 2 types of HLH: primary and secondary. Oftentimes HLH is a diagnosis of exclusion. Gamifant is only indicated for primary HLH, which must be confirmed by genetic testing to determine if there are gene mutations associated with HLH. Patients should have a confirmed diagnosis of primary HLH prior to switching to Gamifant. This medication should not be used for secondary HLH.

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: Discussion was had as to if we should require genetic testing to confirm diagnosis. It was recommended to amend the criteria initial authorization duration to a shorter interval. Reauthorization would require documentation of genetic testing to substantiate diagnosis. No additional comments or questions. Kevin Szczecina made a motion to accept the recommendations as presented. Tricia Heitzman seconded the motion. None were opposed.

Financial Discussion: No comments or questions. Kim Clark made a motion to accept the recommendations as presented. Tricia Heitzman seconded the motion. Bret Yarczower was opposed.

Outcome: Gamifant will be considered a medical benefit requiring prior authorization for GHP Family members. The following criteria should apply:

- Prescription written by or in consultation with a hematologist or oncologist AND
- Medical record documentation of a diagnosis of <u>primary</u> hemophagocytic lymphohistiocytosis (HLH) based on one of the following:
    - A molecular diagnosis (HLH gene mutations) OR
    - A family history consistent with primary HLH (X-linked lymphoproliferative syndrome) OR
    - 5 out of the following 8 criteria fulfilled:
        - Fever ≥ 38.5ºC
        - Splenomegaly
        - Cytopenias affecting 2 of 3 lineages in the peripheral blood; hemoglobin <9 g/dL, platelets <100 x 10^9/L, neutrophils <1 x 10^9/L
        - Hypertriglyceridemia (fasting triglycerides > 3 mmol/L or ≥ 265 mg/dL) and/or hyperfibrinogenemia (≤1.5 g/dL)
        - Hemophagocytosis in bone marrow, spleen, or lymph nodes with no evidence of malignancy
        - Low or absent NK-cell activity
        - Ferritin ≥ 500 mcg/L

- Soluble CD25 level (i.e. soluble IL-2 receptor) of ≥ 2,400 U/mL

AND

- Medical record documentation of refractory, recurrent or progressive disease or intolerance with conventional HLH therapy (e.g. etoposide, dexamethasone, cyclosporine A, intrathecal methotrexate)

Authorization Duration (for members **without** a confirmed molecular diagnosis): Initial approval will be for 4 weeks or less if the reviewing provider feels it is medically appropriate and will require medical record documentation of a diagnosis of primary hemophagocytic lymphohistiocytosis based on molecular diagnosis (HLH gene mutations). Subsequent approvals will be for an additional 6 months of less if the reviewing provider feels it is medically appropriate and will require medical record documentation of continued disease improvement (e.g. improvement in hemoglobin/lymphocyte/platelet counts, afebrile, normalization of inflammatory factors/markers) or lack of disease progression. The medication will no longer be covered if the member experiences unacceptable toxicity or received a hematopoietic stem cell transplantation.

Authorization Duration (for members **with** a confirmed molecular diagnosis): Initial approval will be for 6 months or less if the reviewing provider feels it is medically appropriate. Subsequent approvals will be for an additional 6 months or less if the reviewing provider feels it is medically appropriate and will require medical record documentation of continued disease improvement (e.g. improvement in hemoglobin/lymphocyte/platelet counts, afebrile, normalization of inflammatory factors/markers) or lack of disease progression. The medication will no longer be covered if the member experiences unacceptable toxicity or received a hematopoietic stem cell transplantation.

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

AEMCOLO (rifamycin)

Review: Aemcolo is an ansamycin antibiotic approved for treatment of travelers' diarrhea caused by non-invasive strains of E. coli in adults. It is not approved for use in patients with diarrhea complicated by fever or bloody stools or caused by pathogens other than E. coli. Antibiotics may be used alone or in combination with antimotility drugs for treatment of moderate to severe travelers' diarrhea, where diarrhea is distressing or incapacitating and interferes with planned activities. Travelers' diarrhea is usually self-limited, resolving with only fluid replacement in 3-5 days. Although antibiotic treatment is not routinely recommended in travelers' diarrhea, some circumstances may warrant treatment which could decrease duration of illness to one to two days.

The efficacy of Aemcolo is shown through two multicenter, double-blind, randomized studies conducted in patients traveling to regions with a high incidence of travelers' diarrhea. The first was a placebo-controlled study in which 264 patients with symptoms indicative of acute travelers' diarrhea were randomized to receive Aemcolo 400 mg or placebo twice daily for 3 days. The outcomes measured were time to last unformed stool (TLUS) and clinical cure, defined as passage of two or fewer unformed stools, no fever, and no symptoms of enteric infection during a 24-hour interval or no unformed stools during a 48-hour interval. The study excluded patients with fever, known infection with non-bacterial pathogen, diarrhea more than 72 hours duration, grossly bloody stool, or severe dehydration. The study found that patients treated with Aemcolo had a significantly shorter median duration of diarrhea as well as a higher rate of clinical cure when compared to placebo. The second trial was a double-dummy comparative study of 835 patients with similar inclusion and exclusion criteria to the first trial. This study compared treatment of travelers' diarrhea with Aemcolo 400 mg and ciprofloxacin 500 mg twice daily and supported the efficacy findings of the first trial. The second trial did include 18 patients who had fever and bloody diarrhea at time of enrollment and found that these patients had a prolonged TLUS when treated with Aemcolo.

The safety of Aemcolo was shown in two controlled clinical trials where patients received Aemcolo 388 mg twice daily for three to four days. Adverse events with the highest incidence were constipation, headache, dyspepsia, abdominal pain, and pyrexia and these events led to discontinuation in 1% of patients studied.

Aemcolo has minimal systemic absorption (bioavailability <0.1%) and has no significant drug interactions but should not be taken with alcohol. There are no black box warnings and the only contraindication is a hypersensitivity to rifamycin or any ansamycin antibiotic. Aemcolo has not been studied in the patients less than 18 years of age and the safety and efficacy is not established in this population. The most frequent adverse reactions were constipation, headache, abdominal pain, pyrexia and dyspepsia. Clostridium difficile-associated diarrhea may occur and should considered in patients who present with diarrhea following use of rifamycin.

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 presented. Tricia Hetizman seconded the motion. None were opposed.

Financial Discussion: No comments or questions. Keith Hunsicker made a motion to accept the recommendations as presented. Kim Clark seconded the motion. None were opposed.

Outcome: Aries Pharmaceutical is currently not participating with CMS. For that reason, Aemcolo will be excluded on the GHP Family formulary. If Aemcolo becomes GHP Family eligible, it is recommended that Aemcolo remain non-formulary. Requests for coverage will require the following:

- Medical record documentation of age 18 or older AND
- Medical record documentation of use for treatment of travelers' diarrhea AND
- Medical record documentation of therapeutic failure on, intolerance to, or contraindication to azithromycin and one oral fluoroquinolones

Quantity Limit: 4 tablets per day
Authorization Duration: 3 days
Rx Count: 1

Based on the findings from the Aemcolo review, it is recommended to update the Xifaxan policy for GHP Family:

<u>Prior Authorization Criteria:</u>

- Medical record documentation of use for treatment of travelers' diarrhea **AND**
- Medical record documentation that member is ≥ 12 years of age **AND**
- Medical record documentation of therapeutic failure on, intolerance to, or contraindication to azithromycin and one oral fluoroquinolone

Approved requests for travelers' diarrhea will be approved for a one-time fill of 9 tablets for three days for 200 mg tablets.

OR

- Medical record documentation of use for the treatment of hepatic encephalopathy

AND

- Medical record documentation of concomitant therapy with lactulose or medical record documentation of therapeutic failure on, intolerance to, or contraindication to lactulose.

Quantity Limit: 60 tablets per 30 days for 550 mg tablet

OR

- Medical record documentation of a diagnosis of moderate to severe IBS with diarrhea AND
- Medical record documentation that the member is at least 18 years of age AND
- Medical record documentation that the correct FDA approved strength/dosing is being prescribed (550 mg three times daily for 14 days) AND
- Medical record documentation of a therapeutic failure on, intolerance to, or contraindication to dicyclomine AND loperamide.

Approved requests should be for a one-time fill of 42 tablets for a 14-day supply. Reauthorization should require the following:

- Medical record documentation that the patient is having a recurrence of symptoms related to IBS-D AND
- Medical record documentation that the patient has not received more than two previous courses of Xifaxan treatment for IBS-D.

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

FAST FACTS

FASLODEX (fulvestrant)

Updated Indication: Faslodex is an estrogen receptor antagonist indicated for the treatment of:
Monotherapy:

- Hormone receptor (HR)- positive, human epidermal growth factor receptor 2 (HER2)-negative advanced breast cancer in postmenopausal women not previously treated with endocrine therapy.
- HR-positive advanced breast cancer in postmenopausal women with disease progression following endocrine therapy.

Combination Therapy:

- HR-positive, HER2-negative advanced or metastatic breast cancer in postmenopausal women in combination with ribociclib (Kisqali ©), as initial endocrine based therapy or following disease progression on endocrine therapy.
- HR-positive, HER2-negative advanced or metastatic breast cancer in combination with palbociclib (Ibrance ©) or abemaciclib (Verzenio ©) in women with disease progression after endocrine therapy.

Recommendations: Faslodex is available without restrictions. No formulary changes are recommended.

Discussion: No comments or questions

Outcome: Kim Clark made a motion to accept the recommendations as presented. 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.

TECENTRIQ (atezolizumab)

Updated Indication: Tecentriq is now indicated:

- in combination with paclitaxel protein-bound, for the treatment of adult patients with unresectable locally advanced or metastatic triple-negative breast cancer (TNBC) whose tumors express PD-L1 (PD-L1 stained tumor-infiltrating immune cells [IC] of any intensity covering ≥1% of the tumor area), as determined by an FDA-approved test (under accelerated approval).
- in combination with carboplatin and etoposide, for the first-line treatment of adult patients with extensive-stage small cell lung cancer (ES-SCLC).

Updated Dosing for New Indication[1]:

- TNBC: Tecentriq 840mg IV over 60 minutes on days 1 and 15 of a 28-day cycle. Paclitaxel protein-bound 100mg/m^2 IV on days 1, 8, and 15 of a 28-day cycle. Treatment should be continued until disease progression or unacceptable toxicity. Tecentriq or paclitaxel protein-bound may be discontinued independently of each other.
- SCLC: Tecentriq 1200mg IV over 60 minutes every 3 weeks until disease progression or unacceptable toxicity.

Recommendations: No changes are recommended to the formulary status of Tecentriq at this time. It is recommended that the current policies are updated to account for the new indications as outlined below.

Breast Cancer

- Prescription written by an oncologist **AND**
- Medical record documentation of a diagnosis of advanced or metastatic triple negative (ER-negative, PR-negative, HER2-negative) breast cancer **AND**
- Medical record documentation that tumors express PD-L1 (greater than or equal to 1%) as determined by an FDA-approved test **AND**
- Medical record documentation that Tecentriq will be used in combination with protein-bound paclitaxel (Abraxane).

Small Cell Lung Cancer (SCLC)

- Prescription written by an oncologist **AND**
- Medical record documentation of a diagnosis of extensive stage small cell lung cancer (ES-SCLC) **AND**
- Medical record documentation that Tecentriq will be used in combination with carboplatin and etoposide **AND**
- Medical record documentation of use as first-line treatment of extensive-stage disease.

Discussion: No comments or questions.

Outcome: Aubrielle Prater 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.

RAVICTI (glycerol phenylbutyrate)

Updated Indication: Ravicti is indicated for use as a nitrogen-binding agent for chronic management of patients with urea cycle disorders (UCDs) who cannot be managed by dietary protein restriction and/or amino acid supplementation alone. Ravicti must be used with dietary protein restriction and, in some cases, dietary supplements (e.g., essential amino acids, arginine, citrulline, protein-free calorie supplements).

Note: Previously, Ravicti was only indicated for use in patients greater than or equal 2 months of age.

Updated Dosing for New Indication: Patients less than 2 years: Give Ravicti in 3 or more equally divided dosages, each rounded up to the nearest 0.1 mL.

Recommendation: There are no recommended changes to formulary status at this time. There are no recommended changes to quantity limits at this time. The following should be removed from the prior authorization criteria to reflect new age indication:

1~~. Patient must be ≥ 2 months of age~~

Discussion: No comments or questions.

Outcome: Aubrielle Prater 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.

NPLATE (romiplostim)

Updated Indication[1]: Nplate is now indicated for the treatment of thrombocytopenia in pediatric patients 1 year of age and older with ITP for at least 6 months who have had an insufficient response to corticosteroids, immunoglobulins, or splenectomy.

Previously, this indication was limited to the adult population.

Dosing for New Indication[1]: The dosing of Nplate in the pediatric population is consistent with that of the adult population. The initial weekly dose is 1mcg/kg based on actual body weight. The dose is adjusted based on platelet response and should not exceed a maximum dose of 10mcg/kg per week.

Current Formulary Status/Prior Authorization Criteria: Brand Tier requiring PA or medical benefit requiring PA

Recommendations: Age is not addressed in the current Nplate policies. Additionally, the alternative treatments required to qualify for treatment within the Nplate policies are appropriate for the pediatric population. Because the current criteria within the Nplate policies continue to be appropriate for the updated age in the new indication, no changes are recommended to the criteria at this time. No changes are recommended to the formulary placement of Nplate at this time.

Discussion: No comments or questions.

Outcome: Todd Sponenberg made a motion to accept the recommendations as presented. 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.

LONSURF (trifluridine and tipiracil)

Updated Indication: Lonsurf is now approved for the treatment of adult patients with metastatic gastric or gastroesophageal junction adenocarcinoma previously treated with at least two prior lines of chemotherapy that included a fluoropyrimidine, a platinum, either a taxane or irinotecan, and if appropriate, HER2/neu-targeted therapy.

Previously, Lonsurf was only indicated for the treatment of patients with metastatic colorectal cancer who have been previously treated with fluoropyrimidine-, oxaliplatin-and irinotecan-based chemotherapy, an anti-VEGF biological therapy, and if RAS wild-type, an anti-EGFR therapy.

Updated Dosing for New Indication: The recommended dosage of Lonsurf for use in the treatment of gastric or gastroesophageal junction adenocarcinoma is body surface area-based dosing of 35 mg/m^2/dose by mouth twice daily with food on days 1 through 5 and days 8 through 12 of each 28-day cycle until disease progression or unacceptable toxicity (Table 1). The maximum recommended dosage is 80 mg of the trifluridine component per dose. This is the same dosage recommended for the previously approved indication of metastatic colorectal cancer.

Recommendations: No changes are recommended to the formulary status of Lonsurf at this time. It is recommended that the current policies be updated to include the new indications as outlined below. There is no change recommended to the current quality limitations and authorization duration and they should be applied to the new indication.

Metastatic Colorectal Cancer

- Must be prescribed by a hematologist or oncologist **AND**
- Medical record documentation of the patient being ≥ 18 years of age **AND**
- Medical record documentation of a diagnosis of metastatic colorectal cancer **AND**
- Medical record documentation of previous treatment with fluoropyrimidine-, oxaliplatin-, and irinotecan-based chemotherapy, an anti-VEGF biological therapy, and if RAS wild-type, an anti-EGFR therapy

Metastatic Gastric or Gastroesophageal Junction Adenocarcinoma

- Must be prescribed by a hematologist or oncologist **AND**
- Medical record documentation of the patient being ≥ 18 years of age **AND**
- Medical record documentation of diagnosis of metastatic gastric or gastroesophageal junction adenocarcinoma **AND**

- Medical record documentation of previously treatment with at least two prior lines of chemotherapy that included a fluoropyrimidine, a platinum, either a taxane or irinotecan and if appropriate, HER2/neu-targeted therapy.

Quantity Limit:

15 mg/6.14 mg tablet – 100 tablets per 28 days
20 mg/8.19 mg tablet – 80 tablets per 28 days

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

Discussion: No comments or questions.

Outcome: Todd Sponenberg 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.

IBRANCE (palbociclib)

Updated Indication: Ibrance is now indicated for the treatment of adult patients with hormone receptor (HR)-positive, human epidermal growth factor receptor 2 (HER2)-negative advanced or metastatic breast cancer in combination with:

- An aromatase inhibitor as initial endocrine-based therapy in postmenopausal women or in men; or
- Fulvestrant in patients with disease progression following endocrine therapy.

Note: Previously, Ibrance was indicated for the treatment of HR- positive, HER2-negative advanced or metastatic breast cancer in combination with:

- An aromatase inhibitor as initial endocrine-based therapy in postmenopausal women; or
- Fulvestrant in women with disease progression following endocrine therapy.

Updated Dosing for New Indication: There was no update to the recommended dose. The recommended starting dose is still 125 mg once daily taken with food for 21 days followed by 7 days off treatment. Pre/perimenopausal women treated with Ibrance plus fulvestrant therapy should also be treated with an LHRH agonist according to current clinical practice standards. For men treated with Ibrance plus aromatase inhibitor therapy, consider treatment with an LHRH agonist according to current clinical practice standards.

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.

Ibrance as Initial Endocrine Therapy

- Prescription written by an oncologist AND
- Medical record documentation of a diagnosis of hormone-receptor positive, HER2 negative, advanced or metastatic breast cancer AND
- Ibrance is being prescribed as initial endocrine based therapy AND

- Medical record documentation that Ibrance will be prescribed in combination with an aromatase inhibitor (i.e. letrozole, etc.)

Ibrance Following Disease Progression on Endocrine Therapy

- Prescription written by an oncologist AND
- Medical record documentation of a diagnosis of hormone-receptor positive, HER2 negative, advanced or metastatic breast cancer AND
- Ibrance is being prescribed after disease progression following endocrine therapy AND
- Medical record documentation that Ibrance is being used in combination with fulvestrant

Discussion: No comments or questions.

Outcome: Rajneel Chohan 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.

KEYTRUDA (pembrolizumab)

Updated Indication: Keytruda is now indicated for the adjuvant treatment of patients with melanoma with involvement of lymph node(s) following complete resection.

Previously, for patients with melanoma, Keytruda was only FDA approved for patients with unresectable or metastatic disease.

Keytruda is also now indicated, as a single agent, for the first-line treatment of patients with stage III NSCLC who are not candidates for surgical resection or definitive chemoradiation, or metastatic NSCLC, and whose tumors express PD-L1 [Tumor Proportion Score (TPS) ≥1%] as determined by an FDA-approved test, with no EGFR or ALK genomic tumor aberrations.

This indication replaces the previous indication of first-line treatment of patients with metastatic NSCLC whose tumors have high PD-L1 expression [Tumor Proportion Score (TPS) ≥50%] as determined by an FDA-approved test, with no EGFR or ALK genomic tumor aberrations.

Keytruda is now indicated in combination with axitinib for the first-line treatment of patients with advanced renal cell carcinoma (RCC).

Previously, Keytruda did not maintain any indications for RCC.

Keytruda maintains its other FDA approved indications for HNSCC, cHL, PMBCL, HCC, MCC, urothelial carcinoma, MSI-H/dMMR cancer, gastric cancer, and cervical cancer.

Updated Dosing for New Indication: The recommended dose of Keytruda for the adjuvant treatment of patients with melanoma is 200mg IV over 30 minutes every three weeks until disease recurrence, unacceptable toxicity, or for up to 12 months in patients without disease recurrence.

The recommended dose of Keytruda in RCC is 200mg IV over 30 minutes every 3 weeks in combination with 5mg of axitinib twice daily until disease progression, unacceptable toxicity, or for up to 24 months in patients without disease progression. Dose escalation of axitinib may be appropriate as directed by the prescribing information.

No changes to the recommended dosing for NSCLC.

Recommendations: No changes are recommended to the formulary status of Keytruda at this time. It is recommended that the current policies are updated to account for the new indications as outlined below. It is recommended that the authorization duration of Keytruda be updated as outlined below.

Melanoma

- Prescription written by a hematologist/oncologist **AND**
- Medical record documentation that patient is ≥ 18 years of age **AND**
- Medical record documentation of one of the following:

  Unresectable or metastatic melanoma:
  - A diagnosis of unresectable or metastatic melanoma **AND**
  - Keytruda is not being used in combination with any other agents for the treatment of unresectable or metastatic melanoma.

  OR

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

Metastatic Non-Small Cell Lung Cancer (NSCLC)

- Prescription written by a hematologist/oncologist **AND**
- Medical record documentation that patient is ≥ 18 years of age **AND**
- Medical record documentation of a diagnosis of metastatic NSCLC meeting one of the following situations:
  - Medical record documentation of stage III NSCLC, metastatic NSCLC, OR that the member is not a candidate for surgical resection or definitive chemoradiation **AND**
  - Medical record documentation that Keytruda is being used as first-line treatment **AND**
  - Medical record documentation that Keytruda is being given as monotherapy **AND**
  - ~~Medical record documentation that tumors have high PD-L1 expression (Tumor Proportion Score (TPS)≥50% as determined by an FDA-approved test **AND**~~
  - Medical record documentation that tumors express PD-L1 (TPS) ≥1% as determined by an FDA-approved test **AND**
  - Medical record documentation that tumors do not have EGFR or ALK genomic tumor aberrations

  OR
  - Medical record documentation of metastatic nonsquamous NSCLC **AND**
  - Medical record documentation that Keytruda will be given in combination with pemetrexed AND either carboplatin or cisplatin **AND**
  - Medical record documentation that tumors do not have EGFR or ALK genomic tumor aberrations

  OR
  - Medical record documentation that Keytruda will be given in combination with carboplatin AND either paclitaxel or nab-paclitaxel **AND**
  - Medical record documentation that Keytruda, carboplatin, and paclitaxel (or nab-paclitaxel) are being used as first-line treatment.

  OR
  - Medical record documentation that Keytruda is being given as monotherapy **AND**

- Medical record documentation that tumors express PD-L1 (TPS) ≥1% as determined by an FDA-approved test **AND**
- Medical record documentation of disease progression on or after platinum-containing chemotherapy **AND**
- For patients with EGFR or ALK genomic tumor aberrations: medical record documentation of disease progression on FDA-approved therapy for these aberrations prior to receiving Keytruda.

Renal Cell Carcinoma (RCC)

- Prescription written by a hematologist/oncologist **AND**
- Medical record documentation that patient is ≥ 18 years of age **AND**
- Medical record documentation of a diagnosis of advanced renal cell carcinoma **AND**
- Medical record documentation that Keytruda is being used in combination with axitinib (Inlyta) **AND**
- Medical record documentation that Keytruda and axitinib (Inlyta) are being used as first-line treatment for advanced disease

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

- For patients with EGFR or ALK genomic tumor aberrations: medical record documentation of disease progression on FDA-approved therapy for these aberrations prior to receiving Keytruda.

Renal Cell Carcinoma (RCC)

- Prescription written by a hematologist/oncologist **AND**
- Medical record documentation that patient is ≥ 18 years of age **AND**
- Medical record documentation of a diagnosis of advanced renal cell carcinoma **AND**
- Medical record documentation that Keytruda is being used in combination with axitinib (Inlyta) **AND**
- Medical record documentation that Keytruda and axitinib (Inlyta) are being used as first-line treatment for advanced disease

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

AUTHORIZATION DURATION:

For adjuvant treatment of metastatic melanoma (completely resected melanoma):

Initial approval will be for **6 months** or less if the reviewing provider feels it is medically appropriate. One subsequent approval will be for an additional **6 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.

Authorization of Keytruda for the adjuvant treatment of metastatic melanoma should not exceed the FDA-approved treatment duration of 1 year (12 months). For requests exceeding the above limit, medical record documentation of the following is required:

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

For all other indications:

Initial approval will be for **6 months** or less if the reviewing provider feels it is medically appropriate. Subsequent approvals will be for an additional **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.

Discussion: No comments or questions.

Outcome: Kevin Szczecina 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.

UPDATES

UPTRAVI QUANTITY LIMIT UPDATE

Current Quantity Limits:

Medicaid:
- Uptravi 200 mcg tablet: 240 tablets per 30 days
- Uptravi 200-800 mcg tablet: 200 tablets per 180 days
- Uptravi 400 mcg tablet: 60 tablets per 30 days
- Uptravi 600 mcg tablet: 60 tablets per 30 days
- Uptravi 800 mcg tablet: 60 tablets per 30 days
- Uptravi 1000 mcg tablet: 60 tablets per 30 days
- Uptravi 1200 mcg tablet: 60 tablets per 30 days
- Uptravi 1400 mcg tablet: 60 tablets per 30 days
- Uptravi 1600 mcg tablet: 60 tablets per 30 days

Quantity Limit Recommendations:
For all lines of business, the quantity limit for Uptravi should be updated to the following:

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).
- Uptravi 200 mcg tablet: 140 tablets per 28 days
- Uptravi 200-800 mcg tablet: 200 tablets per 28 days, one (1) fill per 180 days
- Uptravi 400 mcg tablet: 60 tablets per 30 days
- Uptravi 600 mcg tablet: 60 tablets per 30 days
- Uptravi 800 mcg tablet: 60 tablets per 30 days
- Uptravi 1000 mcg tablet: 60 tablets per 30 days
- Uptravi 1200 mcg tablet: 60 tablets per 30 days
- Uptravi 1400 mcg tablet: 60 tablets per 30 days
- Uptravi 1600 mcg tablet: 60 tablets per 30 days

Discussion: No comments or questions.

Outcome: Todd Sponenberg made a motion to accept the recommendations as presented. 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.

COPAXONE

Current Formulary Status:
Medicaid

- Copaxone: Brand Tier
- Glatiramer: Generic Tier

Specialist Feedback: Neurology at Geisinger discussed generic Copaxone at a recent ProvenCare meeting. Some providers said patients are experiencing more injection site reactions with glatiramer acetate and are transitioning back to Copaxone. However, they agreed that all patients should try generic initially and switch back to Copaxone if necessary. Also, they have not seen any differences in outcomes for patients that have already been switched to generic.

Recommendations:
It is recommended to make Copaxone non-formulary for all lines of business. The following prior authorization criteria should apply:

- Medical record documentation of therapeutic failure on, intolerance to, or contraindication to glatiramer acetate

Quantity Limits (entered by GPID):
Copaxone 20 mg/mL: 30 mL per 30 days
Copaxone 40 mg/mL: 12 mL per 28 days

Discussion: No comments or questions.

Outcome: Kim Clark 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.

ENVARSUS XR AND ASTAGRAF XL UPDATE

Summary: Geisinger Health Plan currently covers Astagraf XL as the single preferred long acting tacrolimus product. The Geisinger Transplant surgery team requested a review of Envarsus XR asked for consideration of addition to the formulary.

Current Formulary Status/Prior Authorization Criteria:
Astagraf XL is a pharmacy benefit and is currently available on the GHP Family formulary at the Brand Tier. A prior authorization is required for a BvD benefit determination.

Envarsus XR is a pharmacy benefit and is currently non-formulary. The following criteria apply:

- Prescription must be ordered by a physician experienced in immunosuppressive therapy and management of transplant patients **AND**

- Medical record documentation of kidney transplant **AND**
- Member must be at least 16 years of age or older **AND**
- Medical record documentation of one of the following:
    - Appropriate conversion from immediate-release tacrolimus (using 80% of pre-conversion daily dose of tacrolimus IR) **OR**
    - Use for de novo kidney transplant
      AND
- Medical record documentation of rationale for not using Astagraf XL if clinically appropriate.

Recommendations:
Recommend adding Envarsus XR to the Brand tier for the GHP Family formulary. No prior authorization criteria should apply.

Recommend removing Astagraf XL from GHP Family formulary. A prior authorization for <u>new starts</u> should apply:

- Medical record documentation that Astagraf XL is prescribed by a physician experienced in immunosuppressive therapy and management of transplant patients **AND**
- Medical record documentation of kidney transplant **AND**
- Medical record documentation of age greater than or equal to 4 years **AND**
- If 18 years and older, medical record documentation of rationale for not using Envarsus XR, if clinically appropriate

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.

POTELIGEO POLICY UPDATE

Poteligeo is a CC chemokine receptor type 4 (CCR4)-directed monoclonal antibody indicated for the treatment of adult patients with relapsed or refractory mycosis fungoides or Sézary syndrome after at least one prior systemic therapy.

Mycosis fungoides and Sézary syndromes are the most common types of cutaneous T cell lymphoma (CTCL). It has been brought to our attention that approximately one-third of patients currently treated with Poteligeo are being treated by a dermatologist, but our current prior authorization policy only allows for prescribing by a hematologist or oncologist.

Recommendations: It is recommended that the prescriber criterion in the medical policy is updated to:

- Prescription is written by a hematologist, oncologist, or dermatologist

Discussion: No comments or questions.

Outcome: Tricia Heitzman 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.

HUMIRA UPDATE

Current Quantity Limits:

GHP Family-

- For RA:
  - Biweekly dosing: 2 syringes per 28 days
  - Weekly dosing: 4 syringes per 28 days
- PJIA or juvenile RA:
  - ≥ 30 kg: 2 syringes per 28 days for the 40 mg/0.8 mL (by GPID)
  - 15 kg to < 30 kg: 2 syringes per 28 days for the 20 mg/0.4 mL (by GPID)
  - 10 kg to < 15 kg: 2 syringes per 28 days for the 10 mg/0.2 mL (by GPID)
- PsA:
  - 2 syringes per 28 days
- AS:
  - 2 syringes per 28 days
- Crohn's
  - Adults and peds ≥ 40 kg: one-week auth for QL 6 syringes per 28 days; remainder of 6 month auth, QL 2 syringes per 28 days (biweekly), QL of 4 syringes per 28 days (weekly)
  - Peds < 40 kg: one-week auth for QL 3 syringes per 28 days for the 40 mg/0.8 mL strength (by GPID); remainder of 6 month auth, QL 2 syringes per 28 days for the 20 mg/0.4 mL strength (biweekly), QL of 4 syringes per 28 days (weekly) (by GPID)
- PP:
  - One-week auth for QL 4 syringes per 28 days; remainder of the 6 month auth duration, QL 2 syringes per 28 days
- UC
  - One week auth for QL 6 syringes per 28 days; remainder of the 6 month auth duration, QL 2 syringes per 28 days (biweekly), QL of 4 syringes per 28 days (weekly)
- HS
  - One-week auth for QL of 6 syringes per 28 days; remainder of the 6 month auth duration, QL 4 syringes per 28 days
- Uveitis:
  - One-week auth for QL 4 syringes per 28 days; remainder of the 6 month auth duration, QL 2 syringes per 28 days

Quantity Limit Recommendations: It is recommended to update the quantity limits in the policy to the following

It is recommended to update the quantity limits in the policy to the following:

GHP Family:

- For RA:
  - Biweekly dosing: 2 syringes per 28 days
  - Weekly dosing: 4 syringes per 28 days

- PJIA or juvenile RA:
  - ≥ 30 kg: 2 syringes per 28 days for the 40 mg/0.8 mL or 40 mg/0.4 mL (by GPID)
  - 15 kg to < 30 kg: 2 syringes per 28 days for the 20 mg/0.4 mL or 20 mg/0.2 mL (by GPID)
  - 10 kg to < 15 kg: 2 syringes per 28 days for the 10 mg/0.2 mL or 10mg/0.1 mL (by GPID)
- PsA:
  - 2 syringes per 28 days
- AS:
  - 2 syringes per 28 days
- Crohn's
  - Adults and peds ≥ 40 kg biweekly:
    - If request is for Humira Pen Crohn's, UC-HS 40 mg/0.8 mL (6 pack pen kit) starter: one-week auth for QL 6 syringes per 28 days (by GPID); remainder of 6 month auth, QL 2 syringes per 28 days
    - If request is for Humira CF Crohn's-UC-HS 80 mg/0.8 mL (3 pack pen kit) or Humira CF pediatric Crohn's 80/0.8 mL (3 pack syringe kit) starter: one-week auth for QL 3 syringes per 28 days (by GPID); remainder of 6 month auth, QL 2 syringes per 28 days
  - Peds < 40 kg:
    - If request is for Humira Ped Crohn's 40 mg/0.8 mL (3 pack syringe kit) starter: one-week auth for QL 3 syringes per 28 days (by GPID); remainder of 6 month auth, QL 2 syringes per 28 days for the 20 mg/0.4 mL or 20mg/0.2 mL strength (by GPID)
    - If the request is for the Humira CF Ped Crohn's 80 mg- 40 mg syringe (2 pack syringe kit) starter: one-week auth for QL 2 syringes per 28 days (by GPID); remainder of 6 month auth, QL 2 syringes per 28 days for the 20 mg/0.4 mL or 20mg/0.2 mL strength (by GPID)
  - Crohn's weekly: 4 syringes per 28 days
- PP:
  - If the request is for the Humira Pen Psor-uveitis-adol HS 40mg/0.8 mL (4 pack pen kit) starter: One-week auth for QL 4 syringes per 28 days by GPID); remainder of the 6 month auth duration, QL 2 syringes per 28 days
  - If the request is for Humira CF Pen Psor-UV-Adol-HS 80 mg-40 mg (3 pack pen kit) starter: One-week auth for QL 3 syringes per 28 days by GPID); remainder of the 6 month auth duration, QL 2 syringes per 28 days
- UC
  - If request is for Humira Pen Crohn's, UC-HS 40 mg/0.8 mL (6 pack pen kit) starter: one-week auth for QL 6 syringes per 28 days (by GPID); remainder of 6 month auth, QL 2 syringes per 28 days
  - If request is for Humira CF Crohn's-UC-HS 80 mg/0.8 mL (3 pack pen kit) starter: one-week auth for QL 3 syringes per 28 days (by GPID); remainder of 6 month auth, QL 2 syringes per 28 days
  - Weekly dosing: 4 syringes per 28 days
- HS
  - Adult HS:
    - If request is for Humira Pen Crohn's, UC-HS 40 mg/0.8 mL (6 pack pen kit) starter: one-week auth for QL 6 syringes per 28 days (by GPID); remainder of the 6 month auth duration, QL 4 syringes per 28 days
    - If request is for Humira CF Crohn's-UC-HS 80 mg/0.8 mL (3 pack pen kit) starter: one-week auth for QL 3 syringes per 28 days (by GPID); remainder of the 6 month auth duration, QL 4 syringes per 28 days
  - Age 12- 18 years weighing 30 to <60 kg:
    - If request is for Humira Psor-Uveitis-Adol-HS starter 40 mg/0.8 mL (4 pack kit): one-week auth for QL 4 syringes per 28 days (by GPID); remainder of 6 month auth, QL 2 syringes per 28 days

        - If the request is for the Humira CF Pen Psor-UV-Adol HS 80 mg-40 mg (3 pack kit) starter: one-week auth for QL 3 syringes per 28 days (by GPID); remainder of 6 month auth, QL 2 syringes per 28 days
    - Age 12-18 years weighing > 60 kg:
        - If request is for Humira Pen Crohn's, UC-HS 40 mg/0.8 mL (6 pack pen kit) starter: one-week auth for QL 6 syringes per 28 days (by GPID); remainder of 6 month auth, QL 4 syringes per 28 days
        - If request is for Humira CF Crohn's-UC-HS 80 mg/0.8 mL (3 pack pen kit) starter: one-week auth for QL 3 syringes per 28 days (by GPID); remainder of 6 month auth, QL 4 syringes per 28 days
- Uveitis:
    - If the request is for Humira Pen Psor-uveitis-adol HS 40 mg/0.8 mL (4 pack pen kit), one-week auth for QL 4 syringes per 28 days; remainder of the 6 month auth duration, QL 2 syringes per 28 days
    - If the request is for Humira CF Pen Psor-UV-Adol-HS 80 mg-40 mg pen kit (3 pack pen kit), one-week auth for 3 pens per 28 days; remainder of the 6 month auth duration, QL 2 syringes per 28 days
    - Pediatric Uveitis:
        - ≥ 30 kg: 2 syringes per 28 days for the 40 mg/0.8 mL or 40 mg/0.4 mL (by GPID)
        - 15 kg to < 30 kg: 2 syringes per 28 days for the 20 mg/0.4 mL or 20 mg/0.2 mL (by GPID)
        - 10 kg to < 15 kg: 2 syringes per 28 days for the 10 mg/0.2 mL or 10mg/0.1 mL (by GPID)

Discussion: No comments or questions.

Outcome: Todd Sponenberg 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.

MAY 2019 DUR/ADHERENCE UPDATE
Drug Use Evaluations (DUEs)

- Congestive Heart Failure DUE
    - This is the 2019 2nd quarter MedImpact DUE for GHP Family
    - We are currently in the process of identifying members who have a presumed diagnosis of heart failure taking metoprolol succinate, carvedilol, or bisoprolol, and who were not taking an angiotensin-converting enzyme inhibitor (ACEI) or angiotensin II receptor blocker (ARB) drug therapy in a 3-month timeframe.
- Coronary Artery Disease DUE
    - This is the 2019 1st quarter MedImpact DUE for all LOBs
    - From this report, we identified **100 members** age 40-75 years who are not on a statin drug therapy in a 3-month timeframe and who have at least one of the following cardiovascular disease (CVD) risk factors: diabetes, hypertension, or smoking.
    - Brandy P. completed the mail merge and sent out the letters to the member's providers on 2/19/2019
- Polypharmacy DUE
    - This is the 2018 4th quarter MedImpact DUE for all LOBs

- From this report, we identified **95 members** who were receiving more than 10 unique, chronic medications from 3 or more prescribers over a 3-month timeframe
- Brandy P. completed the mail merge and sent out the letters to their providers on 12/17/2018.
- Adam K. was able to re-run the data on this population vs. a control population on 4/30/19. The population we sent letters to had an 8.9% decrease in total claims after the letters were sent compared to the control population which had an 8.6% decrease in total claims.

- Statin Use in Persons with Diabetes (SUPD)
  - This is the 2018 3rd quarter MedImpact DUE for GHP Family
  - From this report, we identified **99 members** whose medication history was suggestive of the presence of diabetes and who were not receiving a statin drug during the previous three-month period.
  - Brandy P. completed the mail merge and sent out the letters to their providers on 09/13/2018.
  - Adam K. was able to re-run the data on this population on 4/19/19 and of the of original 99 members that we sent letters to 81 members are still active. Of those 81 members 27 members now have a claim for a statin medication. This equates to 33.3% of the members.

In Progress

- Tobacco Cessation Program
  - Quarterly meeting with Wellness/MTDM RPhs to create a program that identifies GHP members who may benefit from tobacco cessation interventions/medications.
  - We gathered drug utilization data to determine which medications are being commonly prescribed and assessed proper utilization. We also informed the group of the Chantix updates approved at the March 2018 P&T meeting: Chantix was added to the Brand Tier for GHP Family without prior authorization.
  - We are in the process of making changes to the report and should start sending out letters/brochures to members June 2019 as both the brochure and letter have been approved by DHS
- Antidepressant Medication Management
  - Kayla Stanishefski will run this proactive HEDIS report **monthly,** and we will send letters to the flagged members who appear non-adherent to their antidepressant medications for **all LOBs**.
- Asthma Medication Ratio
  - Kayla Stanishefski will run this proactive HEDIS report **monthly,** and we will send letters to the flagged members who have a ratio of controller to total asthma medications of < 0.5 **for the Medicaid LOB.**
- Medication Management for People with Asthma
  - Kayla Stanishefski will run this proactive HEDIS report **monthly,** and we will send letters to the flagged members who appear non-adherent to their asthma controller medications **for the Medicaid LOB.**

Ongoing

- DUR Duplicate Anticoagulant Report
  - We get this report **weekly** for **all LOBs** flagging members filling duplicate anticoagulant medications. We personally reach out to the providers/pharmacy of the flagged members to confirm proper medication therapy.
    - For GHS30 in 2019 we have reviewed **41 members** and have made interventions for **4 members**
- Duplicate Specialty Therapy

- We run an in-house retrospective report **quarterly** for **all LOBs** with help from Adam Kelchner and Aubrielle Prater. These members are identified and written up and sent to a medical director if follow up is needed.
    - For Family 2019-we have received the 2019 Q1 report but have not yet reviewed the members yet

- Duplicate Buprenorphine Therapy
    - We are getting this report **quarterly** with help from Adam Kelchner. The report works to identify members who have at least a 7 day overlap period of generic Buprenorphine and generic Buprenorphine/naloxone products. Members identified as being on both products are being forwarded to Dr. Meadows for further outreach.
        - For GHS30 in 2019 we have reviewed **4 members**, no outreach is needed at this time.
- Suboxone with an Opioid Report
    - We are getting this report **weekly** for **all LOBs** from Adam Kelchner and we are writing up each member that flags on the report. These members are being forwarded to Dr. Meadows, and he is looking into whether it is appropriate to end the opioid authorizations still in place
    - For GHS30 in 2019, we have reviewed **45 new members**, and **11 members** were referred to Dr. Meadows
- Ending Opioid Authorizations
    - We are working on identifying members who have active opioid authorizations in place but have since started Buprenorphine therapy. The letter is sent to the members notifying them the opioid authorization has been ended due to the start of buprenorphine therapy.
    - For GHS30 in 2019, we have sent **14 members** letters notifying them of the end of their opioid authorization
- Medicaid Opioid Overutilization Report
    - We are getting this report **monthly** from MedImpact and we are writing up each member that flags on the report. We have been monitoring the members that are continuously showing up on the report by any change in their MED. For those members we deem appropriate we will send a letter to their PCP.
    - For GHS30 in 2019, we have reviewed **6 cases** so far and did not send any prescriber letters
- FWA Reports
    - We are getting this report **weekly** for **all LOBs** from Marie Strausser. We prepare this report by determining which claims need to be verified, and the Wilkes pharmacy students/GHP technicians have been making the calls to pharmacies.
    - We review claims for anti-hypertensives, statins, 1-day supply, and inhalers
    - For GHS30 in 2019, we have reviewed **151 cases** so far and **corrected 116 claims**, resulting in a **cost savings of $10,534.7**
- Stent Antiplatelet Adherence Program
    - We continue to identify new stent patients for **all LOBs** at GMC/GWV/CMC/Susq and follow these members for 1 year after discharge to ensure adherence to their aspirin, beta blocker, antiplatelet, and statin therapy regimens.
    - For GHS30 in 2019, we have identified and outreached to **40 new stent patients**
- Severity Report
    - This is a **monthly** report for **all LOBs** on members who have filled a medication that has a level one interaction with another medication they have a claim for
    - For GHS30 in 2019, we have sent letters to providers on **64 GHP Family members**
- Duplicate Antipsychotics

- Adam Kelchner runs this report **quarterly**, and we send letters to the PCPs to address potential duplicate therapy issues.
- 1Q2019 report was received on 4/16/18 included **140 members** with multiple antipsychotics. We sent these members to Brandy Powell who completed the mail merge and sent letters 4/18/19.

- Adherence to Antipsychotics for Individuals with Schizophrenia (SAA)
  - Kayla Stanishefski runs this report **monthly,** and we send letters to the flagged members who appear non-adherent to their antipsychotic medications.
  - HEDIS Specifications: The percentage of members 19-64 years of age during the measurement year with schizophrenia or schizoaffective disorder who were dispensed and remained on an antipsychotic medication for at least 80% of their treatment period.
  - For GHS30 in 2019, we have not sent any letters to **members as of yet.** Awaiting the 1st proactive HEDIS report of the year.
- Enbrel Overutilization for Treating Plaque Psoriasis
  - A **monthly** report was created to determine members who have been overutilizing Enbrel twice weekly dosing as outlined by the FDA approved dose. One (1) member flagged on the February 2019 report, and the case was written up and sent to Dr. Yarczower on 2/13/19. The member has since switched to once weekly dosing.
    - We put in place QLs for Enbrel, so we should not be seeing these cases moving forward for new starts and at re-authorization periods for members currently on therapy
    - Working on follow up to ensure members are on proper therapy.

Completed

- Medicaid DUR/FWA Program Fliers
  - Last updated 12/2018 next update June 2019
- Current Provider Letters
    - Congestive Heart Failure DUE
    - Coronary Artery Disease DUE
    - Polypharmacy DUE
    - Statin Use in Persons with Diabetes DUE
    - Adherence to Antidepressants DUE
    - Asthma Med Ratio DUE
    - Opioid Overutilization
    - Duplicate Antipsychotics
    - Severity Report
    - Duplicate Anticoagulant Report
- Current Member Letters
    - Ending opioid Authorizations
    - Stent Antiplatelet Adherence Program
    - Adherence to Antipsychotics-SAA
    - Antidepressant Medication Management-AMM

Discussion: No comments or questions.

Outcome: Presented material was informational only. No voting necessary.

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

KUVAN UPDATE

Current formulary status/Prior authorization criteria:
GHP Family- Kuvan is a pharmacy benefit available at the Brand tier. Kuvan requires a prior authorization with the following criteria (policy 1031.0F).

- Prescription is written by a metabolic specialist.
- A diagnosis of hyperphenylalaninemia (as confirmed by lab values).
- The patient is on and compliant with a Phe-restricted diet.
- Initial approval will be given for 8 weeks of therapy. At minimum the patient must have a baseline blood Phe level drawn before initiating therapy and repeat levels at 7 days, 4 weeks, and 8 weeks after initiating therapy. After 8 weeks a re-review will occur. If the patient is a responder (30% or greater reduction from baseline in blood Phe at week 8) the authorization will be extended indefinitely.

Authorization duration: Initial approval will be given for 8 weeks of therapy. At a minimum the patient must have a baseline blood Phe level drawn before initiating therapy and repeat levels at 7 days, 4 weeks, and 8 weeks after initiating therapy. After 8 weeks a re-review will occur. If the patient is a responder, defined as 30% or greater reduction from baseline in blood Phe at week 8, the authorization will be extended indefinitely.

Recommendations from National Agencies or Organizations[2]:

Per UpToDate, classic PKU results in a complete enzyme deficiency and in an untreated, newly diagnosed newborn infant the serum Phe plasma concentrations exceed 1200 micromol/L. Residual enzyme activity causes moderate PKU (Phe concentrations 900 to 1200 micromol/L), mild PKU (Phe concentrations 600 to 900 micromol/L), mild hyperphenylalaninemia (Phe concentrations 360 to 600 micromol/L), and benign mild HPA that typically does not require treatment (Phe concentrations 120 to 360 micromol/L). UpToDate recommends treating newborns with persistent Phe levels of 6 to 10 mg/dL (360 to 600 micromol/L). Treatment for elevated but lower levels of Phe (<360 micromol/L) is controversial.

Per the American College of Medical Genetics and Genomics (ACMG) guidelines, patients with mild PAH deficiency are most likely to respond to Kuvan because some stable protein is required for sapropterin to function. However, patients with complete PAH deficiency have even responded. Kuvan responsiveness is commonly determined by obtaining a baseline blood Phe at baseline and then starting the patient on 20 mg/kg/day of Kuvan. Additional blood Phe levels are obtained at regular intervals, usually at 24 hours, 1 week, 2 weeks, and 3 or 4 weeks. Testing at a dose less than 20 mg/kg is not recommended. Clinical judgement is required to determine a beneficial decline; however, 30% reduction is often cited as evidence of effective Phe reduction. For patients with a baseline Phe level at the lower end of the treatment range rarely show a significant decline in Phe level, even if they are responsive. In these patients, responsiveness is determined by adding additional Phe to the diet to determine if tolerance is achieved. An improvement in neuropsychiatric symptoms or an increase in Phe tolerance without a decrease in blood Phe in any patient is sufficient justification to continue therapy.

Recommendations: There are no recommended changes to formulary status at this time. However, it is recommended to update the Kuvan polices for all the lines of business to the following:

- Medical record documentation that Kuvan is prescribed by a metabolic specialist AND
- Medical record documentation of a diagnosis of hyperphenylalaninemia (baseline blood Phe level $\geq$ 360 μmol/L) AND

- Medical record documentation of baseline Phe level AND
- Medical record documentation that the patient is on and compliant with a Phe-restricted diet

Authorization Duration:
Approval for new starts will be given for an initial authorization duration of eight (8) weeks. For continuation of coverage, the following criteria is required:

- Medical record documentation of a response to Kuvan defined by a reduction in blood Phe levels from baseline OR
- Medical record documentation of an increase in Phe tolerance (addition of Phe in diet with stable Phe level)

After the initial 8 week approval, subsequent approvals will be for a duration of one (1) year. Reevaluation of coverage will be every one (1) year requiring the following:

- Medical record documentation of a sustained reduction in blood Phe levels OR
- Medical record documentation of improvement in neuropsychiatric symptoms or an increase in Phe tolerance.

Discussion: No comments or questions.

Outcome: Keith Hunsicker 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.

NOXAFIL UPDATE

Current formulary status/prior authorization criteria:

Medicaid: Noxafil is non-formulary with the following criteria.

- The patient is 13 years of age or older AND
- The prescription is written by an oncologist, hematologist, infectious disease specialist, or transplant service provider AND
- Medical record documentation of use for prophylaxis of invasive Aspergillus or Candida infections in patients at high risk of developing these infections due to being severely immunocompromised
  OR
- Medical record documentation of treatment of oropharyngeal candidiasis with therapeutic failure on, contraindication to, or intolerance to fluconazole or itraconazole

Recommendations:
It is recommended to add the following authorization duration and quantity limits
For prophylaxis of invasive Aspergillus and Candida infections: Initial approval will be for 3 months or less if the reviewing provider feels it is medically appropriate. Subsequent approvals will be for an additional 6 months or less if the reviewing provider feels it is medically appropriate. The medication will no longer be covered if the member recovers from neutropenia and/or immunosuppression.

For oropharyngeal candidiasis*:* One-time, 28-day authorization.

Quantity Limits:
Medicaid: The QL should be entered by GPID.

- 100 mg tablets: one-time 1-week authorization for QL 93 tablets per 30 days, for the remainder of the authorization, the QL of 90 tablets per 30 days should apply.
- 200 mg/5 mL: 20 mL per day

Discussion: No comments or questions.

Outcome: Kelly Yelenic made a motion to accept the recommendations as presented. 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.

POLICY UPDATE

Discussion: It is recommended the following policy updates be made:

Edarbi and Edarbyclor

Discussion: Following the valsartan recall in 2018 several additional angiotensin receptor blocking agents were added to the prescription drug formulary (candesartan, irbesartan, losartan, olmesartan, telmisartan, valsartan). It is recommended that the Edarbi and Edarbyclor policy is updated to require failure on three formulary alternatives and that a quantity limit is applied based on maximum daily dosing.

Existing Policy Criteria:

GHP Family

- Medical record documentation of a therapeutic failure on, intolerance to, or contraindication to losartan or losartan/hctz **AND** irbesartan or irbesartan/hctz

Recommendation:

- Medical record documentation of therapeutic failure on, intolerance to, or contraindication to three preferred formulary angiotensin receptor blockers

QUANTITY LIMIT: 1 tablet per day

Amlodipine/Olmesartan

Discussion: Following the valsartan recall in 2018 several additional angiotensin receptor blocking agents were added to the prescription drug formulary (candesartan, irbesartan, losartan, olmesartan, telmisartan, valsartan). It is recommended that the amlodipine/olmesartan policy is updated to require failure on preferred formulary alternatives.

Existing Policy Criteria:

GHP Family

- Medical record documentation of a therapeutic failure on, intolerance to, or contraindication to amlodipine used in combination with losartan **AND** amlodipine used in combination with irbesartan **AND** amlodipine used in combination with valsartan

Recommendation:

GHP Family

- Medical record documentation of therapeutic failure on, intolerance to, or contraindication to three preferred formulary angiotensin receptor blockers, one of which be olmesartan, used in combination with amlodipine

Amlodipine/Valsartan and Amlodipine/Valsartan/HCTZ

Discussion: Following the valsartan recall in 2018 several additional angiotensin receptor blocking agents were added to the prescription drug formulary (candesartan, irbesartan, losartan, olmesartan, telmisartan, valsartan). It is recommended that the amlodipine/olmesartan policy is updated to require failure on preferred formulary alternatives.

Existing Policy Criteria:

GHP Family Amlodipine/Valsartan

- Therapeutic failure on, intolerance to, or contraindication to a combination of amlodipine (generic Norvasc) and losartan (generic Cozaar) **AND** amlodipine (generic Norvasc) and

Recommendation:

GHP Family

- Medical record documentation of therapeutic failure on, intolerance to, or contraindication to three preferred formulary angiotensin receptor blockers, one of which be valsartan, used in combination with amlodipine

Kineret

Discussion: The recommended Kineret dosing for the treatment of rheumatoid arthritis is 100 mg/day administered daily by subcutaneous injection. Higher doses did not result in a higher response. Dosing for the treatment of cryopyrin-associated periodic syndromes (CAPS) is weight based up to a maximum daily dose of 8 mg/kg/day.

Recommendation: It is recommended that a quantity limit of 0.67 mL per day, 28 day supply per fill be added to approved Kineret requests for the treatment of rheumatoid arthritis. No QL will apply to approved requests for CAPS given the weight based dosing.

Enoxaparin Syringes

Discussion: Enoxaparin syringes are currently limited by a quantity/day supply of 28 days per fill. Given that enoxaparin is manufactured in boxes containing 10 syringes, it is recommended that the quantity limit is increased to allow up to a 30 day supply per fill.

Recommendation:

- Enoxaparin 30 mg/0.3 mL syringe: 18 per 30 days

- Enoxaparin 40 mg/0.4 mL syringe: 24 mL per 30 days
- Enoxaparin 60 mg/0.6 mL syringe: 36 mL per 30 days
- Enoxaparin 80 mg/0.8mL syringe: 48 mL per 30 days
- Enoxaparin 100 mg/mL syringe: 60 mL per 30 days
- Enoxaparin 120 mg/0.8 mL syringe: 48 mL per 30 days
- Enoxaparin 150 mg/mL syringe: 60 mL per 30 days

Discussion: No comments or questions.

Outcome: Kevin Szczecina 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.

DARAPRIM UPDATE

FDA Approved Indications: Daraprim is indicated for the treatment of toxoplasmosis when used conjointly with sulfonamide, since synergism exists with this combination.

Current Formulary Status/Prior Authorization Criteria:

GHP Family: Daraprim is not on formulary.

Recommendations:

GHP Family: There are no changes to formulary status at this time. However, it is recommended to add the following prior authorization criteria.

Prior Authorization

For Treatment of Toxoplasmosis

- Prescription written by or in consultation with an infectious disease specialist AND
- Medical record documentation of diagnosis of toxoplasmosis AND
- Medical record documentation that Daraprim will be used in combination with leucovorin and a sulfonamide OR therapeutic failure on, intolerance to, or contraindication to a sulfonamide

Authorization Duration: Initial approval will be for six (6) weeks and subsequent approval will be for six (6) months. Requests for continuation of coverage will be approved for members who meet the following criteria:

- Medical record documentation of clinical syndrome (e.g. headache and/or other neurologic symptoms) OR
- Medical record documentation of persistent radiographic disease OR
- If HIV positive, medical record documentation of CD4 count < 200 cells/mm^3 AND medical record documentation that the member is taking anti-retroviral therapy (ART)

For Primary Prophylaxis of Toxoplasmosis with HIV:

- Prescription written by or in consultation with an infectious disease specialist AND
- Medical record documentation of diagnosis of HIV AND
- Medical record documentation of CD4 count < 200 cells/microL AND
- Medical record documentation of therapeutic failure on, intolerance to, or contraindication to trimethoprim-sulfamethoxazole

Authorization Duration: Initial approval will be for three (3) months and subsequent approval will be for six (6) months. Requests for continuation of coverage will be approved for members who meet the following criteria:

- Medical record documentation of CD4 count < 200 cells/mm3 AND
- Medical record documentation that the member is taking anti-retroviral therapy (ART)

Note:

Recommended Dose:

Immunocompetent patients: The recommended dose of Daraprim is 100 mg loading dose followed by 25 to 50 mg daily (25 mg daily for those with ocular disease).

HIV-Treatment: The recommended initial dose of Daraprim 200 mg loading dose followed by 50 mg daily (<60 kg) or 75 mg daily (≥60 kg). The recommended chronic maintenance dose of Daraprim is 25 to 50 mg daily.

HIV-Primary Prophylaxis: The recommended dose is 50 to 75 mg once weekly in combination with dapsone and leucovorin; or 25 mg once daily in combination with atovaquone and leucovorin.

Congenital: The recommended dose of Daraprim is 2 mg/kg (maximum 50 mg/dose) once daily for two days; then 1 mg/kg (maximum 25 mg/dose) once daily for 6 months; then 1 mg/kg (maximum 25 mg/dose) three times per week for 12 months.

Pregnancy: The recommended dose of Daraprim 100 mg/day orally divided into two doses for two days followed by 50 mg orally daily.

Treatment Duration:

Immunocompetent patients with ocular disease: Minimum of 6 weeks

HIV-Treatment: Initial- 6 weeks; chronic maintenance- 6 months or more

HIV- Primary Prophylaxis: 3 months or more

Congenital: 12 months

Pregnancy: 18 week or after gestation and may be up administered until delivery

Discussion: No comments or questions.

Outcome: Kevin Szczecina made a motion to accept the recommendations as presented. 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.

AIMOVIG UPDATE

Current Quantity limits:

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

Quantity Limit Recommendations:
The quantity limit for Aimovig should be updated to the following:

1 ml per 30 days (by ratio). 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).

Discussion: No comments or questions.

Outcome: Todd Sponenberg 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.

MINIMUM AND MAXIMUM DAYS SUPPLY
Currently, we do not have any restrictions in place to prevent a pharmacy from billing GHP more frequently for a medication that should be billed at a greater day supply. For example, Stelara should be billed every 56 or 84 days, however pharmacies have dispensed and billed this medication monthly. We have a restriction in place that does not allow a specialty medication to process at > 34 day supply, which is not applicable to all medications. The following restrictions should be added to the following policies to prevent inappropriate dispensing practices. These restrictions will be included in the reviewer's approval language and entered in the authorization by the pharmacy customer service representatives. These updates will not affect the member's copayment.

Drug Name	Dosage	Recommended Restriction
Aimovig	• 70 or 140 mg per month	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). <u>70 mg/month:</u> • Max Qty Supply: 1 • Min Day Supply: 30 • Max Day Supply: 30 (quantity limit by ratio)

		<u>140 mg/month:</u> • Max Qty Supply: 1 • Min Day Supply: 30 • Max Day Supply:30 (quantity limit by ratio)
Ajovy	• 225 mg per month OR • 675 mg every 3 months	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). • Max Qty Supply: 1.5 • Min Day Supply: 30 • Max Day Supply: 30 (quantity limit by ratio)
Bethkis	• 300 mg every 12 hours (28 days on and 28 days off drug)	• Max Qty Supply: 224 • Max Day Supply: 56 • Min Day Supply: 56
Cosentyx	Maintenance: • 150 mg or 300 mg every 4 weeks	<u>Initial:</u> **150 mg/month:** • Max Qty Supply: 4 • Max Day Supply: 28 • Min Day Supply: 28 **300 mg/month:** • Max Qty Supply: 8 • Max Day Supply: 28 • Min Day Supply: 28 <u>Remainder/Subsequent:</u> **150 mg/month:** • Max Qty Supply: 2 • Max Day Supply: 56 • Min Day Supply: 56 **300 mg/month:** • Max Qty Supply: 2

		• Max Day Supply: 28 • Min Day Supply: 28
Dupixent	• 600 mg initially, then 300 mg every other week	<u>Initial:</u> **300 mg/2mL:** • Max Qty Supply: 8 • Max Day Supply: 42 • Min Day Supply: 42 **200 mg/1.14 mL:** • Max Qty Supply: 4.56 • Max Day Supply: 42 • Min Day Supply: 42 <u>Remainder/Subsequent:</u> **300 mg/2mL** • Max Qty Supply: 4 • Max Day Supply: 28 • Min Day Supply: 28 **200 mg/1.14 mL:** • Max Qty Supply: 2.28 • Max Day Supply: 28 • Min Day Supply: 28
Emgality	• 240 mg for loading dose then 120 mg per month	<u>Initial:</u> One-time, one-week authorization with QL: • Max Qty Supply: 2 • Min Day Supply: 30 • Max Day Supply: 30 <u>Remainder/Subsequent:</u> 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). • Max Qty Supply: 1

		• Min Day Supply: 30 • Max Day Supply:30 (quantity limit by ratio)
Stelara	<u>Crohn's:</u> • Induction (wt based): 260/390/520 mg IV as a single dose • Maintenance (8 wks after initial dose): 90 mg SC every 8 weeks <u>Plaque Psoriasis:</u> • (100 kg or less): 45 mg SC initially & 4 weeks later, then every 12 weeks • (> 100 kg): 90 mg SC initially & 4 weeks later, then every 12 weeks <u>Psoriatic arthritis:</u> • 45 mg SC initially & 4 weeks later, then every 12 weeks • (w/ moderate to severe plaque psoriasis or wt > 100 kg): 90 mg initially & 4 weeks later, then every 12 weeks	***(Remove Rx counts from policies)*** **Crohn's** <u>Initial 6 month auth:</u> One-time (Rx count 1) of up to four 130 mg vials for induction infusion. For the remainder of the 6 month auth duration: • Max Qty Supply: 1 • Max Day Supply: 56 • Min Day Supply: 56 <u>Subsequent:</u> • Max Qty Supply: 1 • Max Day Supply: 56 • Min Day Supply: 56 **Plaque Psoriasis:** 100 kg or less: <u>Initial 6 month auth:</u> One-time 1-week auth: • Max Qty Supply: 0.5 • Max Day Supply: 28 • Min Day Supply: 28 For the remainder of the 6 month auth duration: • Max Qty: 0.5 • Max Day Supply: 84 • Min Day Supply: 84 <u>Subsequent:</u> • Max Qty: 0.5 • Max Day Supply: 84

		• Min Day Supply: 84 >100 kg: <u>Initial 6 month auth:</u> One-time 1-week auth: • Max Qty Supply: 1 • Max Day Supply: 28 • Min Day Supply: 28 For the remainder of the 6 month auth duration: • Max Qty: 1 • Max Day Supply: 84 • Min Day Supply: 84 <u>Subsequent:</u> • Max Qty: 1 • Max Day Supply: 84 • Min Day Supply: 84 **Psoriatic Arthritis:** 100 kg or less: <u>Initial 6 month auth:</u> One-time 1-week auth: • Max Qty Supply: 0.5 • Max Day Supply: 28 • Min Day Supply: 28 For the remainder of the 6 month auth duration: • Max Qty: 0.5 • Max Day Supply: 84 • Min Day Supply: 84 <u>Subsequent:</u> • Max Qty: 0.5 • Max Day Supply: 84 • Min Day Supply: 84

		>100 kg: <u>Initial 6 month auth:</u> One-time 1-week auth: • Max Qty Supply: 1 • Max Day Supply: 28 • Min Day Supply: 28 For the remainder of the 6 month auth duration: • Max Qty: 1 • Max Day Supply: 84 • Min Day Supply: 84 <u>Subsequent:</u> • Max Qty: 1 • Max Day Supply: 84 • Min Day Supply: 84
Tobi/ tobramycin inhaled solution/ Tobi Podhaler	<u>Powder:</u> • 112 mg every 12 hours (28 days on and 28 days off) <u>Solution:</u> • 300 mg every 12 hours (28 days on and 28 days off)	<u>Tobramycin inhalation solution:</u> • Max Qty Supply: 280 • Max Day Supply: 56 • Min Day Supply: 56 <u>Tobi Podhaler:</u> • Max Qty Supply: 224 • Max Day Supply: 56 • Min Day Supply 56
Tremfya	• 100 mg at weeks 0, 4, and then every 8 weeks thereafter	<u>Initial Auth:</u> • Max Qty Supply: 1 • Max Day Supply: 28 • Min Day Supply: 28 <u>Subsequent Auths:</u> • Max Qty Supply: 1 • Max Day Supply: 56 • Min Day Supply: 56

Discussion: No comments or questions.

Outcome: Kevin Szczecina made a motion to accept the recommendations as presented. 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.

FORMULARY UPDATE
It is recommended the following lower cost alternatives be added to the formulary:

Medication	Formulary Placement/Update	Rationale
Prilosec Suspension (Covis)	Tier 1 (GHP Family)	Lower cost alternative ($377.10 AWP for 30 day supply) to Prevacid Solutabs ($498.11) and Protonix Granules ($542.33)
Prevacid Solutabs (Takeda)	Add prior authorization for new starts only (GHP Family)	Prefer lower cost alternatives Nexium Suspension and Prilosec Suspension
Protonix Granules (Wyeth/Pfizer)	Add prior authorization for new starts only (GHP Family)	Prefer lower cost alternatives Nexium Suspension and Prilosec Suspension
Lidocaine Pain Relief 4% Patch (*AmerisourceBergen)*	OTC Tier (GHP Family)	Alternative to Lidocaine 5% Patch

It is recommended the following quantity limits be added:

Medication	QL
Buprenorphine 2 mg SL Tablet (multiple manufacturers)	3 daily
Buprenorphine 8 mg SL Tablet (multiple manufacturers)	3 daily
Buprenorphine/Naloxone 2/0.5 mg SL Tablet (multiple manufacturers)	3 daily
Buprenorphine/Naloxone 8/2 mg SL Tablet (multiple manufacturers)	3 daily
Buprenorphine/Naloxone 2/0.5 mg Film (multiple manufacturers)	3 daily
Buprenorphine/Naloxone 4/1 mg SL Film (multiple manufacturers)	2 daily
Buprenorphine/Naloxone 8/2 mg SL Film (multiple manufacturers)	3 daily
Buprenorphine/Naloxone 12/3 mg SL Film (multiple manufacturers)	2 daily
Suboxone 2/0.5 mg Film (Indivior)	3 daily
Suboxone 4/1 mg Film (Indivior)	2 daily
Suboxone 8/2 mg Film (Indivior)	3 daily
Suboxone 12/3 mg Film (Indivior)	2 daily

Discussion: No comments or questions.

Outcome: Tricia Heizman 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.

MAINTENANCE MEDICATION UPDATE

Effective 4/1/2019 GHP Family members are required to receive a 90-day supply of maintenance medications from either the contracted Mail Order Pharmacy or pharmacies in the Choice90 Network. This becomes mandatory after two one-month supplies at retail. Specialty medications and controlled substances are excluded. It is optional for albuterol, acyclovir, valacyclovir, antipsychotics, antidepressants and medications considered to have a narrow therapeutic index. Members receive a 90-day supply for the same cost as a one-month supply.

Discussion: No comments or questions.

Outcome: No vote was necessary, informational only

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

Meeting adjourned at 4:22 pm.

Future Scheduled Meetings

The next bi-monthly scheduled meeting will be held on Tuesday, July 16, 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.