P&T Committee Meeting Minutes
GHP Family
May 15, 2018

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

Call to Order:
Dr. Bret Yarczower called the meeting to order at 1:02 p.m., Tuesday, May 15, 2018.

Review and Approval of Minutes:
Dr. Bret Yarczower asked for a motion or approval to accept the March 20, 2018 minutes as written. Keith Hunsicker accepted the motion and Todd Sponenberg seconded the motion. None were opposed.

DRUG REVIEWS

ERLEADA (apalutamide)

Review: Erleada is an Androgen Receptor (AR) inhibitor that binds directly to the ligand-binding domain of the AR. Erleada inhibits AR nuclear translocation, inhibits DNA binding, and impedes AR-mediated transcription. A major metabolite, N-desmethyl apalutamide, is a less potent inhibitor of AR, and exhibited one-third the activity of Erleada in an in vitro transcriptional reporter assay. Erleada administration caused decreased tumor cell proliferation and increased apoptosis leading to decreased tumor volume in mouse xenograft models of prostate cancer.

The recommended dose of Erleada is 240 mg (four 60 mg tablets) administered orally once daily. Tablets should be swallowed whole, and can be taken with or without food. Patients should also receive a gonadotropin-releasing hormone (GnRH) analog concurrently or should have had a bilateral orchiectomy.

The efficacy of Erleada is based on the phase 3 SPARTAN trial. SPARTAN was a multicenter, double-blind, randomized (2:1), placebo-controlled trial evaluating the efficacy of Erleada in 1,207 patients with nmCRPC. The major efficacy outcome measure of the study was metastasis-free survival (MFS), defined as the time from randomization to the time of first evidence of blinded independent central review (BICR)-confirmed distant metastasis.

A total of 1207 men underwent randomization (806 to the Erleada group and 401 to the placebo group). In the planned primary analysis, which was performed after 378 events had occurred, median metastasis-free survival was 40.5 months in the Erleada group as compared with 16.2 months in the placebo group Time to symptomatic progression was significantly longer with Erleada than with placebo. The rate of adverse events leading to discontinuation of the trial regimen was 10.6% in the Erleada group and 7.0% in the placebo group. The following adverse events occurred at a higher rate with Erleada than with placebo: rash (23.8% vs. 5.5%), hypothyroidism (8.1% vs. 2.0%), and fracture (11.7% vs. 6.5%).

Among men with nonmetastatic castration-resistant prostate cancer, metastasis-free survival and time to symptomatic progression were significantly longer with Erleada than with placebo. The NCCN now lists Erleada as a category 1 recommendation for the treatment of patients with nonmetastatic castration-resistant prostate cancer (CRPC).

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 criteria as written. Kevin Szczecina seconded the motion. None were opposed.

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

Outcome: For GHP Family, Erleada will be a pharmacy benefit and will be added to the formulary on the Brand Tier requiring prior authorization. The following criteria will apply:

- Medical record documentation that Erleada is prescribed by an oncologist or urologist **AND**
- Medical record documentation of a diagnosis of prostate cancer with evidence of non-metastatic disease **AND**
- Medical record documentation that the member is no longer responding to castration or is hormone resistant **AND**

- Medical record documentation that a gonadotropin-releasing hormone (GnRH) analog will be used concurrently

Quantity Limit: 4 tablets per day

Authorization Duration: Each treatment period will be defined as twelve (12) months. Re-review will occur every twelve (12) months. Erleada will no longer be covered if there is medical record documentation of disease progression.

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

FASENRA (benralizumab)

Review: Fasenra is an interleukin-5 (IL-5) antagonist indicated for the add-on maintenance treatment of severe asthma in adults and children greater than or equal to 12 years of age with an eosinophilic phenotype. Fasenra joins Nucala and Cinqair in the treatment of this condition. Fasenra is not indicated for treatment of other eosinophilic conditions and is not indicated for the relief of acute bronchospasm or status asthmaticus. Fasenra is dosed 30mg subcutaneously every 4 weeks for 3 doses, then 30mg subcutaneously every 8 weeks thereafter, which is favorable among its alternatives (Nucala requires monthly maintenance subcutaneous administrations and Cinqair requires monthly intravenous infusions).

In clinical trials, Fasenra was shown to decrease asthma exacerbations, increase time to first asthma exacerbation, and reduce daily maintenance corticosteroid dose compared to placebo. Patient reported asthma control and quality of life questionnaires were higher in Fasenra treated patients compared to placebo. In all the trials, Fasenra was shown to consistently improve FEV_1 from baseline over time.

The safety profile of Fasenra closely resembles that of Nucala and Cinqair. Fasenra does not have any reported black box warnings; however, does list helminth infections, hypersensitivity reactions, need for slow corticosteroid taper, and acute asthma exacerbations as warnings and precautions. The most common adverse reactions to Fasenra included headache, pyrexia, pharyngitis and hypersensitivity reactions. The safety and effectiveness of Fasenra was shown in patients 12 years of age and older and was not shown to be different between the geriatric population and the younger population.

The GINA guidelines recommend the IL-inhibitors as last line, add-on therapy options for the treatment of asthma (with an eosinophilic phenotype). Dr. Sean Devine felt that the available products for the treatment of eosinophilic asthma were all fairly equivalent, with the main differences being in dosing (Fasenra having the most desirable). He felt that this would be an opportunity to contract and develop a preferred product.

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. Anastasia Mauger made a motion to accept the recommendations as presented. Tricia Heitzman seconded the motion. None were opposed.

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

Outcome: For GHP Family, Fasenra will be a medical benefit requiring prior authorization. Criteria will be as follows:

- Prescribed by an allergist/immunologist or pulmonologist **AND**
- Patient is 12 years of age or older **AND**

- Medical record documentation of a diagnosis of severe eosinophilic asthma AND that Fasenra is being used as add-on maintenance treatment **AND**
- Medical record documentation of blood eosinophil of ≥300 cells/microL (0.3 x10E3/uL) within the past 3 months **AND**
- Medical record documentation of:
    - Intolerance to or not well controlled or very poorly controlled symptoms* despite at least a 3-month trial of: high-dose inhaled corticosteroids and/or oral systemic corticosteroids plus a long-acting beta agonist **OR**
    - Two or more exacerbations in the previous 12 months requiring additional medical treatment (oral corticosteroids, emergency department or urgent care visits, or hospitalization) despite current therapy with high-dose inhaled corticosteroids plus a long-acting beta agonist

  AND

- Medical record documentation that Fasenra is not being used in combination with Xolair (omalizumab), Nucala (mepolizumab), or Cinqair (reslizumab)

Limitations:

- Fasenra is not indicated for treatment of other eosinophilic conditions.
- Fasenra is not indicated for the relief of acute bronchospasm or status asthmaticus.

*Measures of Disease Severity

Measure	**Not Well Controlled**	**Very Poorly Controlled**
Symptoms	> 2 days per week	Throughout the day
Nighttime awakenings	1-3x/week	≥ 4x/week
Interference with normal activity	Some limitation	Extremely limited
SABA use for symptom control (not to prevent exercise-induced bronchospasm)	> 2 days/week	Several times per day
FEV1 (% predicted) or peak flow (% personal best)	60-80%	< 60%
Asthma Control Test (ACT) Score	16-19	≤ 15

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 the following:

- Documentation that patient is not experiencing toxicity or worsening of disease **AND**
- Medical record documentation of at least one of the following:
    - Medical record documentation of continued disease improvement or lack of disease progression as evidenced by a reduction in asthma exacerbations (e.g. reduced use of rescue medications, reduced urgent care visits, reduced hospitalizations) **OR**
    - Medical record documentation of decreased oral corticosteroid use (if on maintenance treatment prior to Fasenra initiation)

Quantity Limit: 1 syringe (1mL) per 28 days

Other Recommendations:

Xolair: MBP 22.0

Add:

- Medical record documentation that Xolair is not being used in combination with Fasenra (benralizumab), Nucala (mepolizumab), or Cinqair (reslizumab)

Nucala: MBP 141.0

Edit:

- Medical record documentation that Nucala is not being used in combination with Fasenra (benralizumab), Cinqair (reslizumab), or Xolair (omalizumab)

Add:

- Medical record documentation of a diagnosis of severe eosinophilic asthma AND that Nucala is being used as add-on maintenance treatment

Cinqair: MBP 145.0

Edit (For MBP 145.0):

- Medical record documentation that Cinqair is not being used in combination with Fasenra (benralizumab), Nucala (mepolizumab), or Xolair (omalizumab).

Edit (For MBP 145.0):

- Patient must have severe persistent eosinophilic asthma AND Cinqair is being used as add-on maintenance treatment

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

GOCOVRI (amantadine)

Review: Gocovri is the first FDA-approved medication indicated for the treatment of dyskinesia in patients with Parkinson's disease (PD) receiving levodopa-based therapy, with or without concomitant dopaminergic medications. Gocovri is an extended-release, high-dose amantadine formulation available through Alliance Rx Walgreens Prime that allows once daily dosing, compared to up to 4 times per day dosing with immediate-release amantadine. Normal dosing for Gocovri is 137 mg orally once daily at bedtime and may be increased to 274 mg after one week. Dosing adjustments are required in renal impairment.

The efficacy of Gocovri was established in two randomized, double-blind, placebo-controlled trials. In both studies, a significant decrease in mean Unified Dyskinesia Rating Scale (UDysRS) was observed at Week 12 in patients treated with Gocovri, compared to placebo. There was also a significant increase in ON time and a significant decrease in OFF time between baseline and Week 12 in patients treated with Gocovri, compared to placebo.

Gocovri has no black box warnings but is contraindicated in patients with end stage renal disease (ESRD) or a creatinine clearance below 15 mL/min/1.73 m^2. Warnings and precautions for Gocovri include depression, suicidality, falling asleep during daily activities, hallucinations or psychotic behavior, dizziness and orthostatic hypotension, withdrawal-emergent hyperpyrexia and confusion, and impulse control or compulsive behaviors. Gocovri has anticholinergic properties and may increase the QT interval, so it should be used in caution with other drugs that may have an additive effect.

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

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

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

Outcome: For GHP Family, Gocovri is a pharmacy benefit and will <u>not</u> be added to the GHP Family formulary at this time. The following criteria will be utilized for requests for coverage:

- Medical record documentation of dyskinesia with a diagnosis of Parkinson's disease AND
- Medical record documentation that the patient is currently receiving and will continue levodopa-based therapy with the addition of Gocovri AND
- Medical record documentation of therapeutic failure on, intolerance to, or contraindication to immediate-release amantadine

<u>Quantity Limit:</u>

- 68.5 mg capsule: one capsule per day
- 137 mg capsule: two capsules per day

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

LUXTURNA (voretigene-neparvovec-rzyl)

Review: Luxturna is an adeno-associated virus vector-based gene therapy indicated for the treatment of patients with confirmed biallelic RPE65 mutation-associated retinal dystrophy. Patients must have viable retinal cells as determined by the treating physician(s).

Luxturna is supplied in a carton which contains one single-dose vial of Luxturna and 2 vials of diluent. The recommended dose of Luxturna is a subretinal injection to each eye on separate days within a close interval, but no fewer than 6 days apart. Systemic oral corticosteroids equivalent to prednisone at 1 mg/kg/day (maximum of 40 mg/day) for a total of 7 days (starting 3 days before administration of Luxturna to each eye), and followed by a tapering dose during the next 10 days. Administration is performed at a specific Ocular Gene Therapy Treatment Center. There are 9 treatment centers in the US. In PA, including Penn Medicine and CHOP.

The safety and efficacy of Luxturna was studied in the pivotal trial, Study 301 - a phase 3, open-label, multicenter, placebo-controlled randomized control trial that consisted of 31 patients. The trial included patients ≥ 3 years of age, confirmed diagnosis of biallelic RPE65 gene mutation, and sufficient vial retinal cells. Patients included in the trial were also able to pass the multi-luminance mobility test (MLMT), but not at the dimmest light

(e.g. moonless summer night). Those who could not pass the MLMT at the brightest level (e.g. office or food court) were not included in the trial due to their extensive disease progression. MLMT was developed by the manufacturer in conjunction with the FDA to measure patients' ability to conduct everyday tasks. The test is an obstacle course at varying light levels that patients must navigate through in a pre-specified time frame. At 1 year, the group of patients that received Luxturna showed significant and clinically relevant improvements in their ability to complete the multi-luminance mobility test (MLMT) at lower light. For secondary endpoints, full-field light sensitivity threshold testing (FST) showed a statistically significant improvement from baseline to year 1 between the Luxturna and the placebo groups. There was no significant difference in the best-corrected visual acuity (BCVA) change from baseline to year 1. Three years after the initial, there was no statistically significant change in the initial gain of functional vision in the Luxturna treated patients. Also, FST and BCVA remained stable at three years. Those originally assigned to placebo who crossed over to Luxturna experienced a similar response to the Luxturna treatment group over a two-year period.
Luxturna does not carry any black box warnings or contraindications. Luxturna was approved with numerous warnings and precautions including endophthalmitis, permanent decline in visual acuity, retinal abnormalities, increased intraocular pressure, expansion of intraocular air bubbles, and cataracts. The most common adverse reactions (incidence ≥ 5%) in the clinical trials were conjunctival hyperemia, cataract, increased intraocular pressure, retinal tear, dellen (thinning of the corneal stroma), macular hole, subretinal deposits, eye inflammation, eye irritation, eye pain, and maculopathy (wrinkling on the surface of the macula). Luxturna is not recommended in patients younger than 12 months of age. Luxturna was not studied in geriatric patients.

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: Bret Yarczower asked if the benefit seen is to the rods (the low light). No benefit to acuity. BCVA was worse than 20/60. Brightened everything for patients, but didn't increase acuity. Patients were able to navigate better. Can you use corrective lenses in conjunction with increased brightness to improve overall vision? Still need specialist feedback. Rods go first, cones go second. No patients with extensive disease were included in clinical trial. Ensure that patient is connected to a genetic counselor as part of review.

Anastasia Mauger made a motion to accept the recommendations as written. Keith Hunsicker seconded the motion. None were opposed.

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

Outcome: For GHP Family, Luxturna will be a medical benefit. Luxturna will require a prior authorization with the following criteria.

- Prescription written by or in consultation with a retinal specialist AND
- Medical record documentation that the patient is ≥ 12 months of age AND
- Medical record documentation of diagnosis of biallelic RPE65 mutation-associated retinal dystrophy confirmed via genetic testing AND.
- Medical record documentation that the member has sufficient viable retinal cells, defined as one of the following:
    - An area of retina within the posterior pole of > 100 micron thickness as shown on optical coherence tomography
    - ≥ 3 disc areas of retina without atrophy or pigmentary degeneration within the posterior pole based on ophthalmoscopy
    - Remaining visual field within 30 degrees of fixation as measured by a III4e isopter or equivalent

Authorization Duration: One-time authorization for one (1) treatment per eye

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

MEPSEVII (vestronidase alfa-vjbk)

Review: Mepsevii is an intravenous enzyme replacement treatment infusion indicated for in pediatric and adult patients for the treatment of Mucopolysaccharidosis VII (MPS VII, Sly syndrome). It is a recombinant human lysosomal beta glucuronidase, which is taken up into cellular lysosomes. Ultimately, Mepsevii allows for subsequent catabolism of accumulated glycosaminoglycans (GAGs) in affected tissues. Prior to the approval of Mepsevii standard of care treatment of MPS VII consisted of supportive symptomatic care. Mepsevii is the first and only FDA approved treatment for MPS VII. Mepsevii is dosed 4mg/kg IV every 2 weeks administered over approximately 4 hours under the supervision of a healthcare professional with the capability to manage anaphylaxis.

In clinical studies, Mepsevii improved the six-minute walk test (6MWT) with increased treatment duration, reduced urinary GAG excretion compared to baseline, and improved pulmonary function in a dose exploration trial completed outside of the United States.

There is a black box warning related to anaphylactic reactions occurring with Mepsevii administration. Mepsevii has no labeled contraindications nor additional warnings and precautions. The most common adverse reactions included infusion site extravasation, diarrhea, rash, anaphylaxis, infusion site swelling, peripheral swelling and pruritus. Mepsevii has been studied in the pediatric population but not in the geriatric population, which is not surprising given the patient population being treated.

Dr. Can Ficicioglu (CHOP Specialist) added that in addition to the traditional screening as presented above, some patients may present with urinary GAGs only mildly elevated (2xULN) and some patients may be diagnosed through newborn or sibling screening, in which cases a diagnosis may be confirmed with elevated GAGs and two mutations consistent with MPS VII.

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

Clinical Discussion: No comments or questions. Kevin Szczecina made a motion to accept the recommendations as written. 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: Mepsevii will be a medical benefit only for GHP Family members and should require prior authorization. The following prior authorization criteria should apply:

- Prescribed by or in consultation with a specialist in genetic disorders OR metabolic disorders **AND**
- Medical record documentation of a diagnosis of Mucopolysaccharidosis VII (MPS VII, Sly syndrome) confirmed by ALL of the following:
    - Elevated urinary glycosaminoglycans (GAGs) at least three times the upper limit of normal (3xULN) **AND**
    - Enzyme activity assay (beta-glucuronidase deficiency) OR genetic testing (mutation of chromosome 7q21.11) **AND**
    - At least <u>one</u> of the following clinical signs or symptoms: enlarged liver and spleen, joint limitations, airway obstructions or pulmonary dysfunction

AND

- Medical record documentation of a baseline evaluation, including a standardized assessment of motor function (e.g. 6-minute walk test (6MWT)), urinary GAGs level, and pulmonary function test (PFT)

Note: Some patients may only have elevated GAGs two times the upper limit of normal (2xULN). Elevated GAGs and two mutations consistent with MPS VII are appropriate to diagnosis patients with MPS VII when diagnosed through newborn screening or sibling screening.

Authorization Duration: If determined to be medically necessary, Mepsevii should be approved for an initial authorization duration of **6 months**. Subsequent authorizations of Mepsevii will be determined medically necessary and should be approved for an authorization duration of **12 months** when the following criteria are met.

- Medical record documentation of improvement or maintenance of motor function, urinary GAGs level, pulmonary function, or other clinical signs/symptoms (i.e. decreased liver/spleen size, improvement in joint function, etc.)

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

ODACTRA (Dermatophagoides farina and Dermatophagoides pteronyssinus)

Review: Odactra is indicated for house dust mite (HDM)-induced allergic rhinitis (AR), with or without conjunctivitis, confirmed by *in vitro* testing for IgE antibodies to *Dermatophagoides farinae* or *Dermatophagoides pteronyssinus* house dust mites, or skin testing to licensed house dust mite allergen extracts. Odactra is approved for use in adults 18 through 65 years of age. HDM allergy is a perennial allergy which may lead to persistent symptoms all year.

The treatment of AR typically consists of patient education, allergen avoidance, and pharmacotherapy. Glucocorticoid nasal sprays are the most effective pharmacologic therapy for AR. Intranasal glucocorticoids are recommended by guidelines as the best therapy class for patients with persistent and significant nasal symptoms. For those with concomitant allergic conjunctivitis, ophthalmic antihistamine drops may be added. Immunotherapy is reserved for patients with demonstrable specific IgE antibodies to relevant allergens who continue to have refractory, persistent, moderate to severe AR symptoms despite pharmacotherapy. Combining different forms of immunotherapy (SCIT or SLIT) may increase the risk of local or systemic reactions.

Odactra is the first sublingual immunotherapy (SLIT) FDA-approved product to treat HDM- associated allergies. Prior to the approval of Odactra, the only option for patients with HDM allergies is a healthcare provider administered subcutaneous injection of standardized mixed mite allergens. Odactra is supplied as 12 SQ-HDM sublingual tablet. The recommended dosing for Odactra is one tablet sublingually per day (taken year-round). The first dose of Odactra should be administered in a healthcare setting under the supervision of a physician, followed by a monitoring period of 30 minutes. If the patient tolerates the first dose, the patient may take subsequent doses at home. All patients using Odactra should be prescribed an auto-injectable epinephrine in case of severe allergic reactions to the immunotherapy. The optimal duration of SLIT has not been defined.

The efficacy of Odactra was evaluated in two double-blind, placebo-controlled, randomized clinical field efficacy studies conducted in North America and Europe, and one environmental exposure chamber study. Studies 1 and 2 were conducted for a total duration of up to 12 months. In the clinical trials, Odactra met its primary endpoint by providing reduction in average total combined rhinitis score compared to placebo at the end of the trial periods. The reduction in symptoms was observed as early as 8 weeks.

Odactra has a boxed warning for severe allergic reactions, similar to all SLIT. Odactra has contraindications which are similar to other SLIT medications. Odactra is contraindicated in those with severe, unstable, or

uncontrolled asthma, history of any severe systemic allergic reaction or any severe local reaction to SLIT, history of eosinophilic esophagitis, and/or hypersensitivity to any of the inactive ingredients in Odactra. The most common adverse reactions reported in ≥10% of subjects treated with Odactra were: throat irritation/tickle, itching in the mouth, itching in the ear, swelling of the uvula/back of the mouth, swelling of the lips, swelling of the tongue, nausea, tongue pain, throat swelling, tongue ulcer/sore on the tongue, stomach pain, mouth ulcer/sore in the mouth, and taste alteration/food tastes different.

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: Keith Hunsicker recommended amending the criteria to include: Medical record documentation that Odactra will not be used in combination with sublingual immunotherapy (e.g Grastek, Oralair, and Ragwitek). No further comments or questions. Kim Clark made a motion to accept the recommendations as ammended. Rajneel Chohan seconded the motion. None were opposed.

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

Outcome: Odactra will not be added to the GHP Family formulary. The following prior authorization criteria will be applied:

- Medical record documentation of age greater than or equal to 18 years and less than or equal to 65 years AND
- Medical record documentation of house dust mite-induced allergic rhinitis confirmed by *in vitro* testing for IgE antibodies to *Dermatophagoides farinae* or *Dermatophagoides pteronyssinus* house dust mites OR skin testing to licensed house dust mite allergen extracts AND
- Medical record documentation that the member has (or will receive) a prescription for epinephrine auto-injector AND
- Medical record documentation that the member does not have severe, unstable, or uncontrolled asthma AND
- Medical record documentation of therapeutic failure on, intolerance to, or contraindication to three (3) formulary alternatives, one of which must be an intranasal glucocorticoid.

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 mons or less if the reviewing provider feels it is medically appropriate.

Quantity Limit: One (1) tablet per day

Additional Policy updates:
GHP Family Grastek Policy

- Medical record documentation that Grastek is prescribed by an allergist, **immunologist**, or a physician qualified to prescribe allergy immunotherapy AND
- Medical record documentation of age greater than or equal to 5 years and less than or equal to 65 years AND
- Medical record documentation of Timothy grass pollen or cross-reactive grass pollen induced allergic rhinitis confirmed by positive skin test or in vitro testing for pollen-specific IgE antibodies AND
- **Medical record documentation that the member has (or will receive) a prescription for epinephrine auto-injector AND**

- **Medical record documentation that the member does not have severe, unstable, or uncontrolled asthma AND**
- Medical record documentation that member will no longer be receiving injectable allergy shots AND
- **Medical record documentation that Grastek will <u>not</u> be used in combination with sublingual immunotherapy (e.g Odactra, Oralair, and Ragwitek) AND**
- **Medical record documentation of therapeutic failure on, intolerance to, or contraindication to three (3) formulary alternatives, one of which must be an intranasal glucocorticoid**

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GHP Family- Ragwitek Policy

- Medical record documentation that Ragwitek is prescribed by an allergist, **immunologist,** or a physician qualified to prescribe allergy immunotherapy AND
- Medical record documentation of age greater than or equal to 18 years and less than or equal to 65 years AND
- Medical record documentation of short ragweed pollen induced allergic rhinitis confirmed by positive skin test or in vitro testing for pollen-specific IgE antibodies AND
- **Medical record documentation that the member has (or will receive) a prescription for epinephrine auto-injector AND**
- **Medical record documentation that the member does not have severe, unstable, or uncontrolled asthma AND**
- Medical record documentation that member will no longer be receiving injectable allergy shots AND
- **Medical record documentation that Ragwitek will <u>not</u> be used in combination with sublingual immunotherapy (e.g Grastek, Oralair, and Odactra) AND**
- **Medical record documentation of therapeutic failure on, intolerance to, or contraindication to three (3) formulary alternatives, one of which must be an intranasal glucocorticoid.**

GHP Family Oralair Policy

- Medical record documentation that Oralair is prescribed by an allergist, **immunologist,** or a physician qualified to prescribe allergy immunotherapy AND
- Medical record documentation of age greater than or equal to 10 years and less than or equal to 65 years AND
- Medical record documentation of grass pollen induced (Timothy, Orchard, Sweet Vernal, Kentucky Blue Grass, Perennial Rye) allergic rhinitis confirmed by positive skin test or in vitro testing for pollen-specific IgE antibodies AND
- **Medical record documentation that the member has (or will receive) a prescription for epinephrine auto-injector AND**
- **Medical record documentation that the member does not have severe, unstable, or uncontrolled asthma AND**
- Medical record documentation that member will no longer be receiving injectable allergy shots AND
- **Medical record documentation that Oralair will <u>not</u> be used in combination with sublingual immunotherapy (e.g Grastek, Odactra, and Ragwitek) AND**
- **Medical record documentation of therapeutic failure on, intolerance to, or contraindication to three (3) formulary alternatives, one of which must be an intranasal glucocorticoid.**

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

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

REBINYN (coagulation factor IX [recombinant], glycoPEGylated)

Review: Rebinyn is a glycoPEGylated, recombinant coagulation factor IX (FIX) concentrate indicated for use in adults and children with hemophilia B for on-demand treatment and control of bleeding episodes and perioperative management of bleeding. Rebinyn is not indicated for routine prophylaxis in the treatment of patients with hemophilia B or for immune tolerance induction in patients with hemophilia B. Dosing for on-demand treatment is 40 IU/kg intravenously (IV) for minor to moderate bleeding or 80 IU/kg IV for major bleeding. Dosing for perioperative management is 40 IU/kg IV preoperatively for minor surgical procedures or 80 IU/kg IV for major surgical procedures. Rebinyn is distributed through several authorized trading partners and is available as 500 IU, 1000 IU, and 2000 IU single-use vials. Rebinyn is a long-acting FIX product that works by replacing the clotting protein FIX to restore hemostasis. The polyethylene glycol (PEG) polymer chains attached to the FIX molecule prolong the circulating half-life allowing longer protection from bleeding.

In clinical trials, previously treated patients with hemophilia B received Rebinyn for routine treatment, on-demand treatment and control of bleeding episodes, and perioperative management. The overall success rate for treatment of bleeding episodes was 93.2%, and the overall success rate for perioperative management was 100%. No data were reported to support the use of Rebinyn in routine treatment. There are no black box warnings for Rebinyn; warnings and precautions include hypersensitivity reactions, neutralizing antibody (inhibitor) formation, thrombotic events, and nephrotic syndrome. The most common adverse events are injection site reactions, itching, and hypersensitivity.

Rebinyn is the first PEGylated FIX formulation and joins Alprolix and Idelvion as the third long-acting recombinant product. The Medical and Scientific Advisory Council (MASAC) of the National Hemophilia Foundation (NHF) recommends recombinant FIX products over plasma-derived products but does not specify a preference among the six available recombinant products.

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

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

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

Outcome: If Rebinyn is <u>not</u> self-administered, it will be a medical benefit for GHP Family members and will not require a prior authorization. If Rebinyn is self-administered, it will be a pharmacy benefit and should <u>not</u> be added to the GHP Family formulary at this time. The current prior authorization criteria for antihemophilic agents will apply in accordance with Policy 1084.0F:

- There is medical record documentation of a diagnosis of hemophilia (a documented Factor VIII or Factor IX deficiency); and
- The antihemophilic agent will be for outpatient use.

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

SOLOSEC (secnidazole)

Review: Solosec is the first and only FDA-approved single-dose oral regimen to treat bacterial vaginosis (BV). Solosec is supplied as a single 2-gram granule packet which is to be sprinkled onto applesauce, yogurt, or pudding and consumed within 30 minutes without chewing or crunching the granules.

In Solosec clinical trials, a statistically significantly greater percent of patients experienced a clinical response, Nugent score cure, and therapeutic response following a single dose of Solosec compared to placebo. Safety concerns are limited, but unlike other nitroimidazoles, Solosec does carry a warning for vulvo-vaginal candidiasis that requires treatment with an antifungal agent.

Solosec is not approved for use in pediatric patients and clinical studies did not include sufficient numbers of subjects aged 65 and over to determine whether they respond differently from younger subjects. Of note, breastfeeding is not recommended during treatment with Solosec and for 96 hours after the administration of Solosec based on the long half-life.

Per UpToDate, compliance is enhanced by the convenience of a single-dose regimen, but there is no evidence demonstrating that single-dose secnidazole is superior to multidose metronidazole therapy, which is typically much less expensive. Therefore, treatment of symptomatic non-pregnant women with metronidazole or clindamycin administered either orally or intravaginally is recommended. As treatment efficacy is similar between metronidazole and clindamycin, regardless of delivery route, the choice of medication is based on availability, patient preference, side effects, and cost. Oral medication is more convenient, but associated with a higher rate of systemic side effects, such as headache, nausea, abdominal pain, and Clostridium difficile associated diarrhea, than vaginal administration. If neither metronidazole nor clindamycin are available, either tinidazole or secnidazole are reasonable oral alternatives.

Additionally, the FDA recommends treatment with oral metronidazole, vaginal metronidazole, or vaginal clindamycin. Tinidazole is recommended as an alternative regimen

A Clinical Review including Clinical Information, Efficacy Evidence, Safety Evidence, and Other Considerations and a Financial Review Based on Cost Analysis were presented.
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Clinical Discussion: Keith questioned if Solosec was compared to other therapy options in clinical trials or only to placebo in order to compare rates of side effects. The reviewer stated it wasn't compared to other agents. No further comments or questions. Kevin Szczecina made a motion to accept the recommendations as written. Tricia Heitzman seconded the motion. None were opposed.

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

Outcome: Solosec will not be added to the GHP Family formulary at this time. The following prior authorization criteria will apply:

- Medical record documentation of a diagnosis of bacterial vaginosis **AND**
- Medical record documentation of age greater than or equal to 18 years **AND**

- Medical record documentation of therapeutic failure on, intolerance to, or contraindication to metronidazole **AND** clindamycin **AND** oral tinidazole

Quantity Limit: 1 packet per 30 days

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

STEGLATRO (Ertugliflozin)

Review: Steglatro is a SGLT2 inhibitor indicated as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus. The recommended starting dose of Steglatro is 5 mg once daily and may be increased to 15 mg once daily. Steglatro is the fourth FDA-approved SGLT2 inhibitor after Jardiance, Invokana, and Farxiga.

Steglatro has been evaluated as monotherapy, in combination with metformin, and in combination with Januvia and has demonstrated superior HbA1c reductions, averaging a reduction of 0.8. The reduction in HbA1c was generally similar across subgroups. Although not directly studied, Steglatro demonstrated similar efficacy and safety to other SGLT-2 inhibitors. Cardiovascular outcomes data for Steglatro are expected to be available in 2019.

Similar to other SGLT-2 inhibitors, Steglatro is contraindicated in patients with severe renal impairment, end-stage renal disease, or dialysis. Steglatro's warnings and precautions are also consistent with other SGLT-2 inhibitors, however Steglatro has an additional warning for lower limb amputation, which may have been included as a precautionary measure due to an increased risk of lower limb amputations observed in the cardiovascular outcomes (CANVAS) trial with Invokana. In the Steglatro clinical trials, non-traumatic lower limb amputations were reported in more frequently in those taking Steglatro, however a causal association between Steglatro and lower limb amputation has not been definitively established. The most common adverse effect was female genital mycotic infections. Similar to Farxiga, use of Steglatro is not recommended in eGFR less than 60ml/min whereas Invokana and Jardiance can be used in eGFR as low as 45ml/min. Steglatro has not been studied in pediatric patients (< 18 years).

Per the ADA, metformin in combination with diet and exercise continues to be the first-line recommendation for all patients. Patients with T2DM and ASCVD on lifestyle and metformin therapy, it is recommended to incorporate an agent with strong evidence for cardiovascular risk reduction after consideration of drug-specific and patient factors. Jardiance and Victoza may be considered to reduce major cardiovascular events (MACE) and cardiovascular mortality, and Invokana may be considered to reduce MACE. For patients without ASCVD, the ADA does not prefer a particular agent for adjunctive use in dual or triple therapy. Jardiance remains a fierce competitor for various reasons: the new indication for CV death risk reduction in patients with established cardiovascular disease, use in patients with a minimum eGFR of 45ml/min, and overall favorable safety profile.

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

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

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

Outcome: Steglatro will be a pharmacy benefit. It is recommended that Steglatro not be added to GHP Family formulary. The following will be utilized for requests for coverage:

- Medical record documentation of a diagnosis of type II diabetes mellitus AND
- Medical record documentation of age greater than or equal to 18 years AND
- Medical record documentation of therapeutic failure on, intolerance to, or contraindication to Invokana* AND Jardiance*

*Step Therapy Required

Quantity Limit: One (1) tablet per day (max labeled dose)

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

STEGLUJAN (Ertugliflozin and Sitagliptin)

Review: Steglujan is combination of ertugliflozin (SGLT2 inhibitor) and sitagliptin (DPP-4 inhibitor), indicated as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus when treatment with both ertugliflozin and sitagliptin is appropriate. Steglujan is supplied as ertugliflozin 5 mg/ sitagliptin 100 mg tablets and ertugliflozin 15 mg/ sitagliptin 100 mg tablets. The recommended starting dose is 5 mg ertugliflozin/100 mg sitagliptin once daily and the dose may be increased to a maximum dose of 15 mg ertugliflozin/100 mg sitagliptin once daily, if tolerating and need additional glycemic control.

There were seven phase 3 clinical trials conducted to demonstrate the glycemic lowering effect of ertugliflozin, see Steglatro drug review. Steglatro has been evaluated as monotherapy, in combination with metformin, and in combination with Januvia and has demonstrated superior HbA1c reductions. The fixed drug combination products have also demonstrated improved glycemic control with each component contributing to the glycemic lowering effect.

Similar to other SGLT-2 inhibitors, ertugliflozin is contraindicated in patients with severe renal impairment, end-stage renal disease, or dialysis. Steglujan is also contraindicated in those who have had a hypersensitivity reaction to sitagliptin or ertugliflozin. Ertugliflozin's warnings and precautions are also consistent with other SGLT-2 inhibitors, however ertugliflozin has an additional warning for lower limb amputation. The safety profile of the fixed drug combination products reflects the combined safety profiles of the individual components (i.e. DPP-4 inhibitors and SGLT2 inhibitors), with no additional safety concerns when administered in combination. The most common adverse reactions associated with ertugliflozin (incidence $\geq$ 5%) was female genital mycotic infections. The most common adverse reactions associated with sitagliptin (incidence $\geq$ 5%) were URTI, nasopharyngitis, and headache. Similar to Farxiga, use of ertugliflozin is not recommended in eGFR less than 60ml/min. Steglujan has not been studied in pediatric patients (< 18 years).

Per the ADA, metformin in combination with diet and exercise continues to be the first-line recommendation for all patients. Patients with T2DM and ASCVD on lifestyle and metformin therapy, it is recommended to incorporate an agent with strong evidence for cardiovascular risk reduction after consideration of drug-specific and patient factors. Jardiance and Victoza may be considered to reduce major cardiovascular events (MACE) and cardiovascular mortality, and Invokana may be considered to reduce MACE. For patients without ASCVD, the ADA does not prefer a particular agent for adjunctive use in dual or triple therapy.

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

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

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

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

- Medical record documentation of a diagnosis of type II diabetes mellitus AND
- Medical record documentation of age greater than or equal to 18 years AND
- Medical record documentation of a therapeutic failure on, intolerance to, or contraindication to, Glyxambi OR
- Medical record documentation of a therapeutic failure on, intolerance to, or contraindication to, Tradjenta and one formulary SGLT2 inhibitor.

*Step Therapy Required

Quantity Limit: One (1) tablet per day

Other policy recommendations: Qtern

There are no changes recommended to formulary status at this time, however it is recommended to update the Qtern policies to the following:

- Medical record documentation of a diagnosis of type II diabetes mellitus AND
- Medical record documentation of age greater than or equal to 18 years AND
- Medical record documentation of a therapeutic failure on, intolerance to, or contraindication to, Glyxambi OR
- Medical record documentation of a therapeutic failure on, intolerance to, or contraindication to, Tradjenta and one formulary SGLT2 inhibitor

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

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

SEGLUROMET (Ertugliflozin and Metformin)

Review: Segluromet is combination of ertugliflozin (SGLT2 inhibitor) and metformin, indicated as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus who are not adequately controlled on a regimen containing ertugliflozin or metformin, or in patients who are already treated with both ertugliflozin and metformin. Segluromet is supplied as ertugliflozin 2.5mg/metformin 500mg tablets, ertugliflozin 2.5mg/metformin 1,000 mg tablets, ertugliflozin 7.5mg/metformin 500mg tablets, and ertugliflozin 7.5mg/metformin 1,000mg tablets. The recommended starting dose is individualized based on patient's current regimen and should not exceed a maximum dose daily dose of 15 mg ertugliflozin and 2,000 mg metformin.

There were seven phase 3 clinical trials conducted to demonstrate the glycemic lowering effect of ertugliflozin, see Steglatro drug review. Steglatro has been evaluated as monotherapy, in combination with metformin, and in combination with Januvia and has demonstrated superior HbA1c reductions. The fixed drug combination products

have also demonstrated improved glycemic control with each component contributing to the glycemic lowering effect.

Similar to other SGLT-2 inhibitors, ertugliflozin is contraindicated in patients with severe renal impairment, end-stage renal disease, or dialysis. Segluromet is also contraindicated in those who have acute or chronic metabolic acidosis, including diabetic ketoacidosis and any history of hypersensitivity to Segluromet or its components. Due to the metformin component, Segluromet has a boxed warning for lactic acidosis. Ertugliflozin's warnings and precautions are also consistent with other SGLT-2 inhibitors, however ertugliflozin has an additional warning for lower limb amputation. The safety profile of the fixed drug combination products reflects the combined safety profiles of the individual components (i.e. metformin and SGLT2 inhibitors), with no additional safety concerns when administered in combination. The most common adverse reactions associated with ertugliflozin (incidence ≥ 5%) was female genital mycotic infections. The most common adverse reactions associated with metformin (incidence ≥ 5%) were mainly GI related. Similar to Farxiga, use of ertugliflozin is not recommended in eGFR less than 60ml/min. Segluromet has not been studied in pediatric patients (< 18 years).

Per the ADA, metformin in combination with diet and exercise continues to be the first-line recommendation for all patients. Patients with T2DM and ASCVD on lifestyle and metformin therapy, it is recommended to incorporate an agent with strong evidence for cardiovascular risk reduction after consideration of drug-specific and patient factors. Jardiance and Victoza may be considered to reduce major cardiovascular events (MACE) and cardiovascular mortality, and Invokana may be considered to reduce MACE. For patients without ASCVD, the ADA does not prefer a particular agent for adjunctive use in dual or triple therapy.

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

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

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

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

- Medical record documentation of a diagnosis of type II diabetes mellitus AND
- Medical record documentation of age greater than or equal to 18 years AND
- Medical record documentation of therapeutic failure on, intolerance to, or contraindication to Jardiance* + metformin, Synjardy*, OR Synjardy XR* AND
- Medical record documentation of therapeutic failure on, intolerance to, or contraindication to Invokana* + metformin, Invokamet*, OR Invokamet XR*

*Step Therapy Required

Quantity Limit (Commercial/Exchange/Medicaid): two (2) tablets per day

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

SUBLOCADE (buprenorphine ER injection – for subcutaneous use)

Review: Sublocade is a subcutaneously administered, long-acting buprenorphine product indicated for the treatment of adult patients with moderate to severe opioid use disorder in patients who have initiated treatment with a transmucosal buprenorphine-containing product, followed by dose adjustment for a minimum of 7 days. Sublocade should be used as part of a complete treatment program that includes counseling and support. Sublocade is dosed as two monthly 300mg injections, followed by monthly 100mg maintenance injections. Some patients may be increased to 300mg monthly maintenance injections if the benefits outweigh the risks. The other long-acting alternative to Sublocade is Probuphine, a subcutaneously administered buprenorphine implant, which is changed every 6 months. In clinical trials, Sublocade was shown to be superior to placebo in achieving treatment success from Weeks 5 through 24, which was defined as patients with ≥80% opioid-free weeks. Opioid use was monitored between Weeks 5 through 24 and was based on weekly urine drug screens combined with self-reported use of illicit opioid use (non-response was counted as positive for opioid use). A grace period was allowed during the first 4 weeks to allow for stabilization on the treatment drug.

There is a black box warning related to intravenous use and the associated REMS program for Sublocade. The warnings and precautions of Sublocade closely resemble those of the other buprenorphine-containing products. Sublocade has been associated to addiction, abuse, and misuse and can cause withdrawal symptoms if abruptly discontinued or when patients transition to Sublocade from full opioid agonists and are dependent on the full opioid agonists. Sublocade is not appropriate for use in opioid naïve patients due to reported deaths in this population. The most common adverse events included gastrointestinal disorders, administration site conditions, and nervous system disorders; the other reported adverse events are similar to the other buprenorphine-containing products. The buprenorphine plasma levels cannot quickly be changed when using Sublocade due to its extended release properties. For that reason, patients with moderate to severe hepatic impairment are not candidates for Sublocade therapy.

A Clinical Review including Clinical Information, Efficacy Evidence, Safety Evidence, and Other Considerations and a Financial Review Based on Cost Analysis were presented. For geriatric patients, the clinical studies of Sublocade did not include sufficient numbers of subjects aged 65 years or older to determine whether they responded differently than younger subjects. Other clinical experience with buprenorphine has not identified differences in responses between geriatric and younger patients; however, due to possible decreased hepatic, renal, or cardiac function, the decision to prescribe Sublocade in the geriatric population should be made cautiously.

Clinical Discussion: Richard Silbert shared concern over the potential for patients being lost to follow up or that there wouldn't be motivation for frequent office visits. He believes this will be the treatment of choice in the future, because you can eliminate diversion. Keith Hunsicker recommended that criteria be amended to include evaluation of PDMP site, in lieu of recently being added to other buprenorphine products. Tricia Heitzman made a motion to accept the recommendations as amended. Kim Clark seconded the motion. None were opposed.

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

Outcome: Sublocade will be a medical benefit for Medicaid members. It is recommended that Sublocade NOT be added to the pharmacy formulary. It is recommended that prior authorization with the following criteria apply.

- Medical record documentation that the patient is 18 years of age or older **AND**
- Medical record documentation of a diagnosis of opioid use disorder (opioid dependence) **AND**
- Medical record documentation that Sublocade will be used as part of a complete-treatment program that includes counseling and psychosocial support **AND**
- Medical record documentation that member has been initiated into treatment with a transmucosal buprenorphine-containing product (e.g. Suboxone, buprenorphine/naloxone, buprenorphine), followed by dose adjustment for a minimum of 7 days AND until cravings and withdrawal symptoms are clinically controlled **AND**

- Medical record documentation that the member will not be receiving supplemental sublingual buprenorphine concurrently with Sublocade **AND**
- Medical record documentation of a history of poor adherence to oral medications AND documentation that education to improve adherence has been attempted **AND**
- If the member has previously been established on Sublocade and the 300mg maintenance dose is requested: Medical record documentation that the member has tried and failed the 100mg maintenance dose AND that the benefits outweigh the risks of increasing to the 300mg maintenance dose **AND**
- Confirmation that the prescriber or prescriber's delegate has conducted a review of Pennsylvania's Prescription Drug Monitoring Program (PA PDMP) prior to administering Sublocade.

Authorization Duration: If approved, initial authorization duration will be for 3 months. After the initial 3-month authorization, subsequent approval will be for 12 months or less if the reviewing provider feels it is medically appropriate and will require medical record documentation of the following:

- Medical record documentation that the member is adherent to buprenorphine and is not using opiates. This must be verified by all urine drug screens from the time of last authorization, one of which much be dated within 28 days of the request date for opiates and buprenorphine. All drug screens must be positive for buprenorphine and norbuprenorphine, and negative for opiates. The presence of other non-opiate controlled substances must be consistent with prescribed controlled substances and documentation that their use is medically necessary and the benefit outweighs any risks associated with their use in the member must be provided **AND**
- Medical record documentation that Sublocade continues to be used as part of a complete-treatment program that includes counseling and psychosocial support **AND**
- Medical record documentation that the member will not be receiving supplemental sublingual buprenorphine concurrently with Sublocade **AND**
- Medical record documentation of one of the following:
    - That the member will continue to receive the 100mg monthly maintenance dose **OR**
    - If 300mg maintenance dose is requested, the member has tried and failed the 100mg monthly maintenance dose AND the benefits outweigh the risks of receiving the 300mg monthly dose

  AND
- Confirmation that the prescriber or prescriber's delegate has conducted a review of Pennsylvania's Prescription Drug Monitoring Program (PA PDMP) prior to administering Sublocade.

Quantity Limit:

- For 100mg dose: 1 syringe (0.5mL) per 28 days
- For 300mg dose: 1 syringe (1.5mL) per 28 days

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

PREVYMIS (letermovir)

Review: Prevymis is indicated for prophylaxis of CMV infection and disease in adult CMV-seropositive recipients [R+] of an allogeneic HSCT. Prevention of CMV disease is recommended in CMV-seropositive recipients (regardless of donor) and CMV-seronegative recipients who receive allografts from CMV-seropositive donors. Two strategies are available for the prevention of CMV infection in HSCT recipients: primary prophylaxis and preemptive therapy. With primary prophylactic therapy, an antiviral therapy is administered even when CMV viral levels are undetectable in the blood. With preemptive therapy, serial monitoring of CMV blood levels is performed

with antiviral therapy initiated only when CMV levels reach a certain pre-specified threshold in high risk asymptomatic patients. The NCCN Guidelines for the Prevention and Treatment of Cancer-Related Infections (V1.2018) recommends preemptive anti-CMV therapy with oral valganciclovir or IV ganciclovir in allogeneic HCT recipients at high risk for CMV.

Prevymis is a first-in-class non-nucleoside CMV inhibitor that prevents viral replication by targeting the viral terminase complex. With its favorable efficacy and safety profile, it fills a void in the therapeutic area of prevention of CMV infection in HSCT recipients.

The recommended dosage of Prevymis is 480 mg administered orally or intravenously once daily. Prevymis should be initiated between Day 0 and Day 28 post-transplantation (before or after engraftment), and continued through Day 100 post-transplantation. Prevymis vial should be used only in patients unable to take oral therapy. The tablets and vial may be used interchangeably at the discretion of the physician and there are no dose adjustments necessary when switching formulations. If oral or intravenous Prevymis is co-administered with cyclosporine, the dosage of Prevymis should be decreased to 240 mg once daily.

The efficacy of Prevymis was evaluated in a phase 3, double-blind, placebo-controlled trial of 565 adult CMV-seropositive recipients of an allogeneic HSCT. A significantly lower proportion of subjects failed prophylaxis in the Prevymis group compared to the placebo group through Week 24. Also, all-cause mortality in patients receiving Prevymis was lower compared to placebo at week 24 and 48 post-transplant.

Prevymis is contraindicated in patients receiving pimozide or ergot alkaloids (ergotamine and dihydroergotamine). Prevymis is also contraindicated with pitavastatin or simvastatin when co-administered with cyclosporine. The most common adverse events (occurring ≥ 10%) are nausea, diarrhea, vomiting, peripheral edema, cough, headache, fatigue, and abdominal pain. The safety and efficacy of Prevymis has not been established in pediatric patients. Prevymis is not recommended for patients with severe (Child-Pugh C) hepatic impairment.

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

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

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

Outcome: It is recommended that Prevymis tablets should be added to the GHP Family formulary on the Brand Tier. Prevymis vial will be covered as a medical benefit for GHP Family members. The following prior authorization criteria should apply.

<u>Prior Authorization Criteria for Prevymis tablets:</u>

- Prescription written by or in consultation with a hematologist/oncologist, infectious disease, and/or transplant specialist AND
- Medical record documentation of age greater than or equal to 18 years AND
- Medical record documentation that the member is a recipient of an allogeneic hematopoietic stem cell transplant AND
- Medical record documentation that the member is a confirmed CMV seropositive recipient (R+) AND
- Medical record documentation that Prevymis is being used for CMV prophylaxis AND
- Medical record documentation that Prevymis is being initiated between Day 0 and Day 28 post-transplantation AND
- Medical record documentation that Prevymis is not being used in combination with pimozide, ergot alkaloids (ergotamine and dihydroergotamine), and/or pitavastatin and simvastatin (if co-administered with cyclosporine)

Quantity Limit: One (1) tablet per day
Authorization Duration: If approved, authorization will be a for a one-time authorization with a 100 day supply.

Prior Authorization Criteria for Prevymis vial:

- Prescription written by or in consultation with a hematologist/oncologist, infectious disease, or transplant specialist AND
- Medical record documentation of age greater than or equal to 18 years AND
- Medical record documentation that the member is a recipient of an allogeneic hematopoietic stem cell transplant AND
- Medical record documentation that the member is a confirmed CMV seropositive recipient (R+)
- Medical record documentation that Prevymis is being used for CMV prophylaxis AND
- Medical record documentation that Prevymis is being initiated between Day 0 and Day 28 post-transplantation AND
- Medical record documentation that Prevymis is not being used in combination with pimozide, ergot alkaloids (ergotamine and dihydroergotamine), and/or pitavastatin and simvastatin (if co-administered with cyclosporine) AND
- Medical record documentation of intolerance to or contraindication to Prevymis tablets

Authorization Duration: If approved, Prevymis will be authorization for 100 days with a maximum of 100 doses.

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

TROGARZO (ibalizumab-uiyk)

Review: Trogarzo is the first monoclonal antibody therapy approved for use in multidrug resistant (MDR) HIV patients. Trogarzo is administered intravenously (IV) as a single loading dose of 2,000 mg followed by a maintenance dose of 800 mg every 2 weeks.

According to the Department of Health and Human Services (DHHS), consensus recommendations on the management of MDR HIV are lacking as treatment options are extremely limited for this patient population. In addition to addressing this gap in therapy, Trogarzo has a unique mechanism of action compared to other viral entry inhibitors, Selzentry (maraviroc) and Fuzeon (enfuviritide) by preventing viral attachment to the CD4 cell earlier. Trogarzo prevents viral entry attachment at the outset by inhibiting the initial interaction between the HIV-1 virus and the CD4 T-cell, while Selzentry and Fuzeon require this attachment prior to their action.

In clinical trials, Trogarzo effectively reduced the viral load by ≥ 0.5 $\log_{10}$ at day 14 in 83% of treated patients (primary efficacy outcome). By Week 25, 43% of treated patients had achieved an HIV RNA <50 copies/mL which is considered to be undetectable. The most common adverse reactions noted from the study were diarrhea, dizziness, nausea/vomiting, and rash, the majority of which were mild to moderate in severity (90%).

Trogarzo is not approved for use in pediatric patients and clinical studies did not include subjects aged 65 and over.

Consensus recommendations on the management of MDR HIV are lacking as treatment options are extremely limited for this patient population. The most recent guidelines related to the management of treatment-experienced HIV patients were last updated on October 17, 2017, prior to the FDA approval of Trogarzo. Trogarzo was included in these guidelines as an investigational agent to be considered for patients with ongoing detectable viremia who lack sufficient treatment options to construct a fully
suppressive regimen.

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

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

Outcome: Trogarzo will be covered as a medical benefit for GHP Family members that does not require prior authorization.

Quantity Limit (medical benefit only): One-time loading dose of 2,000 mg (13.3 mL), followed by one 800 mg (5.32 mL) infusion every 14 days

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

VYZULTA (latanoprostene)

Review: Although the exact mechanism of action for decreasing IOP is unknown, prostaglandins are believed to mimic naturally occurring prostamides to increase uveoscleral outflow through the non-conventional pathway (responsible for 10-20% of the eye's aqueous outflow). Like prostaglandins, Vyzulta is also expected to work via the enhancement of uveoscleral outflow; however, its nitric oxide molecule will most likely have an effect on increasing aqueous outflow through relaxing the trabecular meshwork (the conventional pathway for fluid to leave the eye). Vyzulta is dosed one drop into the affected eye(s) once daily similar to other prostaglandin products. As of the most up to date guidelines the AAO recommends prostaglandin analogs due as first line therapy due to their efficacy, toleration, and ease of once daily administration.

The two trials APOLLO and LUNAR were designed assess the efficacy of Vyzulta compared to Timolol. The primary endpoint examined mean IOP at nine time points. The secondary endpoints examined the number of patients meeting common treatment goals (achieving an IOP reduction of at least 25% or obtaining an IOP of 18 or lower). Although the APOLLO trial met all of its endpoints, the LUNAR trial failed to achieve a significant difference with the 8AM at week 2-time point. Also there was no significant difference between Vyzulta and timolol in regards to the number of patients obtaining an IOP of 18 or lower.

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

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

Outcome: It is recommended that Vyzulta not be added to the formulary at this time. The following prior authorization criteria should apply.

- Medical record documentation of an intolerance to, contraindication to, or therapeutic failure on Latanoprost (generic Xalatan).

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

ZILRETTA (triamcinolone acetonide ER injection)

Review: Zilretta is an extended-release intra-articular injection of triamcinolone that is indicated for the management of osteoarthritis pain of the knee. It is administered as a single injection to one or both knees, and is not suitable to be given in joints other than the knees. Zilretta uses extended-release microsphere technology, which slowly dissolves when in contact with synovial fluid and releases the triamcinolone over an extended amount of time (about 12 weeks).

In the pivotal Phase III clinical study, Zilretta was found to be superior to placebo at reducing the average daily pain intensity score at week 12. A statistical significance was not found between immediate-release triamcinolone and Zilretta at week 12 in a secondary exploratory analysis. In a Phase 2 study, Zilretta demonstrated a significantly greater improvement in average daily pain and Western Ontario and McMaster Universities Osteoarthritis Index measures of pain, stiffness and function compared to immediate-release triamcinolone injections at weeks 5 through 10. Also in this study there was a perceived improvement in the patient assessed change and physician assessed change at 8 weeks relative to immediate-release triamcinolone injections.

Zilretta is contraindicated in patients who are allergic to triamcinolone, other corticosteroids, or components of the injection. In addition to its contraindication, Zilretta maintains warnings and precautions including administration route, neurologic adverse reactions, and joint infection/damage, all of which are specific to Zilretta. Zilretta also maintains warnings and precautions associated with the corticosteroid class; however, the significance of these is unknown.

Intra-articular corticosteroids are conditionally recommended by the 2012 American College of Rheumatology Osteoarthritis Guidelines. These guidelines are expected to be updated in 2018 but have not been released to date. The guidelines do not make mention of a preference of intra-articular steroid injection active ingredient. Dr. Denio of GMC Rheumatology does not prefer to utilize intra-articular steroids; however, due to Zilretta's cost and lack of clear benefit among generic triamcinolone, he recommends not covering Zilretta without a prior authorization.

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. Anastasia Mauger made a motion to accept the recommendations as written. Kim Clark seconded the motion. None were opposed.

Financial Discussion: There was discussion to require failure of <u>two</u> different intra-articular steroids prior to Zilretta rather than one. This was questioned and recommended by Dr.Brt Yarczower. Kevin Szczecina made a motion to accept the proposed change. Kim Clark seconded the motion. None were opposed.

Outcome: Zilretta will be covered as a medical benefit and should not be added to the GHP Family pharmacy formulary. It is recommended that the following prior authorization criteria apply.

- Prescribed by a rheumatologist **AND**
- Patient is 18 years of age or older **AND**
- Medical record documentation of a diagnosis of osteoarthritic pain <u>of the knee</u> **AND**

- Medical record documentation that patient has not received a previous administration of Zilretta to the requested knee **AND**
- Medical record documentation that non-pharmacologic modalities (e.g. Weight loss, aerobic/resistance land-based exercise or aquatic exercise, other physical therapy modalities or exercises) have not promoted satisfactory symptomatic relief.
- Medical record documentation that there has been no significant improvement following a 10-12 week trial of full-dose nonsteroidal anti-inflammatory drug (NSAID) therapy, with or without supplemental acetaminophen **OR** if NSAIDs are contraindicated, a failure of daily acetaminophen regimen over a 4 to 6 week period **AND**
- Medical record documentation of a therapeutic failure on or intolerance to two different intra-articular steroid injections (e.g. triamcinolone, methylprednisolone, betamethasone, dexamethasone).

Authorization Duration/Quantity Limit: One injection per knee per lifetime

Notes:
- The safety and efficacy of repeat administrations of Zilretta have not been studied.
- The safety and efficacy of Zilretta for management of osteoarthritis pain in joints other than the knee have not been studied.
- Zilretta is for intra-articular use only and should not be administered by epidural, intrathecal, intravenous, intraocular, intramuscular, intradermal, or subcutaneous routes.

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

FAST FACTS

ADCETRIS (brentuximab vedotin)

Updated Indication: Adcetris is a CD30-directed antibody-drug conjugate now indicated for treatment of adult patients with previously untreated Stage III or IV classical Hodgkin lymphoma (cHL), in combination with chemotherapy.

Previously, Adcetris was indicated for treatment of adult patients with:
- Classical Hodgkin lymphoma at high risk of relapse or progression as post autologous hematopoietic stem cell transplantation (auto-HSCT) consolidation
- Classical Hodgkin lymphoma after failure of auto-HSCT or after failure of at least two prior multi-agent chemotherapy regimens in patients who are not auto-HSCT candidates
- Systemic anaplastic large cell lymphoma (sALCL) after failure of at least one prior multiagent chemotherapy regimen
- Primary cutaneous anaplastic large cell lymphoma (pcALCL) or CD30-expressing mycosis fungoides (MF) who have received prior systemic therapy

Recommendation: It is recommended that the prior authorization criteria and authorization duration be updated in the Adcetris medical benefit policy (MBP 166.0) as follows to reflect the expanded indication:
- Prescription written by a hematologist/oncologist AND

- Medical record documentation that patient > 18 years of age

AND

- Medical record documentation of a diagnosis of classical Hodgkin Lymphoma (cHL) AND
- Medical record documentation of failure of autologous hematopoietic stem cell transplant (auto-HSCT) OR
- Medical record documentation of failure of at least 2 multi-agent chemotherapy regimens in patients who are not candidates for auto-HSCT OR
- Medical record documentation of use as consolidation treatment following auto-HSCT in patients with high risk of relapse or progression post-auto-HSCT (high risk patients include: refractory to first line therapy, relapse within 12 months of first line therapy, presence of extranodal disease)

OR

- Medical record documentation of a diagnosis of systemic anaplastic large cell lymphoma (sALCL) AND
- Medical record documentation of failure of at least 1 prior multi-agent chemotherapy regimen

OR

- Medical record documentation of a diagnosis of primary cutaneous anaplastic large cell lymphoma (pcALCL) OR CD30-expressing mycosis fungoides (MF) AND
- Medical record documentation of failure of prior radiation or systemic therapy

OR

- Medical record documentation of previously untreated Stage III or IV cHL AND
- Medical record documentation that Adcetris will be used in combination with chemotherapy

Authorization Duration:

For treatment of Stage III or IV cHL: Initial approval will be limited to 12 doses (6 months) or less if the reviewing provider feels it is medically appropriate. Subsequent approval for treatment past the initial 12 doses will require documentation of well-controlled, peer-reviewed literature with evidence to support this request.

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. Adcetris will no longer be covered if the member experiences unacceptable toxicity or worsening of disease.

Discussion: No comments or questions.

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

BLINCYTO (blinatumomab)

Updated Indication: Blincyto is now indicated under accelerated approval for the treatment of adults and children with B-cell precursor acute lymphoblastic leukemia (ALL) in first or second complete remission with minimal residual disease (MRD) greater than or equal to 0.1%.

Blincyto maintains its previous indication for the treatment of adults and children with relapsed or refractory B-cell precursor acute lymphoblastic leukemia (ALL).

Recommendation: No changes are recommended to the formulary status of Blincyto at this time. It is recommended that the existing prior authorization criteria and authorization duration are updated to account for the new indication.

MBP 128.0

Relapsed or Refractory B-cell Precursor ALL

- Prescription written by an oncologist/hematologist **AND**
- Medical record documentation of a diagnosis of relapsed or refractory B-cell precursor acute lymphoblastic leukemia (ALL)

AUTHORIZATION DURATION: Approval will be limited to one lifetime 9 cycle (20 month) course. Subsequent approval for treatment past the initial 9 cycle course will require documentation of well-controlled, peer-reviewed literature with evidence to support this request.

MRD-positive B-cell Precursor ALL

- Prescription written by an oncologist/hematologist **AND**
- Medical record documentation of a diagnosis of B-cell precursor acute lymphoblastic leukemia (ALL) in first or second remission **AND**
- Medical record documentation of a minimal residual disease (MRD) greater than or equal to 0.1%

AUTHORIZATION DURATION: Approval will be limited to one lifetime 4 cycle (6 month) course. Subsequent approval for treatment past the initial 4 cycle course will require documentation of well-controlled, peer-reviewed literature with evidence to support this request.

Discussion: No comments or questions

Outcome: Todd Sponenberg made a motion to accept the recommendations as written. Anastasia Mauger 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.

AFINITOR DISPERZ (everolimus)

Updated Indication: Afinitor Disperz is now indicated for the adjunctive treatment of adult and pediatric patients aged 2 years and older with Tuberous Sclerosis Complex (TSC)-associated partial-onset seizures.

Previously, Afinitor Disperz was only indicated for the treatment of adult and pediatric patients aged 1 year and older with TSC who have subependymal giant cell astrocytoma (SEGA) that requires therapeutic intervention but cannot be curatively resected. This indication was also approved for Afinitor.

Recommendation: No changes are recommended to the formulary placement. It is recommended that a policy for Afinitor Disperz be made with the following criteria:

Tuberous Sclerosis Complex (TSC)-associated subependymal giant cell astrocytoma:

- Prescription is written by an oncologist **AND**

- Medical record documentation of a diagnosis of subependymal giant cell astrocytoma (SEGA) associated with tuberous sclerosis (TS) who require therapeutic intervention but are not candidates for curative surgical resection

Authorization Duration: Each treatment period will be defined as 12 months. Re-review will occur every 12 months. Afinitor will no longer be covered if there is medical record documentation of disease progression.

Tuberous Sclerosis Complex (TSC)-associated parital-onset seizures:

- Medical record documentation of adjunctive treatment for adult OR pediatric patients aged 2 years and older with Tuberous Sclerosis Complex (TSC)-associated partial-onset seizures **AND**
- Medical record documentation of a therapeutic failure on, intolerance to, or contraindication to at least 2 anti-epileptic drug (AED) regimens.

Quantity limit (all indications): one daily

Discussion: No comments or questions.

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

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

XGEVA (denosumab)

Updated Indication: Xgeva is now indicated for the prevention of skeletal-related events in patients with multiple myeloma.

Previously, Xgeva held indications for the prevention of skeletal-related events in patients with bone metastases from solid tumors, treatment of adults and skeletally mature adolescents with giant cell tumor of bone that is unresectable or where surgical resection is likely to result in severe morbidity, and treatment of hypercalcemia of malignancy refractory to bisphosphonate therapy.

Recommendation: No changes are recommended to the formulary placement of Xgeva at this time. It is recommended that the current limitation of "Xgeva is not indicated for the prevention of skeletal-related events in patients with multiple myeloma" be removed from policy MBP 89.0 and that the prior authorization criteria of Xgeva are updated to account for the new indication as follows.

<u>For MBP 89.0</u>

4. Prevention of skeletal-related events in Multiple Myeloma

- Medical record documentation of use for the prevention of skeletal-related events in patients with multiple myeloma; **AND**
- Member has corrected calcium if hypocalcemic prior to initiating therapy and documentation that calcium levels will be monitored and adequately supplemented with calcium and vitamin D to achieve serum calcium levels of 8 to 11.5 mg/dL (2 to 2.9 mmol/L); **AND**
- Member is not concurrently receiving Prolia (denosumab); **AND**

- Medical record documentation of a therapeutic failure on, intolerance to, or contraindication to zoledronic acid (Note: A creatinine clearance less than 35mL/minute is considered a contraindication to the use of zoledronic acid)

Discussion: No questions or comments.

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.

AUVI-Q 0.1 mg (epinephrine)

Updated Availability: Auvi-Q is now available for the emergency treatment of allergic reactions (Type 1) including anaphylaxis as a 0.1 mg/0.1 mL auto-injector for patients weighing 7.5 to 15 kg (16.5 to 33 lbs.).

Previously, Auvi-Q was available as a 0.15 mg auto-injector (for patients weighing 15 to 30 kg) and a 0.3 mg auto-injector (for patients weighing more than 30 kg).

Recommendation: As the only prepackaged EAI currently marketed at a dose of 0.1 mg, it is recommended that Auvi-Q 0.1 mg is added to the brand preferred tier of all formularies with an age restriction of less than or equal to 3 years of age. A quantity limit of 4 auto-injectors per 30 days should apply to GHP Family. For requests outside of the designated age range, the following prior authorization criteria should apply:

- Medical record documentation that member's weight is greater than or equal to 7.5 kg (16.5 lbs.) and less than or equal to 15 kg (33 lbs.)

Discussion: No comments or questions.

Outcome: Keith Hunsicker 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.

IMFINZI (durvalumab)

Updated Indication: Imfinzi is now indicated for the treatment of patients with unresectable, stage III non-small cell lung cancer (NSCLC) whose disease has not progressed following concurrent platinum-based chemotherapy and radiation therapy.

Previously, Imfinzi was only approved under accelerated approval for the treatment of patients with locally advanced or metastatic urothelial carcinoma who have disease progression during or following platinum-containing chemotherapy or have disease progression within 12 months of neoadjuvant or adjuvant treatment with platinum-containing chemotherapy.

Recommendation: No changes are recommended to the formulary status of Imfinzi at this time. It is recommended that the prior authorization criteria and authorization duration be updated to account for the new indication as outlined below.

2. Non-Small Cell Lung Cancer (NSCLC)

- Prescription written by a hematologist/oncologist **AND**
- Medical record documentation that patient is 18 years of age or older **AND**
- Medical record documentation of a diagnosis of unresectable Stage III Non-Small Cell Lung Cancer (NSCLC) **AND**
- Medical record documentation that patient has received and has not progressed following a minimum of two cycles of concurrent platinum-based chemotherapy **AND** radiation therapy

AUTHORIZATION DURATION:

For Non-Small Cell Lung Cancer (NSCLC):
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 Imfinzi for the treatment of non-small cell lung cancer 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 urothelial carcinoma:
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 questions or comments.

Outcome: Kevin Szczecina made a motion to accept the recommendations as written. Anastasia Mauger 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.

LATUDA (lurasidone)

Updated Indication: Latuda is now indicated as monotherapy treatment of adult and pediatric patients (10 to 17 years) with major depressive episode associated with bipolar I disorder (bipolar depression).

The safety and effectiveness of Latuda has not been established in pediatric patients less than 10 years of age with bipolar depression.

Latuda was previously only indicated for bipolar I disorder in adults 18 years of age and older.

Recommendation: No changes to the formulary are recommended at this time. The following updates should be made to the Latuda policy:

- Medical record documentation of a diagnosis of depressive episodes associated with Bipolar I Disorder (bipolar depression) AND
- **For members 18 years of age or older:** Medical record documentation of therapeutic failure on, intolerance to, or contraindication to quetiapine

Discussion: No questions or comments.

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

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

NUCALA (mepolizumab)

Updated Indication: Nucala is now indicated for the treatment of adult patients with eosinophilic granulomatosis with polyangiitis (EGPA).

Previously Nucala was only indicated for add-on maintenance treatment of patients with severe asthma aged 12 years and older, and with an eosinophilic phenotype.

Recommendation: No changes are recommended to the tiering or formulary status of Nucala at this time. It is recommended that the criteria of applicable policies be updated to account for the new indication. The limitation, "Nucala is not indicated for treatment of other eosinophilic conditions" should be removed from applicable policies.

MBP 141.0

Eosinophilic Granulomatosis (EGPA)

1. Prescription written by an allergist/immunologist, pulmonologist, and/or rheumatologist **AND**
2. Medical record documentation that patient is ≥18 years of age **AND**
3. Medical record documentation of eosinophilic granulomatosis (EGPA) confirmed by biopsy evidence of vasculitis AND at least four (4) of the following criteria:
    a. Asthma (a history of wheezing or the finding of diffuse high-pitched wheezes on expiration)
    b. Eosinophilia (blood eosinophil level of ≥10% or ≥1500 cells/microL on differential white blood cell count)
    c. Mononeuropathy (including multiplex) or polyneuropathy
    d. Migratory or transient pulmonary opacities detected radiographically
    e. Paranasal sinus abnormality
    f. Biopsy containing a blood vessel showing the accumulation of eosinophils in extravascular areas

    AND
4. Medical record documentation of a therapeutic failure on, contraindication to, or intolerance to systemic glucocorticoid therapy AND at least one immunosuppressant therapy (cyclophosphamide, azathioprine, methotrexate)

Quantity Limit: 3 vials per 28 days

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 patient experiences toxicity or worsening of disease.

Discussion: No questions or comments.

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

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

PROCYSBI (cysteamine bitartrate)

Updated Indication: Procysbi is now indicated for the treatment of nephropathic cystinosis in adults and pediatric patients 1 year of age and older.

Previously, Procysbi was indicated for the treatment of nephropathic cystinosis in adults and pediatric patients 2 years of age and older.

Recommendation: No changes to formulary placement and/or authorization duration are recommended at this time. It is recommended to update the prior authorization criteria for age to greater than or equal to 1 year of age.

Discussion: No questions or comments.

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.

YERVOY (ipilimumab) and OPDIVO (nivolumab)

Updated Dosing: Yervoy and Opdivo, in combination, are now indicated for the treatment of patients with intermediate or poor risk, previously untreated advanced renal cell carcinoma.

Updated Dosing for New Indication: Nivolumab 3 mg/kg administered intravenously over 30 minutes followed by ipilimumab 1 mg/kg administered intravenously over 30 minutes on the same day, every 3 weeks for a maximum of 4 doses, then nivolumab 240 mg every 2 weeks or 480 mg every 4 weeks, administered intravenously over 30 minutes.

Recommendation: No changes are recommended to the formulary status of Opdivo or Yervoy at this time. It is recommended that the current criteria be updated to account for the new indication. The authorization duration criteria for Opdivo and Yervoy are recommended to be updated as described below.

MBP 126.0 – Opdivo (nivolumab)

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 use as a single agent for relapse or for surgically unresectable advanced or metastatic renal cell carcinoma **AND**
- Medical record documentation of a therapeutic failure on or intolerance to prior anti-angiogenic therapy, including, but not limited to, Sutent (sunitinib), Votrient (pazopanib), Inlyta (axitinib), Nexavar (sorafenib), Avastin (bevacizumab), Afinitor (everolimus), or Torisel (temsirolimus).

OR

- Prescription written by a hematologist/oncologist **AND**
- Medical record documentation that patient is ≥ 18 years of age **AND**
- Medical record documentation of previously untreated advanced renal cell carcinoma **AND**
- Medical record documentation that the patient is at intermediate to poor risk (defined as having 1 or more 6 prognostic risk factors as per the IMDC criteria*) **AND**
- Medical record documentation that Opdivo will be given in combination with ipilimumab (Yervoy)

*IMDC Criteria risk factors include:

1. Less than one year from time of initial renal cell carcinoma diagnosis to randomization
2. Karnofsky performance status <80%
3. Hemoglobin less than the lower limit of normal
4. Corrected calcium of greater than 10 mg/dL
5. Platelet count greater than the upper limit of normal
6. Absolute neutrophil count greater than the upper limit of normal

MBP 91.0 – Yervoy (ipilimumab)

Renal Cell Carcinoma

- Prescription written by a hematologist/oncologist **AND**
- Medical record documentation that patient is ≥ 18 years of age **AND**
- Medical record documentation of previously untreated advanced renal cell carcinoma **AND**
- Medical record documentation that the patient is at intermediate to poor risk (defined as having 1 or more 6 prognostic risk factors as per the IMDC criteria*) **AND**
- Medical record documentation that Yervoy will be given in combination with nivolumab (Opdivo)

*IMDC Criteria risk factors include:

1. Less than one year from time of initial renal cell carcinoma diagnosis to randomization
2. Karnofsky performance status <80%
3. Hemoglobin less than the lower limit of normal
4. Corrected calcium of greater than 10 mg/dL
5. Platelet count greater than the upper limit of normal
6. Absolute neutrophil count greater than the upper limit of normal

Authorization Duration (Yervoy):

For Unresectable or metastatic melanoma and Advanced Renal Cell Carcinoma:

Approval will be for one (1) **6-month** authorization for the FDA-approved maximum of up to four (4) doses of Yervoy. Requests for authorization exceeding these limits will require the following:

- Medical record documentation of continued disease improvement or lack of disease progression **AND**
- Medical record documentation of peer-reviewed literature citing well-designed clinical trials to indicate that the member's healthcare outcome will be improved by dosing beyond the FDA-approved treatment duration

For Adjuvant melanoma:
Initial approval will be for **6 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 questions or comments

Outcome: Tricia Heitzman made a motion to accept the recommendations as presented. Anastasia Mauger 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.

REPATHA (evolocumab)

Updated Indication: Repatha is indicated to:

- Reduce the risk of myocardial infarction, stroke, and coronary revascularization in adults with established cardiovascular disease
- As an adjunct to diet, alone or in combination with other lipid lowering therapies (e.g. statins, ezetimibe), for treatment of adults with primary hyperlipidemia (including heterozygous familial hypercholesterolemia (HeFH)) to reduce low-density lipoprotein cholesterol (LDL-C)
- As an adjunct to diet and other LDL-lowering therapies (e.g. statins, ezetimibe, LDL apheresis) in patients with homozygous familial hypercholesterolemia (HoFH) who require additional lowering of LDL-C.

Previous Indication:
Repatha was previously indicated as an adjunct to diet and:

- *Maximally tolerated statin therapy for the treatment of adults with HeFH or clinical ASCVD, who require additional lowering of LDL-C*
- *Other LDL-lowering therapies (e.g. statins, ezetimibe, LDL apheresis) in patients with HoFH who require additional lowering of LDL-C*

**At this time, the effect of Repatha on CV mortality and morbidity was not determined.*

Recommendation: There are no changes recommended to formulary status at this time. It is recommended to remove the following criteria from the current Reptha policy:

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

Discussion: No questions or comments.

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

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

STELARA (ustekinumab)

Updated Indication: Stelara is now indicated to treat adolescent patients (12 years or older) with moderate to severe plaque psoriasis, who are candidates for phototherapy or systemic therapy.

Recommendation: No changes are recommended to the tiering of Stelara at this time. It is recommended that the Plaque Psoriasis section be updated to account for the new indication.

For Pediatric Plaque Psoriasis

1. Prescription must be written by a dermatologist **AND**
2. Member must be at least 12 years of age **AND**
3. Medical record documentation of a diagnosis of moderate to severe plaque psoriasis characterized by ≥5% of body surface area involved or disease affecting crucial body areas such as hands, feet, face, or genitals **AND**
4. Medical record documentation of intolerance to, contraindication to, or therapeutic failure on at least two topical corticosteroids **AND**
5. Medical record documentation that the prescribed dose is appropriate for the patient's weight

Dosing for plaque psoriasis:

- Patients weighing over 100kg should receive 90 mg every 12 weeks (GPID 28159)
- Patients weighing ≥60kg to ≤100kg should receive 45 mg every 12 weeks (GPID 19903 or 28158)
- Patients weighing less than 60kg should receive 0.75mg/kg every 12 weeks (via single dose vial – GPID 19903)

Authorization should be approved by GPID

Quantity Limit:

Initial: RX count 3 for initial 6 months
Subsequent: RX count 5 for subsequent 12 months

Authorization Duration:

Approval will be given for an initial duration of six (6) months. For continuation, medical record documentation of clinical improvement or lack of progression in thesigns and symptoms of psoriasis on six (6) months of Stelara therapy is required.

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

Discussion: No questions or comments.

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.

TASIGNA (nilotinib)

Updated Indication:

- Treatment of newly diagnosed Ph+ CML in chronic phase in pediatric patients ≥1 year and adults
- Treatment of chronic and accelerated-phase Ph+ CML in adults resistant or intolerant to prior therapy that included Gleevac (imatinib)
- Treatment of chronic phase Ph+ CML in pediatric patients ≥1 year with resistance or intolerance to prior tyrosine-kinase inhibitor therapy

Updated Pediatric Dosing for New Indication:

- CML-Newly diagnosed Ph+ in chronic phase

  ≥1 year of age
  Usual dosage: 230 mg/m^2 orally twice daily (rounded to the nearest 50 mg dose). Continue as long as observing clinical benefit or until unacceptable toxicity occurs
  Maximum dosage: 400 mg (as a single dose) twice daily

- CML-Resistant or intolerant Ph+ in chronic phase

  ≥1 year of age
  Usual dosage: 230 mg/m^2 orally twice daily (rounded to the nearest 50 mg dose). Continue as long as observing clinical benefit or until unacceptable toxicity occurs
  Maximum dosage: 400 mg (as a single dose) twice daily

Recommendation: There are no changes to formulary status recommended at this time. It is recommended that the Tasigna policy be updated to reflect the new indication:

For GHP Family:

- Medical record documentation that Tasigna is prescribed by a hematologist or oncologist **AND**
- Medical record documentation of the use of Tasigna to treat newly diagnosed (not previously treated) **chronic** phase Ph+ CML in *adult or pediatric patients ≥1 year* of age **OR**
- Medical record documentation of the use of Tasigna to treat **chronic or accelerated** phase Ph+ CML in *adult* patients with resistance, or intolerance to prior therapy including Gleevac (imatinib) **OR**
- Medical record documentation of the use of Tasigna to treat **chronic** phase Ph+ CML in *pediatric patients ≥1 year of age* with resistance or intolerance to prior tyrosine-kinase inhibitor therapy

Authorization Duration: Re-review for disease progression every 12 months. Tasigna will no longer be covered if disease progresses.

Additional recommendations:

- Recommend adding the quantity limit of 4 capsules/day

Discussion: No comments or questions.

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

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

ZYTIGA (abiraterone)

Updated Indication: Zytiga is now indicated in combination with prednisone for the treatment of patients with metastatic high-risk castration-sensitive prostate cancer (CSPC).

Previously, Zytiga was maintained the indication to treat patients with metastatic castration-resistant prostate cancer (CRPC) in combination with prednisone.

Updated Dosing for New Indication[1]: Zytiga 1,000mg by mouth once daily with prednisone 5mg by mouth once daily.

Recommendation: It is recommended that Policy 207.0D be updated as outlined below.

- Prescription written by an oncologist or urologist **AND**
- Medical record documentation of a diagnosis of prostate cancer with evidence of metastatic disease **AND**
- Medical record documentation that prednisone will be administered concomitantly with Zytiga **AND**
- Medical record documentation of one of the following:
    - That the member is no longer responding to castration or is hormone resistant **OR**
    - That the member has high-risk*, castration-sensitive disease

*Note: In clinical trials, patients were considered to be high risk if they had two of the following risk factors at baseline: A total Gleason score of ≥8, presence of ≥3 lesions on bone scan, and evidence of measurable visceral metastases.

Discussion: No questions or comments.

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.

UPDATES

Quantity limit updates
Recommendation: It is recommended that quantity limits for the listed medications be updated as follows:

Medication	Recommended Quantity Limit
Afinitor – everolimus	All Strengths: 1 tablet per day, 28 day supply per fill

Caprelsa – vandetanib	100 mg tablet: 2 tablets per day, 30 day supply per fill 300 mg tablet: 1 tablet per day, 30 day supply per fill
Casodex – bicalutamide	1 tablet per day, 30 day supply per fill
Cometriq – cabozantinib	60 mg daily dose: 3 capsules per day, 28 day supply per fill 100 mg daily dose: 2 capsules per day, 28 day supply per fill 140 mg daily dose: 4 capsules per day, 28 day supply per fill
Gleevec – imatinib	100 mg tablet: 3 tablets per day, 30 day supply per fill 400 mg tablet: 2 tablets per day, 30 day supply per fill
Iclusig – ponatinib	All Strengths: 1 tablet per day, 30 day supply per fill
Inlyta – axitinib	1 mg tablet: 6 tablets per day, 30 day supply per fill 5 mg tablet: 4 tablets per day, 30 day supply per fill
Lonsurf – trifluridine/tipiracil	15 mg/6.14 mg tablet: 100 tablets per 28 days 20 mg/8.19 mg tablet: 80 tablets per 28 days
Sprycel – dasatinib	20 mg tablets: 3 tablets per day, 30 day supply per fill 50 mg, 70 mg, 80 mg, 100 mg, and 140 mg tablets: 1 tablet per day, 30 day supply per fill
Tasigna – nilotinib	50 mg capsule: 4 capsules per day, 30 day supply per fill 150 mg and 200 mg capsules: 4 capsules per day, 28 day supply per fill
Tykerb – lapatinib	6 tablets per day, 30 day supply per fill

Zolinza – vorinostat	4 capsules per day, 30 day supply per fill
Pegasys – peginterferon alfa-2a	180 mcg/mL vial: 4 mL per 28 days Syringe/Autoinjectors: 2 mL per 28 days
PegIntron – peginterferon alfa-2b	2 mL per 28 days
Sancuso Patch – granisetron	4 patches per 28 days
Uloric – febuxostat	1 tablet per day
Zavesca – miglustat	3 capsules per day, 30 day supply per fill

Discussion: No comments or questions.

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

White Blood Cell Stimulating Factor Policy Update

The following policy updates are recommended to the White Blood Cell Stimulating Factor Policy, MBP 59.0 and Polcy 902.0F based on recommendations made by DHS during annual policy review, and in accordance with the most current FDA approval language. In addition, risk factors as previously noted from NCCN Guidelines have been updated to reflect additions that were made from NCCN. The following changes are recommended:

Neupogen, Neulasta, Zarxio, Leukine, Granix:

The use of white blood cell stimulating factor [Neupogen (filgrastim), Neulasta (pegfilgrastim), Granix (tbo-filgrastim), Zarxio (filgrastim-sndz), or Leukine (sargramostim)] is considered medically necessary in insured individuals with a diagnosis of cancer, and when any of the following FDA labeled indications or uses supported by clinical guidelines are present:

1. Primary Prophylaxis - 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, etopside, cyclophosphamide, bleomycin)
- A(N)CVB (doxorubicin or mitoxantrone, cyclophosphamide, vindesine, bleomycin)
- DHAP (dexamethasone, cisplatin, cytarabine)

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

OR

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

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

Neupogen, Neulasta, Zarxio, or Leukine: May also be considered medically necessary for any of the following:

2. 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.

3. 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

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

5. 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 leukaphersis)

Note: Neulasta is considered off-label for PBPC mobilization

6. Leukemia or Myelodysplastic Syndromes – insured individuals with any of the following conditions:

- 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.

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

9. Radiation therapy – with any of the following conditions

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

Neupogen, Zarxio: May also be considered medically necessary for the following:

10. 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/mm^3 on three seperate occasions during a 6 month period (for Congential or Idiopathic Neutropenia) OR five consecutive days of ANC <500 cells/mm^3 per cycle (for Cyclic Neutropenia) AND
- Documentation that the member experienced a clinical significant infection, fever, or oropharyngeal ulcer during the past 12 months.

AUTHORIZATION: When approved, the duration of the authorization will be for 6 months.

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.

Discussion: No questions or comments.

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

Fluticasone/Salmeterol (generic AirDuo)

Review: A recent analysis of the inhaled corticosteroid/long acting $beta_2$ adrenergic agonist category revealed an opportunity to improve access and decrease costs to the plan and members by expanding our formulary agents.

Recommendations: It is recommended that fluticasone/salmeterol (generic AirDuo) is added to the prescription drug formularies as follows:

- GHP Family: Generic Tier

  QUANTITY LIMIT: 1 inhaler per 30 days

Discussion: No questions or comments.

Outcome: Aubrielle Prater made a motion to accept the presented recommendations. 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.

GHP Family Formulary Update:

It is recommended that the following be added to the GHP Family Formulary:

Medication	AWP/MAC	Tier/UM
ciclopirox cream	$0.49 per gram MAC	Generic Tier

Discussion: No questions or comments.

Outcome: Kim Clark made a motion to accept the presented recommendations. Anastasia Mauger seconded the motion. None were opposed.

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

GHP Family Formulary Update:GHP Family Antipsychotic Policy Update

To assist in reviewing requests for non-preferred antipsychotics that do not have a policy it is recommended that the following criterion be added to GHP Family Policy 1220.0F "Antipsychotic Use in Members Less Than Age 18":

AND if the request is for a non-preferred antipsychotic:

- Medical record documentation of a therapeutic failure on, intolerance to, or contraindication to three formulary alternatives (aripiprazole, olanzapine, quetiapine IR, risperidone, ziprasidone).

Discussion: No questions or comments.

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

The following recommendations were approved electronically by the P&T Committee on April 30, 2018 with 26 votes of approval and 1 vote of rejection.

Medication Assisted Treatment (MAT) Update

The Commonwealth of Pennsylvania will implement new policies within the Medicaid program that will enhance current guidelines to help ensure access to Medication Assisted Treatment. The Department of Human Services will be implementing these policies within both the Medicaid fee-for-service and managed care programs and have asked commercial plans to take these same steps alongside the Commonwealth. The requirements that apply to MAT are:

- At least one buprenorphine/naloxone combination product(s) must be covered without a requirement for prior authorization
- Prior authorization may be required for the following:
  o Buprenorphine without naloxone
  o Buprenorphine for patients also taking benzodiazepines or other CNS depressants
  o Prescribed quantities that exceed daily dose limits
  o Non-preferred or non-formulary drugs
- Both injectable and oral naltrexone must be covered without a requirement for prior authorization
- At least one form of nasal naloxone must be covered without a requirement for prior authorization and without quantity limits

GHP FAMILY

To be compliant, it is recommended the following changes be made to the GHP Family Formulary:

- Remove the prior authorization requirement from buprenorphine SL tablets and buprenorphine/naloxone SL tablets

GHP Family is currently compliant with all there requriments. In addition, at the request of Pennsylvania Department of Human Services, it is recommended the following criteria be adopted for Suboxone, Bunavail, and Zubsolv.

Suboxone

- There is medical record documentation of a diagnosis of opioid dependence **AND**
- There is confirmation that the prescriber or the prescriber's delegate has conducted a review of Pennsylvania's Prescription Drug Monitoring Program (PDMP) prior to prescribing Suboxone Film

Bunavail and Zubsolv

- There is medical record documentation of a diagnosis of opioid dependence **AND**
- There is confirmation that the prescriber or the prescriber's delegate has conducted a review of Pennsylvania's Prescription Drug Monitoring Program (PDMP) prior to prescribing a non-preferred buprenorphine/naloxone product **AND**
- Medical record documentation of intolerance to or contraindication to use of generic buprenorphine/naloxone SL tablets **AND** Suboxone Film

No changes are recommended to the authorization duration or tiering of Suboxone, Bunavail and Zubsolv.

Meeting adjourned at 5:20 pm.

Future Scheduled Meetings
Tuesday, July 17, 2018 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.