P&T Committee Meeting Minutes
GHP Family
September 19, 2017

Present:	**Absent:**
Bret Yarczower, MD, MBA – Chair	Kenneth Bertka, MD
Kristen Bender, Pharm.D – via phone	Beverly Blaisure, MD
Holly Bones, Pharm.D – via phone	Keith Boell, DO
Rajneel Chohan Pharm.D.	Jamie Dodson, RPh
Dean Christian, MD	Michael Evans, Pharm.D. B.S.
Kimberly Clark, Pharm.D.	John Flaherty, Pharm.D.
Kristi Clarke, Pharm. D. – via phone	Steven Kheloussi, Pharm.D.
Patrick Ferguson, RPh, MBA – via phone	Jonas Pearson, MS, RPh
Sandra Garrett, RPh, MBA – via phone	Michael Spishock RPh
Tricia Heitzman, Pharm.D.	
Jason Howay, Pharm.D. – via phone	
Keith Hunsicker, Pharm.D.	
Phillip Krebs, R.EEG T.	
Susan Leidig, MD, MS – via phone	
Anastasia Mauger Pharm.D.	
Perry Meadows, MD – via phone	
Thomas Morland, MD – via phone	
Steven Moscola, RPh – via phone	
Aubrielle Prater Pharm.D.	
Kristen Scheib, Pharm. D. – via phone	
William Seavey, Pharm.D. – via phone	
Richard Silbert, MD – via phone	
Todd Sponenberg, Pharm.D., RPh	
Kevin Szczecina, RPh	
Elaine Tino, CRNP – via phone	
Lori Zaleski, RPh – via phone	
Collin Strunk, Pharmacy Student	

Call To Order:
Dr. Bret Yarczower called the meeting to order at 1:00 p.m., Tuesday, September 19, 2017. .

Review and Approval of Minutes:
Dr. Bret Yarczower asked for a motion or approval to accept the May 16, 2017 minutes as written. Keith Hunsicker accepted the motion and Todd Sponenberg seconded the motion. None were opposed.

DRUG REVIEWS

BRINEURA (cerliponase alfa)

Review: Brineura is a Hydrolytic lysosomal N-terminal tripeptidyl peptidase indicated to slow the loss of ambulation in symptomatic pediatric patients 3 years of age and older with late infantile neuronal ceroid lipofuscinosis type 2 (CLN2) and is available as a 150 mg/5mL (30 mg/mL) solution for injection: two single-dose vials per carton co-packaged with Intraventricular Electrolytes Injection 5mL in a single-dose vial. It is administered via B Braun Perfusor® Space Infusion Pump System into cerebrospinal fluid by infusion at least 5 to 7 days after surgical implantation of a reservoir and catheter. Recommended dosage in pediatric patients 3 years of age and older is 300 mg administered once every other week. Brineura (10 mL) should be administered first, then followed by Intraventricular Electrolytes (2 mL), each at an infusion rate of 2.5mL/hr. Complete infusion is approximately 4.5 hours. Do not administer as a bolus. Pretreatment with antihistamines with or without antipyretics or corticosteroids is recommended 30 to 60 minutes prior to start of infusion Late infantile neuronal ceroid lipofuscinoses (LINCLs), also known as Jansky-Bielschowsky disease, is a rare and fatal neurodegenerative disorder that affects lysosomal storage in children between the ages of two and eight years of age. LINCLs lead to progressive decline in motor and mental function, and ends in death by early teen years. Brineura (cerliponase alfa) is the first and only medication FDA-approved to slow the loss of ambulation in children 3 years and older with LINCLs. Brineura works by cleaving tripeptides from the N-terminus of proteins in the lysosome. Brineura is administered into the cerebrospinal fluid by intraventricular infusion. In a non-randomized clinical trial, cerliponase alfa showed efficacy in decreasing loss of motor function, when compared to a natural history cohort of untreated 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: Tricia Heitzman recommended adding “medical record documentation that the patient is ambulatory (e.g. able to walk with assistance, not wheelchair bound, does not have full-time dependence on motorized wheelchairs or scooters for mobility)” to the proposed criteria.. Kevin Szczecina made a motion to accept the amended recommendations. Tricia Heitzman seconded the motion. None were opposed

Financial Discussion: Patrick Ferguson recommended amended the reauthorization criteria to be “medical record documentation that patient remains to be ambulatory (e.g. able to walk with assistance, not wheelchair bound, does not have full-time dependence on motorized wheelchairs or scooters for mobility)”. Kevin Szczecina made a motion to accept the amended recommendations. Tricia Heitzman seconded the motion. None were opposed.

Outcome: Brineura will be considered a medical Benefit requiring prior authorization, quantity limit, and authorization duration. The following criteria will apply:

- Medical record documentation that the prescription is written by a pediatric neurologist AND
- Medical record documentation that the patient is 3 years of age or older AND
- Medical record documentation of a diagnosis of late infantile neuronal ceroid lipofuscinosis type 2 (LINCL) confirmed by the following test results:
    - Deficient TPP1 activity in leukocytes on the enzyme activity test AND
    - Pathogenic variant/mutation in the TPP1/CLN2 gene (note- may be absent in up to 20% of patients, but if present is confirmatory of diagnosis) AND
- Medical record documentation of the baseline score on the motor domain of the CLN2 clinical rating scale AND

- Medical record documentation that the patient is ambulatory (e.g. able to walk with assistance, not wheelchair bound, does not have full-time dependence on motorized wheelchairs or scooters for mobility)

Quantity Limit: 2 doses per month (24 doses per year)

Authorization Duration: 1 year

Reauthorization criteria – Medical record documentation that patient remains to be ambulatory (e.g. able to walk with assistance, not wheelchair bound, does not have full-time dependence on motorized wheelchairs or scooters for mobility).

Subsequent authorizations should be for a period of 1 year.

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

VOSEVI (sofosbuvir, velpatasvir, and voxilaprevir)

Review: Vosevi is a fixed-dose combination of sofosbuvir, a hepatitis C virus (HCV) nucleotide analog NS5B polymerase inhibitor, velpatasvir, an HCV NS5A inhibitor, and voxilaprevir, an HCV NS3/4A protease inhibitor. Vosevi is indicated for the treatment of adult patients with chronic HCV infection without cirrhosis or with compensated cirrhosis (Child-Pugh A) who have either genotype 1, 2, 3, 4, 5, or 6 infection and have previously been treated with an HCV regimen containing an NS5A inhibitor or genotype 1a or 3 infection and have previously been treated with an HCV regimen containing sofosbuvir without an NS5A inhibitor. It is available as a 400 mg sofosbuvir, 100 mg velpatasvir, and 100 mg voxilaprevir combination tablet and is dosed once daily with food. Chronic hepatitis C is a blood-borne infectious disease of the liver that affects approximately 2.7-3.9 million people in the United States, and 45-85% of infected individuals are unaware that they are infected. Based on recent CDC guidance, it is recommended that persons born between 1945-1965 be screened for HCV. Also, persons participating in high risk behaviors or at risk for exposure are recommended to be tested for the HCV antibody. Untreated HCV infection can lead to liver complications, including cirrhosis, hepatocellular carcinoma, and liver transplantation. A Clinical Review including Clinical Information, Efficacy Evidence, Safety Evidence, and Other Considerations and a Financial Review Based on Cost Analysis were presented.

Clinical Discussion: No comments or questions. Keith Hunsicker made a motion to accept the recommendations as presented. Tricia Heitzman seconded the motion. None were opposed

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

Outcome: Vosevi will be considered a Non-formulary medication requiring quantity a limit and authorization duration. The following criteria will apply:

- The member is at least 18 years of age or older **AND**
- Medical record documentation of a diagnosis of hepatitis C infection **AND**
- Medical record documentation of the member's hepatitis C genotype **AND**
- Medical record documentation of a diagnosis of hepatitis C virus (HCV) genotype 1, 2, 3, 4 5 or 6 infection **AND**
- Medical record documentation of METAVIR liver scoring **AND**

- Medical record documentation of a hepatocellular carcinoma screening in those with cirrhosis (METAVIR score F4) **AND**
- Is prescribed by a board certified gastroenterology, hepatology, infectious disease or transplant specialist **AND**
- Member must be evaluated and treated by a contracted Center of Excellence in Hepatitis C management **AND**
- Medical record documentation of the member receiving a Food and Drug Administration (FDA) approved medication regimen that is inside the parameters of use approved by the FDA or supported in the widely used compendia available OR
- Medical record documentation of:
    - Genotype 1, 2, 3, 4, 5, or 6: As monotherapy if treatment experienced with an NS5A inhibitor experience (daclatasvir, elbasvir, ledipasvir, ombitasvir, or velpatasvir) **OR**
        - Genotype 1a or 3: As monotherapy if treatment experienced with a prior treatment experience included sofosbuvir with or without any of the following: peginterferon alfa/ribavirin, ribavirin, HCV NS3/4A protease inhibitor (boceprevir, simeprevir or telaprevir) **AND**
- Medical record documentation of appropriate duration of treatment **AND**
- Medical record documentation of previous treatment and treatment response **AND**
- Medical record documentation of any potential drug interactions addressed by the prescriber (such as discontinuation of the interacting drug, dose reduction of the interacting drug, or counseling of the recipient of the risks associated with the use of both medications when they interact) **AND**
- Medical record documentation of receiving the following within the past 3 months:
    - Hepatic function panel
    - Complete blood count including differential
    - Basic metabolic panel
    - Baseline HCV RNA viral load **AND**
- Medical record documentation that member does not have severe renal impairment (estimated glomerular filtration rate < 30 mL/min/1.73 m^2) or end stage renal disease requiring hemodialysis **AND**
- If actively abusing alcohol or IV drugs, or has a history of abuse, has documentation of prescriber counseling regarding the risks of alcohol or IV drug abuse, and an offer of a referral for substance use disorder treatment **AND**
- Medical record documentation that member received pre-treatment readiness education about hepatitis C treatment expectations by a health care provider **AND**
- Medical record documentation that the member commits to the documented planned course of treatment including anticipated blood tests and visits, during and after treatment **AND**
- Medical record documentation that member does not have a limited life expectancy of less than 12 months due to non-liver related co-morbid conditions **AND**
- Medical record documentation of a therapeutic failure on, contraindication to, or intolerance to three formulary alternatives, if appropriate.

QUANTITY LIMITS: one tablet per day, 28 day supply per fill

TREATMENT DURATION: 12 weeks OR Medical record documentation of the member receiving a Food and Drug Administration (FDA) approved medication regimen that is inside the parameters of use approved by the FDA or supported in the widely used compendia available

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

MAVYRET (glecaprevir and pibrentasvir)

Mavyret is indicated for the treatment of patients with chronic HCV genotype 1, 2, 3, 4, 5 or 6 infection without cirrhosis and with compensated cirrhosis. Mavyret is also indicated for the treatment of adult patients with HCV genotype 1 infection, who previously have been treated with a regimen containing an HCV NS5A inhibitor or an NS3/4A protease inhibitor, but not both. It is available as a 100 mg glecaprevir and 40 mg pibrentasvir combination tablet. Three tablets (total daily dose: glecaprevir 300 mg and pibrentasvir 120 mg) taken orally once daily with food. Chronic hepatitis C is a blood-borne infectious disease of the liver that affects approximately 2.7-3.9 million people in the United States, and 45-85% of infected individuals are unaware that they are infected. Based on recent CDC guidance, it is recommended that persons born between 1945-1965 be screened for HCV. Also, persons participating in high risk behaviors or at risk for exposure are recommended to be tested for the HCV antibody. Untreated HCV infection can lead to liver complications, including cirrhosis, hepatocellular carcinoma, and liver transplantation. A Clinical Review including Clinical Information, Efficacy Evidence, Safety Evidence, and Other Considerations and a Financial Review Based on Cost Analysis were presented.

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

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

Outcome: Mavyret will be added to the GHP Family Formulary on Brand Tier requiring prior authorization, quantity limit, and authorization duration. The following criteria will apply:

- The member is at least 18 years of age or older **AND**
- Medical record documentation of a diagnosis of hepatitis C infection **AND**
- Medical record documentation of the member's hepatitis C genotype **AND**
- Medical record documentation of a diagnosis of hepatitis C virus (HCV) genotype 1, 2, 3, 4 5 or 6 infection **AND**
- Medical record documentation of METAVIR liver scoring **AND**
- Medical record documentation of a hepatocellular carcinoma screening in those with cirrhosis (METAVIR score F4) **AND**
- Is prescribed by a board certified gastroenterology, hepatology, infectious disease or transplant specialist **AND**
- Member must be evaluated and treated by a contracted Center of Excellence in Hepatitis C management **AND**
- Medical record documentation of the member receiving a Food and Drug Administration (FDA) approved medication regimen that is inside the parameters of use approved by the FDA or supported in the widely used compendia available **OR**
- Medical record documentation of:
    - Genotype 1, 2, 3, 4, 5 or 6 without cirrhosis or with compensated cirrhosis who are treatment naïve or experienced with peginterferon/ribavirin or Sovaldi/ribavirin +/- peginterferon OR
    - Genotype 1 previously have been treated with a regimen containing an HCV NS5A inhibitor or an NS3/4A protease inhibitor, but not both AND

- Medical record documentation of appropriate duration of treatment **AND**
- Medical record documentation of previous treatment and treatment response **AND**
- Medical record documentation of any potential drug interactions addressed by the prescriber (such as discontinuation of the interacting drug, dose reduction of the interacting drug, or counseling of the recipient of the risks associated with the use of both medications when they interact) **AND**
- Medical record documentation of receiving the following within the past 3 months:
    - Hepatic function panel
    - Complete blood count including differential
    - Basic metabolic panel
    - Baseline HCV RNA viral load **AND**
- If actively abusing alcohol or IV drugs, or has a history of abuse, has documentation of prescriber counseling regarding the risks of alcohol or IV drug abuse, and an offer of a referral for substance use disorder treatment **AND**
- Medical record documentation that member received pre-treatment readiness education about hepatitis C treatment expectations by a health care provider **AND**
- Medical record documentation that the member commits to the documented planned course of treatment including anticipated blood tests and visits, during and after treatment **AND**
- Medical record documentation that member does not have a limited life expectancy of less than 12 months due to non-liver related co-morbid conditions

QUANTITY LIMITS: 3 tablets per day, 28 day supply per fill

TREATMENT DURATION: 8, 12, or 16 weeks consistent with current AASLD/IDSA guidelines or FDA recommendations.

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

IDHIFA (enasidenib)

Idhifa is indicated for the treatment of adult patients with relapsed or refractory acute myeloid leukemia (R/R AML) with an isocitrate dehydrogenase-2 (IDH2) mutation as detected by an FDA approved test. Idhifa is available as 50 mg and 100 mg tablets. Idhifa is administered 100 mg orally once daily until disease progression or unacceptable toxicity. For patients without disease progression or unacceptable toxicity, Idhifa treatment should be used for a minimum of 6 months to allow time for clinical response. There are recommended dosage modifications for various Idhifa related toxicities. Idhifa is a small molecule that inhibits the IDH2 enzyme. By targeting and inhibiting IDH2 mutations, Idhifa promotes cellular differentiation and prevents an accumulation of immature blood cells. The efficacy of Idhifa was evaluated in a Phase I/II open-label, single-arm, multicenter, two-cohort clinical trial. With a median follow-up of 6.6 months, 19% of patients experienced CR for a median 8.2 months, and 4% of patients achieved CRh for a median 9.6 months. Of the 157 patients who required transfusions of blood or platelets due to AML at the start of the study, 34% no longer required transfusions after treatment with Idhifa. Idhifa carries a black box warning for differentiation syndrome and a warning and precaution for embryo-fetal toxicity. The most common adverse reactions (≥20%) included nausea, vomiting, diarrhea, elevated bilirubin, and decreased appetite. Idhifa is a first-in-class targeted therapy approved for use in

relapsed or refractory AML patients with the IDH2 mutation. Currently, the only treatment options available for AML patients in the relapsed or refractory setting include: enrollment in a clinical trial, systemic chemotherapy ± hypomethylating agents (5-azacitidine or decitabine), or allogeneic hematopoietic stem cell transplant. A Clinical Review including Clinical Information, Efficacy Evidence, Safety Evidence, and Other Considerations and a Financial Review Based on Cost Analysis were presented.

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

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

Outcome: Idhifa will be added to the GHP Family Formulary on Brand Tier requiring prior authorization, quantity limit, and authorization duration. The following criteria will apply:

- Prescription written by an oncologist/hematologist AND
- Medical record documentation of the member being ≥ 18 years AND
- Medical record documentation of relapsed or refractory acute myeloid leukemia AND
- Medical record documentation of an isocitrate dehydrogenase-2 (IDH2) mutation as detected by an FDA approved test

Note: The FDA approved test is Abbott RealTi*m*e™ IDH2 assay

Quantity Limit: 1 tablet per day, 30 day supply per fill

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

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

NERLYNX (neratinib)

Review: Nerlynx (neratinib) is an oral Tyrosine Kinase Inhibitor (TKI) indicated for the extended adjuvant treatment of adult patients with early stage HER2-overexpressed/amplified breast cancer, to follow adjuvant trastuzumab-based therapy. Nerlynx exhibits anticancer properties through irreversible inhibition of Epidermal Growth Factor Receptor (EGFR), Human Epidermal Growth Factor Receptor 2 (HER2), and HER4. Nerlynx is available in 40 mg oral tablets, with a recommended starting dose of 240 mg (6 tablets) by mouth once daily with food for 1 year. Prophylaxis for chemotherapy-induced diarrhea is recommended with loperamide, as well as Nerlynx dose reductions in the presence of intolerable adverse effects. In addition, dose adjustments are necessary for patients with severe, pre-existing hepatic impairment (defined as Child Pugh C). There are currently no black box warnings or contraindications for Nerlynx therapy. Warnings and precautions include increased risk of diarrhea, hepatotoxicity, and embryo-fetal toxicity. Significant drug-drug interactions include gastric acid reducing agents (PPIs, H2-RAs, antacids), strong and moderate CYP3A4 inhibitors and inducers, and P-glycoprotein (P-gp)

substrates. Nerlynx was associated with fetal harm in animal studies and should be avoided. Nerlynx should also be avoided in nursing mothers. No data is available specific to the pediatric population. Renal impairment was not found to impact Nerlynx, but severe hepatic impairment requires dose modification. Geriatric use of Nerlynx should be more closely monitored and may require dose reductions or drug discontinuation due to increased severity of adverse reactions. A Phase III multicenter, randomized, double-blind, placebo-controlled trial of Nerlynx in 2,840 patients with HER-2 positive breast cancer who previously received trastuzumab-based treatment was conducted to determine efficacy. The invasive disease free survival rate (iDFS) was significantly higher for patients treated with Nerlynx compared to placebo (approximately 2% higher). No data is available regarding 5-year survival rate. Subgroup analyses suggested no benefit of Nerlynx therapy for patients with HR-negative disease, patients who received sequential trastuzumab therapy in relation to other chemotherapy, or patients that completed trastuzumab greater than 1 year prior to starting the study. An additional meta-analysis focused on the gastrointestinal side effects of Nerlynx showed a significantly increased risk of all-grade diarrhea, vomiting, and nausea, with grade 3 or 4 vomiting and diarrhea also being significantly increased. At this time, the NCCN guidelines do not recommend the use of neratinib in HER2-overexpressed early stage breast cancer after trastuzumab-based therapy. Specialist feedback does not specifically recommend Nerlynx use following trastuzumab therapy due to incomplete evidence from clinical trials and the very significant risk (40%) for Grade 3 diarrhea, which is an indication for hospitalization and may lead to life threatening complications. In addition, lapatinib (Tykerb) therapy is not recommended in patients with HER-overexpression breast cancer. Perjeta (pertuzumab) is considered a therapeutic option for patients with early stage breast cancer at high risk. 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. Dr. Dean Christian made a motion to accept the recommendations as presented. Aubrielle Prater seconded the motion. None were opposed

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

Outcome: Nerlynx will be added to the GHP Family Formulary on Brand Tier requiring prior authorization, quantity limit, and authorization duration. The following criteria will apply:

- Medical record documentation of age greater than or equal to 18 years of age **AND**
- Medical record documentation that Nerlynx is prescribed by an oncologist **AND**
- Medical record documentation of a diagnosis of early stage (Stages I-IIIA) breast cancer **AND**
- Medical record documentation of HER-2 overexpression/amplification **AND**
- Medical record documentation of prior treatment with trastuzumab-based therapy

Quantity Limit: 6 tablets (240 mg) per day, 30 day supply per fill

Authorization Duration: One time authorization for use for 12 months*

*Note: FDA-approved dosing schedule only approves the use of Nerlynx for 1 year following adjuvant trastuzumab therapy

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

AUSTEDO (deutetrabenazine)

Review: Austedo (deutetrabenazine) is a VMAT2 inhibitor indicated for the treatment of chorea in patients with HD and the treatment of TD in adults. Austedo is structurally similar to tetrabenazine (Xenazine), a medication also used for the treatment of chorea in patients with HD. Austedo is a chemical modification of tetrabenazine intended to create a more favorable pharmacokinetic profile to improve tolerability and safety. Austedo is available in 6, 9, and 12 mg oral tablets, and is dosed based on symptom severity and tolerability. It is recommended that patients with HD who have never taken tetrabenazine begin with a starting dose of 6 mg/day and patients with TD begin with 12 mg/day, which can be increased to a total daily dose of 48 mg/day in weekly increments until an appropriate response is achieved. Doses greater than 12 mg should be given in 2 divided doses. For patients who are currently taking tetrabenazine, an equivalent dose of Austedo can be determined using a conversion table provided in the medication package insert and started the 1 day after discontinuing tetrabenazine. A Phase III 12-week double-blind randomized placebo-controlled trial of Austedo therapy in 90 patients with chorea due to HD resulted in overall decreases in Total Maximal Chorea Score compared to placebo, as well as patient and physician-rated global impressions of change in symptoms. An open-label, single arm study evaluating changes in safety and efficacy for patients being converted from tetrabenazine to deutetrabenazine resulted in lower rates of adverse events, dose reduction, and/or drug discontinuation, as well as a significantly improved Total Maximal Chorea Score at week 8 for patients with HD. In addition, a study indirectly comparing tolerability of Austedo and tetrabenazine, based on two similar studies that were previously conducted, showed reductions in major adverse effects, lower rates of dose reduction, and/or lower drug discontinuation rates in patients with HD taking Austedo. In patients with TD, statistically significant reductions in the total AIMs score were observed in comparison to placebo. Austedo carries a black block warning for depression and suicidality, and use is contraindicated in patients who are suicidal, patients untreated or insufficiently treated for depression, patients with hepatic impairment, and patients currently taking MAOIs, reserpine, or tetrabenazine. Warnings and precautions include clinical worsening and adverse events, depression and suicidality, neuroleptic malignant syndrome, akathisia, agitation, restlessness, parkinsonism, sedation and somnolence, QTc prolongation, hyperprolactinemia, and binding to melanin-containing tissues. Significant drug interactions include strong CYP2D6 inhibitors, reserpine, MAOIs, neuroleptic drugs, alcohol and other sedating drugs, drugs than cause QTc prolongation, and tetrabenazine. There is no specific data available on the risks of Austedo in pregnancy, lactation, pediatrics, geriatrics, or renal impairment. Additionally, there is no data on the effects of hepatic impairment in patients taking Austedo, but Austedo is contraindicated in hepatic impairment due to the significant risk tetrabenazine (a similarly related compound) poses in this patient population. 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. Dr. Dean Christian made a motion to accept the recommendations as presented. Tricia Heitzman seconded the motion. None were opposed.

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

Outcome: Austedo will be considered Non-formulary requiring quantity limit and authorization duration**.** The following criteria will apply:

Huntington's Disease

- Medical record documentation of ≥ 18 years of age **AND**
- Medical record documentation that Austedo is prescribed by, or in consultation with, a neurologist or movement disorder specialist **AND**

- Medical record documentation of a diagnosis of Huntington's Disease **AND**
- Medical record documentation of symptoms of chorea **AND**
- Medical record documentation of the patient's baseline Total Maximal Chorea Score prior to initiating therapy **AND**
- One of the following:
    - If patient has a history of a prior suicide attempt, bipolar disorder, or major depressive disorder: Medical record documentation that patient was evaluated and treated by a psychiatrist **OR**
    - For all others: Medical record documentation of a mental health evaluation performed by the prescriber

AND

- Medical record documentation of a therapeutic failure on, intolerance to, or contraindication to tetrabenazine (requires prior authorization).

Tardive Dyskinesia

- Medical record documentation that the patient is ≥ 18 years of age **AND**
- Prescription written by, or in consultation with, a psychiatrist or neurologist **AND**
- Medical record documentation of a diagnosis of tardive dyskinesia (TD) as evidenced by one of the following:
    - Moderate to severe abnormal body movements (AIMS score 3 or 4) in ≥ 1 body area **OR**
    - Mild abnormal body movements (AIMS score 1 or 2) in ≥ 2 body areas

  AND
- Medical record documentation that the patient was assessed for and determined to have no other causes of involuntary movements **AND**
- Medical record documentation of the patient's baseline AIMS score prior to initiating therapy **AND**
- One of the following:
    - If patient has a history of a prior suicide attempt, bipolar disorder, or major depressive disorder: Medical record documentation that patient was evaluated and treated by a psychiatrist **OR**
    - For all others: Medical record documentation of a mental health evaluation performed by the prescriber

  AND
- If the patient's symptoms are related to use of a first-generation antipsychotic, medical record documentation that a switch to a second-generation antipsychotic has been attempted and did not resolve TD symptoms **OR** provider rationale as to why a switch to a second-generation antipsychotic would not be appropriate for this patient

AND

- Medical record documentation of a therapeutic failure on, intolerance to, or contraindication to amantadine

Quantity Limit:

- Austedo 6 mg tablet: 2 tablets per day
- Austedo 9 mg tablet: 4 tablets per day
- Austedo 12 mg tablet: 4 tablets per day

Authorization Duration: It is recommended to provide initial approval for a period of one (1) year. Reevaluation of coverage will be every one (1) year and require documentation of the following reauthorization criteria.

Reauthorization Criteria:

- For patients with Huntington's disease: Medical record documentation of an improvement in chorea associated with Huntington's Disease as evidenced by a reduction in the Total Maximal Chorea Score from baseline.
- For patients with Tardive Dyskinesia: Medical record documentation of an improvement in tardive dyskinesia (TD) as evidenced by a reduction from baseline in the patient's AIMS score

Additional Recommendation: It is recommended that tetrabenazine be added to the GHP Family Formulary on the brand tier requiring PA. It is recommended that a policy with the following prior authorization criteria be created.

- Medical record documentation of a diagnosis of chorea associated with Huntington disease

Quantity Limit: 12.5mg Tablets: 3 tablets per day, 25mg Tablets: 4 tablets per day

Outcome: Kevin Szczecina made a motion to approve the Additional Recommendation 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.

INGREZZA (valbenazine)

Review: Ingrezza is the first FDA approved medication indicated for the treatment of tardive dyskinesia (TD). It is available as a 40 mg capsule that is taken by mouth as two capsules once daily. In clinical trials, Ingrezza use resulted in a significant reduction in patients' AIMS scores, a tool used to measure the severity of TD symptoms. This AIMS lowering effect was sustained over a 48-week period and the benefit was diminished when Ingrezza was stopped, demonstrating that long-term treatment may be needed for sustained clinical response. Ingrezza was well-tolerated by patients enrolled in the trials and the most common adverse effect reported was somnolence (10.9%). There are no black box warnings associated with Ingrezza but it comes with two warnings including somnolence and QT prolongation risk. According to the American Academy of Neurology, there is limited evidence supporting that discontinuing antipsychotic therapy will have any significant effect on reducing TD symptoms. However, there is evidence of improved disease when patients are switched from first generation antipsychotics to either risperidone or olanzapine. A Meta-Analysis published in March 2017 found a higher prevalence of TD in patients on first generation antipsychotics (30%) when compared to those on second generation antipsychotics (20.7%). Currently, clonazepam and ginkgo biloba have moderate evidence for off-label use in TD treatment. Unfortunately, the studies are not robust enough to make definitive clinical justifications for their use. Tetrabenazine, a VMAT2 inhibitor indicated for Huntington's Disease, has evidence supporting its use in TD treatment but comes with two black box warnings for depression and suicide as well as numerous precautions. Deutetrabenazine, another VMAT2 inhibitor, is set to undergo FDA review for a TD indication in August of 2017. Amantadine is FDA approved for "drug-induced extrapyramidal reactions" and has been shown in 2-week and 18-week studies to benefit TD patients with little risk of exacerbating psychosis. Per specialist feedback, however, amantadine is not an appropriate alternative to require prior to the approval of Ingrezza. A Clinical Review including Clinical Information,

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

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

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

Outcome: Ingrezza will be considered Non-formulary requiring quantity limit and authorization duration for GHP Family. The following criteria will apply:

- Medical record documentation that the patient is ≥ 18 years of age **AND**
- Prescription written by, or in consultation with, a psychiatrist or neurologist **AND**
- Medical record documentation of a diagnosis of tardive dyskinesia (TD) as evidenced by one of the following:
    - Moderate to severe abnormal body movements (AIMS score 3 or 4) in ≥ 1 body area **OR**
    - Mild abnormal body movements (AIMS score 1 or 2) in ≥ 2 body areas

  AND
- Medical record documentation that the patient was assessed for and determined to have no other causes of involuntary movements **AND**
- Medical record documentation of the patient's baseline AIMS score prior to initiating therapy **AND**
- If the patient's symptoms are related to use of a first-generation antipsychotic, medical record documentation that a switch to a second-generation antipsychotic has been attempted and did not resolve TD symptoms **OR** provider rationale as to why a switch to a second-generation antipsychotic would not be appropriate for this patient **AND**
- Medical record documentation of a therapeutic failure on, intolerance to, or contraindication to amantadine

Quantity Limit: Two (2) tablets per day, maximum 30-day supply per fill
Authorization Duration: Requests for Ingrezza should be approved for a period of one (1) year. Reevaluation of coverage will be every one (1) year requiring medical record documentation of the following:

- Medical record documentation of an improvement in tardive dyskinesia (TD) as evidenced by a reduction from baseline in the patient's AIMS score

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

<u>TYMLOS (abaloparatide)</u>

Review: Tymlos is indicated for the treatment of postmenopausal women with osteoporosis at high risk for fracture. The recommended dosing for Tymlos is 80 mcg administered subcutaneously into the periumbilical region of the abdomen once daily, rotating the injection site with each dose. Tymlos is a PTH-related protein (PTHrP) analog that interacts with PTH receptor 1 (PTHR1) to produce the observed anabolic effect. The efficacy of Tymlos was evaluated in an 18 month, randomized, multicenter, double-blind, placebo-controlled clinical trial (Study 003/ACTIVE trial) in postmenopausal women aged 49 to 86 years who were randomized 1:1 to receive daily subcutaneous injections of either Tymlos 80 mcg (n =

824) or placebo. As an extension of this efficacy study (Study 005/ACTIVExtend trial), 92% of the patients previously treated with either Tymlos or placebo were all transitioned to receive open-label alendronate 70 mg weekly for an additional 6 months. The primary endpoint for both studies was the incidence of new vertebral fracture in patients treated with Tymlos compared to placebo during the respective treatment durations of the studies. Patients treated with Tymlos had an 86% relative risk reduction in new vertebral fractures compared to placebo during the first 18 months of treatment. Furthermore, patients who were initially treated with Tymlos and then transitioned to weekly alendronate showed to have an 87% relative risk reduction for new vertebral fractures at 25 months compared to placebo. Tymlos has a boxed warning for risk of osteosarcoma. It is unknown whether Tymlos will cause osteosarcoma in humans and the use of Tymlos is not recommended in patients at increased risk for osteosarcoma. Cumulative use of Tymlos and parathyroid hormone analogs (e.g., teriparatide) for more than 2 years during a patient's lifetime is not recommended. The most common adverse reactions (≥ 2%) are hypercalciuria, dizziness, nausea, headache, palpitations, fatigue, upper abdominal pain and vertigo. Previously, Forteo was the only FDA approved osteoanabolic agent used to treat osteoporosis until the approval of Tymlos. Much like Forteo, Tymlos interacts with PTH receptor 1 (PTHR1) to produce the observed anabolic effect but pharmacologically differs in the duration of receptor interaction. In contrast to Forteo, Tymlos has a lower incidence of hypercalcemia, more rapid onset of fracture risk reduction, and does not need to be refrigerated after its first use. Additionally, Tymlos does not have the Forteo indications for the treatment of osteoporosis in men and glucocorticoid-induced osteoporosis. Currently, the American Association of Clinical Endocrinologists and American College of Endocrinology (AACE/ACE) recommend that injectable agents (e.g., teriparatide, denosumab, zoledronic acid) be used to treat postmenopausal osteoporosis for patients unable to tolerate oral therapy and as initial therapy for patients at especially high fracture risk. A Clinical Review including Clinical Information, Efficacy Evidence, Safety Evidence, and Other Considerations and a Financial Review Based on Cost Analysis were presented.

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

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

Outcome: Tymlos will be added to the GHP Family Formulary on Brand Tier requiring prior authorization, quantity limit, and authorization duration. The following criteria will apply:

- There is no medical record documentation of increased baseline risk of osteosarcoma [Paget's disease, open epiphyses (pediatric or young adult patients), prior radiation therapy involving the skeleton, unexplained elevations of alkaline phosphatase] **AND**
- For women:
    - There is medical record documentation of a diagnosis of postmenopausal osteoporosis **AND**
    - There is medical record documentation that member has not previously been on a parathyroid hormone analog for greater than 2 years* **AND**
    - There is medical record documentation of an attempt of therapy with or contraindication to bisphosphonates **OR**
    - There is medical record documentation of a previous osteoporotic fracture or high risk of fracture (T-score –2.5 or below with documented risk factors)

QUANTITY LIMIT: 1.56 mL per 30 days

AUTHORIZATION DURATION: Approval will be for 2 years, or less if there is medical record documentation of a previous incomplete course of therapy with a parathyroid hormone analog. Cumulative use of parathyroid hormone analogs for more than 2 years during a patient's lifetime is not recommended.

***NOTE:** Cumulative use of parathyroid hormone analogs for more than 2 years during a patient's lifetime is not recommended.

Risk Factors Included in the WHO Fracture Risk Assessment Model

- Current age
- Gender
- A prior osteoporotic fracture (including morphometric vertebral fracture)
- Femoral neck BMD
- Low body mass index (kg/m2)
- Rheumatoid arthritis
- Secondary osteoporosis
- Parental history of hip fracture
- Current smoking
- Alcohol intake (3 or more drinks/d)
- Oral glucocorticoids ≥5 mg/d of prednisone for ≥3 mo (ever)

From: WHO Technical Report.8

Additional Recommendation: It is recommended the following updated Forteo policy be approved:

- There is no medical record documentation of increased baseline risk of osteosarcoma [Paget's disease, open epiphyses (pediatric or young adult patients), prior radiation therapy involving the skeleton, unexplained elevations of alkaline phosphatase] **AND**
- **For women:**
  a) There is medical record documentation of a diagnosis of osteoporosis **AND**
  b) There is medical record documentation of postmenopausal status or glucocorticoid induced osteoporosis **AND**
  c) There is medical record documentation that member has not previously been on a parathyroid hormone analog for greater than 2 years* **AND**
  d) There is medical record documentation of an attempt of therapy with or contraindication to bisphosphonates **OR**
  e) There is medical record documentation of a previous osteoporotic fracture or high risk of fracture (T-score –2.5 or below with documented risk factors)

OR

- **For men:**
  a) There is medical record documentation of a diagnosis of osteoporosis **AND**
  b) There is medical record documentation of an attempt of therapy with or contraindication to bisphosphonate therapy **OR**
  c) There is medical record documentation of a previous osteoporotic fracture or high risk of fracture (T-score <-2.5)

QUANTITY LIMIT: 2.4 mL per 28 days

AUTHORIZATION DURATION: Approval will be for 2 years, or less if there is medical record documentation of a previous incomplete course of therapy with a parathyroid hormone

analog. Cumulative use of parathyroid hormone analogs for more than 2 years during a patient's lifetime is not recommended.

***NOTE:** Cumulative use of parathyroid hormone analogs for more than 2 years during a patient's lifetime is not recommended

Outcome: Aubrielle Prater made a motion to approve the Additional Recommendation as presented. Dr. Dean Christian 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.

SILIQ (brodalumab)

Review: Siliq is a human IL-17RA monoclonal IgG2 antibody used to treat moderate-to-severe plaque psoriasis in patients 18 years of age and older. Siliq has shown superiority to placebo and mixed results compared to ustekinumab (Stelara) in clinical trials. Siliq is available in a single-dose, pre-filled syringe allowing patients to easily self-administer. It is available only through the Siliq REMS Program due to the risk of suicidal behavior and ideations seen in clinical trials (4 completed suicides from three total clinical trials). Siliq is dosed 210 mg subcutaneously every two weeks at weeks 0, 1, and 2, and every two weeks thereafter; if response is not seen after 12 to 16 weeks of therapy, consideration should be given to discontinue therapy due to the risk of suicidal ideation and behavior. Otherwise, there is a comparable adverse event profile to other biologics in its class. A Clinical Review including Clinical Information, Efficacy Evidence, Safety Evidence, and Other Considerations and a Financial Review Based on Cost Analysis were presented.

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

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

Outcome: Siliq will be considered Non-formulary requiring prior authorization, quantity limit, and authorization duration. The following criteria will apply:

- Prescription must be written by a dermatologist **AND**
- Documentation that the member is 18 years of age or older **AND**
- Medical record documentation of a diagnosis of moderate-to-severe plaque psoriasis with ≥5% BSA involved OR disease involving crucial areas of the body, such as hands, feet, face and/or genitals **AND**
- Medical record documentation that the patient does not have a history of suicidal thoughts or ideations **AND**
- Medical record documentation that the patient does not have a history of depression **OR** medical record documentation of a concomitant diagnosis of depression and documentation that a psychiatric evaluation has been completed and the patient has been deemed an appropriate candidate for therapy
- Medical record documentation of a therapeutic failure on, intolerance to, or contraindication to Humira* **AND** Enbrel*

Quantity Limit: If approved, Siliq should be approved with the following quantity limits:
One-week auth for QL of 6 mL per 28 days;
Remainder of the 4 month auth duration, QL of 3 mL per 28 days

Authorization duration: Approval will be given for an initial duration of four (4) months. For continuation of coverage, medical record documentation of clinical improvement or lack of progression in the signs and symptoms of plaque psoriasis on four (4) months of brodalumab therapy is required.

After the initial four (4) month approval, subsequent approvals for coverage will be for a duration of one (1) year. Reevaluation of coverage will be every one (1) year requiring medical record documentation of continued or sustained improvement in the signs and symptoms of plaque psoriasis while on brodalumab therapy.

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

TEPADINA (thiotepa)

Review: Tepadina is an alkylating drug indicated to reduce the risk of graft rejection when used in conjunction with high-dose busulfan and cyclophosphamide as a preparative regimen for allogeneic hematopoietic progenitor (stem) cell transplantation (HSCT) for pediatric patients with class 3 beta-thalassemia. This medication is available as a 15 mg and 100 mg lyophilized powder in a single-use vial for reconstitution. The medication is dosed as 5 mg/kg and administered by a healthcare professional on Day -6 before allogeneic HSCT. Tepadina has shown efficacy in an unpublished retrospective study of pediatric patients with class 3 beta-thalassemia who underwent HSCT. The incidence graft rejection in the 25 patients using Tepadina was 0% compared to 25.5% of 51 patients who received the same preparative regimen without Tepadina in a historical cohort. The generic of Tepadina, thiotepa, has been previously approved for treating various forms of cancer, however, it is only available in 15 mg/vial strength. A Clinical Review including Clinical Information, Efficacy Evidence, Safety Evidence, and Other Considerations and a Financial Review Based on Cost Analysis were presented.

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

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

Outcome: Tepadina will be considered a medical benefit requiring prior authorization, auth duration, and quantity limit for GHP Family. The following criteria will apply:

- Prescription written by a pediatric hematologist/oncologist or pediatric transplant specialist **AND**
- Medical record documentation that the patient has a diagnosis of beta-thalassemia major managed with blood transfusions **AND**
- Medical record documentation that the patient's disease is class 3 in severity as evidenced by the presence of ALL of the following:
    - Liver size > 2 cm
    - Presence of liver fibrosis; and
    - Inadequate iron chelation **AND**

- Medical record documentation that the patient is undergoing allogeneic hematopoietic progenitor stem cell transplant (HSCT) **AND**
- Medical record documentation that Tepadina is being used as part of a preparative regimen consisting of high-dose busulfan and cyclophosphamide **AND**
- Medical record documentation that the patient is under 18 years of age

QL, Auth duration: Approved requests should be authorized for a total of two doses, with a quantity limit for an appropriate number of vials of each strength based on the patient's weight.

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

CLASS REVIEW

SGLT2 Inhibitor Class Review

Available SGLT-2 inhibitors and Combination medications containing SGLT-2 inhibitors

Trade Name	Generic	Manufacturer	How Supplied	FDA Approval Date
Invokana	canagliflozin	Janssen	100, 300mg tab	March 29, 2013
Invokamet	canagliflozin/metformin	Janssen	50-500mg, 50-1000mg, 150-500mg, 150-1000mg tab	August 8, 2017
Invokamet XR	canagliflozin/metformin ER	Janssen	50-500mg, 50-1000mg, 150-500mg, 150-1000mg tab	September 20, 2016
Jardiance	empagliflozin	Boehringer Ingelheim Pharmaceuticals, Inc.	10mg, 25mg tab	August 1, 2014
Synjardy	empagliflozin /metformin	Boehringer Ingelheim Pharmaceuticals, Inc.	5-500mg, 5-1000mg, 12.5-500mg, 12.5-1000mg tab	August 26, 2015
Synjardy XR	empagliflozin /metformin ER	Boehringer Ingelheim Pharmaceuticals, Inc.	5-1000 mg, 10-1000 mg, 12.5-1000 mg, 25- 1000 mg	December 9, 2016
Glyxambi	empagliflozin/linagliptin	Boehringer Ingelheim Pharmaceuticals, Inc.	10-5mg, 25-5mg tab	January 30, 2015
Farxiga	dapagliflozin	AstraZeneca	5mg, 10mg tab	January 8, 2014
Xigduo XR	dapagliflozin/metformin ER	AstraZeneca	5-500mg, 5-1000mg, 10-500mg, 10-1000mg tab	October 29, 2019

Review: There are three commercially available SGLT2 inhibitors: canagliflozin (Invokana), empagliflozin (Jardiance), and dapagliflozin (Farxiga). Canagliflozin is available in combination with metformin as Invokamet and Invokamet XR. Empagliflozin is available in combination with metformin as Synjardy and Synjardy XR. Empagliflozin is also available in combination with Tradjenta as Glyxambi. Dapagliflozin is available in combination with metformin as Xigduo XR. All SGLT2 inhibitors are indicated for the treatment of type 2 diabetes mellitus (noninsulin dependent, NIDDM) as an adjunct to diet and exercise to improve glycemic control. Empagliflozin is also indicated to reduce the risk of cardiovascular mortality in adults with type 2 diabetes mellitus and established cardiovascular disease. The indications for Synjardy, Synjardy XR, and Glyxambi mention that empagliflozin may reduce the risk of CV mortality, however the effectiveness of these specific products for reduced risk of CV death

have not been established. All SGLT2 inhibitors are administered orally. Invokana, Invokamet XR, Jardiance, Synjardy XR, Glyxambi, Farxiga, and Xigduo XR are administered once daily. Invokamet and Synjardy are administered twice daily. All SGLT2 inhibitors reduce A1C by 0.5-1% as monotherapy or in combination with other medications. A meta-analysis compared Invokana 100 & 300 mg, Farxiga 5 & 10mg, and Jardiance 10 & 25 mg for efficacy and safety outcomes. For A1C reduction, Invokana 300 mg resulted in a larger A1C reduction compared to the other agents. Invokana 300 mg also reduced fasting blood glucose to a greater extent than the other medications. Significant reductions in body weight were seen by all SGLT2 inhibitors compared to placebo. Invokana 300 mg reduced systolic blood pressure greater than other SGLT2 inhibitors and there was no difference among SGLT2 inhibitors for diastolic blood pressure. All agents slightly increased HDL cholesterol levels compared to placebo. Canagliflozin reduced triglyceride levels and canagliflozin 300 mg increased LDL cholesterol. Canagliflozin (both doses) increased the risk of hypoglycemia compared to dapagliflozin and empagliflozin. All SGLT2 inhibitors increase the risk for genital mycotic infections. An increased risk for UTI was observed with Farxiga 10 mg compared to placebo and Jardiance 25 mg. The EMPA-REG trial evaluated Jardiance added to standard glucose-lowering therapy in patients with type 2 diabetes and underlying CV disease. A reduction was seen in the composite outcome of the study (CV mortality, non-fatal MI, and non-fatal stroke). Jardiance also reduced the risk of all-cause mortality, CV mortality, and HF hospitalization. However, Jardiance did not reduce the rates of non-fatal MI or non-fatal stroke, as individual outcomes. The CANVAS trial evaluated Invokana added to standard glucose-lowering therapy in patients with type 2 diabetes and high CV risk. A reduction was seen in the composite outcome of the study (CV mortality, nonfatal MI, or nonfatal stroke). However, when these endpoints were evaluated individually, there was not a significant reduction. Farxiga is currently being studied in the DECLARE-TIMI58 trial for its effect on MI, ischemic stroke, and CV death. Invokana has a new black box warning: patients with type 2 diabetes who have established CVD or at risk for CVD, Invokana has been associated with lower limb amputations, most frequently of the toe and midfoot; some also involved the leg. Before initiating, consider factors that may increase the risk of amputation. Monitor patients for infections or ulcers of the lower limbs, and discontinue if these occur. From clinical trials (CANVAS and CANVAS-R), amputations are seen in about are seen in about 6 in 1,000 patients taking Invokana per year compared to 3 in 1,000 patients taking placebo per year. It is unknown whether this warning applies to other SGLT2 inhibitors. All SGLT2 inhibitors are contraindicated if a patient has a hypersensitivity and/or severe renal impairment (eGFR <30 mL/min/1.73m^2), ESRD, or patients on dialysis. All SGLT2s carry warnings for hypotension, ketoacidosis, acute kidney injury, urosepsis, pyelonephritis, genital mycotic infections, and increased LDL. Invokana has a warning for bone fractures and Farxiga has a warning for bladder cancer. The most common adverse reactions include: female genital mycotic infections and urinary tract infections. It is recommended to avoid SGLT2 inhibitors during the second and third trimesters of pregnancy. It is also recommended to avoid SGLT2 inhibitors while breastfeeding. None of the SGLT2s are approved for pediatric patients. There may be an increased risk for volume depletion-related adverse reactions and UTIs in geriatric patients. All the SGLT2 inhibitors have recommendations for dosing based on renal function. Per the labeling, Invokana and Farxiga were not studied in patients with severe hepatic impairment. There are no recommendations for dose changes based on hepatic function for any of the SGLT2 inhibitors. Per the carepath, Jardiance and/or Victoza is recommended as an add-on to metformin, due to the CV risk reduction. Per the ADA, in patients with long-standing, uncontrolled type 2 diabetes and established ASCVD, empagliflozin and liraglutide should be considered. Empagliflozin and liraglutide have been shown to reduce cardiovascular and all-cause mortality when added to the standard of care 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. Tricia Heitzman made a motion to accept the recommendations as presented. Todd Sponenberg seconded the motion. None were opposed.

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

Outcome:

Approved Recommendations for GHP Family Based on Clinical Review		
Medication	Current Policy	Recommendations
Invokana	Step Therapy: • Medical record documentation that Invokana is being used in combination with (or therapeutic failure on, intolerance to, or contraindication to) metformin.	No changes recommended to the policy at this time.
Invokamet	Step Therapy: • Medical record documentation of a therapeutic failure on, intolerance to, or contraindication to metformin	No changes recommended to the policy at this time.
Invokamet XR	Step Therapy: • Medical record documentation of a therapeutic failure on, intolerance to, or contraindication to metformin	No changes recommended to the policy at this time.
Jardiance	Step Therapy: • Medical record documentation that Jardiance is being used in combination with (or therapeutic failure of, intolerance to, or contraindication to) metformin.	No changes recommended to the policy at this time.
Synjardy	Step Therapy: • Medical record documentation of therapeutic failure on, intolerance to or	No changes recommended to the policy at this time.

	contraindication to metformin	
Synjardy XR	No current criteria.	Synjardy XR is a pharmacy benefit and should be added to formulary. Synjardy XR will require step therapy: • Medical record documentation of therapeutic failure on, intolerance to, or contraindication to metformin
Glyxambi	July 2017 P&T: <u>Step Therapy:</u> • Medical record documentation of current utilization of metformin or intolerance to or contraindication to metformin.	No changes recommended to the policy at this time.
Farxiga	<u>Non-formulary:</u> • Medical record documentation of a therapeutic failure on, intolerance to, or contraindication to Jardiance* AND Invokana* *Step Therapy Required	It is recommended to update the policy 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 Jardiance* AND Invokana* *Step Therapy Required
Xigduo XR	<u>Non-formulary:</u> • Medical record documentation of a diagnosis of type II diabetes mellitus AND • Medical record documentation of age greater than or equal to 18 years of age AND • Medical record documentation of a eGFR greater than or equal to 60 mL/min/1.73 m2 AND • Medical record documentation of therapeutic failure on, intolerance to, or contraindication to metformin AND Jardiance^	It is recommended to update the last criteria point "Medical record documentation of therapeutic failure on, intolerance to, or contraindication to metformin AND Jardiance^ used in combination AND Invokamet^" to the following: • 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 It is recommended to remove the following criteria: "Medical record documentation of a

	used in combination AND Invokamet^	eGFR greater than or equal to 60 mL/min/1.73 m2 AND".
Approved Recommendations for GHP Family Based on Financial Review		
Medication	Current Formulary Status	Recommendations
Invokana	Brand Preferred Tier Quantity Limit: 1 tablet per day	No changes recommended to formulary status at this time.
Invokamet	Brand Preferred Tier Quantity Limit: 2 tablets per day	No changes recommended to formulary status at this time.
Invokamet XR	Brand Preferred Tier Quantity Limit: 2 tablets per day	No changes recommended to formulary status at this time.
Jardiance	Brand Preferred Tier Quantity Limit: 1 tablet per day	No changes recommended to formulary status at this time.
Synjardy	Brand Preferred Tier Quantity Limit: 2 tablets per day	No changes recommended to formulary status at this time.
Synjardy XR	Pending	Synjardy XR should be added to the GHP Family formulary at the Brand Tier. Quantity Limit: Synjardy XR 5-1000 mg & 12.5-1000 mg: 2 tablets per day Synjardy XR 10-1000 mg & 25-1000 mg: 1 tablet per day
Glyxambi	Brand Preferred Tier (July P&T) Quantity Limit: 1 tablet per day	No changes recommended to formulary status at this time.
Farxiga	Non-formulary Quantity Limit: 1 tablet per day	No changes recommended to formulary status at this time.
Xigduo XR	Non-formulary Quantity Limit: 1 tablet per day	No changes recommended to formulary status at this time. Xigduo XR 5-1000 mg: 2 tablets per day All other strengths: 1 tablet per day

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

FAST FACTS

KALYDECO (ivacaftor)

Updated Indication: Kalydeco is indicated for the treatment of cystic fibrosis (CF) in patients age 2 years and older who have one mutation in the *CFTR* gene that is responsive to ivacaftor potentiation based on clinical and/or in vitro assay data. Previously indicated in patients age 2 years and older who have one of the following mutations in the *CFTR* gene: *G551D, G1244E, G1349D, G178R, G551S, S1251N, S1255P, S549N,* or *S549R.* Also in patients age 2 years and older who have an *R117H* mutation in the *CFTR* gene.

Recommendation: It is recommended that the current list of covered genetic mutations be removed from the policies and the following updated list be included for all lines of business.

2789+5G→A	*D110H*	*F1052V*	*G551S*	*R117H*	*S549R*
3272-26A→G	*D1152H*	*F1074L*	*K1060T*	*R347H*	*S945L*
3849+10kbC→T	*D1270N*	*G1069R*	*L206W*	*R352Q*	*S977F*
711+3A→G	*D579G*	*G1244E*	*P67L*	*R74W*	
A1067T	*E193K*	*G1349D*	*R1070Q*	*S1251N*	
A455E	*E56K*	*G178R*	*R1070W*	*S1255P*	
D110E	*E831X*	*G551D*	*R117C*	*S549N*	

Discussion: No questions or comments.

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

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

BLINCYTO (blinatumomab)

Updated Indication: Blincyto is now indicated for the treatment of relapsed or refractory B-cell precursor Acute Lymphoblastic Leukemia (ALL) in adults and children.

Previous Indication**:** Treatment of *Philadelphia chromosome-negative* relapsed or refractory B-cell precursor acute lymphoblastic leukemia (ALL)

- Note: The previously FDA-approved indication was approved via FDA-accelerated approval

Recommendation: No changes are recommended to the formulary placement of Blincyto at this time. It is recommended that the criteria outlined by policy MBP 128.0 be updated as outlined below.

MBP 128.0

- Blincyto (blinatumomab) will be considered medically necessary when all of the following criteria are met:
  - 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: Initial 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.

Discussion: No questions or comments.

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

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

CUBICIN (daptomycin)

Updated Indication: Cubicin is now indicated for the treatment of pediatric patients (1 to 17 years of age) with complicated skin and skin structure infections (cSSSI) caused by susceptible isolates of the following Gram-positive bacteria: *Staphylococcus aureus* (including methicillin-resistant isolates), *Streptococcus pyogenes*, *Streptococcus agalactiae*, *Streptococcus dysgalactiae* subsp. equisimilis, and *Enterococcus faecalis* (vancomycin-susceptible isolates only). Note: Cubicin was previously indicated for the treatment of complicated skin and skin structure infections (cSSSI) in adult patients AND for the treatment of adult patients with *Staphylococcus aureus* bloodstream infections (bacteremia), including those with right-sided infective endocarditis, caused by methicillin-susceptible and methicillin-resistant isolates

Recommendation: No changes are recommended. Cubicin (daptomycin) is a medical benefit without prior authorization.

Discussion: No questions or comments.

Outcome: Kevin Szczecina made a motion to accept the recommendations as presented. Dr. Dean Christian seconded the motion. None were opposed.

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

RAVICTI (glycerol phenylbutyrate)

Updated Indication: Ravicti is indicated for chronic management of patients 2 months of age and older with urea cycle disorders (UCDs) who cannot be managed by dietary protein restriction and/or amino acid supplementation alone. Ravicti must be used with dietary protein restriction and, in some cases, dietary supplements. Note: Ravicti was previously indicated for patients 2 years of age and older.

Recommendation: No changes are recommended (was updated previously during annual review by Pennsylvania Department of Human Services).

Discussion: No questions or comments.

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

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

BAVENCIO (avelumab)

Updated Indication: Bavencio is now indicated to treat 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. This indication is approved under the accelerated approval process.

Previously, Bavencio was indicated under accelerated approval for the treatment of adult and pediatric patients with metastatic Merkel cell carcinoma.

Recommendation: No changes are recommended to the formulary placement of Bavencio at this time. It is recommended that the prior authorization criteria are updated to account for the updated indication as follows.

Merkel Cell Carcinoma

- Prescribed by a hematologist/oncologist **AND**
- Medical record documentation of a diagnosis of metastatic Merkel Cell Carcinoma (MCC) **AND**
- Medical record documentation of age ≥12 years

Urothelial Carcinoma

- Prescribed by a hematologist/oncologist **AND**
- Medical record documentation of a diagnosis of locally advanced or metastatic urothelial carcinoma **AND**
- Medical record documentation of one of the following:
    - Disease progression during or following platinum-containing chemotherapy OR
    - Disease progression within 12 months of neoadjuvant or adjuvant treatment with platinum-containing chemotherapy

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

ORENCIA (abatacept)

Updated Indication: Orencia is now indicated for reducing signs and symptoms in patients 2 years of age and older with moderately to severely active polyarticular juvenile idiopathic arthritis (PJIA). Orencia may be used as monotherapy or concomitantly with methotrexate.Orencia is now indicated for the treatment of adult patients with active psoriatic arthritis (PsA).

Note: Orencia was previously indicated for moderately to severely active RA in adults and moderately to severely active polyarticular juvenile idiopathic arthritis in pediatric patients 6 years of age and older.

Recommendation: No changes are recommended to the formulary placement of Orencia at this time.

It is recommended that the following prior authorization criteria are added to the Orencia SC policy to account for the new PJIA age indication:

For Polyarticular Juvenile Idiopathic Arthritis (PJIA):

- Medical record documentation that patient is 2 years of age or older **AND**
- Medical record documentation of a diagnosis of moderate to severe polyarticular juvenile idiopathic arthritis or juvenile rheumatoid arthritis **AND**

- Must be prescribed by a rheumatologist **AND**
- Medical record documentation of therapeutic failure on, intolerance to, or contraindication to a minimum 4 month trial of one preferred TNF alpha inhibitor (Enbrel* OR Humira*) **AND**
- If Orencia ClickJect autoinjector is prescribed, member is greater than or equal to 18 years of age

NOTE: The safety and efficacy of Orencia ClickJect autoinjector for subcutaneous injection has not been studied in patients under 18 years of age.

AUTHORIZATION DURATION: Approval will be given for an initial duration of six (6) months. For continuation of coverage, medical record documentation of clinical improvement or lack of progression in the signs and symptoms of polyarticular juvenile idiopathic arthritis on six (6) months of abatacept therapy is required.

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

It is recommended that the following prior authorization criteria are added to all Orencia policies to account for the new PsA indication:

For Psoriatic Arthritis (PsA):

- Prescription written by a rheumatologist or dermatologist **AND**
- Medical record documentation of a diagnosis of active psoriatic arthritis **AND**
- Medical record documentation of age ≥ 18 years of age **AND**
- Medical record documentation of an inadequate response to a minimum 3 month trial of one preferred TNF-alpha inhibitor (Humira* **OR** Enbrel*)

AUTHORIZATION DURATION: Approval will be given for an initial duration of six (6) months. For continuation of coverage, medical record documentation of clinical improvement or a lack of progression in the signs and symptoms of the targeted disease state at six (6) months of Orencia therapy is required.

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

RECOMMENDATIONS TO QUANTITY LIMITS: Quantity limits do not require updating.

Discussion: No questions or comments.

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

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

MEKINIST (trametinib) and TAFINLAR (dabrafenib)

Updated Indication: Mekinist and Tafinlar are both now indicated in combined use for the treatment of patients with metastatic non-small cell lung cancer (NSCLC) with BRAF V600E mutation as detected by an FDA-approved test.

Limitation of use: Tafinlar is not indicated for treatment of patients with wild-type BRAF NSCLC
Limitation of use: Mekinist is not indicated for treatment of patients with melanoma who have progressed on prior BRAF-inhibitor therapy.

Previous indications:

- Mekinist
  - BRAF V600E or V600K mutation-positive unresectable or metastatic melanoma as a single agent or in combination with Tafinlar
- Tafinlar
  - BRAF V600E mutation-positive unresectable or metastatic melanoma as a single agent
  - BRAF V600E or V600K mutation-positive unresectable or metastatic melanoma in combination with Mekinist, as detected by an FDA-approved test

Recommendation: No changes to formulary placement are recommended at this time. It is recommended to update the prior authorization criteria for both Tafinlar and Mekinist to account for the new indication.

Tafinlar:

Metastatic Non-Small Cell Lung Cancer

- Prescription written by a hematologist or oncologist AND
- Medical record documentation of metastatic non-small cell lung cancer AND
- Medical record documentation of concomitant use of Mekinist (trametinib) AND
- Medical record documentation of BRAF V600E mutation as detected by an FDA-approved test

QUANTITY LIMIT: 75 mg – 120 capsules per 30 days
50 mg – 120 capsules per 30 days

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

Mekinist:

Metastatic Non-Small Cell Lung Cancer

- Prescription written by an oncologist or hematologist AND
- Medical record documentation of metastatic non-small cell lung cancer AND
- Medical record documentation of concomitant use of Tafinlar (dabrafenib) AND
- Medical record documentation of BRAF V600E mutation as detected by an FDA-approved test

QUANTITY LIMITS:

- GHP Family: 1mg and 2 mg: 30 tablets per 30 days, 0.5mg: 90 tablets per 30 days.

AUTHORIZATION DURATION: Each treatment period will be defined as 12 months. Re-review will occur every 12 months. Mekinist will no longer be considered medically necessary if there is medical record documentation of disease progression.

Discussion: No questions or comments.

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

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

VECTIBIX (panitumumab)

Updated Indication: Vectibix is indicated for the treatment of wild-type *RAS* (defined as wild-type in both *KRAS* and *NRAS* as determined by an FDA-approved test for this use) metastatic colorectal cancer (mCRC):

- In combination with FOLFOX for first-line treatment
- As monotherapy following disease progression after prior treatment with fluoropyrimidine, oxaliplatin, and irinotecan-containing chemotherapy

Limitation of use: Vectibix is not indicated for the treatment of patients with *RAS*-mutant mCRC or for whom *RAS* mutation status is unknown.

Previously, Vectibix was indicated for the treatment of wild-type *KRAS* (exon 2) metastatic colorectal cancer (mCRC) as determined by an FDA-approved test for this use in combination with FOLFOX for first-line treatment or as monotherapy following disease progression after prior treatment with fluoropyrimidine, oxaliplatin, and irinotecan-containing chemotherapy.

Recommendation: No changes are recommended to the formulary placement of Vectibix or the authorization duration of Vectibix at this time. It is recommended that the following changes are made to the existing criteria outlined in policy MBP 50.0.

1. Prescribed by a hematologist or oncologist **AND**
2. Medical record documentation of a diagnosis of metastatic colorectal cancer **AND**
    a. Used in combination with FOLFOX as first-line treatment **OR**
    b. Used as monotherapy with disease progression on (or intolerance or contraindication to) fluoropyrimidine, oxaliplatin, and irinotecan containing chemotherapy regimens **AND**
3. Medical record documentation of wild-type *RAS* (defined as wild-type (negative) in both *KRAS* and *NRAS* as determined by an FDA-approved test for this use)

Limitation of Use: Vectibix is not indicated for the treatment of patients with *RAS*-mutant metastatic colorectal cancer or for whom *RAS* mutation status is unknown

Note: Vectibix is not effective for the treatment of patients with *RAS*-mutant mCRC (defined as a *RAS* mutation in exon 2 (codons 12 and 13), exon 3 (codons 59 and 61), or exon 4 (codons 117 and 146) of *KRAS* and *NRAS*.

Discussion: No questions or comments.

Outcome: Dr. Dean Christian made a motion to accept the recommendations as presented. Todd Sponenberg seconded the motion. None were opposed.

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

ACTEMRA (tocilizumab)

Updated Indication: Actemra is an interleukin-6 (IL-6) receptor antagonist indicated for treatment of:

- Adult patients with giant cell arteritis (GCA)
- Adults and pediatric patients 2 years of age and older with chimeric antigen receptor (CAR) T cell-induced severe or life-threatening cytokine release syndrome (CRS)

Note: Previous indications for rheumatoid arthritis, polyarticular juvenile idiopathic arthritis and systemic juvenile idiopathic arthritis.

Recommendation: There are no changes recommended to the formulary status or tiering at this time. It is recommended that the pharmacy drug policy for Actemra SC are updated with the following criteria for the treatment of giant cell arteritis:

- Medical record documentation of a diagnosis of giant cell arteritis **AND**
- Prescription is written by a rheumatologist **AND**
- Medical record documentation that Actemra is being prescribed in combination with oral glucocorticoids

QUANTITY LIMIT: 4 syringes per 28 days

AUTHORIZATION DURATION: Approval will be given for an initial duration of six (6) months. After the initial six (6) month approval, subsequent approvals for coverage will be for a duration of one (1) year. For continuation of coverage, medical record documentation of clinical improvement or lack of progression in signs and symptoms of giant cell arteritis and/or a decrease from baseline in the erythrocyte sedimentation rate (ESR) is required.

NOTE: Although traditionally the erythrocyte sedimentation rate and/or C-reactive protein are high in GCA, the range of values for both tests is broad and nonspecific.

IV

There are no changes recommended to the formulary status or tiering at this time. It is recommended that the medical drug policy for Actemra IV be updated to indicate that prior authorization is not required for chimeric antigen receptor (CAR) T cell-induced severe or life-threatening cytokine release syndrome (CRS). The following criteria should be added to the Part D policy for Actemra IV and the medical benefit policy in the event a request is received:

- Medical record documentation of a diagnosis of chimeric antigen receptor (CAR) T cell-induced severe or life-threatening cytokine release syndrome (CRS)

Discussion: No questions or comments.

Outcome: Keith Hunsicker made a motion to accept the recommendations as presented. Dean Christian 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

IMBRUVICA (ibrutinib)

Updated Indication: Imbruvica is a kinase inhibitor now indicated for the treatment of adult patients with chronic graft versus host disease (cGVHD) after failure of one or more lines of systemic therapy.

Note: Imbruvica was previously indicated for the treatment of patients with:

- Mantle cell lymphoma (MCL) who have received at least one prior therapy (accelerated approval)
- Chronic lymphocytic leukemia (CLL)/ Small lymphocytic lymphoma (SLL)
- Chronic lymphocytic leukemia (CLL)/ Small lymphocytic lymphoma (SLL) with 17p deletion
- Waldenström's macroglobulinemia (WM)
- Marginal Zone Lymphoma (MZL) who require systemic therapy and have received at least one prior anti-CD20-based therapy (accelerated approval)

Recommendation: There are no changes to formulary status recommended at this time. The current Imbruvica policy (1242.0F) should be updated to reflect the new indication. The following prior authorization criteria should be added to the current policy:
…OR

- Medical record documentation of Chronic Graft Versus Host Disease after failure of one or more lines of systemic therapy
  Quantity Limit: 3 capsules per day

Discussion: No questions or comments.

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

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

ABILIFY MAINTENA (aripiprazole)

Updated Indication: Abilify Maintena is now indicated for the treatment of maintenance monotherapy treatment of bipolar I disorder in adults. Previously, Abilify Maintena was only indicated for treatment of schizophrenia in adults.

Recommendation: No changes are recommended to the formulary placement of Abilify Maintena at this time. It is recommended that the criteria in Policy MBP 106.0 be updated for the new indication

Discussion: No questions or comments.

Outcome: Dr. Richard Silbert 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

BUNAVAIL (buprenorphine and naloxone)

Updated Indication: Bunavail buccal film is indicated for the treatment of opioid dependence and should be used as part of a complete treatment plan to include counseling and psychosocial support. Previously indicated only for maintenance treatment of opioid dependence.

Recommendation: Bunavail buccal films are a pharmacy benefit but are not currently on formulary. No changes to the current formulary status or quantity limits are recommended at this time. No changes are recommended to the authorization duration. The following criteria should be removed from the existing Bunavail policy (1281.0F):

- Patient has been initially inducted on buprenorphine sublingual tablets and is being switched to Bunavail for maintenance therapy

Discussion: No questions or comments.

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

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

OPDIVO (nivolumab)

Updated Indication: Opdivo is now indicated under accelerated approval for the treatment of adult and pediatric patients 12 years of age and older with microsatellite instability-high (MSI-H) or mismatch repair deficient (dMMR) metastatic colorectal cancer (CRC) that has progressed following treatment with a fluoropyrimidine, oxaliplatin, and irinotecan. Other previously approved indications include: Unresectable or metastatic melanoma, metastatic non-small cell lung cancer, renal cell carcinoma, classical Hodgkin lymphoma, squamous cell carcinoma of the head and neck, and urothelial carcinoma.

Recommendation: No changes are recommended to the formulary placement of Opdivo at this time. It is recommended that the Opdivo prior authorization criteria of applicable policies are changed to account for the new indication:

Colorectal Cancer

- Prescription written by a hematologist/oncologist **AND**
- Medical record documentation that patient is ≥ 12 years of age **AND**
- Medical record documentation of a diagnosis of metastatic colorectal cancer **AND**
- Medical record documentation of microsatellite instability-high (MSI-H) or mismatch repair deficient (dMMR) disease **AND**
- Medical record documentation of progression following treatment with a fluoropyrimidine, oxaliplatin, or irinotecan

Discussion: No questions or comments.

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

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

UPDATES

CONTINUITY OF CARE

Recommendation: It is recommended the following Continuity of Care Policy be approved by the Committee:

For initial requests, Geisinger Health Plan will not require members to meet prior authorization or step therapy criteria if they are currently taking a medication in one of the following drug classes:

- Immunosuppressants (for prophylaxis of organ transplant rejection)
- Antidepressants
- Antipsychotics
- Anticonvulsants
- Antiretrovirals
- Antineoplastics
- Tumor Necrosis Factor Blockers
- Multiple Sclerosis
- Attention Deficit Hyperactivity Disorder/Attention Deficit Disorder

If members are currently receiving one of these medications requests for coverage will be approved as long as there is medical record documentation that the safety and effectiveness of use for the prescribed indication is supported by Food and Drug Administration (FDA) approval or adequate medical and scientific evidence in the medical literature.

For initial requests, Geisinger Health Plan will not require new members (members who have enrolled with the plan in the last 120 days) to meet prior authorization or step therapy criteria for medications in all other categories if medical record documentation of the following is provided:

- Member has been utilizing the requested medication for greater than or equal to six (6) months **AND**
- Member was not stabilized on samples of the requested medication **AND**
- Medical record documentation that the safety and effectiveness of use for the prescribed indication is supported by Food and Drug Administration (FDA) approval or adequate medical and scientific evidence in the medical literature

Exclusions from Continuity of Care:

- Acthar
- Active Ingredients on Formulary as a Different Formulation (e.g., Lialda vs. Delzicol)
- Allergy Eye Drops
- Asthma/COPD Inhalers
- Brands with a Generic
- GLP-1 Agonists
- High Risk Medications in the Elderly
- Insulin
- Nasal Steroids
- Oral Contraceptives
- Pancreatic Enzymes

- Combination Agents when all ingredient are on formulary (e.g., Vytorin)
- Compounds
- Diabetic Testing Supplies When Not Used in Conjunction with a Pump
- DPP4 Inhibitors
- Proton Pump Inhibitors
- SGLT2 Inhibitors
- Testosterone Products
- Topical Acne Products
- Topical Antifungals
- Topical Steroids

Discussion: Dr. Bret Yarczower recommended adding Hereditary Angioedema agents to the list of exclusions.

Outcome: Keith Hunsicker made a motion to accept the amended recommendations. 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.

AUTHORIZATION DURATION UPDATES FOR ONCOLOGY MEDICATIONS

Recommendation: It is recommended the authorizations duration be updated per the table below:

Oncology Medication	Manufacturer	Current Authorization Duration	Updated Policy
Afinitor – everolimus	Novartis Pharmaceuticals	3 months	12 months
Alecensa – alectinib	Hoffman-La Roche	6 months	12 months
Bosulif – bosutinib	PF Prism CV	3 months	12 months
Cabometyx – cabozantinib	Exelixis	6 months	12 months
Caprelsa – vandetanib	Genzyme Corp	No auth duration	12 months
Cometriq – cabozantinib	Exelixis	No auth duration	12 months
Cotellic – cobimetinib	Genentech	6 months	12 months
Erivedge – vismodegib	Genentech	6 months	12 months
Iclusig – ponatinib	Ariad	3 months	Initial: 3 months Subsequent: 12 months
Inlyta – axitinib	PF Prism CV	3 months	12 months
Iressa – gefitinib	AstraZeneca	6 months	12 months
Lenvima – lenvatinib	Eisai Inc	6 months	12 months
Lonsurf – trifluridine/tipiracil	Taiho Oncology	6 months	12 months
Mekinist - trametinib	Novartis Pharmaceuticals	6 months	12 months
Nexavar – sorafenib		3 months	12 months

	Bayer HealthCare Pharmaceuticals		
Ninlaro - ixazomib	Millennium Pharmaceuticals	6 months	12 months
Odomzo – sonidegib	Sun Pharma Global	6 months	12 months
Pomalyst- pomalidomide	Celgene	3 months	12 months
Revlimid – lenalidomide	Celgene	No auth duration	12 months
Sprycel – dasatinib	Bristol Myers Squibb	3 months	12 months
Stivarga - regorafenib	Bayer HealthCare Pharmaceuticals	6 months	12 months
Sutent – sunitinib	Pfizer	3 months	12 months
Tafinlar – dabrafenib	Novartis Pharmaceuticals	6 months	12 months
Tagrisso - osimertinib	AstraZeneca	6 months	12 months
Tasigna – nilotinib	Novartis Pharmaceuticals	3 months	12 months
Tykerb – lapatinib	Novartis Pharmaceuticals	No auth duration	12 months
Valchlor – mechlorethamine *Topical*	Actelion Pharmaceuticals	6 months	12 months
Venclexta - venetoclax	AbbVie Inc	6 months	12 months
Votrient – pazopanib	Novartis Pharmaceuticals	No auth duration	12 months
Xalkori – crizotinib	PF Prism CV	6 months	12 months
Xtandi - enzalutamide	Astellas	6 months	12 months
Zelboraf – vemurafenib	Hoffman-La Roche	3 months	12 months
Zolinza – vorinostat	Merck	No auth duration	12 months
Zydelig – idelalisib	Gilead Sciences Inc	6 months	12 months
Zykadia – ceritinib	Novartis Pharmaceuticals	6 months	12 months
Zytiga- abiraterone acetate	Janssen Biotech	6 months	12 months

Discussion: No questions or comments.

Outcome: Tricia Heitzman made a motion to accept the recommendation 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

OCREVUS (ocrelizumab)

Recommendation: A comprehensive drug review for Ocrevus (ocrelizumab) was presented at July 2017 P&T committee. Please refer to materials/minutes from July 2017 for complete details for Ocrevus (ocrelizumab). Ocrevus will remain a medical benefit and should not be added to the GHP Family Formulary at this time. It is recommended to change the existing prior authorization criteria to the following:

- Medical record documentation of age ≥ 18 years **AND**
- Medical record documentation Ocrevus is prescribed by a neurologist **AND**
- Medical record documentation of a diagnosis of primary progressive MS (PPMS) **OR**
- Medical record documentation of a diagnosis of **a relapsing form of MS AND**
- For members with a diagnosis of RRMS, medical record documentation of therapeutic failure on, intolerance to, or contraindication to **two** formulary alternatives.

Authorization Duration/Quantity Limit:

If an exception is made, Ocrevus will be paid for under the member's prescription drug benefit initially for a period of 12 months with a limit of 3 doses.
Subsequent approvals will be for a period of 12 months with a limit of 2 doses and require medical record documentation of improvement in signs and symptoms or maintenance of condition while on Ocrevus therapy.

Discussion: Tricia Heitzman recommended that "RRMS" be update to be "relapsing form of MS".

Outcome: Keith Hunsicker made a motion to accept the amended 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

HEPATITIS C POLICY UPDATES

Recommendation: It is recommended that Harvoni, Sovaldi and Zepatier be removed from the GHP Family Formulary.

Discussion: No comments or questions.

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

FORMULARY CHANGES:

JANUVIA, JANUMET, JANUMET XR

Recommendation: It is recommended that Januvia and Janumet be removed from the GHP Family Formulary. The following prior authorization criteria should apply to requests for Januvia:

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

QUANTITY LIMIT: 1 tablet per day

The following prior authorization criteria should apply to requests for Janumet and Janumet XR:

- Medical record documentation of therapeutic failure on, intolerance to, or contraindication to Tradjenta + metformin, Jentadueto, OR Jentadueto XR

QUANTITY LIMIT: Janumet – 2 tablets per day

Janumet XR 50-1000 mg & 50-500 mg – 2 tablets per day

Janumet XR 100-1000 mg – 1 tablet per day

Discussion: No comments or questions.

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

DESVENLAFAXINE

Recommendation: It is recommended that generic desvenlafaxine extended release (Pristiq) be added to the GHP Family Formulary on the generic tier with a quantity limit of 1 per day.

Discussion: No comments or questions.

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

EPIPEN

Recommendation: Because of the availability of an authorized generic for EpiPen, it is recommended that the branded product, Adrenaclick, and non-authorized generics be removed from the GHP Family Formulary. A quantity limit of 4 auto injectors per 30 days should apply to the authorized generic EpiPen.

Discussion: No comments or questions.

Outcome: Todd Sponenberg made a motion to accept the amended 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

FORMULARY ADDITIONS

Recommendation: It is recommended the following formulary additions be approved for GHP Family:

Medication	Proposed Change
Xiidra Ophthalmic Drops	Brand Tier
Restasis Ophthalmic Drops	Brand Tier
Align (Bifidobacterium Infantis) Chewable Tablets, Capsules	OTC Tier
Moxifloxacin Ophthalmic Drops	Generic Tier
Cytra-2 Oral Solution	Brand Tier
Sodium Citrate-Citric Acid 334 -500 mg Oral Solution	Generic Tier
Celecoxib Capsules	Remove step, keep QL (2/day)

Discussion: No comments or questions.

Outcome: Kim Clark made a motion to accept the amended recommendations. Aubrielle Prater seconded the motion. None were opposed

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

Meeting adjourned at 4:34 pm.

Future Scheduled Meetings
November 21, 2017 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.