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

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

Call to Order:
Dr. Bret Yarczower called the meeting to order at 1:03 p.m., Tuesday, March 20, 2018.

Review and Approval of Minutes:
Dr. Bret Yarczower asked for a motion or approval to accept the January 16, 2018 minutes as written. Tricia Heitzman accepted the motion and Aubrielle Prater seconded the motion. None were opposed.

DRUG REVIEWS

AURYXIA (ferric citrate)

Review: Auryxia is a phosphate binder indicated for the control of serum phosphorus levels in adult patients with chronic kidney disease on dialysis AND Auryxia is an iron replacement product indicated for the treatment of iron deficiency anemia in adult patients with chronic kidney disease not on dialysis. Auryxia is supplied as 210 mg ferric iron tablets equivalent to 1 g of ferric citrate. For hyperphosphatemia, the recommended dose is 2 tablets orally 3 times per day with meals. For iron deficiency anemia, the recommended starting dose is 1 tablet orally 3 times per day with meals. For both indications the maximum dose is 12 tablets per day. In the hyperphosphatemia clinical trials, for patients with CKD on dialysis and hyperphosphatemia, Auryxia lowered serum phosphorus after initiation, which was maintained over 52 weeks. It was also found that a significantly higher reduction in serum phosphorus from baseline to Week 4 was observed in patients taking 6-8 tabs/day compared to those taking 1 tablet/day. In the iron deficiency anemia clinical trials, for patients with CKD not on dialysis, the proportion of patients achieving an increase in hemoglobin of ≥ 1.0 g/dL at any time during the 16 week period was statistically higher in the Auryxia arm. Auryxia is contraindicated in patients with iron overload syndromes. Auryxia has a warning for iron overload and risk of overdose in children due to accidental ingestion. The most common adverse reactions (incidence ≥5%) are discolored feces, diarrhea, constipation, nausea, vomiting, cough, abdominal pain, and hyperkalemia. There is no data on the use of Auryxia in pregnant or lactating women. However, an overdose of iron in pregnant woman can cause fetal malformation and iron has been transferred into the milk of rats. The safety and efficacy of Auryxia have not been established in pediatric patients. There have been no identified differences between the elderly and younger populations. There are no renal/hepatic dose adjustments provided in the manufacturer's labeling. Auryxia is the only oral iron tablet FDA-approved for the treatment of iron deficiency anemia specifically in adult patients with CKD not on dialysis. Similar to Velphoro, Auryxia is an iron-based phosphate binder. In contrast to Velphoro, the iron in Auryxia is absorbed and can improve anemia. Auryxia can be considered for patients who need both a phosphate binder and IV iron. According to KDIGO, for patients with CKD not on dialysis, 1-3 months of oral therapy can be tried if an increase in Hb concentration is desired, TSAT ≤30% and ferritin ≤500 ng/mL. UpToDate, recommends ferrous sulfate 325 mg three times daily as the oral iron product. Per UpToDate, ferric citrate may be useful for oral iron supplementation. Per KDIGO, the recent availability of iron-containing phosphate binders was discussed within the Work Group but did not affect recommendations given the absence of data on long-term patient-centered outcomes. Per UpToDate, Ferric citrate is generally not recommended. Citrate has been shown to enhance the absorption of aluminum, which can increase aluminum toxicity. There is a concern that ferric citrate may enhance the aluminum absorption from drinking water, food, and drugs. However, one randomized control trial of 185 patients found no different in aluminum levels between ferric citrate and active control. Although, more long-term studies are needed.

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 questions or comments. Keith Hunsicker made a motion to accept the criteria as written. Tricia Heitzman seconded the motion. None were opposed.

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

Outcome: For GHP Family, Auryxia will be added to the formulary requiring prior authorization. The following criteria will apply:

For Hyperphosphatemia:

- Prescription written by or in consultation with a nephrologist **AND**
- Medical record documentation of the member being ≥ 18 years **AND**
- Medical record documentation of diagnosis of chronic kidney disease (CKD) on dialysis **AND**
- Medical record documentation that Auryxia is being used to control serum phosphorus levels **AND**
- Medical record documentation of therapeutic failure on, intolerance to, or contraindication to calcium acetate, sevelamer carbonate, **AND** lanthanum carbonate

For Iron Deficiency Anemia:

- Prescription written by or in consultation with a nephrologist **AND**
- Medical record documentation of the member being ≥ 18 years **AND**
- Medical record documentation of diagnosis of iron deficiency anemia and chronic kidney disease **AND**
- Medical record documentation that the member is not receiving dialysis **AND**
- Medical record documentation of therapeutic failure on, intolerance to, or contraindication to ferrous sulfate.

Quantity Limit: 12 tablets per day

Other Recommendations:

Renagel - There are no changes to formulary status at this time, however it is recommended to update the Renagel policy to the following:

- Medical record documentation of a diagnosis of Chronic Kidney Disease (CKD) on dialysis AND
- Medical record documentation of a contraindication to, intolerance to, or therapeutic failure on calcium acetate, sevelamer carbonate, AND lanthanum carbonate

Velphoro - There are no changes to formulary status at this time, however it is recommended to add a non-formulary policy with the following criteria:

- Medical record documentation of a diagnosis of Chronic Kidney Disease (CKD) on dialysis AND
- Medical record documentation of a contraindication to, intolerance to, or therapeutic failure on calcium acetate, sevelamer carbonate, AND lanthanum carbonate

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

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

CONTEMPLA XR-ODT (methylphenidate extended-release orally disintegrating tablets)

Review: Cotempla XR-ODT is indicated for the treatment of Attention Deficit Hyperactivity Disorder (ADHD) in pediatric patients 6 to 17 years of age. The recommended starting dose for pediatric patients 6 to 17 years of age is 17.3mg given orally once daily in the morning. The dose may be titrated weekly in increments of 8.6mg to 17.3mg. It is not recommended to take a daily dose above 51.8mg. Cotempla XR-ODT should be taken consistently either with or without food.

The efficacy of Cotempla XR-ODT was evaluated in a laboratory classroom study conducted in 87 pediatric patients (6 to12 years) with ADHD. Following washout of previous methylphenidate medication, there was a 4-week dose-optimization period with an initial dose of Cotempla XR-ODT 17.3 mg once daily in the morning titrated up to an optimal dose or the maximum dose of 51.8mg daily. Subjects then entered a 1- week randomized, double-blind, parallel group treatment period with the individually optimized dose of Cotempla XR-ODT or placebo. Raters evaluated the attention and behavior of the subjects in a laboratory classroom setting using the SKAMP rating scale. The SKAMP-Combined scores test day average was statistically significantly lower (improved) with Cotempla XR-ODT compared to placebo (Table 1) and were also statistically significantly lower (improved) at time points (1, 3, 5, 7, 10, 12 hours) post-dosing with Cotempla XR-ODT compared to placebo (Figure 1).

Cotempla XR-ODT has a black box warning for abuse and dependence. Warnings and precautions with Cotempla XR-ODT include risk of serious cardiovascular reactions, blood pressure and heart rate increases, psychiatric adverse reactions, peripheral vasculopathy including Raynaud's phenomenon, and long-term suppression of growth. The most common adverse reactions based on accumulated data from other methylphenidate products include decreased appetite, insomnia, nausea, vomiting, dyspepsia, abdominal pain, decreased weight, anxiety, dizziness, irritability, affect lability, tachycardia, and increased blood pressure. No fetal and/or neonatal adverse reactions have been reported with the use of therapeutic doses of methylphenidate during pregnancy; however, premature delivery and low birth weight infants have been reported in amphetamine-dependent mothers. There are no reports of adverse effects on the breastfed infant and no effects on milk production. Monitor breastfeeding infants for adverse reactions, such as agitation, insomnia, anorexia, and reduced weight gain. The safety and efficacy of Cotempla XR-ODT have been established in pediatric patients 6 to 17 years of age but not in patients less than 6 years of age. The safety and efficacy of Cotempla XR-ODT have not been studied in patients over the age of 65 years. There are no dosage adjustments for those with renal or hepatic impairment. Cotempla XR-ODT is the first methylphenidate product and the second ADHD treatment available as an orally disintegrating tablet.

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

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

Outcome: For GHP Family, Calquence will not be added to the GHP Family formulary and will require prior authorization with the following criteria:

- Medica record documentation of a diagnosis of attention deficit hyperactivity disorder (ADHD) **AND**
- Medical record documentation of patient age greater than or equal to 6 years **AND**
- Medical record documentation of a therapeutic failure on, intolerance to, or contraindication to methylphenidate CD (generic Metadate CD) **AND** amphetamine/dextroamphetamine SR combination

Note: Per the Metadate CD prescribing information: "Metadate CD may be swallowed whole with the aid of liquids, or alternately, the capsule may be opened and the capsule contents sprinkled onto a small amount (tablespoon) of applesauce and given immediately, and not stored for future use. Drinking some fluids e.g. water, should follow the intake of the sprinkles with applesauce. The capsules and the capsule contents must not be crushed or chewed." **Per the Adderall XR prescribing information:** "The capsules may be taken whole or the contents of the capsule may be sprinkled on applesauce. If using the sprinkle method, the applesauce should be consumed immediately and swallowed without chewing. The dose of a single capsule should not be divided and the contents of the entire capsule should be taken."

Quantity Limit: 8.6mg and 17.3mg tablets: 1 tablet per day, 25.9mg tablets: 2 tablets per day

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

MYDAYIS (mixed salts of a single-entity amphetamine product)

Review: Mydayis is CNS stimulant indicated for the treatment of Attention Deficit Hyperactivity Disorder (ADHD) in patients 13 years and older. The recommended starting dose for both adults (18 to 55 years) and pediatric patients (13 to 17 years) is 12.5mg once daily. Initial doses of 25mg once daily may be considered for some patients. The dose is titrated weekly by 12.5mg based on the therapeutic needs and response of the patient until the maximum daily dose is reached. The maximum daily dose for adults is 50mg and for pediatrics (13 to 17 years) is 25 mg. Mydayis should be taken orally once daily in the morning upon awakening with or without food; however, patients should be consistent.

The efficacy of Mydayis in the treatment of ADHD was established in 5 short-term trials (3 trials for adults and 2 trials for pediatric patients). Two of the studies (one adult and one pediatric) looked at the change from baseline of the adult ADHD-Rating Scale (RS) with prompts total score at Week 4. Mydayis demonstrated a statistically significant treatment effect compared with placebo on the change of ADHD RS-IV total scores from baseline at Week 4 and also showed statistically significantly greater improvement on the Clinical Global Impression of Improvement (CGI-I) score at Week 4. Three of the studies (two adult and one pediatric) looked at the Permanent Product Measure of Performance (PERMP), a skill-adjusted math test that measures attention in ADHD. PERMP total score results from the sum of the number of math problems attempted plus the number of math problems answered correctly. Efficacy assessments were conducted at 2, 4, 8, 12, 14, and 16 hours post-dose using the PERMP. Mydayis treatment, compared to placebo, reached statistical significance at 2 to 16 hours post-dose.

Mydayis has a black box warning for abuse and dependence. Warnings and precautions with Mydayis include risk of serious cardiovascular reactions, blood pressure and heart rate increases, psychiatric adverse reactions, long term suppression of growth, peripheral vasculopathy including Raynaud's phenomenon, seizures, serotonin syndrome, and potential overdose due to medication errors. The most common adverse reactions for pediatric patients (13 to 17 years) include insomnia, decreased appetite, decreased weight, irritability, and nausea. The most common adverse reactions for adults include insomnia, decreased appetite, decreased weight, dry mouth, increased heart rate, and anxiety. Infants born to amphetamine-dependent mothers have an increased risk of premature delivery and low birth weight. Monitor infants born to mothers taking amphetamines for symptoms of withdrawal such as feeding difficulties, irritability, agitation, and excessive drowsiness. Breastfeeding is not recommended while taking Mydayis. The safety and efficacy of Mydayis have not been established in patients 12 years

and younger. Dose selection should start at the low end of the dosing range for geriatric patients. Dose adjustment of Mydayis is needed in patients with severe renal insufficiency, and Mydayis is not recommended in patients with ESRD. There are no dosage adjustments for those with hepatic impairment. The effects of Mydayis may last up to 16 hours unlike other long-acting stimulants, which may last between 8 to 12 hours

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

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

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

Outcome: For GHP Family, Mydayis will not be added to the GHP Family formulary and will require prior authorization. The following criteria will apply:

- Medica record documentation of a diagnosis of attention deficit hyperactivity disorder (ADHD) **AND**
- Medical record documentation of patient age greater than or equal to 13 years **AND**
- Medical record documentation of a therapeutic failure on, intolerance to, or contraindication to methylphenidate CD (generic Metadate CD) **AND** amphetamine/dextroamphetamine SR combination

Quantity Limit: one tablet daily

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

VABOMERE (meropenem/vaborbactam)

Review: Vabomere is a combination of meropenem, a penem antibacterial, and vaborbactam, a beta-lactamase inhibitor, indicated for the treatment of patients 18 years and older with complicated urinary tract infections (cUTI) including pyelonephritis caused by designated susceptible bacteria. Vabomere is dosed 4grams (2 grams of each component) IV every 8 hours over a 3-hour administration period. There are recommended renal dose adjustments included in the package insert.

The associated warnings and precautions are significant for hypersensitivity reactions, seizures and other adverse Central Nervous System (CNS) experiences, *Clostridium difficile*-associated diarrhea, risk of breakthrough seizures due to the drug interaction with valproic acid, thrombocytopenia, potential for neuromotor impairment, development of drug-resistant bacteria, and overgrowth of nonsusceptible organisms. The most commonly reported adverse reactions in clinical trials included headache, infusion site reactions, diarrhea, hypersensitivity nausea, increased AST/ALT, pyrexia and hypokalemia. Significant drug interactions include valproic acid, which may decrease valproic acid concentrations and increase the risk of breakthrough seizures, and probenecid, which may increase the plasma concentrations of meropenem.

Vabomere was studied in 545 adult patients with a complicated urinary tract infection, including pyelonephritis, as part of a randomized, double-blind, double-dummy, multi-center trial. Patients were randomized to receive either Vabomere or piperacillin/tazobactam IV every 8 hours for at least 15 doses.

Vabomere demonstrated efficacy in clinical and microbiological response at the eradication at the end of IV treatment (EOIVT) visit and the test of cure (TOC) visit (see **Table 1** above).

Representatives from Geisinger Medical Center's (GMC) Infectious Diseases (ID) team currently believe that the use of Vabomere will be relatively limited. GMC ID plan on reserving Vabomere for significantly severe and resistant cases. GMC ID currently prefers Avycaz as the "go to" drug for *Klebsiella pneumoniae* carbapenemase (KPC)-producing bacteria; however, GMC ID may start to use Vabomere more frequently for KPC cases as KPC rates increase. It is expected that Vabomere be restricted to inpatient administration due to the typically poor presentation of patients who would require this medication and due to the demanding dosage of the medication.

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 suggested the susceptible microorganisms be clarified. Tricia Heitzman made a motion to accept the recommendations as amended. Kevin Szczecina seconded the motion. None were opposed.

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

Outcome: For GHP Family, Vabomere will be considered a medical benefit requiring prior authorization. The following criteria will apply:

- Prescribed by or in consultation with an infectious disease specialist **AND**
- Age of 18 years or greater **AND**
- Medical record documentation of a diagnosis of complicated urinary tract infections (cUTI) including pyelonephritis caused by the following susceptible microorganisms: *Enterobacter cloacae species* complex, *Escherichia coli, or Klebsiella pneumoniae* **AND**
- Medical record documentation of culture and sensitivity showing the patient's infection is not susceptible to alternative antibiotic treatments **OR** a documented history of previous intolerance to or contraindication to other antibiotics shown to be susceptible on the culture and sensitivity

Authorization duration: 14 days
Quantity Limit: 6 vials per day

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

JULUCA (dolutegravir/rilpivirine)

Review: Once patients achieve virologic suppression on a three-drug regimen, DHHS guidelines support switching to a two-drug regimen for maintenance treatment. Juluca will fill in this gap in therapy as the first two-drug once-daily regimen to combine an INSTI with a NNRTI as a single-tablet medication to maintain virologic suppression. The current guideline update includes Juluca as a treatment option, and recommends this agent for patients in whom the use of a NRTI is not desired. Overall, two-drug regimens can maintain virologic suppression, and reduce overall toxicity and side effects, making this a desired treatment option for patients. Because Juluca is a complete regimen, coadministration with other antiretroviral medications for the treatment of HIV-1 infection is not recommended. Both dolutegravir and rilpivirine have a potential for drug-drug interactions; detailed information on these interactions can

be found in the Juluca prescribing information, and in the prescribing information for each of the two drug components.

Juluca does not contain any black box warnings, but does share a few warnings and precautions with its individual components, dolutegravir and rilpivirine, when given separately. Juluca has warnings and precautions for severe skin and hypersensitivity reactions, hepatotoxicity, and depressive disorders. Use of Juluca is contraindicated in patients who have had previous hypersensitivity reactions to dolutegravir or rilpivirine, coadministration with dofetilide, and concomitant administration with drugs which may cause a significant decrease in rilpivirine plasma concentration as this may result in a loss of virologic response.

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 written. Todd Sponenberg seconded the motion. None were opposed.

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

Outcome: Juluca will added to the GHP Family formulary on the brand tier with a quantity limit of one tablet daily.

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

SYMPROIC (naldemedine)

Review: Symproic is a peripherally acting mu-opioid receptor antagonist indicated for the treatment of opioid-induced constipation in adults with chronic non-cancer pain, including patients with chronic pain related to prior cancer or its treatment who do not require frequent (e.g., weekly) opioid dosage escalation. Patients receiving opioids for less than 4 weeks may be less responsive to Symproic.

In clinical trials, Symproic was used without laxatives in patients with opioid-induced constipation and chronic non-cancer pain. Only patients receiving a stable opioid morphine equivalent daily dosage of at least 30 mg for at least 4 weeks before study enrollment were eligible for participation in the study. Symproic led to a significantly higher responder rate than did placebo in two clinical trials. Responder rate to the drug was measured by a minimum of 3 spontaneous bowel movements (SBM) per week and an increase from baseline of at least one SBM per week for at least 9 weeks of the 12-week treatment period including at least 3 of the last 4 weeks.

Symproic is available in 0.2 mg tablets to be taken once daily without regard to meals. Symproic is well tolerated with reported adverse reactions of abdominal pain, diarrhea, nausea, and gastroenteritis. Drug interactions should closely be reviewed as this medication has significant interactions with CYP3A4 inducers and inhibitors.

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

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

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

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

- Medical record documentation that the patient is ≥ 18 years of age **AND**
- Medical record documentation of use for opioid-induced constipation associated with chronic non-cancer pain, including patients with chronic pain related to prior cancer or its treatment **AND**
- Medical record documentation of current use of an opioid medication for ≥ 4 weeks **AND**
- Medical record documentation of a therapeutic failure on, intolerance to, or contraindication to one stimulant laxative **AND** one osmotic laxative

Quantity Limit: one tablet daily

Additional Policy updates: Relistor Oral, Relistor Syringes and Movantic

- Update from: Medical record documentation of a diagnosis of chronic non-cancer pain
- Update to: Medical record documentation of a diagnosis of chronic non-cancer pain, including patients with chronic pain related to prior cancer or its treatment

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

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

PARSABIV (etelcalcetide)

Review: Parsabiv is a calcium-sensing receptor agonist, or calcimimetic, indicated for the treatment of secondary hyperparathyroidism (SHPT) in adult patients with chronic kidney disease (CKD) on hemodialysis (HD). Parsabiv has not been studied in adult patients with parathyroid carcinoma, primary hyperparathyroidism, or CKD and are not on HD and should not be used in these populations. Dosing for Parsabiv starts at 5 mg administered intravenously (IV) three times per week after each HD session and may be titrated up in 2.5 mg or 5 mg increments no more frequently than every 4 weeks to maintain PTH levels within recommended target range and corrected serum calcium within the normal range. Parsabiv is supplied through several specialty distributors and is available as 2.5 mg/0.5 mL, 5 mg/mL, and 10 mg/2 mL single-dose vials for injection. Parsabiv works by allosterically binding and activating the calcium-sensing receptor (CaSR) on parathyroid chief cells. This action on the parathyroid gland sensitizes CaSR to promote negative feedback, thus decreasing parathyroid hormone (PTH) secretion and serum calcium and phosphorus levels.

In clinical trials, a significantly higher proportion of patients receiving Parsabiv achieved a reduction in PTH levels from baseline compared to placebo, regardless of PTH at baseline, total duration of HD, whether or not the patient had been previously treated with another calcimimetic, and whether or not patients were receiving vitamin D sterols. In a Phase 3 trial comparing Parsabiv to Sensipar, Parsabiv met both outcomes of non-inferiority and superiority with 52.4% of patients in the Parsabiv group achieving a

reduction in PTH ≥ 50% compared to 40.2% of patients taking Sensipar. There are no black box warnings for Parsabiv; warnings and precautions include risks for hypocalcemia, worsening heart failure, upper gastrointestinal bleeding, and adynamic bone. The most common adverse events are decreased serum calcium, muscle spasms, diarrhea, nausea, and vomiting.

Parsabiv is the second calcimimetic approved for SHPT and the first available as an IV injection administered by a healthcare professional after each HD session, which may improve adherence. The 2017 Kidney Disease: Improving Global Outcomes (KDIGO) Clinical Practice Guidelines recommend the use of calcimimetics in patients with CKD requiring PTH-lowering therapy but do not indicate a preference of any specific agent.

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

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

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

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

- Medical record documentation that patient is ≥ 18 years of age AND
- Medical record documentation of a diagnosis of secondary hyperparathyroidism (SHPT) in patients with chronic kidney disease (CKD) AND
- Medical record documentation that the patient is on hemodialysis (HD) AND
- Medical record documentation that the patient does <u>not</u> have parathyroid carcinoma or primary hyperparathyroidism AND
- Medical record documentation that Parsabiv is <u>not</u> being used in combination with another calcimimetic (ie. Sensipar) AND
- Medical record documentation of baseline PTH level > 300 pg/mL AND corrected serum calcium ≥ 7.5 mg/dL AND
- Medical record documentation of failure on, intolerance to, or contraindication to Sensipar

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

Reauthorization Criteria:

- Medical record documentation of updated labs since the date of previous review showing the patient has had a clinically significant response to treatment with Parsabiv as evidenced by:
    - PTH level decreased from baseline AND > 300 pg/mL AND
    - Corrected serum calcium ≥ 7.5 mg/dL

Other Recommendations:

To increase access and ensure appropriate utilization, it is recommended that Sensipar be added to the GHP Family formulary on the Brand tier with the following prior authorization criteria:

- Medical record documentation that patient is ≥ 18 years of age AND
- Medical record documentation of one of the following:
    - Medical record documentation of a diagnosis of secondary hyperparathyroidism (SHPT) in patients with chronic kidney disease (CKD) AND
    - Medical record documentation that the patient is on dialysis AND
    - Medical record documentation of failure on, intolerance to, or contraindication to calcitriol AND paricalcitol

  OR
    - Medical record documentation of hypercalcemia in patients with parathyroid carcinoma

  OR
    - Medical record documentation of hypercalcemia in patients with primary hyperparathyroidism for whom parathyroidectomy would be indicated on the basis of serum calcium levels, but who are unable to undergo parathyroidectomy

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

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

BENZNIDAZOLE

Review: Benznidazole is a nitroimidazole antimicrobial drug that can cure acute *T. cruzi* infections and prevent chronic manifestations with a 60-day treatment course. Benznidazole will not reverse the existing cardiac, digestive, and cardiodigestive complications of Chagas disease. Benznidazole does not have any black box warnings, but is contraindicated in patients with previous hypersensitivity reaction to benznidazole or other nitroimidazole derivatives, disulfiram usage within the last two weeks, as well as alcoholic beverage consumption during and for at least three days after therapy. The label has warnings and precautions for potential risk for genotoxicity and carcinogenicity, embryo-fetal toxicity, hypersensitivity skin reactions, paresthesia or symptoms of peripheral neuropathy, and hematological manifestations of bone marrow depression. As per the clinical trials Benznidazole treatment resulted in a significantly higher percentage of seronegative patients at the end of the follow up period compared to placebo.

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

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

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

Outcome: For GHP Family, Benznidazole will not be added to the formulary. The following prior authorization criteria will apply:

- Prescribed by or in consultation with an infectious disease specialist **AND**
- Medical record documentation that the member is between the ages of 2 to ≤ 12 years old **AND**

- Medical record documentation of a diagnosis of Chagas disease confirmed by one (1) of the following diagnostic tests:
    - Detection of circulating *T. cruzi* trypomastigotes on microscopy **OR**
    - Detection of *T. cruzi* DNA by polymerase chain reaction assay **OR**
    - Two positive diagnostic serologic tests* using different techniques (ex. enzyme-linked immunoassay (ELISA), indirect fluorescent antibody (IFA)) and antigens (ex. whole-parasite lysate, recombinant antigens) showing IgG antibodies to *T. cruzi*;

Quantity Limit: 100 mg tablets: 4 tablets per day 12.5 mg tablets:2 tablets per day (Note: must enter as two authorizations)

Authorization Duration: Rx count of 2, 30-day supply for each fill

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

BAXDELA (delafloxacin)

Review: Baxdela is a fluoroquinolone indicated for the treatment of acute bacterial skin and skin structure infections (ABSSSI) caused by susceptible isolates of Gram-positive organisms: Staphylococcus aureus (including methicillin-resistant [MRSA] and methicillin-susceptible [MSSA] isolates), Staphylococcus haemolyticus, Staphylococcus lugdunensis, Streptococcus agalactiae, Streptococcus anginosus Group (including Streptococcus anginosus, Streptococcus intermedius, and Streptococcus constellatus), Streptococcus pyogenes, and Enterococcus faecalis AND Gram-negative organisms: Escherichia coli, Enterobacter cloacae, Klebsiella pneumoniae, and Pseudomonas aeruginosa. The term "ABSSSI" was developed by the FDA in 2010 as part of its effort to update the approval process for new antimicrobials to treat SSTIs. ABSSSI is defined as a skin infection with a lesion surface area of at least 75 cm^2 and includes the three following types of infection: (1) cellulitis/erysipelas, (2) wound infections, and (3) major cutaneous abscesses. The patients included in the Baxdela clinical trials all met criteria for ABSSSI. ABSSSIs do not include infections resulting from animal or human bites, necrotizing fasciitis, diabetic foot infections, decubitus ulcer formation, myonecrosis, or ecthyma gangrenosum. The use of Baxdela should not be indiscriminately promoted as empiric therapy for the treatment of mild ABSSSI. Rather, consistent with the principles of antimicrobial stewardship, the use of Baxdela should be judiciously reserved for patients who do not respond to or cannot tolerate other antibiotics. Baxdela is the only FQ that has activity against MRSA. Baxdela is also being evaluated for CAP and UTI. In addition to its broad spectrum of activity, Baxdela was demonstrated to be as effective as vancomycin (the empiric drug of choice for treating MRSA-related ABSSI), which may prove beneficial in its ability to treat polymicrobial ABSSSI involving drug-resistant organisms with a single consolidated regimen. There are 3 possible dosage regimens for Baxdela, however generally it is given as 300 mg by IV infusion over 60 minutes, every 12 hours, or a 450-mg Baxdela tablet orally every 12 hours for 5 to 14 days total duration. As Baxdela is available in both IV and oral dosage forms, patients can be transitioned from an IV regimen to a single agent oral regimen upon discharge to an outpatient setting. Similar to other FQs, Baxdela has boxed warnings for tendinitis and tendon rupture, peripheral neuropathy, central nervous effects, exacerbation of myasthenia gravis. Unlike other FQs, Baxdela has not been associated with QT prolongation, photosensitivity, adverse effects on the liver, kidney, glucose metabolism, or significant CYP450 drug interactions. The most common adverse reactions reported by patients taking Baxdela were

diarrhea and nausea. Due to toxicity of developing cartilage, FQs are generally avoided during pregnancy and lactation. Baxdela was not studied in pediatric patients under 18 years of age. Baxdela is not recommended in pediatrics. Geriatric patients are at increased risk for developing severe tendon disorders including tendon rupture when being treated with a fluoroquinolone. This risk is further increased in patients receiving concomitant corticosteroid therapy. Although dose adjustment is not required for hepatic impairment, patients with renal impairment may require dosage adjustment if the IV formulation is used. With both formulations, Baxdela is not recommended in patients with end stage renal disease (ESRD) or those requiring hemodialysis. Ricky Rampulla, PharmD mentioned that he said that he does not anticipate that Baxdela will be used for simple skin and soft tissue infections. The niche for this antibiotic is in combined MRSA and pseudomonas polymicrobial infections (e.g. sacral ulcer infections, diabetic foot infections, polymicrobial osteomyelitis), which was not studied in the clinical trials.

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

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

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

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

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

- Medical record documentation that patient is greater than or equal to 18 years of age AND
- Medical record documentation of a diagnosis of acute bacterial skin and skin structure infections (ABSSSI)* caused by susceptible isolates of the following: *Staphylococcus aureus* (including methicillin-resistant [MRSA] and methicillin-susceptible [MSSA] isolates), *Staphylococcus haemolyticus, Staphylococcus lugdunensis, Streptococcus agalactiae, Streptococcus anginosus Group* (including S*treptococcus anginosus, Streptococcus intermedius, and Streptococcus constellatus*), *Streptococcus pyogenes, Enterococcus faecalis, Escherichia coli, Enterobacter cloacae, Klebsiella pneumoniae,* or *Pseudomonas aeruginosa* AND
- Prescription written by or in consultation with Infectious Disease AND
- Medical record documentation of culture and sensitivity showing the patient's infection is not susceptible to alternative antibiotic treatments OR a documented history of previous intolerance to or contraindication to other antibiotics shown to be susceptible on the culture and sensitivity OR
- Medical record documentation that Baxdela therapy was started during an inpatient setting

<u>Prior Authorization Criteria for Baxdela Injection:</u>

- Medical record documentation that patient is greater than or equal to 18 years of age AND
- Medical record documentation of a diagnosis of acute bacterial skin and skin structure infections (ABSSSI)* caused by: *Staphylococcus aureus* (including methicillin-resistant [MRSA] and methicillin-susceptible [MSSA] isolates), *Staphylococcus haemolyticus, Staphylococcus lugdunensis, Streptococcus agalactiae, Streptococcus anginosus Group* (including S*treptococcus anginosus, Streptococcus intermedius, and Streptococcus constellatus*), *Streptococcus pyogenes, Enterococcus faecalis, Escherichia coli, Enterobacter cloacae, Klebsiella pneumoniae,* and *Pseudomonas aeruginosa* AND

- Prescription written by or in consultation with Infectious Disease AND
- If Baxdela was initiated during an inpatient stay, medical record documentation of culture and sensitivity showing the patient's infection is not susceptible to alternative antibiotic treatments OR a documented history of previous intolerance to or contraindication to other antibiotics shown to be susceptible on the culture and sensitivity AND
- Medical record documentation of therapeutic failure on, intolerance to, contraindication to Baxdela tablets.

*Note to reviewer: ABSSSI is defined as a skin infection with a lesion surface area of at least 75 cm^2 and includes the three following types of infection: (1) cellulitis/erysipelas, (2) wound infections, and (3) major cutaneous abscesses.

Baxdela tablets:
Authorization Duration: If approved, authorization will be a one-time authorization with a 14-day supply
Quantity Limit: 2 tablets per day

Baxdela Injection:
Authorization Limit: If approved, Baxdela IV will be authorized for 14 days, with a maximum of 28 doses.

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

QTERN (dapagliflozin/saxagliptin)

Review: Clinical Summary

Qtern (dapagliflozin/saxagliptin) is a SGLT2/DPP-4 inhibitor combination indicated as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus (T2DM) who have inadequate control with dapagliflozin or who are already treated with dapagliflozin and saxagliptin. The recommended dose is 10mg/5mg orally once daily in the morning. The tablet should not be split or cut.

Saxagliptin was studied as part of a triple therapy with dapagliflozin and metformin. The patients taking the triple therapy had statistically significant greater reductions in HbA1c from baseline than those patients taking only dapagliflozin and metformin. Also, more patients treated with the additional saxagliptin achieved HbA1c <7% at the end of the trial (week 24). In another study, SAVOR-TIMI, saxagliptin was studied to determine if it there was any cardiovascular benefit when added to the standard of care in adult patients with type 2 diabetes at high risk for atherosclerotic cardiovascular disease. This study demonstrated several things. Saxagliptin was associated with significantly improved glycemic control. However, saxagliptin neither reduces nor increases the risk of cardiovascular death, myocardial infarction, or ischemic stroke when added to the standard of care in patients at high risk for cardiovascular events (no cardioprotective benefits), increases the risk of hospitalization for heart failure, and increases the risk of hypoglycemic events.

Qtern does not have any black box warnings. Warnings and precautions with Qtern include risk of pancreatitis, heart failure, hypotension, ketoacidosis, acute kidney injury and impairment in renal function, urosepsis, pyelonephritis, hypersensitivity reactions, genital mycotic infections, increased LDL-C, bladder cancer, arthralgia, and bullous pemphigoid, and no macrovascular outcomes have been established. The most common adverse reactions include upper respiratory tract infection, urinary tract infection, and dyslipidemia. Geriatric patients are more likely to experience adverse reactions related to

volume depletion and reduced renal function. Qtern in not recommended for use during pregnancy and in nursing mothers. The safety and efficacy of Qtern have not been established for pediatric patients. There are renal considerations with Qtern, and renal function should be assessed and monitored prior to initiation and periodically throughout therapy. There are no dosage adjustments recommended for hepatic impairment; however, safety and efficacy have not been studied in severe hepatic impairment.

Qtern is the second SGLT2/DPP-4 inhibitor combination to come to the market joining Glyxambi. Unlike Glyxambi, neither one of the components of Qtern has been indicated risk reduction of cardiovascular mortality in adults with type 2 diabetes mellitus and established cardiovascular disease. Jardiance (empagliflozin), a component of Glyxambi, is indicated for this and is a preferred add-on agent to metformin for those patients with established atherosclerotic cardiovascular disease to reduce major adverse cardiovascular events.

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

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

Financial Discussion: Dr. Bret Yarczower suggested that it be required a member fail formulary medications before receiving authorization for Qtern. Kevin Szczecina made a motion to accept the recommendations as amended. Rajneel Chohan seconded the motion. None were opposed.

Outcome: It is recommended that Qtern should not be added to the GHP Family formulary. Qtern will require prior authorization and it is recommended that the following prior authorization criteria apply:

- 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 metformin, a formulary SGLT2 inhibitor, **AND** a formulary DPP-4 inhibitor

Quantity Limit: one tablet daily

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

LUTATHERA (lutetium Lu 177 dotatate)

Review: Lutathera is a radiolabeled somatostatin analog indicated for the treatment of somatostatin receptor-positive gastroenteropancreatic neuroendocrine tumors (GEP-NETs), including foregut, midgut, and hindgut neuroendocrine tumors in adults. Lutathera is dosed 7.4 GBq (200mCi) every 8 weeks for 4 doses along with somatostatin analogs, antiemetics, and the suggested amino acid solution.

There are no contraindications or black box warnings with Lutathera, but it has warnings and precautions for risk from radiation exposure, myelosuppression, secondary myelodysplastic syndrome (MDS) and leukemia, as well as renal toxicity, hepatotoxicity, neuroendocrine hormonal crisis, embryo-fetal toxicity and risk of infertility.

Treatment related serious adverse events were experienced by 9% of patients treated with Lutathera versus 1% in the octreotide arm. The most common grade 3-4 adverse reactions (≥4% with a higher incidence in Lutathera arm) were lymphopenia, increased GGT, vomiting, nausea, increased AST,

increased ALT, hyperglycemia and hypokalemia. In the NETTER-1 study, 5 patients discontinued Lutathera for renal-related events and 4 discontinued for hematological toxicities.

Lutathera can cause fetal harm based on its mechanism of action, though there are no available data on Lutathera use in pregnant women. Additionally, there are no data on the presence of Lutathera in human milk or its effects on the breastfed infant or milk production. Women are advised not to breastfeed during treatment with Lutathera and for 2.5 months after the final dose. Lutathera can lead to temporary or permanent infertility following external beam radiotherapy.

The efficacy of Lutathera was established in a randomized, multicenter, open-label, active-controlled trial (NETTER-1) in patients with progressive, well-differentiated, locally advanced/inoperable or metastatic somatostatin receptor-positive midgut carcinoid tumors. Patients in this trial received either Lutathera or high-dose long -acting octreotide. The primary endpoint of the study was progression-free survival (PFS). Secondary endpoints focused on objective response rates (ORR), overall survival (OS), and safety. Median PFS had not been reached in the Lutathera arm compared with 8.5 months in the high-dose octreotide arm. There was a 79% reduction in the risk of progression or death with Lutathera plus octreotide LAR compared with octreotide LAR alone. The ORR with Lutathera was 13% versus 4% with octreotide. At the interim analysis of OS there was a 48% reduction in the risk of death seen with Lutathera versus octreotide.

The efficacy of Lutathera in patients with foregut, midgut, and hindgut GEP-NETs was assessed in 360 patients in the ERASMUS study. A total of 1,214 patients received Lutathera in ERASMUS, of which 601 (50%) were assessed per RECIST criteria. Of the 601 patients evaluated by investigators using RECIST criteria, 360 (60%) had GEP-NETs. All patients received Lutathera 7.4 GBq (200 mCi) every 6 to 13 weeks for up to 4 doses. The investigator assessed ORR was 16% in the 360 patients with GEP-NETs. Three complete responses were observed (< 1%). The median duration of response in the 58 responding patients was 35 months.

The NCCN guidelines have not yet been updated to include Lutathera; however, Lutathera provides a new treatment option for patients who have progressed on initial therapy with long-acting somatostatin analogs (e.g., octreotide, lanreotide).

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

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

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

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

- Prescribed by a hematologist/oncologist **AND**
- Patient is 18 years of age or older **AND**
- Medical record documentation of a diagnosis of gastroenteropancreatic neuroendocrine tumor (GEP-NET) (including foregut, midgut, and hindgut tumors) **AND**
- Medical record documentation of presence of somatostatin receptors on all lesions (somatostatin receptor positive disease) **AND**
- Medical record documentation that long-acting somatostatin analogs have been (or will be) discontinued at least 4 weeks prior to initiation of treatment with Lutathera

Note: Per the package labeling, short-acting somatostatin analogs may be used within 4 weeks of treatment with Lutathera but must be discontinued 24 hours prior to Lutathera treatment. Long-acting somatostatin analogs may be given between 4 and 24 hours after each Lutathera dose provided that it is again discontinued 4-weeks prior to retreatment with Lutathera. After completing Lutathera treatment, long-acting somatostatin analogs may be restarted for 18 months.

Authorization Duration/Quantity Limit: Approval will be for a one-time authorization of **4 visits (7 months)** of therapy. For requests exceeding the above limit, medical record documentation of the following is required:

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

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

TRELEGY ELLIPTA (fluticasone furoate, umeclidinium, and vilanterol inhalation powder)

Review: Trelegy Ellipta is a dry powder inhaler device indicated for long term maintenance treatment of patients with COPD, including chronic bronchitis and/or emphysema. This inhaler is the first approved product made up of three drugs, an inhaled corticosteroid, a long-acting muscarinic antagonist, and a long-acting beta agonist; fluticasone furoate, umeclidinium, and vilanterol respectively. All previous triple therapy treatment options required the use of at least two different inhaler devices. Trelegy Ellipta is dosed as one inhalation once daily. In clinical trials, triple therapy with umeclidinium, fluticasone furoate, and vilanterol was shown to be more effective than dual therapy with either budesonide/formoterol or fluticasone/vilanterol. No additional safety concerns exist at this time for the combination inhaler as compared to those seen with the individual components.

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

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

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

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

- Documentation that the patient is 18 years of age or older **AND**
- Prescription is written by a pulmonologist **AND**
- Medical record documentation of a diagnosis of COPD **AND**
- Medical record documentation of poor disease control (history of exacerbations, poorly controlled symptoms, etc.) on dual therapy with either an ICS/LABA or a LABA/LAMA combination inhaler **OR** current use of any combination of triple therapy of an ICS, LABA, and LAMA**.**

Quantity Limit: 60 blisters per 30 days

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

BIKTARVY (bictegravir/emtricitabine/tenofovir alafenamide)

Review: Biktarvy combines the novel, unboosted integrase strand transfer inhibitor (INSTI) bictegravir, with the demonstrated safety and efficacy profile of the Descovy® (FTC/TAF) dual nucleoside reverse transcriptase inhibitor (NRTI) backbone, and is the smallest INSTI-based triple-therapy STR available.

Biktarvy is indicated as a complete regimen for the treatment of HIV-1 infection in adults who have no antiretroviral treatment history or to replace the current antiretroviral regimen in those who are virologically suppressed (HIV-1 RNA <50 c/mL) on a stable antiretroviral regimen for at least three months with no history of treatment failure and no known substitutions associated with resistance to the individual components of Biktarvy. No dosage adjustment of Biktarvy is required in patients with estimated creatinine clearance greater than or equal to 30 mL per minute.

Biktarvy does not require testing for HLA-B*5701, has no food intake requirements, and has no baseline viral load or CD4 count restrictions. According to Biktarvy's Prescribing Information, prior to or when initiating treatment with Biktarvy, healthcare providers should test for hepatitis B virus (HBV) infection and renal function, and monitor renal function as clinically appropriate during therapy.

Biktarvy has a Boxed Warning in its product label regarding the risk of post treatment acute exacerbation of hepatitis B. See below for Important Safety Information

The most common adverse reactions include: Headache (4% to 5%), abnormal dreams (≤3%), fatigue (2% to 3%), dizziness (2%), insomnia (2%), depression (<2%), skin rash (<2%), diarrhea (3% to 6%), nausea (3% to 5%), increased serum bilirubin (3% to 9%), increased serum ALT (1% to 2%), increased serum AST (1% to 2%), increased creatine phosphokinase (4%), and increased serum creatinine (3%).

The approval of Biktarvy is supported by data from four ongoing Phase 3 studies: Studies 1489 and 1490 in treatment-naïve HIV-1 infected adults, and Studies 1844 and 1878 in virologically suppressed adults (summarized in the sections above).

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

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

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

Outcome: Biktarvy will be added to the GHP Family formulary on the Brand Tier with a quantity limit of one tablet daily

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

ENDARI (L-glutamine oral powder)

Review: Endari is an amino acid indicated to reduce the acute complications of SCD in adult and pediatric patients 5 years of age and older. It is supplied as 5 grams of L-glutamine as white crystalline powder in a paper-foil-plastic laminate packets. Endari is administered twice daily. Ranging from 5 to 15 grams per dose. Endari was evaluated in a phase 3 multicenter, randomized, double-blind, placebo-controlled trial evaluating 230 patients (ages 5-58) with sickle cell anemia or sickle β^0-thalassemia who had two or more painful crises within the previous 12 months. After 48 weeks, treatment with Endari resulted in a lower median incidence of sickle cell crisis than placebo. The secondary endpoints also favored treatment with Endari: fewer hospitalizations, less cumulative hospital days, longer time to first crisis, and a reduction in the number of ACS occurrences. Endari does not have any contraindications, warnings, or precautions. The most common adverse reactions reported in patients taking Endari were back pain, pain in extremities, nausea, chest pain, constipation, and headache. Endari was not studied in pregnant or lactating women, patients with hepatic impairment, or patients with renal impairment. Hydroxyurea is expected to cause fetal harm in pregnant women based on embryotoxic and teratogenic findings in rats and rabbits. Furthermore, hydroxyurea is not recommended in lactating mothers since it is excreted in human milk and has carcinogenic risk towards the infant. Endari is the second therapeutic option approved for SCD after Droxia (hydroxyurea). Endari can be used as monotherapy or in conjunction with hydroxyurea but has a broader indication than hydroxyurea, which is approved to reduce the frequency of sickle cell crises and the need for blood transfusions in patients with SCD. Last updated in 2014, the NHLBI guidelines strongly recommend hydroxyurea for adults with three or more VOCs in a year, severe or recurrent ACS, or those whose symptoms interfere with daily activities. Hydroxyurea should also be offered in infants 9 months and older, in children, and adolescents regardless of severity to reduce SCD-related complications (i.e., pain, dactylitis, ACS, anemia). NHLBI has not commented on the use of L-glutamine in SCD management. Per UpToDate, glutamine can be suggested for patients with repeated vaso-occlusive events. This would include patients who cannot take hydroxyurea and those taking hydroxyurea who wish to further reduce vaso-occlusive events. However, long-term efficacy of Endari is not known at this time. Per the Medical Letter, the clinical data for Endari is limited and it is expensive. Droxia has established efficacy and safety data and is available at a much lower cost. Endari could be considered for patients who cannot take hydroxyurea or as an add-on therapy to hydroxyurea for patients who continue to have severe pain episodes despite hydroxyurea.

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

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

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

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

- Prescription written by or in consultation with a hematologist **AND**
- Medical record documentation of the member being ≥ 5 years **AND**
- Medical record documentation of diagnosis of sickle cell disease **AND**
- Medical record documentation of Endari being used to reduce the acute complications of sickle cell disease* **AND**
- Medical record documentation of therapeutic failure on#, intolerance to, or contraindication to hydroxyurea**.

*Note to reviewer: In the clinical trials, patients were included if they had two or more painful crises within the previous 12 months.

**Note to reviewer: Per NHLBI guidelines, a clinical response to treatment with hydroxyurea may take 3–6 months

Quantity Limit: 6 packets per day, 30 day supply per fill

Authorization Duration: Each treatment period will be defined as 12 months. Re-review will occur every 12 months. The following criteria is recommended for reauthorization:

- Medical record documentation of continued or sustained improvement in the acute complications of sickle cell disease (i.e. number of sickle cell crises, hospitalizations, and number of ACS occurrences)

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

CLASS REVIEW

GROWTH HORMONE UPDATE

FDA Approved Indications[1-9]

	Genotropin	Humatrope	Norditropin	Nutropin AQ	Omnitrope	Saizen	Serostim	Zomacton	Zorbtive
Pediatric GHD	✓	✓	✓	✓	✓	✓		✓	
Prader-Willi Syndrome (Q87.1)	✓		✓		✓				
Small for Gestational Age	✓[a]	✓[b]	✓[b]		✓[a]				
Turner Syndrome	✓	✓	✓	✓	✓				
Idiopathic Short Stature (R62.52)	✓	✓	✓	✓	✓				
SHOX Deficiency (E34.3, Q78.8, Q96.9)		✓							
Noonan Syndrome			✓						
Growth Failure Secondary to CKD (N25.0)				✓[c]					
Adult GHD[d]	✓	✓	✓	✓	✓	✓		✓	
Wasting or cachexia in HIV patients[e]							✓		
Short Bowel Syndrome[e]									✓

GHD – Growth Hormone Deficiency; SHOX – short stature homeobox-containing gene; CKD – Chronic Kidney Disease

a. Indicated for the treatment of pediatric patients with short stature born small for gestational age (SGA) with no catch-up growth by age 2 years.
b. Indicated for the treatment of pediatric patients with short stature born SGA with no catch-up growth by age 2 to 4 years.
c. Up to the time of renal transplantation
d. Includes “Adult or Childhood Onset GHD” and “Replacement of endogenous growth hormone in adults with GHD”
e. Not included from this point on due to unique indications not related to growth failure.

Review:

Norditropin Labeling Update

Updated Indications[3]

- Norditropin is now indicated for the treatment of pediatric patients with:
    - Idiopathic Short Stature, height standard deviation score (SDS) < -2.25*, and associated with growth rates unlikely to permit attainment of adult height in the normal range, and
    - Growth failure due to Prader-Willi syndrome.

Updated Dosing[3]

- The recommended weekly dose of Norditropin in mg/kg of body weight for pediatric patients is:
    - Idiopathic Short Stature: Up to 0.47 mg/kg/week (up to 0.067 mg/kg/day)
    - Prader-Willi Syndrome: 0.24 mg/kg/week (0.034 mg/kg/day)

Updated Adverse Events[3]

- *Idiopathic Short Stature*: In two open-label clinical studies with another somatropin product in pediatric patients, the most common adverse reactions were upper respiratory tract infections, influenza, tonsillitis, nasopharyngitis, gastroenteritis, headaches, increased appetite, pyrexia, fracture, altered mood, and arthralgia.
- *Prader-Willi syndrome*: In two clinical studies in pediatric patients with PWS carried out with another somatropin product, the following adverse reactions were reported: edema, aggressiveness, arthralgia, benign intracranial hypertension, hair loss, headache, and myalgia.
    - *Notable existing Warning* – There have been reports of sudden death after initiating therapy with somatropin in pediatric patients with Prader-Willi syndrome who had one or more of the following risk factors:
        - Severe obesity
        - History of upper airway obstruction or sleep apnea, or
        - Unidentified respiratory infection
    - Male patients with one or more of these factors may be at greater risk than females. Patients with Prader-Willi syndrome should be evaluated for signs of upper airway obstruction and sleep apnea before initiation of treatment with somatropin.

Updated Clinical Trials[3]

- Safety and effectiveness of Norditropin have been established in pediatric patients with Idiopathic Short Stature based on data from a randomized, open-label clinical study with another somatropin product
    - Patients – 105 pediatric patients enrolled on the basis of short stature, stimulated GH secretion > 10 ng/mL, and prepubertal status. Patients had a mean (±SD):
        - Age of 11.4 (1.3) years
        - Height SDS -2.4 (0.4), height velocity SDS -1.1 (0.8), and height velocity 4.4 (0.9) cm/yr
        - Insulin-like growth factor 1 (IGF-1) SDS -0.8 (1.4).
    - Intervention/Comparison – After observation for height progression for 12 months, patients were randomized to another somatropin product at a dose of 0.23 mg/kg/week (0.033 mg/kg/day) or 0.47 mg/kg/week (0.067 mg/kg/day) or observation. Patients were treated for a median duration of 5.7 years.
    - Outcomes – Patients were followed to final height. The observed mean gain in final height was 9.8 cm for females and 5.0 cm for males for both doses combined compared to untreated control subjects. A height gain of 1 SDS was observed in 10% of untreated subjects, 50% of subjects receiving 0.23 mg/kg/week and 69% of subjects receiving 0.47 mg/kg/week.

- Safety and effectiveness of Norditropin have been established in pediatric patients with growth failure due to Prader-Willi Syndrome based on data from two randomized, open label, controlled clinical trials with another somatropin product in pediatric patients.
    - Intervention/Comparison – Patients received either another subcutaneous (SQ) somatropin product or no treatment for the first year of the studies, while all patients received this other SQ somatropin

product during the second year. The dose of the other somatropin product was recalculated every 3 months.
    - In Study 1, the treatment group received a dose of 0.24 mg/kg/week during the entire study. During the second year, the control group received this other somatropin product at a dose of 0.48 mg/kg/week.
    - In Study 2, the treatment group received the other somatropin product at a dose of 0.36 mg/kg/week during the entire study. During the second year, the control group received this other somatropin product at a dose of 0.36 mg/kg/week.
- Outcomes – Results are presented in Table 1. Linear growth continued to increase in the second year, when both groups received treatment with this other somatropin product.

Zomacton Labeling Update

Updated Indications[8]

- Zomacton is now indicated for the replacement of endogenous GH in adults with GH deficiency.

Updated Dosing (for adults)[8]

- Consider using a lower starting dose and smaller dose increment increases for geriatric patients as they may be at increased risk for adverse reactions with Zomacton than younger individuals.
- Either of two Zomacton daily dosing regimens may be used:
    - Non-weight based
        - Initiate at a dose of approximately 0.2 mg/day (range, 0.15 mg/day to 0.3 mg/day) and increase the dose every 1-2 months by increments of approximately 0.1 mg/day to 0.2 mg/day, according to individual requirements based on clinical response and serum IGF-1 levels.
        - Decrease the dose as necessary on the basis of adverse reactions and/or serum IGF-1 concentrations above the age- and gender-specific normal range.
        - Maintenance doses will vary from person to person, and between males and females.
    - Weight-based
        - Initiate Zomacton at 0.006 mg/kg daily and increase the dose according to individual patient requirements to a maximum of 0.0125 mg/kg daily.
        - Use the patient's clinical response, adverse reactions, and determination of age- and gender-adjusted serum IGF-1 concentrations as guidance in dose titration.
        - This regimen is not recommended for obese patients as they are more likely to experience adverse reactions with this regimen.

Updated Adverse Events (for adults)[8]

- Based on trials with another somatropin product, in the first 6 months patients who received this other somatropin product experienced a statistically significant increase in edema (another somatropin product 17% vs. placebo 4%, p=0.043) and peripheral edema (12% vs. 0%, respectively, p=0.017). Edema, muscle pain, joint pain, and joint disorder were reported early in therapy and tended to be transient or responsive to dosage titration.
- Adverse events seen in $\geq$10% of patients with adult onset growth hormone deficiency treated with another somatropin product for at least 12 months included edema, arthralgia, paresthesia, myalgia, pain, rhinitis, peripheral edema, back pain, and headache.
- Adult patients treated with another somatropin product who had been diagnosed with GH deficiency in childhood reported adverse reactions less frequently than those with adult-onset GH deficiency. Adverse events seen in $\geq$10% of patients previously treated for childhood-onset GH deficiency treated as adults with a somatropin product for at least 12 months included flu syndrome, AST increased, and headache.

Updated Clinical Trials for Adult Patients with Growth Hormone Deficiency[8]

- Four 6-month randomized, blinded, placebo-controlled studies, followed by 12 months of open-label treatment
    - Patients – Two studies were done in patients with adult-onset GH deficiency (total n=98) and two studies in adult patients with childhood-onset GH deficiency (total n=67). Adult-onset patients and childhood-onset patients differed by diagnosis (organic vs. idiopathic pituitary disease), body size (average vs. small [mean height and weight]), and age (mean 44 vs. 29 years).
    - Intervention/Comparison – Approximately half of the patients received placebo injections, while the other half received injections of another somatropin product. The doses were identical between trials:
        - 1 month at 0.00625 mg/kg/day followed by 5 months at 0.0125 mg/kg/day
    - Outcomes – The primary efficacy measures were body composition (lean body mass and fat mass) and lipid parameters. In patients with adult-onset GH deficiency, treatment with another somatropin product (vs. placebo) resulted in an increase in mean lean body mass (2.59 vs. -0.22 kg, $p<0.001$) and a decrease in body fat (-3.27 vs. 0.56 kg, $p<0.001$). Similar changes were seen in childhood-onset GH deficient patients. Changes in lean body mass persisted throughout the 18-month period for both the adult-onset and childhood-onset groups; the changes in fat mass persisted in the childhood-onset group. Serum concentrations of HDL cholesterol which were low at baseline (mean, 30.1 mg/mL and 33.9 mg/mL in adult- and childhood-onset patients, respectively) had normalized by the end of 18 months of treatment with this other somatropin product (mean change of 13.7 mg/dL and 11.1 mg/dL for the adult-onset and childhood-onset groups, respectively $p<0.001$).

Current Utilization: No current utilization of alternative growth hormone products for indications not shared with Norditropin

- Indications other products did not share with Norditropin at the time of review included Prader-Willi Syndrome, Idiopathic Short Stature, SHOX Deficiency, and Growth Failure Secondary to CKD.
- Norditropin is now indicated for Prader-Willi Syndrome and Idiopathic Short Stature

Based on the updated clinical review and contracting opportunities, there are no changes recommended to the current formulary or prior authorization criteria.

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

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

FAST FACTS

OPDIVO (nivolumab)

Updated Indication: Opdivo is now indicated for the treatment of patients with melanoma with lymph node involvement or metastatic disease who have undergone complete resection, in the adjuvant setting.

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, urothelial carcinoma, MSI-H or dMMR metastatic colorectal cancer, and previously treated hepatocellular 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.

For Melanoma

- Prescription written by a hematologist/oncologist **AND**
- Medical record documentation that patient is ≥ 18 years of age **AND**
- Medical record documentation of one of the following:
    - A diagnosis of unresectable or metastatic melanoma **AND**
    - Opdivo is not being used in combination with any other agents for the treatment of unresectable or metastatic melanoma (with the exception of ipilimumab).

    OR
    - A diagnosis of completely resected (no evidence of disease) metastatic melanoma with distant metastases, which may include lymph nodes **AND**
    - Medical record documentation of complete resection of distant metastases **AND**
    - Opdivo is being used in the adjuvant setting **AND**
    - Opdivo is being used as a single agent

Note: The FDA-approved treatment duration for use of Opdivo in the adjuvant setting is for up to 1 year.

It is recommended that the authorization duration criteria be updated to the following.

AUTHORIZATION DURATION:

For adjuvant treatment of metastatic melanoma:
Initial approval will be for **6 months** or less if the reviewing provider feels it is medically appropriate. One subsequent approval will be for an additional **6 months** or less if the reviewing provider feels it is medically appropriate and will require medical record documentation of continued disease improvement or lack of disease progression. The medication will no longer be covered if patient experiences toxicity or worsening of disease.

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

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

For all other indications:
Initial approval will be for **6 months** or less if the reviewing provider feels it is medically appropriate. Subsequent approvals will be for an additional **12 months** or less if the reviewing provider feels it is medically appropriate and

will require medical record documentation of continued disease improvement or lack of disease progression. The medication will no longer be covered if patient experiences toxicity or worsening of disease.

No changes are recommended to the other prior authorization criteria at this time.

Discussion: No comments or questions.

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

LYNPARZA (olaparib)

Updated Indication: Lynparza is a poly (ADP-ribose) polymerase (PARP) inhibitor indicated in patients with deleterious or suspected deleterious *gBRCAm*, human epidermal growth factor receptor 2 (HER2)-negative metastatic breast cancer who have previously been treated with chemotherapy in the neoadjuvant or metastatic setting. Patients with hormone receptor (HR)-positive breast cancer should have been treated with a prior endocrine therapy or be considered inappropriate for endocrine treatment. Select patients for therapy based on an FDA-approved companion diagnostic for Lynparza.

Note: Previously Lynparza tablets were approved for:

- the maintenance treatment of adult patients with recurrent epithelial ovarian, fallopian tube or primary peritoneal cancer, who are in a complete or partial response to platinum-based chemotherapy.
- the treatment of adult patients with deleterious or suspected deleterious germline *BRCA*-mutated advanced ovarian cancer who have been treated with three or more prior lines of chemotherapy. Select patients for therapy based on an FDA-approved companion diagnostic for Lynparza.

Recommendation: No changes are recommended to existing formulary status, quantity limit, or authorization duration. It is recommended that the Lynparza policy be updated to include the new indication as follows:

- Medical record documentation that Lynparza is prescribed by an oncologist or hematologist **AND**
- Medical record documentation of age greater than or equal to 18 years **AND**
- Medical record documentation of deleterious or suspected deleterious germline BRCA-mutated advanced ovarian cancer as verified by a Food and Drug Administration (FDA) approved test **AND** medical record documentation of therapeutic failure on, intolerance to, or contraindication to three or more prior lines of chemotherapy **OR**
- Medical record documentation of diagnosis of recurrent epithelial ovarian, primary peritoneal, or fallopian tube cancer **AND** medical record documentation of Lynparza being used as maintenance therapy after a complete or partial response to platinum-based chemotherapy **OR**
  Medical record documentation of a diagnosis of deleterious or suspected deleterious *gBRCAm*, HER2-negative metastatic breast cancer **AND** medical record documentation that member has been previously treated with chemotherapy in the neoadjuvant, adjuvant, or metastatic setting **AND** if hormone receptor (HR)-positive, medical record documentation that prior treatment included endocrine therapy or documentation that endocrine therapy would be considered inappropriate

  QUANTITY LIMIT: 150 mg tablets: 4 tablets per day, 28 day supply per fill

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

Discussion: Aubrielle Prater recommended that treatment for those with a diagnosis of deleterious or suspected deleterious gBRCAm, HER2-negative metastatic breast cancer and are hormone receptor positive be addressed in the policy.

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

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

SOLIRIS (eculizumab)

Updated Indication: Generalized myasthenia gravis (gMG): treatment of adult patients with generalized myasthenia gravis who are anti-acetylcholine (AchR) antibody-positive.

Previous Indication:
Paroxysmal Nocturnal Hemoglobinuria (PNH): treatment of patients with paroxysmal nocturnal hemoglobinuria (PNH) to reduce hemolysis.

Atypical Hemolytic Uremic Syndrome (aHUS): treatment of patients with atypical hemolytic uremic syndrome (aHUS) to inhibit complement-mediated thrombotic microangiopathy.

Limitation of use: Soliris is not indicated for the treatment of patients with Shiga toxin E.coli related hemolytic uremic syndrome (STEC-HUS).

Recommendation: No changes are recommended to the formulary placement of Soliris at this time for all lines of business. It is recommended that the Soliris prior authorization criteria of the medical policy, MBP 54.00, be updated to include the new indication of Generalized Myasthenia Gravis (gMA).

.Generalized Myasthenia Gravis (gMA)

- Medical record documentation supporting a confirmed diagnosis of Generalized Myasthenia Gravis **AND**
- Medical record documentation that member is anti-acetylcholine receptor (AchR) antibody positive **AND**
- Prescribed by or in consultation with a neuromuscular specialist **AND**
- Medical record documentation of Myasthenia Gravis Foundation of America Clinical Classification (MGFA) Class II to IV **AND ***
- Medical record documentation Myasthenia Gravis-Activities of Daily Living (MG-ADL) score of 6 or more at baseline **AND**
- Medical record documentation of age $\geq$ 18 years **AND**
- Medical record documentation of therapeutic failure on, intolerance to, or contraindication to corticosteroids **AND**
- Medical record documentation of therapeutic failure on, intolerance to, or contraindication to cholinesterase inhibitors **AND**
- Medical record documentation of therapeutic failure on intolerance to, or contraindication to at least two (2) immunosuppressive therapies **OR** has failed at least one (1) immunosuppressive therapy and required chronic plasmapheresis or plasma exchange (PE) **AND**
- Medical record documentation of failure on intolerance to, or contraindication to Rituxan **AND**
- Medical record documentation of failure on intolerance to, or contraindication to intravenous immunoglobulin (IVIG)

AUTHORIZATION DURATION: Initial approval will be given for six months.

Subsequent approvals will be for an additional six months and will require:

- Medical record documentation of continued disease improvement or lack of disease progression **AND**
- Medical record documentation that the member is responding positively to therapy as evidenced by a 3-point reduction in MG-ADL total score;

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

Additional Recommendation: To remove the current note under the Myasthenia Gravis indication in reference to the IVIG medical policy (MBP 4.0). The note states "for chronic forms of Myasthenia Gravis, treatment with IVIG is considered investigational and is not covered."

Note: Class I Myasthenia gravis is indicated by any eye muscle weakness, possible ptosis (drooping or falling of the upper eyelid), no other evidence of muscle weakness elsewhere

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

IV infusion: 900 mg every 7 days for the first 4 weeks, followed by a single dose of 1,200 mg 7 days after the fourth dose, and then 1,200 mg every 2 weeks thereafter. **Max dosage is 1,200 mg per dose.**

Discussion: There was much discussion about the use of Rituxan for the treatment of MG. At the suggestion of Dr. Bret Yarczower is was decided to approve criteria which included the use of Rituxan prior to using Soliris, but Dr. Scott Friedenberg, a neurologist with Geisinger, and UPMC would be consulted to determine the final status.

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

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

VARUBI (rolapitant)

Updated Indication: Varubi is now available as an injectable emulsion and is indicated in combination with other antiemetic agents in adults for the prevention of delayed nausea and vomiting associated with initial and repeat courses of emetogenic cancer chemotherapy, including, but not limited to, highly emetogenic chemotherapy. Previously, Varubi was only available as an oral tablet for the above indication.

Recommendation: Varubi injectable emulsion is a medical benefit and should not be added to the GHP Family formulary. The following prior authorization criteria and authorization duration should apply.

- Medical record documentation that Varubi injectable emulsion is being used for the prevention of delayed nausea and vomiting associated with initial and repeat courses of highly emetogenic cancer chemotherapy OR
- Medical record documentation that Varubi is being used for the prevention of delayed nausea and vomiting associated with initial and repeat courses of moderately emetogenic cancer chemotherapy for insured individuals who have a treatment failure or contraindication to ondansetron (Zofran) or granisetron (Kytril). Treatment failure is defined as allergy, intolerable side-effects, significant drug-drug interaction, or lack of efficacy.

The following antineoplastic agents are considered highly emetogenic (refer to NCCN for complete list):

- AC combination defined as any chemotherapy regimen that contains an anthracycline and cyclophosphamide

- Carboplatin
- Carmustine
- Cisplatin
- Cyclophosphamide at doses >1500 mg/m^2
- Dacarbazine
- Dactinomycin
- Daunorubicin
- Doxorubicin
- Epirubicin
- Ifosfamide
- Irinotecan
- Mechlorethamine
- Methotrexate at doses $\geq$ 250mg/m^2
- Oxaliplatin
- Streptozotocin
- Trabectedin

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

Discussion: No questions or comments.

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

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

SIMPONI ARIA (golimumab [for infusion])

Updated Indication: Simponi Aria is now indicated for the treatment of adult patients with active psoriatic arthritis (PsA) and adult patients with active ankylosing spondylitis (AS). Previously, Simponi Aria was only indicated in combination with methotrexate (MTX) for the treatment of adult patients with moderately to severely active rheumatoid arthritis (RA).

Note: The indications of Simponi Aria differ from those of Simponi, which is indicated for AS, PsA, RA, and ulcerative colitis (UC). Simponi Aria is NOT indicated for the treatment of patients with UC

Recommendation: No changes are recommended to the formulary placement of Simponi Aria at this time. It is recommended that the criteria of applicable policies are updated to reflect the following changes to account for the updated indications.

Rheumatoid Arthritis

- Requesting provider must be a rheumatologist **AND**
- Medical record documentation of age ≥18 years **AND**
- Medical record documentation of a diagnosis of moderate to severe rheumatoid arthritis according the American College of Rheumatology Criteria for the Classification and Diagnosis of Rheumatoid Arthritis **AND**
- Medical record documentation that Simponi Aria will be given in combination with methotrexate **AND**

- Medical record documentation that Simponi Aria is not being used concurrently with a TNF blocker or other biologic agent **AND**
- Medical record documentation of an inadequate response to, contraindication to, or failure on 12 weeks of etanercept (Enbrel*) AND adalimumab (Humira*) therapy.

Psoriatic Arthritis
- Requesting provider must be a rheumatologist or dermatologist **AND**
- Medical record documentation of age ≥18 years **AND**
- Medical record documentation of a diagnosis of moderately to severely active psoriatic arthritis, which must include the following:
    - Documentation of active psoriatic lesions OR documentation of a history of psoriasis

  AND
- Medical record documentation that Simponi Aria is not being used concurrently with a TNF blocker or other biologic agent **AND**
- Medical record documentation of an inadequate response to, contraindication to, or failure on 12 weeks of secukinumab (Cosentyx*) AND adalimumab (Humira*) therapy.

Ankylosing Spondylitis
- Requesting provider must be a rheumatologist **AND**
- Medical record documentation of age ≥18 years **AND**
- Medical record documentation of a diagnosis of ankylosing spondylitis **AND**
- Medical record documentation that Simponi Aria is not being used concurrently with a TNF blocker or other biologic agent **AND**
- Medical record documentation of an inadequate response to, contraindication to, or failure on 12 weeks of secukinumab (Cosentyx*) AND adalimumab (Humira*) therapy.

(*requires prior authorization)

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 rheumatoid arthritis at six (6) months of Simponi Aria therapy is required.

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

Discussion: No comments or questions.

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

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

IMBRUVICA (ibrutinib)

Updated Dosing: Imbruvica is now available as a 70 mg capsule for administration once daily in the following patient populations:
- Concomitant administration with posaconazole when patient is being treated for a B-cell malignancy and the posaconazole daily dose exceeds 400 mg
- Moderate hepatic impairment

Previous Dosing: It was previously recommended to avoid concomitant use in the above listed patient populations.

How Supplied: In addition to the 70 mg and 140 mg capsules, Imbruvica is now available as tablets in the following strengths: 140 mg, 280 mg, 420 mg, and 560 mg. The availability of these strengths allows for the administration of one tablet, once daily.

Per the manufacturer website, the original Imbruvica 140 mg capsules will no longer be available after May 15, 2018.

Recommendation: There are no changes recommended to the current formulary status or prior authorization criteria. It is recommended to update the quantity limits for all available strengths of Imbruvica to 1 capsule/tablet per day, 28 day supply per fill.

Discussion: No questions or comments.

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

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

GILOTRIF (afatinib)

Updated Indication: Gilotrif, a kinase inhibitor, is indicated for:

- First-line treatment of patients with metastatic non-small cell lung cancer (NSCLC) whose tumors have non-resistant epidermal growth factor receptor (EGFR) mutations as detected by an FDA-approved test
    - Limitation of Use: Safety and efficacy of GILOTRIF were not established in patients whose tumors have resistant EGFR mutations

Previous Indication: First-line treatment of patients with metastatic non-small cell lung cancer (NSCLC) whose tumors have epidermal growth factor receptor (EGFR) exon 19 deletions or exon 21 (L858R) substitution mutations as detected by an FDA-approved test

- Limitation of Use: Safety and efficacy of GILOTRIF were not established in patients whose tumors have other EGFR mutations

Recommendation: No changes to the formulary placement, quantity limits, and authorization durations of Gilotrif are recommended at this time. It is recommended the prior authorization criteria be updated to:

- Must be prescribed by hematologist/oncologist **AND**
- Medical record documentation of first-line treatment of patients with metastatic non-small cell lung cancer (NSCLC) whose tumors have non-resistant epidermal growth factor receptor (EGFR) mutations as detected by an FDA-approved test **OR**
- Medical record documentation of a diagnosis of metastatic, squamous non-small cell lung cancer (NSCLC) which has progressed after platinum-based chemotherapy **OR**
- (For Gold Only) Medical record documentation of use for a medically accepted indication

Discussion: No questions or comments.

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

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

PERJETA (pertuzumab)

Updated Indication: Perjeta is now indicated for use in combination with trastuzumab and chemotherapy as adjuvant treatment of patients with human epidermal growth factor receptor 2 (HER2)-positive early breast cancer at high risk of recurrence.

Previously, Perjeta was indicated for:

- Use in combination with trastuzumab and docetaxel for treatment of patients with HER2-positive metastatic breast cancer (MBC) who have not received prior anti-HER2 therapy or chemotherapy for metastatic disease
- Use in combination with trastuzumab and chemotherapy as neoadjuvant treatment of patients with HER-2 positive, locally advanced, inflammatory, or early stage breast cancer (either greater than 2 cm in diameter or node positive) as part of a complete treatment regimen for early breast cancer

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

Discussion: No questions or comments.

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

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

TALTZ (ixekizumab)

Updated Indication: Taltz is now indicated for the treatment of adult patients with active psoriatic arthritis.

Previously, Taltz was only indicated for the treatment of adults with moderate-to-severe plaque psoriasis who are candidates for systemic therapy or phototherapy.

Recommendation: No changes are recommended to the formulary status of Taltz at this time. It is recommended that the policy be updated to read as follows:

Plaque Psoriasis

- Prescription must be written by a dermatologist **AND**
- Member must be at least 18 years of age **AND**
- Medical record documentation of a diagnosis of moderate to severe plaque psoriasis characterized by >5% of body surface area involved or disease involving crucial body areas such as the hands, feet, face, or genitals **AND**
- Medical record documentation that Taltz is <u>not</u> being used concurrently with a TNF blocker or other biologic agent **AND**
- Medical record documentation of an intolerance to, contraindication to, or therapeutic failure on a minimum 3-month trial of Humira* AND Cosentyx*

Quantity Limit (Plaque Psoriasis):

- At time of initial authorization (loading dose):
    - Three (3) month authorization for a maximum total quantity of 8 mL

    - Remainder of six (6) month authorization duration: 1 mL per 28 days
- For ongoing or reauthorization: 1 mL per 28 days

Psoriatic Arthritis

- Prescription must be written by a dermatologist or rheumatologist **AND**
- Member is at least 18 years of age **AND**
- Medical record documentation of a diagnosis of moderately to severely active psoriatic arthritis which must include the following:
    - Documentation of either active psoriatic lesions or a documented history of psoriasis

  AND
- Medical record documentation that Taltz is not being used concurrently with a TNF blocker or other biologic agent **AND**
- Medical record documentation of an intolerance to, contraindication to, or therapeutic failure on a minimum 3-month trial of Humira* AND Cosentyx*

Quantity Limit (Psoriatic Arthritis):

- At time of initial authorization (loading dose):
    - One-time one-week authorization of 3 mL per 28 days
    - Remainder of six (6) month authorization duration: 1 mL per 28 days
- For ongoing or reauthorization: 1 mL per 28 days

Note: If patient has coexistent plaque psoriasis, the loading dose quantity limit should be entered as outlined under the Plaque Psoriasis subsection of the Taltz criteria.

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 psoriasis on six (6) months of Taltz therapy is required.

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

Discussion: No questions or comments.

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

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

ZYKADIA (ceritinib)

Updated Dosing: Zykadia is to be administered as a single 450 mg oral dose once daily with food until disease progression or unacceptable toxicity.

Previous Dosing: Zykadia was previously administered as a single 750 mg oral dose once daily until disease progression or unacceptable toxicity. The dose was to be administered at least 1 hour before or at least 2 hours after a meal.

Recommendation: It is recommended that the existing quantity limit is updated to reflect the new dosing regimen: 3 capsules per day, 1 month supply per fill.

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.

VERZENIO (abemaciclib)

Updated Indication: Verzenio is now indicated in combination with an aromatase inhibitor as initial endocrine-based therapy for the treatment of postmenopausal women with hormone receptor (HR)-positive, human epidermal growth factor receptor 2 (HER2)-negative advanced or metastatic breast cancer

Recommendation: the following updates should made to existing prior authorization criteria:

- One of the following:
    - Medical record documentation that Verzenio is being prescribed as initial endocrine-based therapy **AND**
    - Medical record documentation of postmenopausal status **AND**
    - Medical record documentation that Verzenio will be prescribed in combination with an aromatase inhibitor (i.e. letrozole, anastrozole, etc.)

OR

    - Medical record documentation that the patient experienced disease progression following prior endocrine therapy* AND prior chemotherapy^ in the metastatic setting **AND**
    - Medical record documentation that Verzenio is being used as monotherapy

OR

    - Medical record documentation that the patient experienced disease progression following prior endocrine therapy* **AND**
    - Medical record documentation that fulvestrant (Faslodex) will be administered along with Verzenio **AND**
    - Medical record documentation of postmenopausal status **OR** if the patient is pre/perimenopausal, that they have received a gonadotropin-releasing hormone agonist (e.g. LHRH agonist; goserelin) for at least 4 weeks prior to and will continue for the duration of Verzenio therapy.

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.

TRISENOX (arsenic trioxide)

Updated Indication: Trisenox is an arsenical now indicated in combination with tretinoin for treatment of adults with newly-diagnosed low-risk acute promyelocytic leukemia (APL) whose APL is characterized by the presence of the t(15;17) translocation or PML/RAR-alpha gene expression.

Previously, Trisenox was indicated for induction of remission and consolidation in patients with acute promyelocytic leukemia (APL) who are refractory to, or have relapsed from, retinoid and anthracycline chemotherapy, and whose APL is characterized by the presence of the t(15;17) translocation or PML/RAR-alpha gene expression

Recommendation: No changes are recommended to the formulary placement of Trisenox. The following medical benefit prior authorization criteria should apply.

Prior Authorization Criteria:

- Prescription written by a hematologist or oncologist AND
- Medical record documentation of newly-diagnosed low-risk acute promyelocytic leukemia (APL) characterized by the presence of the t(15,17) translocation of PML/RAR-alpha gene expression AND that Trisenox is being used in combination with tretinoin OR
- Medical record documention the Trisenox is being used for induction of remission and consolidation in patients with acute promyelocytic leukemia (APL) who are refractory to, or have relapsed from, retinoid and anthracycline chemotherapy, and whose APL is characterized by the presence of the t(15,17) translocation or PML/RAR-alpha gene expression

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

Discussion: No questions or comments.

Outcome: Tricia Heitzman 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.

XELJANZ/XELJANZ XR (tofacitinib)

Updated Indication: Xeljanz and Xeljanz XR (collectively referred to as "Xeljanz") are now indicated for the treatment of adult patients with active psoriatic arthritis (PsA) who have had an inadequate response or intolerance to methotrexate or other disease-modifying antirheumatic drugs (DMARDs).

Previously, Xeljanz was only indicated for the treatment of adult patients with rheumatoid arthritis (RA) who have had inadequate response or intolerance to methotrexate (MTX).

Recommendation: No changes are recommended to the formulary status of Xeljanz. It is recommended that the policy is updated to read as follows. No changes are recommended to the quantity limits or authorization duration..

Rheumatoid Arthritis

- Medical record documentation of a diagnosis of moderate to severe rheumatoid arthritis (made in accordance with the American College of Rheumatology Criteria for the Classification and Diagnosis of Rheumatoid Arthritis) **AND**

- Medical record documentation of an inadequate response to or intolerance to a 3-month trial of methotrexate or another disease-modifying antirheumatic drug (DMARD) **AND**
- Medical record documentation that Xeljanz or Xeljanz XR is being prescribed by a rheumatologist **AND**
- Member is at least 18 years of age **AND**
- Medical record documentation that Xeljanz or Xeljanz XRis not being used concurrently with a TNF blocker or other biologic agent **AND**
- Medical record documentation of an intolerance to, contraindication to, or therapeutic failure on a minimum 3-month trial of Humira* **AND** Enbrel*

Psoriatic Arthritis

- Medical record documentation of a diagnosis of moderately to severely active psoriatic arthritis which must include the following:
    - Documentation of either active psoriatic lesions or a documented history of psoriasis

  AND
- Medical record documentation of an inadequate response to or intolerance to a 3-month trial of methotrexate or another disease-modifying antirheumatic drug (DMARD) **AND**
- Medical record documentation that Xeljanz or Xeljanz XR is being prescribed by a rheumatologist or dermatologist **AND**
- Member is at least 18 years of age **AND**
- Medical record documentation that Xeljanz or Xeljanz XR is being prescribed in combination with non-biologic DMARD therapy (including but not limited to methotrexate, sulfasalazine, and/or leflunomide) **AND**
- Medical record documentation that Xeljanz or Xeljanz XR is not being used concurrently with a TNF blocker or other biologic agent **AND**
- Medical record documentation of an intolerance to, contraindication to, or therapeutic failure on a minimum 3-month trial of Humira* **AND** Cosentyx*

Discussion: Tricia Heitzman recommended adding the requirement of failure on methotrexate or another DMARD.

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

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

UPDATES

Use of buprenorphine/naloxone or buprenorphine for pain

Recommendation: Based on the clinical review, oral buprenorphine with or without naloxone has a role in pain therapy, primarily in palliative care and cancer pain. Notably, it is less likely to be abused, associated with less risk of overdose, and less costly than many opioids. Therefore, the following updates should be made to the existing buprenorphine and buprenorphine/naloxone policies:

Commercial Suboxone, buprenorphine, buprenorphine/naloxone Policy
For Palliative Care/Cancer Pain

1. Medical record documentation of a diagnosis of cancer pain or pain in the palliative care setting **AND**
2. Medical record documentation that the prescription is written by a provider specializing in palliative care, hematology, oncology, or pain management.

AUTHORIZATION DURATION:

Indication	Initial Authorization	Reauthorization
Opioid dependence (unchanged)	3 months	12 months
Pain (palliative care or cancer pain) (new auth duration)	12 months	12 months

Discussion: No comments or questions.

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

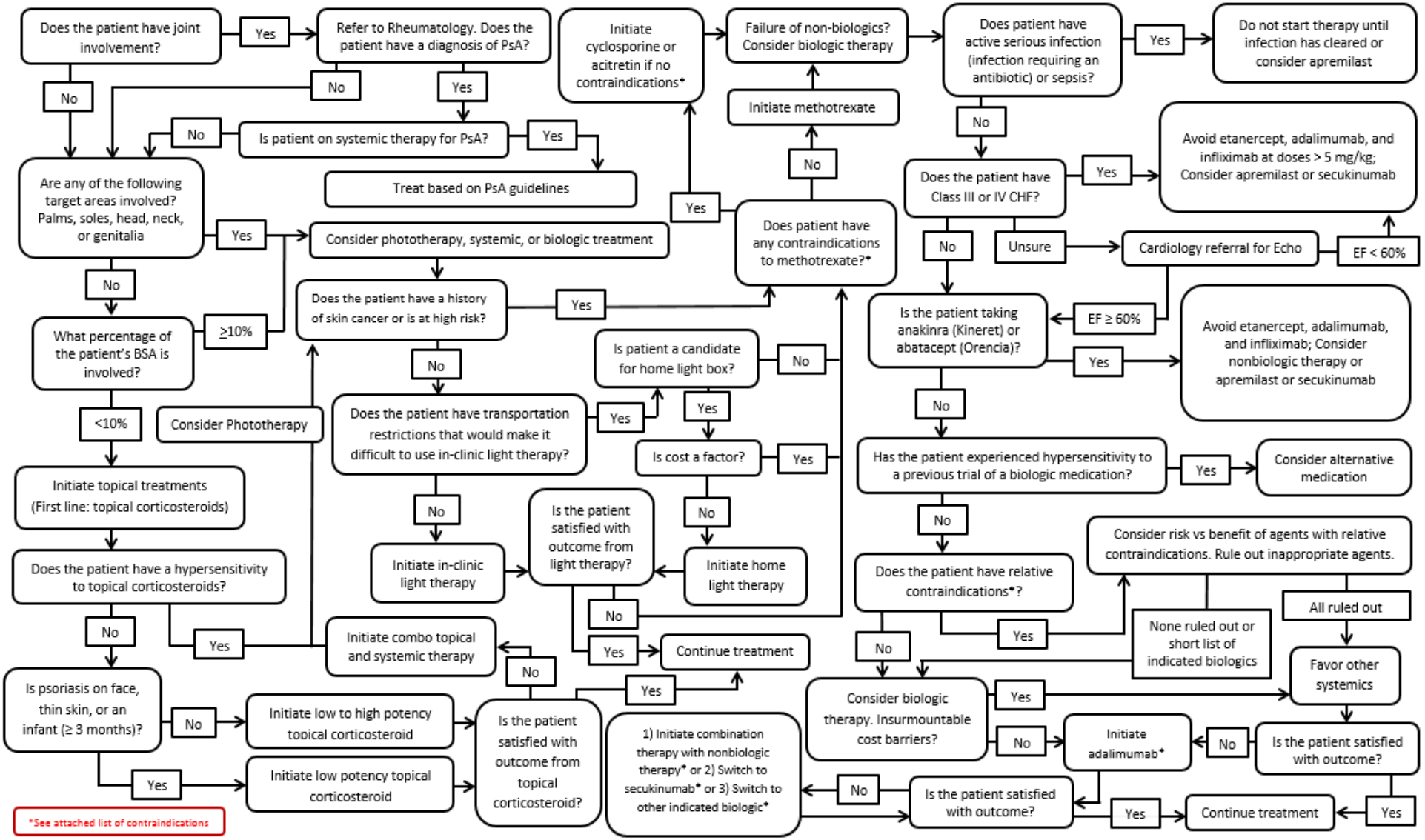
Additional evidence of the criteria used to make this decision can be found in the drug review presented to the committee.

Plaque Psoriasis, Psoriatic Arthritis, and Ankylosing Spondylitis Update

Available Biologics and Indications:

	Ankylosing Spondylitis	Crohn's Disease	Pediatric Crohn's Disease	Hidradenitis Suppurativa	Juvenile Idiopathic Arthritis	Plaque Psoriasis	Psoriatic Arthritis	Rheumatoid Arthritis	Ulcerative Colitis	Pediatric Ulcerative Colitis	Uveitis
Abatacept (Orencia)					x		x	x			
Adalimumab (Humira)	x	x	x	x	x	x	x	x	x		x
Anakinra (Kineret)								x			
Apremilast (Otezla)						x	x				
Brodalumab (Siliq)						x					
Certolizumab (Cimzia)	x	x					x	x			
Etanercept (Enbrel)	x				x	x	x	x			
Golimumab (Simponi, Simponi Aria)	x						x	x	(Simponi Only)		
Guselkumab (Tremfya)						x					
Infliximab (Remicade)	x	x	x			x	x	x	x	x	
Infliximab-dyyb (Inflectra)	x	x	x			x	x	x	x		
Infliximab-abda (Renflexis)	x	x	x			x	x	x	x		
Ixekizumab (Taltz)						x	x				
Natalizumab (Tysabri)		x									
Rituximab (Rituxan)								x			
Sarilumab (Kevzara)								x			
Secukinumab (Cosentyx)	x					x	x				
Tocilizumab (Actemra)					x			x			
Tofacitnib (Xeljanz, Xeljanz XR)							x	x			
Ustekinumab (Stelara)		x				x	x				
Vedolizumab (Entyvio)		x							x		

Geisinger Health System Psoriasis ProvenCare Pathway:



Currently, GHP prefers the use of Humira and Enbrel as first line biologics for the plaque psoriasis, psoriatic arthritis, and ankylosing spondylitis indications. As outlined by the available biologics and indications table above, there are a wide variety of products indicated for the treatment of these conditions, which include various mechanisms of action as well as administration route, including oral, intravenous, and subcutaneous routes. To ensure GHP's formularies are clinically appropriate and align with the wants and needs of GHP's members and providers, a review of the treatment of plaque psoriasis, psoriatic arthritis, and ankylosing spondylitis as well as the biologic therapies utilized to treat these conditions was performed.

Consulted prescribers generally concluded that indicated biologics are efficaciously similar and the preference of biologics with two different mechanisms of action would maximize treatment options and allow for better treatment of complex patients. Physicians on the Geisinger Psoriasis ProvenCare Pathway committee explained that while some agents such as Stelara, Cosentyx, and Tremfya have some comparative evidence that suggests they are statistically significantly better than some of the other biologic alternatives, the physicians are not seeing a clinically significant difference between the available biologic treatment options. It was concluded by the Psoriasis ProvenCare committee that for this reason, the two most cost-effective biologic options of two different mechanisms of action should be preferred.

The American College of Rheumatology guidelines for Axial Spondylarthrosis and Psoriatic Arthritis are currently under development. The 2015 American College of Rheumatology/Spondylitis Association of America/Spondyloarthritis Research and Treatment Network guidelines strongly recommends the use of TNFi treatment in patients with active AS despite treatment with NSAIDs, the committee did not prefer one TNFi over another except for patients with concomitant inflammatory bowel disease or recurrent iritis. The ACR/SAA/SPARTAN treatment recommendations in AS did not make mention of the IL-inhibiting products. The American Academy of Dermatology guidelines for treatment of psoriasis recommend anti-TNF therapy in patients with psoriasis (limited disease) secondary to topicals/targeted phototherapy +/- UVB/PUVA and other systemic therapies, or in patients with psoriasis (extensive disease), before or after UVB/PUVA and other systemic therapies. The guidelines do not prefer one anti-TNF agent over another. The guidelines do not make specific recommendation for interleukin inhibiting agents; however, the guidelines to mention that IL-12/23 inhibitors demonstrate therapeutic efficacy in the treatment of psoriasis. The American Academy of Dermatology guidelines for treatment of psoriatic arthritis recommend NSAIDs for the treatment of mild PsA. The guidelines recommend treatment with non-biologic DMARDs and TNF inhibitors for moderate to severe disease. The guidelines do not recommend one TNFi over another and do not make mention of non-TNFi biologics.

Recommendation:

GHP Family		
Medication	**Current Policy**	**Recommendations**
Cimzia	Medical record documentation of: For PsA: • A diagnosis of moderately to severely active PsA which must include the following: o Documentation of either active psoriatic lesions or a documented history of psoriasis AND • Prescription written by a dermatologist or rheumatologist AND • Age at least 18 years of age For AS: • A diagnosis of ankylosing spondylitis AND • Prescription written by a rheumatologist AND • Age at least 18 years of age	For all indications Add: • Medical record documentation that Cimzia is <u>not</u> being used concurrently with a TNF blocker or other biologic agent
Cosentyx	Medical record documentation of: For PP: • Prescription written by a dermatologist AND • Age at least 18 years of age AND	For all indications Add:

	• A diagnosis of moderate to severe plaque psoriasis characterized by greater than or equal to 5 % of body surface area involved or disease involving crucial body areas such as the hands, feet, face, or genitals For PsA: • A diagnosis of moderately to severely active PsA which must include the following: o Documentation of either active psoriatic lesions or a documented history of psoriasis AND • Prescription written by a dermatologist or rheumatologist AND • Age at least 18 years of age For AS: • A diagnosis of ankylosing spondylitis AND • Prescription written by a rheumatologist AND • Age at least 18 years of age AND • Medication being dosed as 150mg every 4 weeks with or without a loading dose of 150mg at weeks 0, 1, 2, 3 and 4	• Medical record documentation that Cosentyx is <u>not</u> being used concurrently with a TNF blocker or other biologic agent
Enbrel	Medical record documentation of: For PsA: • A diagnosis of moderately to severely active PsA which must include the following: o Documentation of either active psoriatic lesions or a documented history of psoriasis AND • Prescription written by a dermatologist or rheumatologist AND • Age at least 18 years of age For AS: • A diagnosis of ankylosing spondylitis AND • Prescription written by a rheumatologist AND • Age at least 18 years of age For PP: • Prescription written by a dermatologist AND • Age at least 18 years of age AND • A diagnosis of moderate to severe plaque psoriasis characterized by greater than or equal to 5 % of body surface area involved or disease involving crucial body areas such as the hands, feet, face, or genitals	For all indications Add: Medical record documentation that Enbrel is <u>not</u> being used concurrently with a TNF blocker or other biologic agent
Humira	Medical record documentation of: Biweekly injections for PsA: • A diagnosis of moderately to severely active PsA which must include the following: o Documentation of either active psoriatic lesions or a documented history of psoriasis AND • Prescription written by a dermatologist or rheumatologist AND • Age at least 18 years of age AND • Dosage at a maximum of 40 mg every other week OR medical record documentation of peer-reviewed literature citing well-designed clinical trials to indicate that the member's healthcare outcome will be improved by dosing that exceeds Food and Drug Administration (FDA) approved labeling Biweekly injections for AS: • A diagnosis of ankylosing spondylitis AND • Prescription written by a rheumatologist AND • Age at least 18 years of age AND • Dosage at a maximum of 40 mg every other week OR medical record documentation of peer-reviewed literature citing well-designed clinical trials to indicate that the member's healthcare outcome will be improved by dosing that exceeds Food and Drug Administration (FDA) approved labeling Biweekly injections for PP:	For all indications Add: • Medical record documentation that Humira is <u>not</u> being used concurrently with a TNF blocker or other biologic agent

	• Prescription written by a dermatologist AND • Age at least 18 years of age AND • A diagnosis of moderate to severe plaque psoriasis characterized by greater than or equal to 5 % of body surface area involved or disease involving crucial body areas such as the hands, feet, face, or genitals AND • Dosage at a maximum of 40 mg every other week OR medical record documentation of peer-reviewed literature citing well-designed clinical trials to indicate that the member's healthcare outcome will be improved by dosing that exceeds Food and Drug Administration (FDA) approved labeling	
Infliximab (Inflectra, Remicade, Renflexis)	Medical record documentation of: For AS: • A diagnosis of ankylosing spondylitis AND • Prescription written by a rheumatologist AND • Age at least 18 years of age For PP: • Prescription written by a dermatologist AND • Age at least 18 years of age AND • A diagnosis of moderate to severe plaque psoriasis characterized by greater than or equal to 5% body surface area involved or disease affecting crucial body areas such as the hands, feet, face, or genitals For PsA: • A diagnosis of active PsA which must include the following: o Documentation of either active psoriatic lesions or a documented history of psoriasis AND • Prescription written by a dermatologist or rheumatologist AND • Age at least 18 years of age	For all indications Add: • Medical record documentation that the infliximab product is <u>not</u> being used concurrently with a TNF blocker or other biologic agent
Orencia	Medical record documentation of: For PsA: • A diagnosis of active PsA AND • Prescription written by a dermatologist or rheumatologist AND • Age at least 18 years of age	Update PsA diagnosis criterion to the following: • Medical record documentation of a diagnosis of moderately to severely active psoriatic arthritis which must include the following: o Documentation of either active psoriatic lesions or a documented history of psoriasis. For All Indications Add: • Medical record documentation that Orencia is <u>not</u> being used concurrently with a TNF blocker or other biologic agent
Otezla	Medical record documentation of: For PsA: • A diagnosis of active PsA which must include the following: o Documentation of either active psoriatic lesions or a documented history of psoriasis AND • Prescription written by a dermatologist or rheumatologist AND • Age at least 18 years of age For PP: • Prescription written by a dermatologist AND • Age at least 18 years of age AND • A diagnosis of moderate to severe plaque psoriasis characterized by greater than or equal to 5 % of body surface area involved or disease involving crucial body areas such as the hands, feet, face, or genitals	No changes recommended to clinical criteria at this time.

Siliq	Medical record documentation of: • Age at least 18 years of age AND • Prescription written by a dermatologist AND • A diagnosis of moderate-to-severe plaque psoriasis with greater than or equal to 5% body surface area involved OR disease involving crucial areas of the body such as hands, feet, face, and/or genitals AND • Member does not have a history of suicidal thoughts or ideations AND • Member 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 member has been deemed an appropriate candidate for therapy	For All Indications Add: • Medical record documentation that Siliq is <u>not</u> being used concurrently with a TNF blocker or other biologic agent
Simponi	Medical record documentation of: For PsA: • Age at least 18 years of age AND • Prescription written by a rheumatologist or dermatologist AND • A diagnosis of active PsA which must include the following: o Documentation of either active psoriatic lesions or a documented history of psoriasis For AS: • Age at least 18 years of age AND • Prescription written by a rheumatologist AND • A diagnosis of ankylosing spondylitis	For All Indications Add: • Medical record documentation that Simponi is <u>not</u> being used concurrently with a TNF blocker or other biologic agent
Simponi Aria	Medical record documentation of: For PsA: Not created yet (New indication 10/2017) For AS: Not created yet (New indication 10/2017)	For PsA: • Requesting provider must be a rheumatologist or dermatologist AND • Medical record documentation of age ≥18 years AND • Medical record documentation of a diagnosis of moderately to severely active psoriatic arthritis, which must include the following: o Documentation of active psoriatic lesions OR documentation of a history of psoriasis • Medical record documentation that Simponi Aria is <u>not</u> being used concurrently with a TNF blocker or other biologic agent For AS: • Requesting provider must be a rheumatologist AND • Medical record documentation of age ≥18 years AND • Medical record documentation of a diagnosis of ankylosing spondylitis • Medical record documentation that Simponi Aria is <u>not</u> being used concurrently with a TNF blocker or other biologic agent For RA: Add: • Medical record documentation that Simponi Aria is <u>not</u> being used concurrently with a TNF blocker or other biologic agent
Stelara	Medical record documentation of: For PP:	For All Indications Add:

	• Prescription written by a dermatologist AND • Age at least 18 years of age AND • A diagnosis of moderate to severe plaque psoriasis characterized by greater than or equal to 5% of body surface area involved or disease affecting crucial body areas such as hands, feet, face or genitals AND • Prescribed dosing is appropriate for patient's weight For PsA: • Prescription written by a dermatologist or rheumatologist AND • Age at least 18 years of age AND • A diagnosis of active PsA which must include the following: o Documentation of either active psoriatic lesions or a documented history of psoriasis AND • If the patient is going to receive a dose of 45 mg every 12 weeks OR medical record documentation that the patients has a co-existing diagnosis of moderate-to-severe plaque psoriasis and weight greater than 100 kg	• Medical record documentation that Stelara is <u>not</u> being used concurrently with a TNF blocker or other biologic agent
Taltz	Medical record documentation of: For PP: • Prescription written by a dermatologist AND • Age at least 18 years of age AND • A diagnosis of moderate-to-severe plaque psoriasis with greater than or equal to 5% body surface area involved OR disease involving crucial areas of the body such as hands, feet, face, and/or genitals For PsA: • Not created yet (new indication 12/2017)	For PP: Add: • Medical record documentation that Taltz is <u>not</u> being used concurrently with a TNF blocker or other biologic agent For PsA: • Prescription must be written by a dermatologist or rheumatologist AND • Member is at least 18 years of age AND • Medical record documentation of a diagnosis of moderately to severely active psoriatic arthritis, which must include the following: o Documentation of active psoriatic lesions OR documentation of a history of psoriasis AND • Medical record documentation that Taltz is <u>not</u> being used concurrently with a TNF blocker or other biologic agent
Tremfya	Medical record documentation of: • Age at least 18 years of age AND • Prescription written by a dermatologist AND • A diagnosis of moderate-to-severe plaque psoriasis with greater than or equal to 5% body surface area involved OR disease involving crucial areas of the body such as hands, feet, face, and/or genitals	Add: • Medical record documentation that Tremfya is <u>not</u> being used concurrently with a TNF blocker or other biologic agent
Xeljanz(XR)	Medical record documentation of: For PsA: Not created yet (new indication 12/2017)	For RA: Add: • Medical record documentation that Xeljanz or Xeljanz XR is <u>not</u> being used concurrently with a TNF blocker or other biologic agent • Medical record documentation of an inadequate response to or intolerance to a 3-month trial of

		methotrexate or another disease-modifying antirheumatic drug (DMARD) For PsA: • Medical record documentation of a diagnosis of moderately to severely active psoriatic arthritis, which must include the following: o Documentation of active psoriatic lesions OR documentation of a history of psoriasis AND • Medical record documentation of an inadequate response to or intolerance to a 3-month trial of methotrexate or another disease-modifying antirheumatic drug (DMARD) AND • Medical record documentation that Xeljanz or Xeljanz XR is being prescribed by a rheumatologist or dermatologist AND • Member is at least 18 years of age AND • Medical record documentation that Xeljanz or Xeljanz XR is being prescribed in combination with non-biologic DMARD therapy (including but not limited to methotrexate, sulfasalazine, and/or leflunomide) AND • Medical record documentation that Xeljanz or Xeljanz XR is <u>not</u> being used concurrently with a TNF blocker or other biologic agent

GHP Family		
Medication	**Current Policy**	**Recommendations**
Cimzia	**Formulary Status:** Brand tier requiring PA or Medical benefit requiring PA Medical record documentation of: For PsA: • A therapeutic failure on, intolerance to, or contraindication to a minimum 3-month trial of Humira* AND Enbrel* For AS: • A therapeutic failure on, intolerance to, or contraindication to a minimum 3-month trial of Humira* AND Enbrel* Authorization Duration: • Initial: Six (6) Months • Subsequent: Twelve (12) Months Quantity Limit: None	**Formulary Status**: No changes recommended at this time Medical record documentation of: For PsA: • Therapeutic failure on, intolerance to, or contraindication to a minimum three-month trial of Humira* AND Cosentyx* For AS: • Therapeutic failure on, intolerance to, or contraindication to a minimum three-month trial of Humira* AND Cosentyx* Quantity Limit (All Indications): One-week authorization for QL of 6 syringes (3 kits) per 28 days; Remainder of the 6-month authorization duration: QL of 2 syringes (1 kit) per 28 days No other changes recommended at this time
Cosentyx	**Formulary Status:** NF Medical record documentation of: For PP:	**Formulary Status:** It is recommended that Cosentyx be added to the **Brand tier** requiring PA. Change current criteria to:

<table>
<tr>
<td></td>
<td>
A therapeutic failure on, intolerance to, or contraindication to a minimum 3-month trial of Humira* AND Enbrel*
For PsA:
A therapeutic failure on, intolerance to, or contraindication to a minimum 3-month trial of Humira* AND Enbrel*
For AS:
A therapeutic failure on, intolerance to, or contraindication to a minimum 3-month trial of Humira* AND Enbrel*
Authorization Duration:
Initial: Six (6) Months
Subsequent: Twelve (12) Months
Quantity Limit:
<table>
<tr><th>If requesting a dose of:</th><th>In this dosage form:</th><th>Approve only this NDC:</th><th>With a QL of:</th></tr>
<tr><td>150 mg every 4 weeks</td><td>Prefilled Syringe</td><td>00078-0639-98</td><td>2 mL per 56 days*</td></tr>
<tr><td>300 mg every 4 weeks</td><td>Prefilled syringe</td><td>00078-0639-98</td><td>2 mL per 28 days^</td></tr>
<tr><td>150 mg every 4 weeks</td><td>Sensoready Pen</td><td>00078-0639-41</td><td>2 mL per 56 days*</td></tr>
<tr><td>300 mg every 4 weeks</td><td>Sensoready Pen</td><td>00078-0639-41</td><td>2 mL per 28 days^</td></tr>
</table>
* Members who are new to therapy and using the 150 mg dose should receive a one-time 1-week authorization for a QL of 4 mL for 28 days. This is intended to cover the starting dosing of 150 mg at Weeks 0, 1, 2, 3, and 4 plus the following month's dose. For the remainder of the 6 month authorization, the QL of 2 mL per 56 days should apply.
^ Members who are new to therapy and using the 300 mg dose should receive a one-time 1-week authorization for a QL of 8 mL for 28 days to cover the starting dose of 300 mg at Weeks 0, 1, 2, 3, and 4. For the remainder of the 6 month authorization, the QL of 2 mL per 28 days should apply.
</td>
<td>
Medical record documentation of:
For PP:
A therapeutic failure on, intolerance to, or contraindication to topical corticosteroids AND at least two to three months of systemic therapy (including but not limited to methotrexate and/or cyclosporine) or phototherapy OR medical record documentation of a therapeutic failure on or intolerance to prior biologic therapy.
For PsA:
<u>For peripheral disease</u>: Medical record documentation of an intolerance to, contraindication to, or therapeutic failure on methotrexate AND an adequate trial of at least two (2) formulary NSAIDs OR medical record documentation of a therapeutic failure on or intolerance to prior biologic therapy OR
<u>For axial disease</u>: Medical record documentation of an intolerance to, contraindication to, or therapeutic failure to an adequate trial of at least two (2) formulary NSAIDs OR medical record documentation of a therapeutic failure on or intolerance to prior biologic therapy
For AS:
A therapeutic failure on, contraindication to, or intolerance to an adequate trial of at least two (2) NSAIDs OR a therapeutic failure on or intolerance to prior biologic therapy
No other changes recommended at this time
</td>
</tr>
<tr>
<td>Enbrel</td>
<td>
Formulary Status: Brand tier requiring PA

Medical record documentation of:
For PsA:
<u>For peripheral disease</u>: Medical record documentation of an intolerance to, contraindication to, or therapeutic failure on methotrexate AND an adequate trial of at least two (2) formulary NSAIDs OR medical record documentation of a therapeutic failure on or intolerance to prior biologic therapy OR
<u>For axial disease</u>: Medical record documentation of an intolerance to, contraindication to, or therapeutic failure to an adequate trial of at least two (2) formulary NSAIDs OR medical record documentation of a therapeutic failure on or intolerance to prior biologic therapy
For AS:
A therapeutic failure on, contraindication to, or intolerance to an adequate trial of at least two (2) NSAIDs OR a therapeutic failure on or intolerance to prior biologic therapy
For PP:
A therapeutic failure on, intolerance to, or contraindication to topical corticosteroids AND at least two to three months of systemic therapy (including but not limited to methotrexate and/or cyclosporine) or phototherapy OR medical record documentation of a therapeutic failure on or intolerance to prior biologic therapy.
Authorization Duration:
Initial: Six (6) Months
Subsequent: Twelve (12) Months
Quantity Limit: 8 syringes per 28 days, all strengths
</td>
<td>
Formulary Status: No changes recommended at this time

Change current criteria to:
Medical record documentation of:
For PsA:
A therapeutic failure on, intolerance to, or contraindication to a minimum 3-month trial of Humira* AND Cosentyx*
For AS:
A therapeutic failure on, intolerance to, or contraindication to a minimum 3-month trial of Humira* AND Cosentyx*
For PP:
For adult plaque psoriasis, medical record documentation of a therapeutic failure on, intolerance to, or contraindication to a minimum 3-month trial of Humira* AND Cosentyx*
For pediatric (age 4 to 18) plaque psoriasis, medical record documentation of a therapeutic failure on, intolerance to, or contraindication to two topical corticosteroids
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<td>Quantity Limits:
<table>
<tr><th>Indication</th><th>Strength</th><th>Quantity Limit
(Approve by GPID)</th></tr>
<tr><td rowspan="3">RA, AS, PsA, Pediatric PP,
Juvenile Idiopathic Arthritis</td><td>50mg Syringe/Pen</td><td>4 syringes (3.92mL) per 28 days</td></tr>
<tr><td>25mg Syringe</td><td>8 syringes (4.08mL) per 28 days</td></tr>
<tr><td>25mg Vial</td><td>8 vials per 28 days</td></tr>
</table>
<table>
<tr><th>Indication</th><th>Strength</th><th>Induction QL
(Approve by GPID)</th><th>Maintenance QL
(Approve by GPID)</th></tr>
<tr><td rowspan="3">Plaque Psoriasis</td><td>50mg Syringe/Pen</td><td>One 3-month authorization for 8 syringes (7.84mL) per 28 days</td><td>Remainder of 6-month authorization: 4 syringes (3.92mL) per 28 days</td></tr>
<tr><td>25mg Syringe</td><td>One 3-month authorization for 16 syringes (8.16mL) per 28 days</td><td>Remainder of 6-month authorization: 8 syringes (4.08mL) per 28 days</td></tr>
<tr><td>25mg Vial</td><td>One 3-month authorization for 16 vials per 28 days</td><td>Remainder of 6-month authorization: 8 vials per 28 days</td></tr>
</table>
No other changes recommended at this time.</td>
</tr>
<tr>
<td>Humira</td>
<td>Formulary Status: Brand tier requiring PA

Medical record documentation of:
For PsA:
• <u>For peripheral disease</u>: Medical record documentation of an intolerance to, contraindication to, or therapeutic failure on methotrexate AND an adequate trial of at least two (2) formulary NSAIDs OR medical record documentation of a therapeutic failure on or intolerance to prior biologic therapy OR
• <u>For axial disease</u>: Medical record documentation of an intolerance to, contraindication to, or therapeutic failure to an adequate trial of at least two (2) formulary NSAIDs OR medical record documentation of a therapeutic failure on or intolerance to prior biologic therapy
For AS:
• A therapeutic failure on, contraindication to, or intolerance to an adequate trial of at least two (2) NSAIDs OR a therapeutic failure on or intolerance to prior biologic therapy
For PP:
• A therapeutic failure on, intolerance to, or contraindication to topical corticosteroids AND at least two to three months of systemic therapy (including but not limited to methotrexate and/or cyclosporine) or phototherapy OR medical record documentation of a therapeutic failure on or intolerance to prior biologic therapy.
Authorization Duration:
• Initial: Six (6) Months
• Subsequent: Twelve (12) Months
Quantity Limit:
• PsA/AS: 2 syringes per 28 days
• PP: One-time 4 syringes per 28 days, Subsequent 2 syringes per 28 days</td>
<td>Formulary Status: No changes recommended at this time

No changes recommended to cost effectiveness criteria at this time.</td>
</tr>
</table>

Infliximab (Inflectra, Remicade, Renflexis)	**Formulary Status:** Medical benefit requiring PA Medical record documentation of: For AS: • An intolerance to, contraindication to, or therapeutic failure on a minimum 3-month trial of Humira* AND Enbrel* AND • For new start Remicade or Renflexis requests, an intolerance to, contraindication to, or therapeutic failure on a minimum 3-month trial of Inflectra* For PP: • An intolerance to, contraindication to, or therapeutic failure on a minimum 3-month trial of Humira* AND Enbrel* AND • For new start Remicade or Renflexis requests, an intolerance to, contraindication to, or therapeutic failure on a minimum 3-month trial of Inflectra* For PsA: • An intolerance to, contraindication to, or therapeutic failure on 12 weeks of Humira* AND Enbrel* AND • For new start Remicade or Renflexis requests, an intolerance to, contraindication to, or therapeutic failure on a minimum 3-month trial of Inflectra* Authorization Duration: • Initial: Six (6) Months • Subsequent: Twelve (12) Months Quantity Limit: None	**Formulary Status**: No changes recommended at this time Medical record documentation of: For AS: • An intolerance to, contraindication to, or therapeutic failure on a minimum 3-month trial of Humira* AND Cosentyx* AND • For new start Remicade or Renflexis requests, an intolerance to, contraindication to, or therapeutic failure on a minimum 3-month trial of Inflectra* For PP: • An intolerance to, contraindication to, or therapeutic failure on a minimum 3-month trial of Humira* AND Cosentyx* AND • For new start Remicade or Renflexis requests, an intolerance to, contraindication to, or therapeutic failure on a minimum 3-month trial of Inflectra* For PsA: • An intolerance to, contraindication to, or therapeutic failure on 12 weeks of Humira* AND Cosentyx* AND • For new start Remicade or Renflexis requests, an intolerance to, contraindication to, or therapeutic failure on a minimum 3-month trial of Inflectra* No other changes recommended at this time.
Orencia	**Formulary Status:** Orencia - Brand tier requiring PA **Formulary Status:** Orencia IV – Medical benefit requiring PA Medical record documentation of: For PsA: • An inadequate response to a minimum 3-month trial of one preferred TNF-alpha inhibitor (Humira* OR Enbrel*) Authorization Duration: • Initial: Six (6) Months • Subsequent: Twelve (12) Months Quantity Limit: 4 syringes per 28 days	**Formulary Status:** No changes recommended at this time Medical record documentation of: For PsA: • Therapeutic failure on, intolerance to, or contraindication to a minimum three-month trial of Humira* AND Cosentyx* No other changes recommended at this time.
Otezla	**Formulary Status:** NF Medical record documentation of: For PsA: • A therapeutic failure on, intolerance to, or contraindication to at least 3 months of therapy with Humira* AND Enbrel* For PP: • A therapeutic failure on, intolerance to, or contraindication to at least 3 months of therapy with Humira* AND Enbrel* Authorization Duration: • Initial: Six (6) Months	**Formulary Status:** No changes recommended at this time Medical record documentation of: For PsA: • A therapeutic failure on, intolerance to, or contraindication to at least 3 months of therapy with Humira* AND Cosentyx* For PP: • A therapeutic failure on, intolerance to, or contraindication to at least 3 months of therapy with Humira* AND Cosentyx* No other changes recommended at this time.

	• Subsequent: Twelve (12) Months Quantity Limit: 2 tablets per day	
Siliq	**Formulary Status:** NF Medical record documentation of: • A therapeutic failure on, intolerance to, or contraindication to Humira* AND Enbrel* Authorization Duration: • Initial: Four (4) Months • Subsequent: Twelve (12) Months Quantity Limit: One-time 6mL per 28 days, Subsequent 3mL per 28 days	**Formulary Status:** No changes recommended at this time Medical record documentation of: • A therapeutic failure on, intolerance to, or contraindication to Humira* AND Cosentyx* No other changes recommended at this time
Simponi	**Formulary Status:** NF Medical record documentation of: For PsA: • An intolerance to, contraindication to or therapeutic failure on a minimum 3-month trial of Enbrel* AND Humira* For AS: • An intolerance to, contraindication to or therapeutic failure on a minimum 3-month trial of Enbrel* AND Humira* Authorization Duration: • Initial: Six (6) Months • Subsequent: Twelve (12) Months Quantity Limit: None	**Formulary Status:** No changes recommended at this time Medical record documentation of: For PsA: • An intolerance to, contraindication to or therapeutic failure on a minimum 3-month trial of Cosentyx* AND Humira* For AS: • An intolerance to, contraindication to or therapeutic failure on a minimum 3-month trial of Cosentyx* AND Humira* Quantity Limit: • For RA, PsA, AS: 1 syringe (0.5mL) per 28 days (Approve ONLY Simponi 50mg/0.5mL by GPID) • For UC: One-week authorization with a QL of 3 syringes (3mL) per 28 days; Remainder of the 6-month authorization duration, QL: of 1 syringe (1mL) per 28 days (Approve both authorizations for ONLY Simponi 100mg/mL by GPID) No other changes recommended at this time.
Simponi Aria	**Formulary Status:** Medical benefit requiring PA Medical record documentation of: For PsA: Not created yet (New indication 10/2017) For AS: Not created yet (New indication 10/2017) Authorization Duration: • Initial: Six (6) Months • Subsequent: Twelve (12) Months Quantity Limit: None	**Formulary Status:** No changes recommended at this time Medical record documentation of: For PsA: • An intolerance to, contraindication to or therapeutic failure on 12 weeks of Cosentyx* AND Humira* For AS: • An intolerance to, contraindication to or therapeutic failure on 12 weeks of Cosentyx* AND Humira* No other changes recommended at this time.
Stelara	**Formulary Status:** Stelara – Brand tier requiring PA **Formulary Status:** Stelara IV – Medical benefit requiring PA Medical record documentation of: For PP: • An intolerance to, contraindication to or therapeutic failure on a minimum 3-month trial of Enbrel* AND Humira* For PsA:	**Formulary Status:** No changes recommended at this time Medical record documentation of: For PP: • An intolerance to, contraindication to or therapeutic failure on a minimum 3-month trial of Cosentyx* AND Humira* For PsA: • An intolerance to, contraindication to or therapeutic failure on a minimum 3-month trial of Cosentyx* AND Humira*

	• An intolerance to, contraindication to or therapeutic failure on a minimum 3-month trial of Enbrel* AND Humira* Authorization Duration: • Initial: Six (6) Months • Subsequent: Twelve (12) Months Quantity Limit: None	Quantity Limit: • For CD – No changes • For PP and PsA o Initial Authorization- RX Count 3 for initial 6 months o Subsequent Authorization(s)- RX Count 5 for subsequent 12 months **Note: All requests should be approved by GPID for the correct strength (as determined by weight)**
Taltz	**Formulary Status:** NF Medical record documentation of: For PP: • An intolerance to, contraindication to, or therapeutic failure on a minimum 3-month trial of Humira* AND Enbrel* For PsA: Not created yet (New indication 12/2017) Authorization Duration: • Initial: Six (6) Months • Subsequent: Twelve (12) Months Quantity Limit: One-time 8mL per 3 months, Subsequent 1mL per 28 days	**Formulary Status:** No changes recommended at this time Medical record documentation of: For PP: • An intolerance to, contraindication to, or therapeutic failure on a minimum 3-month trial of Humira* AND Cosentyx* For PsA: • An intolerance to, contraindication to, or therapeutic failure on a minimum 3-month trial of Humira* AND Cosentyx* Quantity Limits: • For PP: One-time 8mL per 3 months, Subsequent 1mL per 28 days • For PsA: One time 3mL per 28 days, Subsequent 1mL per 28 days No other changes recommended at this time
Tremfya	**Formulary Status:** NF Medical record documentation of: • An intolerance to, contraindication to, or therapeutic failure on a minimum 3-month trial of Humira* AND Enbrel* Authorization Duration: • Initial: Six (6) Months • Subsequent: Twelve (12) Months Quantity Limit: One-time 1mL per 28 days, Subsequent 1mL per 56 days	**Formulary Status:** No changes recommended at this time Medical record documentation of: • An intolerance to, contraindication to, or therapeutic failure on a minimum 3-month trial of Humira* AND Cosentyx* No other changes recommended at this time.
Xeljanz(XR)	**Formulary Status:** NF Medical record documentation of: For PsA: Not created yet (new indication 12/2017) Authorization Duration: • Initial: Six (6) Months • Subsequent: Twelve (12) Months Quantity Limit: • Xeljanz: 2 tablets per day, 30-day supply per fill • Xeljanz XR: 1 tablet per day, 30-day supply per fill	**Formulary Status:** No changes recommended at this time Medical record documentation of: For PsA: • An intolerance to, contraindication to, or therapeutic failure on a minimum 3-month trial of Humira* AND Cosentyx* No other changes recommended at this time

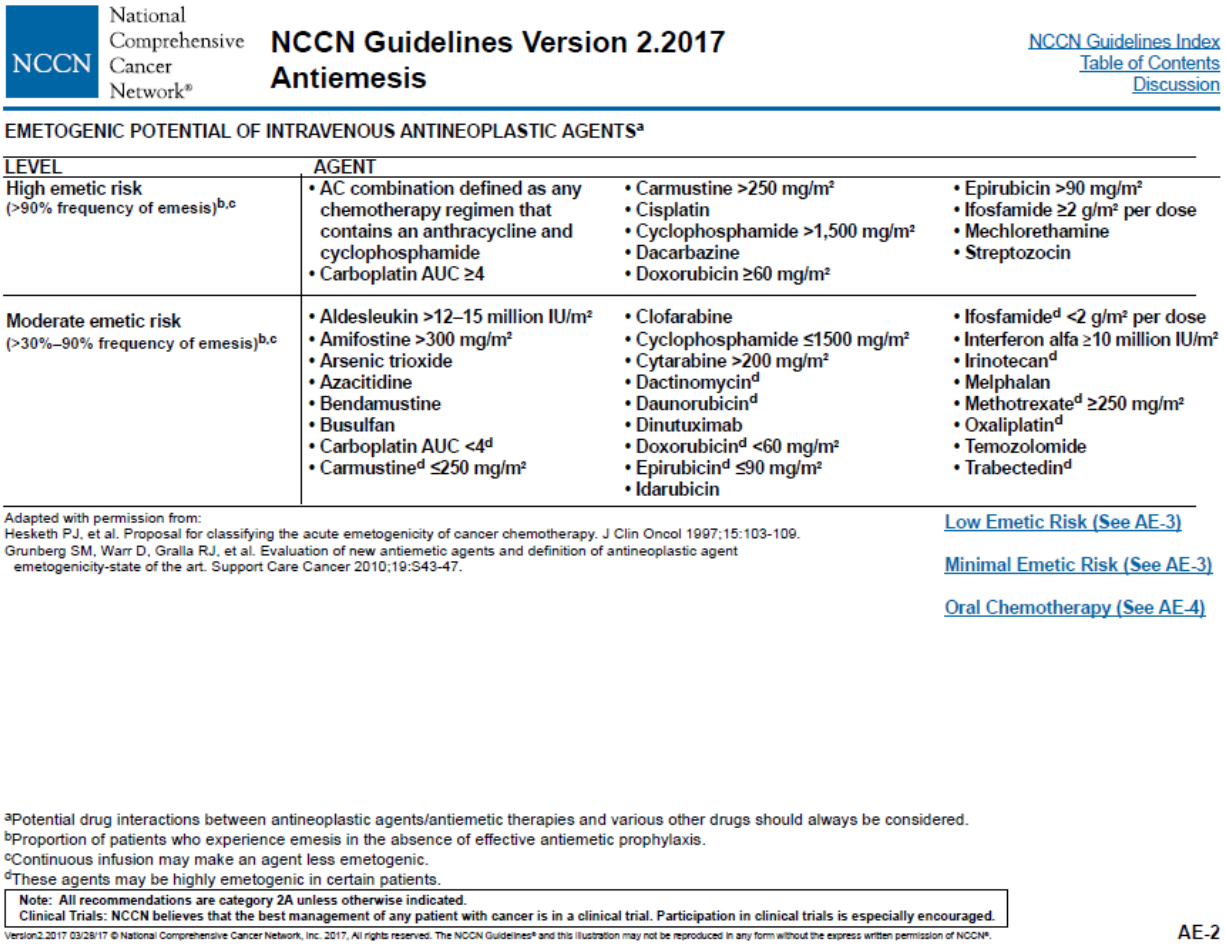
Discussion: No questions or comments.

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

ALOXI AND EMEND UPDATE

Review: The following policy updates were made to the Aloxi MBP 24.0 and Emend MBP 104.0 Medical Benefit policies to align emetogenic potential of chemotherapeutic agents based on the most up to date NCCN guideline recommendations (listed below). It is noted per NCCN that many moderately emetogenic chemotherapeutic agents may be highly emetogenic in certain patients. To ensure the most appropriate regimen for antiemetogenic coverage we are updating our highly emetogenic chemotherapeutic agent list to include these agents. It is recommended that these changes also apply to GHP Family and Part D policies for Emend and Part D for Aloxi.



National Comprehensive Cancer Network®

NCCN Guidelines Version 2.2017
Antiemesis

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EMETOGENIC POTENTIAL OF INTRAVENOUS ANTINEOPLASTIC AGENTS[a]

LEVEL	AGENT		
High emetic risk (>90% frequency of emesis)[b,c]	• AC combination defined as any chemotherapy regimen that contains an anthracycline and cyclophosphamide • Carboplatin AUC ≥4	• Carmustine >250 mg/m² • Cisplatin • Cyclophosphamide >1,500 mg/m² • Dacarbazine • Doxorubicin ≥60 mg/m²	• Epirubicin >90 mg/m² • Ifosfamide ≥2 g/m² per dose • Mechlorethamine • Streptozocin
Moderate emetic risk (>30%–90% frequency of emesis)[b,c]	• Aldesleukin >12–15 million IU/m² • Amifostine >300 mg/m² • Arsenic trioxide • Azacitidine • Bendamustine • Busulfan • Carboplatin AUC <4[d] • Carmustine[d] ≤250 mg/m²	• Clofarabine • Cyclophosphamide ≤1500 mg/m² • Cytarabine >200 mg/m² • Dactinomycin[d] • Daunorubicin[d] • Dinutuximab • Doxorubicin[d] <60 mg/m² • Epirubicin[d] ≤90 mg/m² • Idarubicin	• Ifosfamide[d] <2 g/m² per dose • Interferon alfa ≥10 million IU/m² • Irinotecan[d] • Melphalan • Methotrexate[d] ≥250 mg/m² • Oxaliplatin[d] • Temozolomide • Trabectedin[d]

Adapted with permission from:
Hesketh PJ, et al. Proposal for classifying the acute emetogenicity of cancer chemotherapy. J Clin Oncol 1997;15:103-109.
Grunberg SM, Warr D, Gralla RJ, et al. Evaluation of new antiemetic agents and definition of antineoplastic agent emetogenicity-state of the art. Support Care Cancer 2010;19:S43-47.

Low Emetic Risk (See AE-3)
Minimal Emetic Risk (See AE-3)
Oral Chemotherapy (See AE-4)

[a]Potential drug interactions between antineoplastic agents/antiemetic therapies and various other drugs should always be considered.
[b]Proportion of patients who experience emesis in the absence of effective antiemetic prophylaxis.
[c]Continuous infusion may make an agent less emetogenic.
[d]These agents may be highly emetogenic in certain patients.

Note: All recommendations are category 2A unless otherwise indicated.
Clinical Trials: NCCN believes that the best management of any patient with cancer is in a clinical trial. Participation in clinical trials is especially encouraged.

AE-2

In addition to the changes made to the emetogenic lists, the indication for Aloxi was updated to include "delayed" nausea and vomiting for moderately emetogenic potential chemotherapy per the request of DHS. The Emend policy was corrected to require failure of ondansetron OR granisteron.

Recommendations: The changes were made as follows (additions are noted in bold italics):

MBP 24.0 Aloxi (palonosetron)

Aloxi (Palonosetron) will be considered medically necessary when all of the following criteria are met:

1. **PREVENTION OF ACUTE NAUSEA AND VOMITING**
   - Medical record documentation that Aloxi is being used for prevention of chemotherapy induced nausea or vomiting from low, or minimally, emetogenic cancer chemotherapy for members who have a treatment failure or contraindication to Granisetron (Kytril) or Ondansetron (Zofran). Treatment failure is defined as an allergy, intolerable side effects, significant drug-drug interactions, or lack of efficacy; **OR**
   - ~~Medical record documentation that Aloxi is being used for prevention of acute nausea or vomiting associated with initial and repeat courses of moderately or highly emetogenic cancer chemotherapy.~~
   - ***Medical record documentation that Aloxi is being used for prevention of acute and/or delayed nausea or vomiting associated with initial and repeat courses of moderately emetogenic cancer chemotherapy OR acute nausea or vomiting associated with initial and repeat courses of highly emetogenic cancer chemotherapy.***

   The following antineoplastic agents are considered MODERATELY emetogenic (***refer to NCCN for complete list*** ~~not a complete list~~):
   - Aldesleukin >12-15 million IU/m^2
   - Amifostine >300 mg/m^2
   - Arsenic trioxide
   - Azacitidine
   - Bendamustine
   - Busulfan
   - ~~Carboplatin~~
   - ~~Carmustine ≤ 250 mg/m^2~~
   - Clofarabine
   - Cyclophosphamide ≤ 1500mg/m^2
   - Cytarabine >200mg/m^2
   - ~~Dactinomycin~~
   - ~~Daunorubicin~~
   - Dinutuximab
   - ~~Doxorubicin <60 mg/m^2~~
   - ~~Epirubicin ≤ 90 mg/m^2~~
   - Idarubicin
   - ~~Ifosfamide <2 g/m^2 per dose~~
   - Interferon alfa ≥ 10 million IU/m^2
   - ~~Irinotecan~~
   - Melphalan
   - ~~Methotrexate ≥250 mg/m^2~~
   - ~~Oxaliplatin~~
   - Temozolomide
   - ~~Trabectedin~~

   The following antineoplastic agents are considered highly emetogenic (***refer to NCCN for complete list*** ~~not a complete list~~):
   - AC combination defined **as** ***any chemotherapy regimen that contains an anthracycline and cyclophosphamide*** ~~either doxorubicin or epirubicin with cyclophosphamide~~
   - ***Carboplatin***
   - Carmustine ~~at doses >250mg/m^2~~
   - Cisplatin
   - Cyclophosphamide at doses >1500 mg/m^2
   - Dacarbazine
   - ***Dactinomycin***
   - ***Daunorubicin***
   - Doxorubicin ~~at doses ≥ 60mg/m^2~~
   - Epirubicin ~~at doses >90mg/m^2~~
   - Ifosfamide ~~at doses ≥2g/m^2~~
   - ***Irinotecan***
   - Mechlorethamine
   - ***Methotrexate at doses ≥ 250mg/m^2***
   - ***Oxaliplatin***
   - Streptozotocin
   - ***Trabectedin***

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

MBP 104.0 Emend IV (fosaprepitant)

Emend IV (fosaprepitant) will be considered medically necessary when all of the following criteria are met:

1. Medical record documentation that Emend is being used for the prevention of acute and delayed nausea and vomiting associated with initial and repeat courses of highly emetogenic cancer chemotherapy; **OR**

2. Medical record documentation that Emend is being used for the prevention of acute and delayed nausea and vomiting associated with initial and repeat courses of moderately emetogenic cancer chemotherapy for insured individuals who have a treatment failure or contraindication to ondansetron (Zofran) ***or*** ~~and~~ granisetron (Kytril). Treatment failure is defined as allergy, intolerable side-effects, significant drug-drug interaction, or lack of efficacy.

ADDITIONAL INFORMATION:
The following antineoplastic agents are considered highly emetogenic ***(refer to NCCN for complete list*** ~~not a complete list~~):

- AC combination defined as ***any chemotherapy regimen that contains an anthracycline and cyclophosphamide*** ~~either doxorubicin or epirubicin with cyclophosphamide~~
- ***Carboplatin***
- Carmustine ~~at doses >250mg/m^2~~
- Cisplatin
- Cyclophosphamide at doses >1500 mg/m^2
- Dacarbazine
- ***Dactinomycin***
- ***Daunorubicin***
- Doxorubicin ~~at doses ≥ 60mg/m^2~~
- Epirubicin ~~at doses >90mg/m^2~~
- Ifosfamide ~~at doses ≥2g/m^2~~
- ***Irinotecan***
- Mechlorethamine
- ***Methotrexate at doses ≥ 250mg/m^2***
- ***Oxaliplatin***
- Streptozotocin
- ***Trabectedin***

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

Discussion: No questions or comments.

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

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

Xtandi Policy Update

Review: Based on the current evidence, Xtandi and Zytiga have similar efficacy and safety and both now are category 1 recommendations in NCCN guidelines for patients without visceral metastases. In addition, Xtandi has a category 1 recommendation for patients with visceral metastases, while Zytiga is considered to be category 2A. Finally, considering pill burden, Zytiga must be used in combination with prednisone, while Xtandi does not require prednisone therapy.

Recommendations: For the Xtandi policy, it is recommended to remove the requirement of failure on, intolerance to, or contraindication to Zytiga for all lines of business.

Discussion: No questions or comments.

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

Viscosupplementation Update

Review: Upon review of the hyaluronic acid derivative products (viscosupplementation products), it was found that the Viscosupplementation Medical Benefit Policy was due for update to account for new products since the creation/update of the policy and to account for changes to the cost/contracting strategy of the products. Geisinger Health System prefers products such as Synvisc, Synvisc One, and Gelsyn-3 due to the abbreviated number of administrations (one to three weekly administrations) compared to products such as Supartz FX, Hyalgan, and GenVisc 850, which require five weekly administrations.

Recommendations: No changes are recommended to the tiering of the hyaluronic acid derivative products at this time. It is recommended that MBP 13.0 be updated as follows to account for changes in available products, preferred products, and non-preferred products (changes highlighted in yellow).

CRITERIA FOR USE: Requires Prior Authorization by Medical Director or Designee

NOTE: ~~Euflexxa~~Gelsyn-3, Synvisc, and Synvisc One are preferred agents and DO NOT Require Prior Authorization

Euflexxa, Gel-One, GenVisc 850, Hyalgan, **Hymovis**, **Monovisc, Orthovisc**, **Supartz FX,** and **Visco-3** require Prior Authorization and will be considered medically necessary when all of the following criteria are met:

- Physician documented symptomatic osteoarthritis of the knee, defined as knee pain associated with radiographic evidence of osteophytes in the knee joint provided the clinical presentation is not that of "bone-on-bone", morning stiffness of less than or equal to 30 minutes in duration, crepitus on range of motion; **AND**
- Physician documented knee joint pain sufficient to interfere with ambulatory functional activities; **AND**
- Physician documentation of non-pharmacologic modalities, e.g., weight loss, quadriceps muscle strengthening, other physical therapy modalities, or exercises that have not promoted satisfactory symptomatic relief; **AND**
- Physician documentation that there has been no significant improvement following pharmacologic therapy with a

full-dose nonsteroidal anti-inflammatory drug (NSAID) regimen, with or without supplemental acetaminophen, over a 10-12 week period of time or if NSAID's are contraindicated, a failure of daily acetaminophen regimen over a 4 to 6 week period; **AND**

- Physician documentation that there has been no significant improvement following standard dose intra-articular corticosteroid injection(s) e.g., a satisfactory clinical response of greater than or equal to 3 months; this requirement does not apply if the use of corticosteroids might increase the risk of local or systemic bacterial infection, e.g., diabetes mellitus; **AND**
- Physician documentation of failure on, intolerance to or contraindication to ~~Euflexxa~~, Gelsyn-3, Synvisc, and Synvisc One

AUTHORIZATION DURATION/QUANTITY LIMIT: Initial approval will be for **six (6) months** and will be **limited to one (1) treatment course** to the affected knee(s) (bilateral injections may be allowed if both knees meet the required coverage criteria). Subsequent approvals will be for six (6) months and will be limited to one (1) treatment course to the affected knee(s) when members meet the following criteria:

- Repeat treatment cycles are considered medically necessary when ALL of the following criteria are met:
  1. Medical record documentation of significant improvement in pain and function following the previous injection; **AND**
  2. Documented reduction of the doses of nonsteroidals or analgesics during the six-month period following the last injection in the previous series as well as no need for accompanying intra-articular steroid injections; **AND**
  3. Six months or longer have elapsed since the last injection in the previous series.

LIMITATIONS:

- Euflexxa™ treatment course is limited to 3 injections, one week apart, in a 6-month period
- Gel-One® treatment course is limited to 1 injection in a 6-month period.
- Gelsyn-3™ treatment course is limited to 3 injections in a 6-month period.
- GenVisc 850® treatment course is limited to 5 injections in a 6-month period.
- Hyalgan® (sodium hyaluronate) treatment course is limited to 5 injections in a 6-month period.
- Hymovis® treatment course is limited to 2 injections in a 6-month period.
- Monovisc® treatment course is limited to 1 injection in a 6-month period.
- Orthovisc® treatment course is limited to 4 injections in a 6-month period.
- Supartz™ treatment course is limited to 5 injections in a 6-month period.
- Synvisc® (Hylan G-F 20) treatment course is limited to 3 injections in a 6-month period.
- Synvisc One™ treatment is limited to 1 injection in a 6-month period.
- Visco-3™ treatment course is limited to 3 injections in a 6-month period.
- Treatment requires referral to, and should be rendered by a participating Orthopedic surgeon or Rheumatologist.
- Bilateral injections may be allowed if both knees meet the required coverage criteria.

CONTRAINDICATIONS:

- The use of these products for injection into any joint other than the knee.
- Injection of these products for indications other than the diagnosis of osteoarthritis.
- Documented allergy to chickens or eggs.
- Knee joint infection, skin disease or infection around the area where the injection will be given.
- The insured individual has known sensitivity or contraindication to the use of either sodium hyaluronate or hylan G-F 20, e.g., crystal synovitis or hypersensitivity to hyaluronan preparations

Discussion: No questions or comments.

Outcome: Kevin Szczecina made a motion to accept the presented recommendations. Todd Sponenberg seconded the motion. None were opposed.

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

Center of Excellence Policy Update

Recommendations: Credentialing is made by the Credentials Committee only. Any reference to Quality Improvement Committee and Medical Executive Committee should be removed from the policy.

Discussion: No questions or comments.

Outcome: Tricia Heitzman made a motion to accept the presented 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.

Zelboraf Policy Update

Review: During a recent review of the GHP Family Zelboraf policy by DHS it was noted that our current criterion for use in Erdheim-Chester disease (ECD) includes documentation of the BRAF V600E mutation. However, the indication is:

- Treatment of Erdheim-Chester disease (ECD) in patients with a BRAF V600 mutation

Recommendations: It is recommended that the criteria for treating Erdheim-Chester disease in all polices be updated to:

- Medical record documentation of Erdheim-Chester (ECD) **AND**
- Medical record documentation of an FDA-approved test documenting the presence of the BRAF V600 mutation

Discussion: No questions or comments.

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

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

Chantix Update

Review: GHP Pharmacy is working with GHP Wellness and MTDM pharmacists from the system to create and implement a comprehensive smoking cessation program for GHP members and Geisinger patients. The workgroup would like to increase the accessibility of pharmacologic options to members across all lines of business.

Recommendations: It is recommended that Chantix be added to the GHP Family formulary on the Brand tier to increase access to smoking cessation medications and improve member health outcomes. The prior authorization criteria should be removed. The following quantity limits should apply.

Quantity Limits:

- Starter pack: 1 fill per 180 days
- Continuation box, 0.5 mg tablets, and 1 mg tablets: 2 tablets per day

Discussion: No questions or comments.

Outcome: Todd Sponenberg made a motion to accept the presented recommendations. Rajneel Chohan seconded the motion. None were opposed.

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

Medical Benefit Policy Updates

Review: The following policy updates were made to the following Medical Benefit Policies based on recommendations from the Department of Health (DHS) during policy review submissions. The recommended policy changes were suggested and/or required for further policy approval from DHS. Additions to the policies are noted in bold italics, and removals of prior criteria are noted via strikethrough.

Recommendations: **MBP 113.0 Gazyva (obinutuzumab)-** The criteria that had previously been included in the section for CLL were based on old recommendations from NCCN, which have since expanded. DHS questioned why the other information now included in NCCN weren't included in the policy. In an effort to align with our current process of following FDA approved indication in policy criteria we removed the recommendations that were part of NCCN, and not part of the FDA approved indication. DHS accepted our explanation that our standard practice is to review every oncology case against the most current NCCN Guidelines, in addition to our policy criteria.

The policy was updated as follows under the section for CLL:

1. **Chronic Lymphocytic Leukemia**
   - Prescribed by a hematologist/oncologist; **AND**
   - Medical record documentation of previously untreated chronic lymphocytic leukemia; **AND**
   - ***Medical record documentation that Gazyva will be used in combination with chlorambucil***
   - ~~Medical record documention that Gazyva will be used as a monotherapy or in combination with chlorambucil for disease without del(17p) or del(11q) in patients age ≥70 years or in younger patients with significant comorbidities;~~ ~~**OR**~~
   - ~~Medical record documention that Gazyva will be used in combination with chlorambucil for disease with del(11q) or del(17p)~~

MBP 165.0 Rituxan Hycela (rituximab/hyaluronidase)- According to the package insert Rituxan Hycela should be initiated only after patients have received at least one full dose of a rituximab product by intravenous infusion. For the diagnosis of Chronic Lymphocytic Leukemia (CLL) and Diffuse Large B-Cell Lymphoma (DLBCL) the first "cycle" always consists of just one full dose of rituximab per cycle. However, for Follicular lymphoma (FL)

there are some instances where Rituxan Hycela is dosed every week, rather than per "cycle" therefore DHS requested we changed our policy criteria to reflect the phrase "full dose" rather than "cycle" for the diagnosis of FL.

The policy was updated as follows under the section for follicular lymphoma:

Follicular Lymphoma (FL)

- Prescription written by a hematologist/oncologist **AND**
- Medical record documentation of a diagnosis of Follicular Lymphoma (FL) **AND**
- Medical record documentation that member has received and tolerated a minimum of one (1) ***full dose*** ~~cycle~~ of intravenous rituximab (Rituxan)

MBP 157.0 Brineura (cerliponase alfa)- Criteria submitted to DHS which included documentation that the patient must be ambulatory to receive treatment was not approved by DHS. DHS specified that "Specialists that consulted with the Department attested that preservation of any functional status and slowing of disease progression is of benefit to the member with CLN2." GHP pushed back on DHS noting the following: "Per the FDA indication for the medication, delaying the loss of ambulation is the specific indication for this medication, therefore the requirement of ambulation was added. We respect that different specialists will have differences in opinions in treating rare and serious conditions such as this one, therefore in addition to policy criteria we review each request based on medical necessity. As a general practice, if a member does not meet our criteria in rare diseases such as this one, our Medical Directors prefer to make an outreach to the requesting physician to have a clinical discussion about each individual patient and their specific case to determine if there is a possibility of benefit even if there is no ambulation. Our intent of including this language in our policy is to stay in accordance with the actual FDA approved indication of the medication, and to prompt this sort of discussion for those cases that do not clearly meet our requirements to determine if medical necessity is met." DHS responded that they appreciated Geisinger's willingness to communicate with providers in these difficult cases but that the policy would not be approved until it was removed. Medical Benefit policies are not specific by line of business, and Geisinger Health Plan feels strongly about the clinical importance of leaving the ambulation requirement in the policy for the reasons states above, therefore to policy was broken out with different criteria based on the line of business.

The policy was updated as follows:

- 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**
- ***For Commercial Lines of Business only:*** 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: 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 the following Reauthorization criteria are **met:**

- ***For Medicaid Lines of Business only: Medical record documentation that there is continued benefit from treatment based on the prescriber's professional judgment***
- ***For Commercial Lines of Business only:*** 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).

MBP 158.0 Tepadina (thiotepa)- DHS noted that in addition to Beta thalassemia major Tepadina is also FDA approved for other indications that thiotepa had previously been approved for, which were added to the policy. DHS also questioned our requirement that the patient be managed with blood transfusions as this is not part of the indication, nor was it part of the clinical trial. We explained that a specialist we consulted with specified that this is how you should treat beta thalassemia major vs intermediate or minor, however DHS felt that the criteria listed in the policy of liver size, liver fibrosis, and iron chelation were diagnostic for class 3 disease and if they were treating them with blood transfusions was irrelevant. We agreed to remove that criteria for the policy to be approved.

The policy was updated as follows:

- 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 **AND** ~~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

OR

Requests for any of the following indications will be reviewed based on medical necessity:

- ***For treatment of adenocarcinoma of the breast or ovary***
- ***For controlling intracavitary effusions secondary to diffuse or localized neoplastic diseases of various serosal cavities.***
- ***For treatment of superficial papillary carcinoma of the urinary bladder.***

AUTHORIZATION DURATION: Approved requests should be authorized one time 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 (dose is 5mg/kg).

*Supplied as 15mg single-dose vial or 100mg single-dose vial

Discussion: No questions or comments.

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

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

GHP Family Formulary Update

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

Medication	AWP/MAC	Tier/UM
ivermectin 3 mg tablet	$4.96 per tablet AWP	Generic Tier
Flonase Sensimist (fluticasone furoate)	$21.72 per 15.8 mL bottle (AWP)	OTC Tier, QL of 15.8 mL per 30 days
Flonase Allergy Relief (fluticasone propionate)	$23.34 per 15.8 mL bottle (AWP)	OTC Tier, QL of 15.8 mL per 30 days
omega-3 acid ethyl esters 1 g capsule (generic Lovaza)	$0.49 per capsule (MAC)	Generic Tier, QL of 4/day

Discussion: No questions or comments.

Outcome: Rajneel Chohan made a motion to accept the presented 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.

RESULTS OF ELECTRONIC VOTE

ADCETRIS (brentuximab vedotin)

The following recommendations were approved electronically by the P&T Committee on February 2, 2018 with 27 votes of approval.

Review: Adcetris is a CD30-directed antibody-drug conjugate (ADC) indicated for treatment of adult patients with classical Hodgkin lymphoma (cHL) at high risk of relapse or progression as post autologous hematopoietic stem cell transplantation (auto-HSCT) consolidation; cHL after failure of at least two prior multi-agent chemotherapy regimens in patients who are not auto-HSCT candidates; systemic anaplastic large cell lymphoma (sALCL) after failure of at least one prior multi-agent chemotherapy regimen; and primary cutaneous anaplastic large cell lymphoma (pcALCL) or CD30-expressing mycosis fungoides (MF) who have received prior systemic therapy. Dosing for Adcetris is 1.8 mg/kg up to a maximum of 180 mg, and the medication is administered as an intravenous (IV) infusion over 30 minutes every 3 weeks. Dosing adjustments are required in patients with renal or hepatic impairment. Adcetris is supplied through several specialty distributors as a 50 mg powder in a single-dose vial. The anticancer activity of Adcetris is due to the binding of the ADC to CD30-expressing cells, followed by internalization of the ADC-CD30 complex, and release of monomethyl auristatin E (MMAE) via proteolytic cleavage.

In clinical trials, Adcetris was found to increase progression-free survival (PFS) in patients with cHL post-auto-HSCT and in patients with pcALCL or CD30-expressing MF. The overall response rate (ORR) in the four clinical studies demonstrated Adcetris to be efficacious. Adcetris has a black box warning for progressive multifocal leukoencephalopathy (PML) and is contraindicated with use of bleomycin due to pulmonary toxicity. Severe adverse reactions include peripheral neuropathy, anaphylaxis, hematologic toxicities, infections, tumor lysis syndrome, hepatotoxicity, pulmonary toxicity, dermatologic reactions, and gastrointestinal complications. Adcetris should be avoided in pregnant and nursing women. Adcetris should not be used in patients with severe renal impairment (CrCl <30 mL/min) or moderate (Child-Pugh B) or severe (Child-Pugh C) hepatic impairment.

Adcetris is the first biologic to receive FDA-approval for pcALCL and sALCL. Adcetris can be used as a second-line treatment alternative to standard chemotherapy regimens for relapsed or refractory cHL.

Outcome: Adcetris is available as a medical benefit without prior authorization. It is recommended that Adcetris continue to be covered as a medical benefit for GHP Family members and that the following prior authorization criteria apply.

Prior Authorization Criteria:

- Prescription written by a hematologist/oncologist AND
- Medical record documentation that patient > 18 years of age

AND

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

OR

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

OR

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

Authorization Duration: Initial approval will be for 6 months or less if the reviewing provider feels it is medically appropriate. Subsequent approvals will be for an additional 12 months or less if the reviewing provider feels it is medically appropriate and will require medical record documentation of continued disease improvement or lack of disease progression. Adcetris will no longer be covered if the member experiences unacceptable toxicity or worsening of disease.

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

Meeting adjourned at 5:11 pm.

Future Scheduled Meetings
Tuesday, May 15, 2018 at 1:00 HCN3A & 3B Conference room

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