GHP FAMILY MINUTES

P&T Meeting Minutes

May 16, 2017

P&T Committee Meeting Minutes
GHP Family
May 16, 2017

Present:	**Absent:**
Bret Yarczower, MD, MBA – via phone	Beverly Blaisure, MD
Dean Christian, MD – via phone	Keith Boell, DO
Kimberly Clark, Pharm.D.	John Flaherty, Pharm.D.
Kristi Clarke, Pharm. D. – via phone	Perry Meadows, MD
Jamie Dodson, RPh - chair	Jonas Pearson, MS, RPh
Tricia Heitzman, Pharm.D.	William Seavey, Pharm.D.
Keith Hunsicker, Pharm.D.	Michael Spishock RPh
Phillip Krebs, R.EEG T. – via phone	Michael Evans, Pharm.D. B.S.
Susan Ledig, MD, MS – via phone	Steven Kheloussi, Pharm.D.
Thomas Morland, MD – via phone	Elaine Tino, CRNP – via phone
Aubrielle Prater Pharm.D.	
Kristen Scheib, Pharm. D. – via phone	
Richard Silbert, MD – via phone	
Todd Sponenberg, Pharm.D., RPh	
Kevin Szczecina, RPh	
Kristen Bender, Pharm.D – via phone	
Holly Bones, Pharm.D – via phone	
Jason Howay, Pharm.D. – via phone	
Lori Zaleski, RPh – via phone	
Lisa Mazonkey, RPh - via phone	

Call to Order:
Jamie Dodson called the meeting to order at 1:01 p.m., Tuesday, May 16, 2017.

Review and Approval of Minutes:
Jamie Dodson asked for a motion or approval to accept the March 21, 2017 minutes as written. Tricia Heitzman accepted the motion and Kevin Szczecina seconded the motion. None were opposed.

DRUG REVIEWS:

EMFLAZA **Keith Hunsicker**
(deflazacort)

Keith Hunsicker provided a review of Emflaza to the committee for consideration as a pharmacy benefit. Deflazacort is indicated for the treatment of Duchenne muscular dystrophy (DMD) in patients 5 years of age and older.

Deflazacort is a corticosteroid prodrug. Its active metabolite is 21-desDFZ, which acts through the glucocorticoid receptor and exerts anti-inflammatory and immunosuppressive effects.

Formulary alternatives: prednisone

Proposed Clinical Recommendations: Emflaza will be a pharmacy benefit for GHP Family members. It is recommended that Emflaza not be added to the GHP Family formulary. The following prior authorization criteria should apply.

- Prescribed by a neurologist/pediatric neurologist AND
- Medical record documentation of interdisciplinary team involvement including, but not limited to, neurology, pulmonology, and cardiology AND
- Medical record documentation of a diagnosis of Duchenne muscular dystrophy (DMD), confirmed by genetic testing AND
- Medical record documentation of age $\geq$ 5 years

Clinical Discussion: FDA Approved Indications, Pharmacology/MOA, Clinical Evidence of Safety and Efficacy, Adverse Reactions, Dosing Schedule, Monitoring, Safety Profile, Black Box Warnings, Contraindications, Warnings and Precautions, Drug Interactions, Patent Life, Unique Therapeutic Features, Recommendations of National Agencies and Organizations, Special Population Precautions were discussed, and Specialist Feedback from Dr. Maguire (Pediatric neurology, GMC) was discussed.

Emflaza is an oral corticosteroid approved for the treatment of DMD in pediatric and adult patients ages 5 years and older. Emflaza is available as an oral tablet and suspension in various strengths. In clinical trials, Emflaza was found to increase muscle strength and motor function compared to placebo. There is limited evidence in clinical trials that may suggest deflazacort had better muscle improvement and better time to climb stairs compared to prednisone. Both prednisone and deflazacort proved to benefit patients more than placebo in clinical trials. The side effect profile of deflazacort is very comparable to that of other corticosteroids. It is possible that Emflaza leads to less weight gain but more cataract risk than prednisone. The AAN recommends the use of prednisone with moderate strength evidence and the use of deflazacort with weak strength evidence. The CDC recommends prednisone as first-line treatment unless the patient has pre-existing weight and/or behavioral issues, for which the CDC recommends deflazacort as first-line treatment. Deflazacort has been available from other countries for many years and has just now been approved for use by the FDA. Emflaza is not yet commercialized by PTC Therapeutics. It is expected that when commercially available, Emflaza will be restricted to limited distribution through US Bioservices. Pediatric neurology specialist, Dr. Maguire states that Emflaza is not superior to prednisone in terms of safety and efficacy, and the cost of Emflaza is unreasonable and unjustifiable. For these reasons, Dr. Maguire does not plan on utilizing deflazacort, and does not feel that deflazacort should be utilized by GHS or covered by GHP.

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

Proposed Financial Recommendations: Emflaza will be a pharmacy benefit for GHP Family members. It is recommended that Emflaza be added to the GHP Family formulary. The following additional prior authorization criteria should apply.

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

Note to reviewer: Emflaza tablets may be crushed and served immediately after mixing with applesauce.

Authorization Duration/Quantity Limit: If approved, the approval shall be open-ended and entered by GPID with the following quantity limits

- 6mg: 2 Tablets per day
- 18mg: 1 Tablet per day
- 30mg: 2 Tablets per day
- 36mg: No quantity limit
- 22.75mg/mL: No quantity limit

Financial Discussion: No questions or comments.

Financial Outcome: Kevin Szczecina made a motion to accept the recommendation as written. Kimberly Clark seconded the motion. None were opposed.

Approved Recommendations: Emflaza will be a pharmacy benefit. Emflaza will not be added to the GHP Family formulary. Emflaza will require a prior authorization with the following criteria:

- Prescribed by a neurologist/pediatric neurologist AND
- Medical record documentation of interdisciplinary team involvement including, but not limited to, neurology, pulmonology, and cardiology AND
- Medical record documentation of a diagnosis of Duchenne muscular dystrophy (DMD), confirmed by genetic testing AND
- Medical record documentation of age ≥ 5 years
- Medical record documentation of a therapeutic failure on, intolerance to, or contraindication to prednisone

Authorization Duration/Quantity Limit: If approved, the approval shall be open-ended and entered by GPID with the following quantity limits

- 6mg: 2 Tablets per day
- 18mg: 1 Tablet per day
- 30mg: 2 Tablets per day
- 36mg: No quantity limit
- 22.75mg/mL: No quantity limit

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

JADENU **Aubrielle Prater**
(Deferasirox)

Aubrielle Prater provided a review of Jadenu to the committee for consideration as a pharmacy benefit. Jadenu is indicated for:

- The treatment of chronic iron overload due to blood transfusions in patients 2 years of age and older.
    - This indication is approved under accelerated approval based on a reduction of liver iron concentrations and serum ferritin levels. Continued approval for this indication may be contingent upon verification and description of clinical benefit in confirmatory trials.
- The treatment of chronic iron overload in patients 10 years of age and older with non-transfusion-dependent thalassemia (NTDT) syndromes and with a liver iron concentration (LIC) of at least 5 mg iron per gram of dry weight (Fe/g dw) and a serum ferritin > 300 mcg/L.
    - This indication is approved under accelerated approval based on a reduction of liver iron concentrations (to less than 5 mg Fe/g dw) and serum ferritin levels. Continued approval for this indication may be contingent upon verification and description of clinical benefit in confirmatory trials.

Limitations: There have been no clinical trials in patients with myelodysplastic syndromes and chronic iron overload due to blood transfusion. The safety and efficacy of Jadenu when administered with other iron chelation therapy have not been established.

Note: Exjade (deferasirox) has the same indications as Jadenu. Desferal (deferoxamine) is indicated for the treatment of acute iron intoxication and for chronic iron overload due to transfusion-dependent anemias. Ferriprox (deferiprone) is indicated for the treatment of transfusional iron overload due to thalassemia syndromes with inadequate response to other chelation therapy.

Proposed Clinical Recommendations: Jadenu will be a pharmacy benefit. It is recommended that Jadenu should be non-formulary for GHP Family added to Policy 1168.0F with modifications to the reauthorization criteria

Prior authorization of Exjade and Jedenu will be made for members who meet the following criteria:

1. Prescription is written by a hematologist AND
2. Medical record documentation of being used for the treatment of chronic iron overload caused by blood transfusions (transfusional hemosiderosis) in patients 2 years of age and older and with a serum ferritin level > 1000 mcg/L OR
3. Medical record documentation of being used for the treatment of chronic iron overload in patients 10 years of age and older with non-transfusion dependent thalassemia syndromes and with a liver iron (Fe) concentration (LIC) of at least 5 mg Fe per gram of dry weight and a serum ferritin greater than 300 mcg/L.

Authorization Duration: If approved, approval is for 3 months. To continue to be considered medically necessary there must be medical record documentation of a decreased serum ferritin level from baseline for overload caused by blood transfusions OR of a decreased LIC from baseline AND serum ferritin level >300 mcg/ml for overload caused by non-transfusional dependent thalassemia syndromes.

Prior authorization of Ferriprox will be made for members who meet the following criteria:

1. Prescription is written by a hematologist AND
2. Medical record documentation of being used for the treatment of transfusional iron overload due to thalassemia syndromes AND
3. Medical record documentation of ANC > 1.5 x 109/L AND
4. Therapeutic failure on, intolerance to, or contraindication to Exjade

NOTE: It was also recommended for all lines of business to update the reauthorization criteria for other medications in this class for Chronic Iron Overload caused by Transfusion-Dependent Thalassemia and Non-Transfusion Dependent Thalassemia to the following:

Initial approval will be for 6 months or less if the reviewing provider feels it is medically appropriate. Subsequent approvals will be for an additional 6 months or less if the reviewing provider feels it is medically appropriate and will require medical record documentation of serum ferritin level > 300 mcg/L.

Clinical Discussion: FDA Approved Indications, Pharmacology/MOA, Clinical Evidence of Safety and Efficacy, Adverse Reactions, Dosing Schedule, Monitoring, Safety Profile, Black Box Warnings, Contraindications, Warnings and Precautions, Drug Interactions, Patent Life, Unique Therapeutic Features, Recommendations of National Agencies and Organizations, Special Population Precautions were discussed, and Specialist Feedback from Dr. Ramdas (pediatric hematologist/oncologist, GMC) was discussed.

Both Jadenu and Exjade have the same indication and contain the same active ingredient, deferasirox. Novartis is the manufacturer of both products. Jadenu was produced to simplify the administration of deferasirox. Jadenu is a newer product available as oral tablets taken once daily directly by mouth. Exjade is supplied as a tablet for oral suspension, that must be dissolved in water, orange juice, or apple juice prior to ingesting. Jadenu can be taken on an empty stomach or with a light meal. Exjade must be taken on an empty stomach at the same time each day 30 minutes before food. Some of the inactive ingredients in Exjade are no longer present in Jadenu, including lactose and sodium lauryl sulfate. Jadenu also has expanded access through more pharmacies.

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

Proposed Financial Recommendations: It is recommended that Jadenu not be added to the GHP Family formulary. No additional criteria should apply.

Financial Discussion: No questions or comments.

Financial Outcome: Kimberly Clark made a motion to accept the recommendation as written. Keith Hunsicker seconded the motion. None were opposed.

Approved Recommendations: Jadenu will be considered non-formulary for GHP Family. The following prior authorization criteria will apply:

Prior authorization of Exjade or Jadenu will be made for members who meet the following criteria:

1. Prescription is written by a hematologist AND

2. Medical record documentation of being used for the treatment of chronic iron overload caused by blood transfusions (transfusional hemosiderosis) in patients 2 years of age and older and with a serum ferritin level > 1000 mcg/L OR
3. Medical record documentation of being used for the treatment of chronic iron overload in patients 10 years of age and older with non-transfusion dependent thalassemia syndromes and with

a liver iron (Fe) concentration (LIC) of at least 5 mg Fe per gram of dry weight
and a serum ferritin greater than 300 mcg/L.

Initial approval will be for 6 months or less if the reviewing provider feels it is medically appropriate. Subsequent approvals will be for an additional 6 months or less if the reviewing provider feels it is medically appropriate and will require medical record documentation of serum ferritin level > 300 mcg/L.

Prior authorization of Ferriprox will be made for members who meet the following criteria:

1. Prescription is written by a hematologist AND
2. Medical record documentation of being used for the treatment of transfusional iron overload due to thalassemia syndromes AND
3. Medical record documentation of ANC > 1.5 x 10^9/L AND
4. Therapeutic failure on, intolerance to, or contraindication to Exjade

Initial approval will be for 6 months or less if the reviewing provider feels it is medically appropriate. Subsequent approvals will be for an additional 6 months or less if the reviewing provider feels it is medically appropriate and will require medical record documentation of serum ferritin level > 300 mcg/**L.**

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

BAVENCIO **Keith Hunsicker**
(avelumab)

Keith Hunsicker provided a review of Bavencio to the committee for consideration as a medical benefit. Bavencio is indicated for the treatment of adults and pediatric patients 12 years and older with metastatic Merkel cell carcinoma (MCC).

This indication is approved under accelerated approval based on tumor response and duration of response. Continued approval for this indication may be contingent upon verification and description of clinical benefit in confirmatory trials.

Formulary alternatives: none

Proposed Clinical Recommendations: Bavencio will be covered as medical benefit for GHP Family. To ensure appropriate utilization, Bavencio should require prior authorization. The following prior authorization criteria should apply.

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

- Medical record documentation of age ≥12 years
  OR
- Medical record documentation of use for a medically accepted indication.

Clinical Discussion: FDA Approved Indications, Pharmacology/MOA, Clinical Evidence of Safety and Efficacy, Adverse Reactions, Dosing Schedule, Monitoring, Safety Profile, Black Box Warnings, Contraindications, Warnings and Precautions, Drug Interactions, Patent Life, Unique Therapeutic Features, Recommendations of National Agencies and Organizations, and Special Population Precautions were discussed.

Bavencio is a human monoclonal antibody that functions by preventing the interaction between programmed cell death-1 ligands and receptors indicated to treat metastatic Merkel Cell Carcinoma in patients 12 years of age and older. Bavencio is currently the only medication indicated to treat this disease state. In a clinical trial, Bavencio achieved an overall response rate of 33%. 86% of responders in this trial had a duration of response greater than 6 months, 45% greater than 12 months. While there are not any black box warnings or contraindications listed for Bavencio, there are several immune-mediated reactions, which may require dosage adjustments. The NCCN guidelines have not yet been updated to include treatment recommendations with Bavencio. UpToDate lists Bavencio, Opdivo, and Keytruda as possible immunotherapy options for treatment of metastatic MCC, with Bavencio having the most evidence for treatment and Opdivo having the least.

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

Proposed Financial Recommendations: It is recommended that Bavencio be covered as a medical benefit requiring prior authorization. No additional prior authorization criteria should apply.

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

Financial Discussion: No comments or questions.

Financial Outcome: Aubrielle Prater made a motion to accept the recommendations as written. Kimberly Clark seconded the motion. None were opposed.

Approved Recommendations: Bavencio will be added considered a medical benefit for GHP Family. The following prior authorization criteria will apply:

- Prescribed by a hematologist/oncologist AND
- Medical record documentation of a diagnosis of metastatic Merkel Cell Carcinoma (MCC) AND
- Medical record documentation of age ≥12 years
  OR
- Medical record documentation of use for a medically accepted indication.

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

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

KISQALI **Aubrielle Prater**
(ribociclib succinate)

Aubrielle Prater provided a review of Kisqali to the committee for consideration as a pharmacy benefit. Kisqali is 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 2 (HER2)-negative advanced or metastatic breast cancer.

Formulary alternatives: Ibrance*

Proposed Clinical Recommendations: Kisqali will be a pharmacy benefit. It is recommended that Kisqali should be added to the GHP Family formulary. Kisqali will require a prior authorization with the following criteria.

- Prescription is written by an oncologist AND
- Medical record documentation of postmenopausal status AND
- Medical record documentation that Kisqali will be prescribed in combination with an aromatase inhibitor AND
- Medical record documentation of diagnosis of hormone-receptor positive, HER2-negative, metastatic breast cancer
-

Quantity Limit:
For Kisqali (HICL 44151): 63 tablets per 28 days, maximum 28 day supply per fill
For Kisqali Femara Co-Pack (HICL 44246): 91 tablets per 28 days, maximum 28 day supply per fill

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

Clinical Discussion: FDA Approved Indications, Pharmacology/MOA, Clinical Evidence of Safety and Efficacy, Adverse Reactions, Dosing Schedule, Monitoring, Safety Profile, Black Box Warnings, Contraindications, Warnings and Precautions, Drug Interactions, Patent Life, Unique Therapeutic Features, Recommendations of National Agencies and Organizations, and Special Population Precautions were discussed.

Kisqali is the second CDK inhibitor approved for the treatment of breast cancer. Ibrance is the other CDK inhibitor which has been on the market for 2 years as first-line therapy in combination with letrozole for HR-positive, HER2 negative advanced breast cancer. Ibrance is also approved for use in combination with fulvestrant in women with disease progression following endocrine therapy. Kisqali is currently being studied for this additional indication, but approval is likely years away. Kisqali is also being studied as a first-line agent with endocrine therapy in premenopausal women. Kisqali has concerns for hepatotoxicity and QT prolongation and Ibrance has a risk for pulmonary embolism. Like Ibrance, Kisqali has warnings and precautions for neutropenia and embryo-fetal toxicity. A third CDK inhibitor, abemaciclib, is in phase 3 studies and may reach the market in 2018.

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

Proposed Financial Recommendations: Kisqali is a pharmacy benefit for GHP Family members. It is recommended that Kisqali be added to the GHP Family formulary on the Brand Tier. No additional criteria should apply

Financial Discussion: Kisqali is also available pre-packaged with letrozole. Quantity limits recommended for those packs as well

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

Approved Recommendations: Kisqali is a pharmacy benefit and will be added to the Brand Tier of the requiring prior authorization. The following prior authorization criteria will apply:

- Prescription is written by an oncologist AND
- Medical record documentation of postmenopausal status AND
- Medical record documentation that Kisqali will be prescribed in combination with an aromatase inhibitor AND
- Medical record documentation of diagnosis of hormone-receptor positive, HER2-negative, metastatic breast cancer
-

Quantity Limit:
For Kisqali (HICL 44151): 63 tablets per 28 days, maximum 28 day supply per fill
For Kisqali Femara Co-Pack (HICL 44246): 91 tablets per 28 days, maximum 28 day supply per fill

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

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

ZINPLAVA **Keith Hunsicker**

(bezlotoxumab)

Keith Hunsicker provided a review of Zinplava to the committee for consideration as a medical benefit. Zinplava is indicated to reduce recurrence of Clostridium difficile infection (CDI) in patients 18 years of age or older who are receiving antibacterial drug treatment of CDI and are at a high risk for CDI recurrence.

Limitation of use: Zinplava is not indicated for the treatment of CDI. Zinplava is not an antibacterial

Formulary alternatives: none

Proposed Clinical Recommendations: Zinplava will be considered a medical benefit for GHP Family members. It is recommended that Zinplava require a prior authorization. The following prior authorization criteria should apply.

1. Prescribed in conjunction with a recommendation from an infectious disease team consult **AND**
2. Patient age greater than or equal to 18 years **AND**
3. Medical record documentation that patient is at high risk for *Clostridium difficile* (*C. diff*.) infection recurrence, as evidenced by one of the following points:
    - Patient has at least one risk factor for recurrent disease (age greater than or equal to 75 years, greater than or equal to 10 unformed stools per 24 hours, serum creatinine greater than or equal to 1.2 mg/dL) OR
    - Patient has had at least one previous *C. difficile* infection within the past 6 months OR
    - Patient has a history of at least 2 previous *C. difficile* infections ever **AND**
4. Medical record documentation that Zinplava is being administered concurrently with a standard-of-care antibacterial treatment indicated for the treatment of *Clostridium difficile* (e.g. oral vancomycin, oral metronidazole, oral fidaxomicin) **AND**
5. One of the following:
    - Medical record documentation that patient DOES NOT have heart failure OR
    - Medical record documentation of rationale for use in a heart failure patient (e.g. The benefits of Zinplava administration outweigh the risks of Zinplava administration)

    AND
6. Medical record documentation that patient has not received a previous dose of Zinplava

Note to reviewer: Zinplava is not an antibacterial drug and is not indicated for the treatment of Clostridium difficile infections. Repeat doses have not been studied.

Clinical Discussion: FDA Approved Indications, Dosing Schedule, Clinical Evidence of Safety and Efficacy, Adverse Reactions, Dosing Schedule, Monitoring, Safety Profile, Contraindications, Warnings and Precautions, Drug Interactions, Patent Life, Unique Therapeutic Features, Recommendations of National Agencies and Organizations, Distribution, Special Population Precautions and Specialist Feedback from Dr. Stanley Martin (Infectious diseases, GMC) was discussed.

Zinplava is a human monoclonal antibody indicated for the prevention of recurrent C. difficile infections in adults 18 years of age and older who are at high risk for recurrent CDI. Zinplava is not an antibacterial agent and does not treat CDI. Because of this, Zinplava must be given in combination with a standard-of-care antibacterial drug. Zinplava functions by binding to C. difficile toxin B and neutralizing its effects. Zinplava does not bind to C. difficile toxin A. Zinplava is given at a dose of 10mg/kg as a single dose intravenous infusion. The safety and efficacy of repeat infusions has not been studied. In clinical trials, Zinplava was found to have lower rates of recurrent CDI as well as a higher sustained clinical response compared to placebo. In clinical trials, patients with a history of CHF and treated with Zinplava had a higher adverse reaction of heart failure and a higher incidence of death related to cardiac failure, infections, and respiratory failure than patients with a history of CHF and treated with placebo. The American College of Gastroenterology clinical guidelines currently recommend standard-of-care antibacterial drugs for first and second recurrent episodes of CDI, utilizing pulsed oral vancomycin for the second recurrence if not already being utilized. The guidelines have not yet been updated to include Zinplava in the clinical treatment pathway. Currently, the placement of Zinplava in treatment of recurrent CDI is not clearly defined; however, given the limited treatment options of patients with recurrent CDI, Zinplava may be a viable option for patients, especially those who have already failed treatments such as pulsed vancomycin and/or fecal microbiota transplant.

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

Proposed Financial Recommendations: Zinplava will be considered a medical benefit for GHP Family members requiring prior authorization. The following additional prior authorization criteria should apply.

7. Medical record documentation of a therapeutic failure on at least one regimen of pulsed oral vancomycin **OR**
8. (For patients with intolerance to or contraindication to vancomycin) medical record documentation of therapeutic failure on at least one regimen of an appropriate antibacterial treatment for C. diff (e.g. oral metronidazole, oral fidaxomicin).

Authorization Duration/Quantity Limit:If approved, authorization shall be for a one-time authorization of one (1) Zinplava dose (infusion).

Financial Discussion: No comments or questions.

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

Approved Recommendations: It is recommended that Zinplava considered a medical benefit requiring prior authorization for GHP Family. The following criteria should apply:

1. Prescribed in conjunction with a recommendation from an infectious disease team consult **AND**

2. Patient age greater than or equal to 18 years **AND**
3. Medical record documentation that patient is at high risk for *Clostridium difficile* (*C. diff*.) infection recurrence, as evidenced by <u>one</u> of the following points:
    - Patient has at least one risk factor for recurrent disease (age greater than or equal to 75 years, greater than or equal to 10 unformed stools per 24 hours, serum creatinine greater than or equal to 1.2 mg/dL) OR
    - Patient has had at least one previous *C. difficile* infection within the past 6 months OR
    - Patient has a history of at least 2 previous *C. difficile* infections ever

      AND
4. Medical record documentation that Zinplava is being administered concurrently with a standard-of-care antibacterial treatment indicated for the treatment of *Clostridium difficile* (e.g. oral vancomycin, oral metronidazole, oral fidaxomicin) **AND**
5. One of the following:
    - Medical record documentation that patient DOES NOT have heart failure OR
    - Medical record documentation of rationale for use in a heart failure patient (e.g. The benefits of Zinplava administration outweigh the risks of Zinplava administration) **AND**
6. Medical record documentation that patient has not received a previous dose of Zinplava **AND**
7. Medical record documentation of a therapeutic failure on at least one regimen of pulsed oral vancomycin **OR**
8. (For patients with intolerance to or contraindication to vancomycin) medical record documentation of therapeutic failure on at least one regimen of an appropriate antibacterial treatment for C. diff (e.g. oral metronidazole, oral fidaxomicin).

Note to reviewer: Zinplava is not an antibacterial drug and is not indicated for the treatment of Clostridium difficile infections. Repeat doses have not been studied.

Authorization Duration/Quantity Limit: If approved, authorization shall be for a one-time authorization of one (1) Zinplava dose (infusion).

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

FAST FACTS:

JARDIANCE **Kim Clark**
(empagliflozin)

Updated Indication: Jardiance is now indicated to reduce the risk of cardiovascular death in adult patients with type 2 diabetes mellitus and established cardiovascular disease.

Limitations of use: Not for the treatment of type 1 diabetes mellitus or diabetic ketoacidosis.

Jardiance was previously approved as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus.

Current Formulary Status/Prior Authorization Criteria:

GHP Family: Brand tier with a quantity limit requiring step therapy

On-line prescription drug claim history showing 15 days use of metformin. If step therapy criteria are not met, prescribing provider should request an exception for coverage.

Prior authorization of Jardiance will be made for members who meet the following criteria:

- Medical record documentation that Jardiance is being used in combination with (or therapeutic failure of, intolerance to, or contraindication to) metformin.

Recommendations:
No changes are recommended to current formulary placement or utilization management criteria.

Discussion: No comments or questions.

Outcome: Todd Sponenberg 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.

REVLIMID **Keith Hunsicker**
(lenalidomide)

Updated Indication: Revlimid is now indicated for the treatment of patients with multiple myeloma, in combination with dexamethasone and in patients with multiple myeloma, as maintenance following autologous hematopoietic stem cell transplantation (auto-HSCT).

Previously, Revlimid was approved for transfusion-dependent anemia due to low- or intermediate-1-risk myelodysplastic syndromes (MDS) associated with a deletion 5q and for mantle cell lymphoma (MCL) whose disease has relapsed or progressed after two prior therapies, one of which included bortezomib.

Updated Dosing for New Indication[1]:

Combination Therapy: 25mg once daily on days 1-21 of repeated 28-day cycles in combination with dexamethasone until disease progression or unacceptable toxicity.

Current Formulary Status/Prior Authorization Criteria:
GHP Family: Pharmacy benefit on the **Brand** tier requiring PA.

- Must be prescribed by hematologist/oncologist **AND**

For Myelodysplastic Syndromes (MDS)

- Medical record documentation of the treatment of a patient with myelodysplastic syndromes (MDS) associated with a deletion 5q cytogenetic abnormality with or without additional cytogenetic abnormalities

OR

With no deletion 5q cytogenetic abnormality:

- Medical record documentation of initial use in lower risk patient with symptomatic anemia and serum erythropoietin levels greater than 500 mU/mL and a low probability of response to immunosuppressive therapy* **OR**
- Medical record documentation of lower risk patient with symptomatic anemia and no response to initial treatment with epoetin alfa or darbopoetin alfa, hypomethylating agents, or immunosuppressive therapy

*Low probability is defined as members who lack any of the following features: age ≤ 60, those with hypocellular marrows, HLA-DR15 or PNH clone positivity

For Multiple Myeloma:

- Medical record documentation of a diagnosis of multiple myeloma

OR

For Non-Hodgkin Lymphomas (NHL)

- Medical record documentation of a diagnosis of NHL (relapsed, refractory, progressive disease, or members who are not candidates for high dose therapy)

OR

For Mantle Cell Lymphomas

- Medical record documentation of relapsed, refractory, or progressive Mantle cell lymphoma AND
- Medical record documentation of therapeutic failure on, intolerance to, or contraindication to one prior therapy

Quantity Limit: 30 capsules of 5 mg, 10 mg, 15 mg and 25 mg per 30 days

Recommendations:

GHP Family: Revlimid is currently a pharmacy benefit on the **Brand** tier requiring PA. No changes are recommended at this time

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

It is recommended that the quantity limits of all lines of business be updated to the following:

Quantity Limit: 30 capsules of 2.5mg, 5 mg, 10 mg, 15 mg, 20mg, and 25 mg per 30 days, 34-day supply per fill.

Discussion: No comments or questions.

Outcome: Tricia Heitzman made a motion to accept the recommendations as modified. 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.

(omalizumab)

Updated Indication: Xolair is an anti-IgE antibody indicated for moderate to severe persistent asthma in patients 6 years of age and older with a positive skin test or in vitro reactivity to a perennial aeroallergen and symptoms that are inadequately controlled with inhaled corticosteroids

Previously indicated for patients 12 years of age or older.

Updated Dosing for New Indication[1]:
Xolair 75 to 375 mg SC every 2 or 4 weeks. Determine dose (mg) and dosing frequency by serum total IgE level (IU/mL), measured before the start of treatment, and body weight (kg). See the dose determination charts. Adjust doses for significant changes in body weight during treatment.

Current Formulary Status/Prior Authorization Criteria:
GHP Family: NF (medical benefit requiring PA)

MBP 22.0 – Xolair Medical PA Criteria

1. **For Asthma:**
   - Must be prescribed by an allergist or pulmonologist **AND**
   - Insured individual must be compliant with current therapeutic regimen **AND**
   - Insured individual is at least 12 years of age **AND**
   - Physician provided documentation of a diagnosis of moderate to severe persistent asthma* with evidence of reversible airway disease [i.e. greater than 12% improvement in forced expiratory volume in one second (FEV_1) with at least 200 ml increase or at least a 20% or greater improvement in peak expiratory flow (PEF) after administration of albuterol] **AND**
   - Physician provided documentation of inadequate control or intolerance, despite a 3-month trial of: medium –high dose inhaled corticosteroids or systemic corticosteroids **and** long-acting beta agonists or leukotriene receptor antagonists **AND**
   - Physician provided documentation of an IgE level of greater than 30 IU/ml and less than 700 IU/ml **AND**
   - Physician provided documentation of evidence of a specific allergic reactivity to a perennial aeroallergen by positive skin or blood test for a specific IgE **AND**
   - Known environmental triggers within the member's control have been eliminated.

*Moderate persistent asthma is defined by the National Heart, Lung and Blood institute (NHLBI) as:

1. Daily symptoms
2. Daily use of inhaled short-acting beta agonist
3. Exacerbations affect activity
4. Exacerbations at least twice a week, which may last days
5. Nighttime symptoms more frequently than one time per week
6. Lung function of FEV1 greater than 60% but less than 80%

*Severe persistent asthma is defined by the NHLBI as:

1. Continual symptoms
2. Limited physical activity
3. Frequent exacerbations
4. Frequent nighttime symptoms
5. Lung function of FEV1 less than or equal to 60% predicted

**The 12% improvement target value is calculated using the following methodology: The target value = baseline FEV_1 x 1.12

The actual clinical calculation is: $\frac{\text{post-treatment } FEV_1 - \text{baseline } FEV_1}{\text{baseline } FEV_1} = \%$ improvement

2. **For Chronic Idiopathic Urticaria:**
   - Prescription is written by an allergist, immunologist, or dermatologist **AND**
   - Patient is at least 12 years of age **AND**
   - Diagnosis of moderate-to-severe chronic idiopathic urticaria **AND**
   - At least 6 week history of symptoms (e.g., hives associated with itching, angioedema) **AND**
   - Medical record documentation of a therapeutic failure on Xolair 150 mg dose, when Xolair 300 mg dose is requested **AND**
   - Medical record documentation of contraindication to, therapeutic failure on, or intolerance to a four week trial of ALL of the following treatment alternatives:
     - At least two different high dose antihistamines
     - Maximum dose antihistamine(s) used in combination with a leukotriene receptor antagonist (e.g., montelukast)
     - High dose antihistamine used in combination with H_2 receptor antagonist (e.g., ranitidine
     - Dose advancement of potent antihistamine (e.g., hydroxyzine or doxepin)

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.

Recommendations:
GHP Family: Xolair is currently a medical benefit requiring prior authorization. No changes are recommended at this time.

It is recommended that the MBP 22.0 policy for the diagnosis of Asthma be changed to reflect the following:

For Asthma:
- Must be prescribed by an allergist or pulmonologist **AND**
- Insured individual must be compliant with current therapeutic regimen **AND**
- Insured individual is at least *6 years* of age **AND**
- Physician provided documentation of a diagnosis of moderate to severe persistent asthma* with evidence of reversible airway disease [i.e. greater than 12% improvement in forced expiratory volume in one second (FEV_1) with at least 200 ml increase or at least a 20% or greater improvement in peak expiratory flow (PEF) after administration of albuterol] **AND**
- Physician provided documentation of inadequate control or intolerance, despite a 3-month trial of: medium–high dose inhaled corticosteroids or systemic corticosteroids **and** long-acting beta agonists or leukotriene receptor antagonists **AND**
- Physician provided documentation of an IgE level of greater than 30 IU/ml and less than 700 IU/ml *for individuals age 12 and older OR IgE level of greater than 30 IU/ml and less than 1300 IU/ml for individuals age 6 through 11* **AND**
- Physician provided documentation of evidence of a specific allergic reactivity to a perennial aeroallergen by positive skin or blood test for a specific IgE **AND**
- Known environmental triggers within the member's control have been eliminated.

Discussion: No questions or comments.

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.

KEYTRUDA **Keith Hunsicker**
(pembrolizumab)

Updated Indication: Keytruda is now indicated for the treatment of adult and pediatric patients with refractory Classical Hodgkin Lymphoma (cHL), or who have relapsed after 3 or more prior lines of therapy.

This indication is approved under accelerated approval based on tumor response rate and durability of response. Continued approval for this indication may be contingent upon verification and description of clinical benefit in the confirmatory trials.

Keytruda is also approved for treatment of patients with metastatic melanoma, metastatic non-small cell lung cancer, and metastatic head and neck squamous cell carcinoma.

Updated Dosing for New Indication[1]:
Adults: Keytruda 200mg IV over 30 minutes every 3 weeks until disease progression or unacceptable toxicity, or up to 24 months in patients without disease progression.

Pediatrics: Keytruda 2mg/kg (up to a maximum of 200mg) IV over 30 minutes every 3 weeks until disease progression or unacceptable toxicity, or up to 24 months in patients without disease progression

Current Formulary Status/Prior Authorization Criteria:
GHP Family: NF (Medical Benefit requiring PA)

MBP 119.0

1. **Unresectable or Metastatic Melanoma**
   - Prescription written by a hematologist/oncologist **AND**
   - Medical record documentation that patient is ≥ 18 years of age **AND**
   - Medical record documentation of a diagnosis of unresectable or metastatic melanoma **AND**
   - Medical record documentation that Keytruda is not being used in combination with any other agents for the treatment of unresectable or metastatic melanoma.

2. **Metastatic Non-Small Cell Lung Cancer**
   - Prescription written by a hematologist/oncologist **AND**
   - Medical record documentation that patient is ≥ 18 years of age **AND**
   - Medical record documentation of a diagnosis of metastatic NSCLC meeting one of the following situations:
     - Medical record documentation that tumors have high PD-L1 expression (Tumor Proportion Score (TPS)≥50% as determined by an FDA-approved test **AND**
     - Medical record documentation that tumors do not have EGFR or ALK genomic tumor aberrations

OR

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

3. Head and Neck Squamous Cell Carcinoma

- Prescription written by a hematologist/oncologist **AND**
- Medical record documentation that patient is ≥ 18 years of age **AND**
- Medical record documentation of a diagnosis of Head and Neck Squamous Cell Carcinoma that is recurrent or metastatic and had disease progression on or after platinum-containing chemotherapy

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 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.

Recommendations:
GHP Family: Keytruda is currently a medical benefit requiring prior authorization.

It is recommended that the following prior authorization criteria are added to MBP 119.0 to account for the new indication.

For Classical Hodgkin Lymphoma

1. Prescription written by a hematologist/oncologist **AND**
2. Medical record documentation of Classical Hodgkin Lymphoma **AND**
3. One of the following:
    a. Medical record documentation of a diagnosis of refractory Classical Hodgkin Lymphoma **OR**
    b. Medical record documentation of relapse following three (3) or more prior lines of therapy

No changes are recommended to the other listed indications at this time.

It is recommended that the authorization duration be edited to the following:

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

Discussion: No other questions or comments.

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

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

QUDEXY XR AND TROKENDI XR **Kim Clark**
(topiramate extended release)

Updated Indication: Qudexy XR and Trokendi XR are now indicated for the prophylaxis of migraine headache in adults and adolescents 12 years of age and older.

Previously indicated for the treatment of partial onset seizures, primary generalized tonic-clonic seizures, and Lennox Gastaut Syndrome (Qudexy XR: 2 yeard and older, Trokendi XR: 6 years and older).

Updated Dosing for New Indication[1]:

- Initial Dose: 25 mg once daily administered for first week
- Titration: Increase dosage by 25 mg increments to achieve desired clinical outcome
- Recommended Dose: 100 mg once daily

Recommendations:
Topiramate ER should be added to the GHP Family formulary on the generic tier requiring prior authorization and the prior authorization criteria are recommended to be updated as follows:

GHP Family –

- Topiramate ER
    - Medical record documentation of use for prophylaxis of migraine headache **AND**
    - Medical record documentation of age greater than or equal to 12 years **AND**
    - Medical record documentation of therapeutic failure on, intolerance to, or contraindication to three formulary alternatives, one of which must be immediate-release topiramate

OR

    - Medical record documentation of a diagnosis of partial onset seizures, primary generalized tonic-clonic seizures, or Lennox Gastaut Syndrome **AND**
    - Medical record documentation of age greater than or equal to 2 years **AND**
    - Medical record documentation of therapeutic failure on, intolerance to, or contraindication to three formulary alternatives, one of which must be immediate-release topiramate

- Trokendi XR
    - Medical record documentation of use for prophylaxis of migraine headache **AND**
    - Medical record documentation of age greater than or equal to 12 years **AND**
    - Medical record documentation of therapeutic failure on, intolerance to, or contraindication to topiramate ER*

OR

- Medical record documentation of a diagnosis of partial onset seizures, primary generalized tonic-clonic seizures, or Lennox Gastaut Syndrome **AND**
- Medical record documentation of age greater than or equal to 6 years **AND**
- Medical record documentation of therapeutic failure on, intolerance to, or contraindication to topiramate ER*

Discussion: No questions or comments.

Outcome: Tricia Hetizman 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.

CEREBYX **Keith Hunsicker**
(fosphenytoin)

Updated Indication: Cerebyx is now labeled for the treatment of generalized tonic-clonic status epilepticus and prevention and treatment of seizures occurring during neurosurgery in the pediatric population (evaluated in ages as low as 5 years).

Current Formulary Status/Prior Authorization Criteria:
GHP Family:

- Cerebyx: Medical benefit (PA not required)
- Fosphenytoin: Medical benefit (PA not required)

Recommendations:
GHP Family: Cerebyx and Fosphenytoin are available as a medical benefit without restrictions.

- Cerebyx: No changes recommended at this time
- Fosphenytoin: No changes recommended at this time

Discussion: No questions or comments

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

TECHNIVIE **Kristi Clarke**
(ombitasvir/paritaprevir/ritonavir)

Updated Indication: Technivie is now indicated for genotype 4 with ribavirin for the treatment of HCV (hepatitis C virus) with cirrhosis or without compensated cirrhosis. It was previously not indicated for cirrhotic patients.

Updated Dosing for New Indication:

Table 1. Treatment Regimen and Duration for Patients with HCV Genotype 4 without Cirrhosis or with Compensated Cirrhosis

Patient Population	Treatment	Duration
Genotype 4 without cirrhosis or with compensated cirrhosis (Child-Pugh A)	TECHNIVIE + ribavirin*	12 weeks
*TECHNIVIE administered without RBV for 12 weeks may be considered for treatment-naïve patients without cirrhosis who cannot take or tolerate ribavirin		

Recommendations: There are no changes recommended to formulary status at this time but criteria change is below:
GHP Family:
Remove: Medical record documentation of F2 – F3 liver fibrosis based on METAVIR liver (not FDA approved for F4 and will not be approved)

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.

RENVELA **Keith Hunsicker**
(sevelamer)

Updated Indication: Renvela is now indicated for the control of serum phosphorus in adults and children 6 years of age and older with chronic kidney disease (CKD) on dialysis.

Previously, Renvela was only indicated in adults 18 years of age and older.

Updated Dosing for New Indication[1]:
Starting Dose for Pediatric Patients Not Taking a Phosphate Binder:

- The recommended starting dose for patients 6 years of age and older is 0.8g to 1.6g three times per day with meals based on the body surface area (BSA) category of the patient (below).

BSA (m^2)	Starting Dose per Meal/Snack	Titration Increases/Decreases per Dose
≥0.75 to <1.2	0.8g	Titrate by 0.4g
≥1.2	1.6g	Titrate by 0.8g

Current Formulary Status/Prior Authorization Criteria:
GHP Family: Renvela tablets and powder packets are a pharmacy benefit on the **Brand** tier requiring prior authorization for GHP Family members. The following prior authorization criteria currently apply.

1. Medical record documentation of a contraindication to, intolerance to, or therapeutic failure on calcium acetate.

Renvela Recommendations:

GHP Family: Renvela tablets and powder packets are currently a pharmacy benefit on the Brand tier requiring prior authorization. It is recommended that the existing prior authorization criteria are removed so that Renvela may be utilized without prior authorization.

Renagel Recommendations
GHP Family: Renagel is currently a pharmacy benefit on the Brand tier not requiring prior authorization. It is recommended that Renagel be removed from the formulary and require the following prior authorization criteria.

1. Medical record documentation of a diagnosis of Chronic Kidney Disease (CKD) on dialysis **AND**
2. Medical record documentation of a contraindication to, intolerance to, or therapeutic failure on calcium acetate AND Fosrenol AND Renvela

Discussion: No questions or comments.

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

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

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LUCENTIS **Kim Clark**
(ranibizumab)

Updated Indication: Lucentis, a vascular endothelial growth factor (VEGF) inhibitor, is now indicated for the treatment of patients with: diabetic retinopathy (DR) and myopic choroidal neovascularization (mCNV).

Previously indicated for neovascular (wet) age-related macular degeneration (AMD), macular edema following retinal vein occlusion (RVO), and diabetic macular edema (DME).

Updated Dosing for New Indication[1]:

- DR: Lucentis 0.3 mg (0.05 mL) administered by intravitreal injection once a month (approximately 28 days).
- mCNV: Lucentis 0.5 mg (0.05 mL) administered by intravitreal injection once a month (approximately 28 days) for up to three months. Patients may be retreated if needed.

Formulary Alternatives Via the Medical Benefit:
Avastin: mCNV only (off label use) Eylea: DR only

Current Formulary Status: Covered via the medical benefit, no prior authorization required

Recommendations: No changes are recommended based on newly approved indications.

Discussion: No comments or questions

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

TECENTRIQ **Keith Hunsicker**
(atezolizumab)

Updated Indication: Tecentriq is now indicated for the treatment of patients with locally advanced or metastatic urothelial carcinoma who are not eligible for cisplatin-containing chemotherapy.

Previously, Tecentriq was indicated for the treatment of patients with:

- Locally advanced or urothelial carcinoma who have disease progression during or following platinum-containing chemotherapy or who have disease progression within 12 months of neoadjuvant or adjuvant treatment with platinum-containing chemotherapy; and
- Metastatic non-small lung cancer who have disease progression during or following platinum-containing chemotherapy. Patients with EGFR or ALK genomic tumor aberrations should have disease progression on FDA-Approved therapy for these aberrations prior to receiving Tecentriq.

The treatment of locally advanced or metastatic urothelial carcinoma is approved under accelerated approval based on tumor response rate and duration of response. Continued approval for this indication may be contingent upon verification and description of clinical benefit in confirmatory trials.

Current Formulary Status/Prior Authorization Criteria:
GHP Family: NF (Medical Benefit requiring PA)

MBP 144.0 Tecentriq

1. **Locally Advanced or Metastatic Urothelial Carcinoma:**

- Prescription written by an oncologist **AND**
- Medical record documentation of a diagnosis of locally advanced or metastatic urothelial carcinoma **AND**
- Medical record documentation that the patient has had either:
    - Disease progression during or following platinum-containing chemotherapy **OR**
    - Disease progression within 12 months of neoadjuvant or adjuvant treatment with platinum-containing chemotherapy

2. **Non-Small Cell Lung Cancer:**

- Prescription written by an oncologist **AND**
- Medical record documentation of a diagnosis of non-small cell lung cancer **AND**
- Medical record documentation that the patient has had either:
    - Disease progression during or following platinum-containing chemotherapy **OR**
    - Disease progression on at least one FDA-approved therapy targeting EGFR or ALK if the patient has EGFR or ALK genomic tumor aberrations (e.g. mutation, deletion, insertion, etc.).

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.

Recommendations:

GHP Family: Tecentriq is currently a medical benefit requiring PA for GHP Family members. No changes are recommended at this time.

It is recommended that the following changes be made to the locally advanced or metastatic urothelial carcinoma criteria of policy MBP 144.0.

MBP 144.0

1. **Locally Advanced or Metastatic Urothelial Carcinoma:**

- Prescription written by an oncologist **AND**
- Medical record documentation of a diagnosis of locally advanced or metastatic urothelial carcinoma **AND**
- Medical record documentation of a contraindication to, intolerance to, or therapeutic failure on platinum-containing chemotherapy

It is recommended that the following notes are added to applicable policy:

Notes to reviewer:

- In clinical trials, contraindications to cisplatin-containing chemotherapy included: impaired renal function (CrCl greater than 30mL/min but less than 60mL/min), grade 2 or higher hearing loss or peripheral neuropathy, or ECOG performance status of 2.

- A therapeutic failure of platinum-containing chemotherapy is defined as disease progression during or following any platinum-containing chemotherapy, or within 12 months of neoadjuvant or adjuvant treatment.

Discussion: No comments or questions

Outcome: Tricia Heitzman 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

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IBRANCE **Keith Hunsicker**
(palbociclib)

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

Updated Dosing for New Indication[1]:

- Ibrance 125mg PO with food once daily for 21 consecutive days followed by 7 days off treatment for a 28-day cycle.
- When given with Ibrance, the recommended dose of fulvestrant is 500mg on days 1, 15, 29, and once monthly thereafter.
- Pre/perimenopausal women treated with Ibrance plus fulvestrant therapy should be treated with luteinizing hormone-releasing hormone (LHRH) agonists.

Current Formulary Status/Prior Authorization Criteria:
GHP Family: Pharmacy benefit on the **Brand** tier requiring PA

The current prior authorization criteria are:
1. Prescription written by an oncologist **AND**
2. Medical record documentation of age greater than or equal to 18 years **AND**
3. Medical record documentation of a diagnosis of hormone receptor positive, HER2 negative metastatic breast cancer **AND**
4. Medical record documentation that Ibrance will be prescribed in combination with letrozole **OR**
5. Medical record documentation that Ibrance is being used in combination with fulvestrant after disease progression on endocrine therapy

QUANTITY LIMIT: 21 capsules per 28 days, 28 day supply per fill

AUTHORIZATION DURATION: Initial approval will be for 3 months or less if the reviewing provider feels it is medically appropriate. Subsequent approvals will be for an additional 3 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.

Recommendations:
GHP Family: Ibrance is currently a pharmacy benefit on the **Brand** tier requiring PA. No changes are recommended at this time.

It is recommended that the existing policy be edited to read as the following:

- Prescription is written by an oncologist **AND**
- Medical record documentation of diagnosis of hormone-receptor positive (HR-positive), HER2-negative, advanced or metastatic breast cancer **AND**
- One of the following:
    - Ibrance is being prescribed as initial endocrine based therapy **AND**
    - Medical record documentation of postmenopausal status **AND**
    - Medical record documentation that Ibrance will be prescribed in combination with an aromatase inhibitor (i.e. letrozole, etc.)

    OR
    - Ibrance is being prescribed after disease progression following endocrine therapy **AND**
    - Medical record documentation of postmenopausal status OR pre/peri-menopausal status receiving ovarian suppression with a luteinizing hormone-releasing hormone (LHRH) agonist (i.e. goserelin, etc.) **AND**
    - Medical record documentation that Ibrance is being used in combination with fulvestrant

QUANTITY LIMIT: 21 capsules per 28 days, 28 day supply per fill

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

Discussion: No comments or questions

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

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

CLASS REVIEW:

GLP-1 AGONIST REVIEW **Aubrielle Prater**

Formulary Status

	GHP Family
Generic	
Brand	Victoza[#],Tanzeum[#]

* [#]ST Required

	Bydureon[1]	**Victoza[2]**	**Tanzeum[3]**	**Trulicity[4]**	**Soliqua[5]**	**Adlyxin[6]**	**Xultophy[7]**	**Byetta[8]**
Generic Name	Exenatide	Liraglutide	Albiglutide	Dulaglutide	Insulin glargine & lixisenatide	Lixisenatide	Insulin Degludec; Liraglutide	Exenatide
Manufacturer	AstraZeneca	Novo Nordisk	GlaxoSmithKline	Eli Lilly and Company	Sanofi-Aventis	Sanofi-Aventis	Novo Nordisk	AstraZeneca
How Supplied	Cartons of 4 single dose trays each containing: 1 vial with 2mg of exenatide, 1 syringe with 0.65ml diluent, 1 vial connector, 2 custom needles (23G, 5/16") specific to this delivery system (one needle is an extra)	Prefilled pens; 6 mg/mL solution	30 mg or 50 mg lyophilized powder in a single-dose Pen (pen injector) for reconstitution	0.75mg/0.5mL or 1.5mg/0.5mL in a single-dose pen	3mL single-patient use prefilled pens; 100 units/mL insulin glargine & 33 mcg/mL lixisenatide	50 mcg/mL in 3 mL (14 pre-set doses; 10 mcg/dose) 100 mcg/mL in 3 mL (14 pre-set doses; 20 mcg/dose)	100 units of insulin degludec per mL and 3.6 mg of liraglutide per mL in a 3-mL single-patient-use pen	250 mcg/mL exenatide in: 5 mcg/dose (60 doses), 1.2mL pen and 10 mcg/dose (60 doses), 2.4 mL pen
FDA Approval Date[6]	January 27, 2012	January 25, 2010	April 15, 2014	September 18, 2014	November 21, 2016	July 27, 2016	November 21, 2016	April 28, 2005

Clinical Review

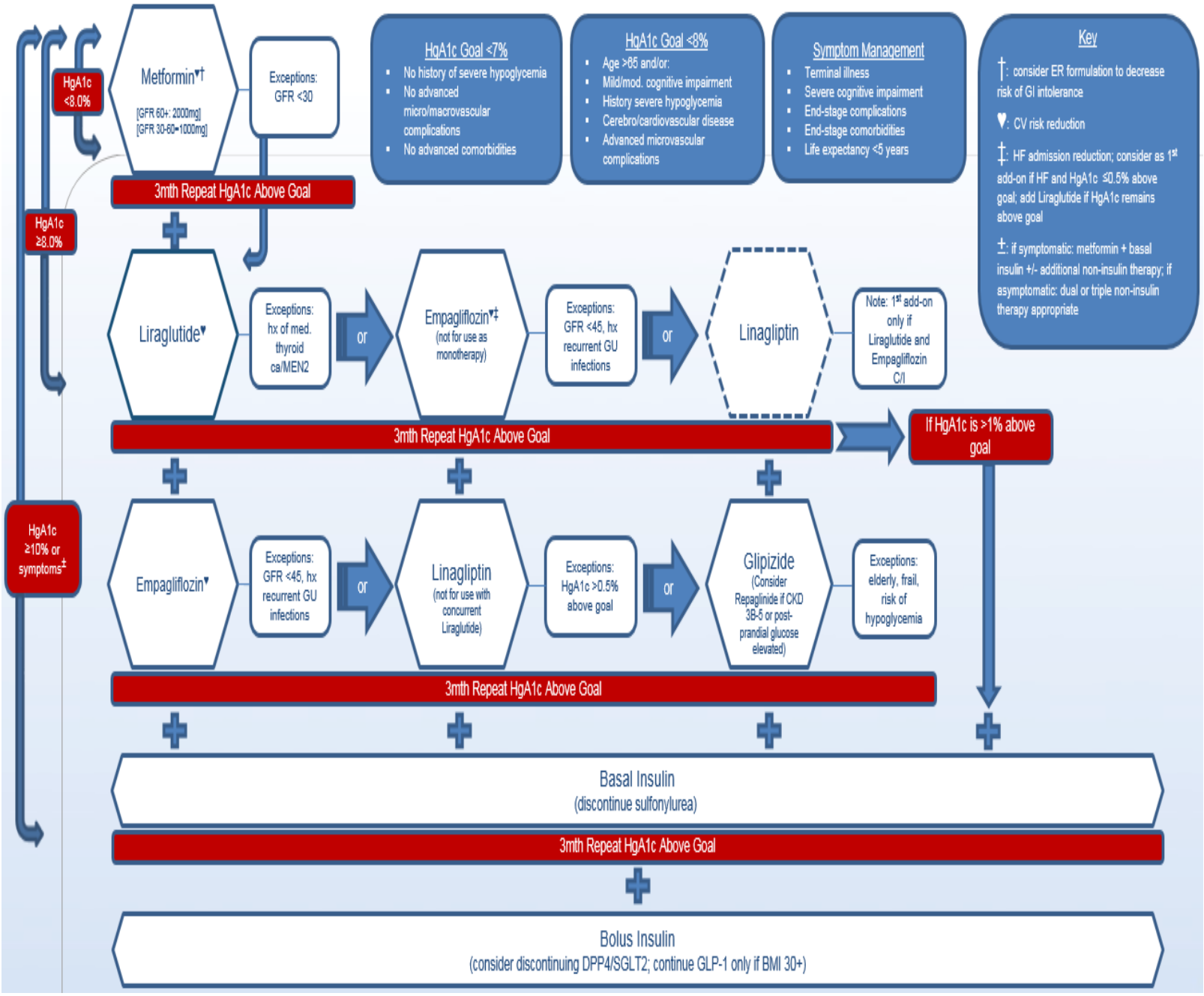
FDA Approved Indications[1-8]:

- Bydureon is indicated as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus.
- Victoza is indicated as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus.
- Tanzeum is indicated as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus.
- Trulicity is indicated as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus.
- Soliqua is indicated as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus inadequately controlled on basal insulin (less than 60 units daily) or lixisenatide.
- Adlyxin is indicated as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus.
- Xultophy is indicated as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus inadequately controlled on basal insulin (less than 50 units daily) or liraglutide (less than or equal to 1.8 mg daily).
- Byetta is indicated as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus.

Clinical Studies: Major clinical studies reviewed. Refer to class review

Other Considerations

System Carepath:



Clinical Summary

All GLP-1 agonists are indicated as adjunct to diet and exercise to improve glycemic control in patients with type 2 diabetes. Soliqua is indicated in patients inadequately controlled on basal insulin (less than 60 units daily) or lixisenatide. Xultophy is indicated in patients inadequately controlled on basal insulin (less than 50 units daily) or liraglutide (≤ 1.8 mg daily). All GLP-1 agonists are administered subcutaneously. Bydureon, Tanzeum, and Trulicity are once weekly formulations. Victoza, Soliqua, Adlyxin, Xultophy are administered once daily. Byetta is administered twice daily.

In the clinical comparator trials, Bydureon lowered A1c greater than Byetta. Liraglutide had statistically greater A1c reduction than Bydureon. Liraglutide also reduced fasting glucose and triglycerides greater than Bydureon. Liraglutide also had greater reduction in A1c compared to Byetta. Tanzeum provided less A1c reduction than liraglutide. Trulicity met non-inferiority margin when compared to liraglutide for A1c reduction. Patients taking liraglutide showed greater weight loss than those taking Trulicity. Trulicity reduced A1c greater than Byetta. Byetta lowered A1c more than Adlyxin. There was no difference in CV events comparing Adlyxin to placebo in patients taking metformin, sulfonylurea, or insulin. Xultophy lowered A1c more than liraglutide alone and basal insulin alone. Soliqua lowered A1c more than insulin glargine alone.

The LEADER trial demonstrated that Victoza reduced composite primary outcome (MI, stroke, or CV death) in patients at high risk or in patients with established CV disease. It is not known if other GLP-1 receptor agonists will have the same cardiovascular risk reduction, however Xultophy contains Victoza as a component, so it is suggested this product may provide CV risk reduction.

Most GLP-1 agonists have a black box warning for thyroid C-cell tumors, except for Soliqua, Adlyxin, and Byetta. The carepath directs clinicians to using metformin, Victoza, and Jardiance, due to the CV risk reduction. In patients who are taking metformin and Victoza for 3 months and A1c is > 1% of goal, a basal insulin can be added. The combination product, Xultophy, contains Victoza and Tresiba in one product, however it can only be used if a patient requires 16 units (Tresiba component) and no more than 50 units. The other GLP-1 agonist/basal insulin product, Soliqua, has a minimum dose of 15 units (Lantus component) and a maximum dose of 60 units. If patients require different doses outside of the ranges, a different product must be used.

For the long-acting agents, Trulicity has met the non-inferiority margin when compared to Victoza, in terms of A1c reduction. In other comparator trials, Bydureon and Tanzeum provided less A1c reduction than Victoza.

Formulary recommendations based on review:

GHP Family	
Bydureon	Bydureon is a pharmacy benefit and should remain non-formulary. Bydureon will require a prior authorization on the pharmacy benefit with the following criteria: • Medical record documentation of a diagnosis of Type 2 diabetes AND • Medical record documentation of a therapeutic failure on, intolerance to, or contraindication to Victoza* AND Tanzeum* *Step therapy required
Victoza	Victoza is a pharmacy benefit and should remain on formulary. Victoza will require step therapy: • Medical record documentation of current utilization of metformin or intolerance to or contraindication to metformin
Tanzeum	Tanzeum is a pharmacy benefit and should remain on formulary. Tanzeum will require step therapy: • Medical record documentation of current utilization of metformin or intolerance to or contraindication to metformin
Trulicity	Trulicity is a pharmacy benefit and should remain non-formulary. Trulicity will require prior authorization on the pharmacy benefit with the following criteria: • Medical record documentation of a diagnosis of type 2 diabetes mellitus AND • Medical record documentation of patient age > 18 years AND • Medical record documentation of a therapeutic failure on, intolerance to, or contraindication to Victoza* AND Tanzeum*

	*Step therapy required
Soliqua	Soliqua is a pharmacy benefit and should not be added to the formulary. Soliqua should require a prior authorization on the pharmacy benefits with the following criteria: • Medical record documentation of a diagnosis of Type 2 diabetes AND • Medical record documentation of therapeutic failure on, intolerance to, or contraindication to Xultophy* AND • Medical record documentation that the dose of Soliqua is being prescribed at a minimum of 15 units (15 units insulin glargine/5 mcg lixisenatide) and no more than 60 units (60 units of insulin glargine and 20 mcg of lixisenatide). *Step therapy required
Adlyxin	Adlyxin is a pharmacy benefit and should not be added to the formulary. Adlyxin should require a prior authorization on the pharmacy benefit with the following criteria: • Medical record documentation of a diagnosis of Type 2 diabetes AND • Medical record documentation of therapeutic failure on, intolerance to, or contraindication to metformin, Victoza*, and Tanzeum* *Step therapy required
Xultophy	Xultophy is a pharmacy benefit and should be added to the formulary. Xultophy will require step therapy: • Medical record documentation of therapeutic failure on, intolerance to, or contraindication to one formulary GLP-1 agonist or one formulary basal insulin product
Byetta	Byetta is a pharmacy benefit and should remain non-formulary. Byetta will require a prior authorization on the pharmacy benefit with the following criteria: • Medical record documentation of a diagnosis of Type 2 diabetes **AND** • Medical record documentation of therapeutic failure on, intolerance to, or contraindication to Victoza* and Tanzeum*

GHP Family	
Bydureon	Bydureon should remain non-formulary. Quantity Limit: 4 vials per 28 days
Victoza	Victoza should remain on the GHP Family formulary at the Brand Tier. Quantity Limit: 9 mL per 30 days
Tanzeum	Tanzeum should remain on the GHP Family formulary at the Brand Tier. Quantity Limit: 4 pens per 28 days
Trulicity	Trulicity should remain non-formulary. Quantity Limit: 2 mL per 28 days
Soliqua	Soliqua should not be added to the GHP Family formulary. No additional criteria should apply.
Adlyxin	Adlyxin should not be added to the GHP Family formulary. Quantity Limit: 6 mL per 30 days
Xultophy	Xultophy should be added to the GHP Family formulary at the Brand Tier. Quantity Limit: 15 mL per 30 days
Byetta	Byetta should remain non-formulary. Quantity Limit: For 5 mcg twice daily: 1.2 mL per 30 days For 10 mcg twice daily: 2.4 mL per 30 days

Discussion: No comments or questions

Outcome: Kim Clark 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

POLICY UPDATES:

GHP Family Policy Updates **Kevin Szczecina**

Recommendations:
Pulmozyme: While not approved for patients younger than 5 years, studies using Pulmozyme in small numbers of children as young as 3 months have reported efficacy and similar side effects. It is recommended that the age requirement be removed from the policies for all lines of business.

Itraconazole: Itraconazole is indicated for extrapulmonary aspergillosis but was missing from a list of acceptable diagnosis. It is recommended this indication be added to the policies for all lines of business.

Voriconazole: Itraconazole is indicated for esophageal candidiasis but was missing from the policies for all lines of business. It is recommended the applicable criterion be updated to (addition is underlined):

- There is medical record documentation of a diagnosis of invasive aspergillosis or <u>esophageal candidiasis</u> or fungal infection caused by *Scedosporium apiospermum* or fungal infection caused by *Fusarium* species with an Infectious Disease consult, preferably with a culture report to back the diagnosis.

Discussion: No comments or questions.

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.

Sovaldi **Kristi Clarke**

Recommendation:
Add: Medical record documentation of the member receiving an Food and Drug Administration (FDA) approved medication regimen that is inside the parameters of use approved by the FDA or supported in the widely used compendia available

Discussion: No comments or questions.

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

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

Quantity Limit Update **Kevin Szczecina**

Recommendation: The following quantity limits should be approved:

Brand Name	Generic Name	Dosage	QL to be added
Isentress 25 mg tablet	raltegravir	Based on weight	6 per day
Lexiva 700 mg tablet	fosamprenavir	Up to 1400 mg twice daily	4 per day
Lexiva 50 mg/mL suspension	fosamprenavir	Up to 1400 mg twice daily	56 mL per day
Oseltamivir 30 mg capsules	oseltamivir	Based on weight	20 capsules per 180 days
Synarel 2 mg/mL nasal solution	nafarelin	Up to 1800 mcg/day	1.14 mL per day

Discussion: No comments or questions.

Outcome: Tricia Heitzman 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.

AMPYRA **Kristen Scheib**

Recommendation: It is recommended that the criteria in the Ampyra policy be updated for GHP Family to reflect the following changes:

1.) Prescription is written by a neurologis AND
2.) Medical record documentation of a diagnosis of multiple sclerosis AND
3.) For members with a diagnosis of relapsing-remitting MS, medical record documentation that the member is currently receiving therapy with a formulary disease modifying agent or has had therapeutic failure on, intolerance to, or contraindication to ALL formulary disease modifying agents AND
4.) Medical record documentation that the member has difficulty walking or ambulating AND
5.) Medical record documentation of a baseline 25-foot walking speed

Authorization Duration:

Initial authorization will be for a period of 3 months. Continued authorization, after the initial 3 months, will be indefinite and will require medical record documentation of at least a 10% improvement in the timed 25 food walk speed, as compared to baseline submission.

Quantity Limit: 2 tablets/day

Discussion: No comments or questions.

Outcome: Todd Sponenberg 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.

FORTEO (teriparatide) **Aubrielle Prater**

Current Formulary Status: Forteo is a pharmacy benefit at the Brand Tier requiring a prior authorization for GHP Family.

Current Criteria for GHP Family Policy:

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

OR

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

Indication: Forteo is indicated for the treatment of postmenopausal women and osteoporosis at high risk for fracture, increase of bone mass in men with primary or hypogonadal osteoporosis at high risk for fracture, and treatment of men and women with glucocorticoid-induced osteoporosis at high risk of fracture. For the treatment of men and women with glucocorticoid-induced osteoporosis, the clinical trials included patients aged 22 to 89 years.

Recommendations: It is recommended that the criteria in the Forteo policies be updated for all lines of business to reflect the following changes:

- There is no medical record documentation of increased baseline risk of osteosarcoma [Paget's disease, open epiphyses (pediatric or young adult patients), prior radiation therapy involving the skeleton, unexplained elevations of alkaline phosphatase] **AND**
- **For women:**
    - There is medical record documentation of a diagnosis of osteoporosis **AND**

- There is medical record documentation of postmenopausal status or glucocorticoid-induced osteoporosis **AND**
- There is medical record documentation of an attempt of therapy with or contraindication to bisphosphonates **OR**
- There is medical record documentation of a previous osteoporotic fracture or high risk of fracture (T-score –2.5 or below with documented risk factors)

OR

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

Discussion: No comments or questions.

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

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

OPIOID AND BENZODIAZEPINE REFILL % — Kim Clark

The GHP Family point of sale claims systems is currently set-up to allow members to refill a medication after their on-hand supply is 85% exhausted.

Recommendation: In order to further combat the opioid crisis, it is recommended that the refill percentage be increased to 90% for medications which are classified as opioid analgesics and benzodiazepines.

Discussion: No comments or questions.

Outcome: Tricia Heitzman made a motion to accept the recommendations as written. 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.

Repatha and Praluent — Aubrielle Prater

Recommendation to Repatha Policy: It is recommended that the criteria in the Repatha policy be updated for GHP Family to reflect the following changes:

• Medical record documentation of a diagnosis of:

o Clinical atherosclerotic cardiovascular disease (ASCVD), including acute coronary syndromes (a history of myocardial infarction or unstable angina), coronary or other arterial revascularization, stroke, transient ischemic attack, or peripheral arterial disease presumed to be of atherosclerotic origin OR

o Heterozygous familial hypercholesterolemia (HeFH) AND either:

☐Genetic testing to confirm a mutation in the low-density lipoprotein (LDL) receptor, PCSK9, or ApoB gene OR

☐Medical record documentation of definite heterozygous familial hypercholesterolemia (HeFH) (score greater than 8) on the diagnostic criteria scoring system (Table 1) as defined by the European Society of Cardiology/European Atherosclerosis Society (ESC/EAS) guidelines and the World Health Organization OR

o Homozygous familial hypercholesterolemia (HoFH) AND either:

☐Genetic testing to confirm diagnosis showing at least one low density lipoprotein (LDL) receptor-defective mutation OR

☐Diagnosis made based on a history of an untreated low density lipoprotein cholesterol (LDL-C) greater than 500 mg/dL AND either xanthoma before 10 years of age OR evidence of heterozygous familial hypercholesterolemia (HeFH) in both parents AND

• Prescription must be written by a cardiologist or lipidologist AND

• Medical record documentation of a baseline low density lipoprotein (LDL) drawn within 3 months of the start of PCSK9 therapy

o Low density lipoprotein (LDL) greater than 100 if the patient has a diagnosis of heterozygous familial hypercholesterolemia (HeFH) or homozygous familial hypercholesterolemia (HoFH) and is using Repatha for primary prevention OR

o Low density lipoprotein (LDL) greater than 70 if the patient has a diagnosis of atherosclerotic cardiovascular disease (ASCVD) or either heterozygous familial hypercholesterolemia (HeFH) or homozygous familial hypercholesterolemia (HoFH) and is using Repatha for secondary prevention AND

• Medical record documentation that the patient is greater than or equal to 18 years of age if the diagnosis is clinical atherosclerotic cardiovascular disease (ASCVD) or heterozygous familial hypercholesterolemia (HeFH) OR medical record documentation that the patient is greater than or equal to 13 years of age if the diagnosis is homozygous familial hypercholesterolemia (HoFH) AND

• Medical record documentation that patient is currently on and is adherent to (taking at least 90% of prescribed doses over the past three months) maximally tolerated dose of atorvastatin or rosuvastatin or has documented therapeutic failure on, intolerance to, or contraindication to atorvastatin and rosuvastatin AND

• Medical record documentation that non-pharmacologic therapies are in place including cholesterol lowering diet, exercise, and weight management strategies AND

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

• Medical record documentation of a therapeutic failure on, intolerance to, or contraindication to ezetimibe AND

• Medical record documentation that Repatha is not being used in combination with another PCSK9 inhibitor, Juxtapid, or Kynamro

Recommendations to Praluent Policy: It is recommended that the criteria in the Praluent policy be updated for GHP Family to reflect the following changes:

• Medical record documentation of a diagnosis of:

o Clinical atherosclerotic cardiovascular disease (ASCVD), including acute coronary syndromes (a history of myocardial infarction or unstable angina), coronary or other arterial revascularization, stroke, transient ischemic attack, or peripheral arterial disease presumed to be of atherosclerotic origin OR

o Heterozygous familial hypercholesterolemia AND either:

☐Genetic testing to confirm a mutation in the low-density lipoprotein (LDL) receptor, PCSK9, or ApoB gene OR

☐Medical record documentation of definite heterozygous familial hypercholesterolemia (HeFH) (score greater than 8) on the diagnostic criteria scoring system (Table 1) as defined by the European Society of Cardiology/European Atherosclerosis Society (ESC/EAS) guidelines and the World Health Organization AND

• Prescription must be written by a cardiologist or lipidologist AND
• Medical record documentation of a baseline low density lipoprotein (LDL) drawn within 3 months of the start of PCSK9 therapy showing:
  o Low density lipoprotein (LDL) greater than 100 if the patient has a diagnosis of heterozygous familial hypercholesterolemia (HeFH) and is using Praluent for primary prevention OR
  o Low density lipoprotein (LDL) greater than 70 if the patient has a diagnosis of atherosclerotic cardiovascular disease (ASCVD) or heterozygous familial hypercholesterolemia (HeFH) and is using Praluent for secondary prevention AND
• Medical record documentation that the patient is greater than or equal to 18 years of age AND
• Medical record documentation that patient is currently on and is adherent to (taking at least 90% of prescribed doses over the past three months) maximally tolerated dose of atorvastatin or rosuvastatin or has documented therapeutic failure on, intolerance to, or contraindication to atorvastatin and rosuvastatin AND
• Medical record documentation that non-pharmacologic therapies are in place including cholesterol lowering diet, exercise, and weight management strategies AND
• Medical record documentation of a therapeutic failure on, intolerance to, or contraindication to a bile acid sequestrant or fibrate OR medical record documentation of a low-density lipoprotein (LDL) greater than or equal to 100 AND
• Medical record documentation of a therapeutic failure on, intolerance to, or contraindication to ezetimibe AND
• Medical record documentation that Praluent is not being used in combination with another PCSK9 inhibitor, Juxtapid, or Kynamro

Recommendations to Reauthorization Criteria: It is recommended that the criteria for reauthorization in the Repatha/Praluent policies be updated for GHP Family to reflect the following changes:

- Medical record documentation of an up to date low density lipoprotein (LDL) cholesterol level since the date of the previous review showing the patient has had a clinically significant response to treatment with a PCSK9 inhibitor AND
- Medical record documentation that the patient is not experiencing any significant adverse events related to therapy AND
- Claims history and attestation from the provider showing the patient is adherent to PCSK9 therapy AND
- Claims history or attestation from the provider that the patient is staying adherent to (filling at least 90% of doses) statin therapy (if statin tolerant) AND
- Medical record documentation that Repatha continues to not be used in combination with another PCSK9 inhibitor, Juxtapid, or Kynamro

Recommendations to Quantity Limit for Repatha: It is recommended to update the Quantity Limit for GHP Family Repatha policy to include:
Repatha Pushtronex 3.5 ml every 28 days

Discussion: No comments or questions.

Outcome: Kim Clark 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.

KINERET/ CAPS UPDATE **Aubrielle Prater**
(anakinra)

Current Criteria for GHP Family Kineret Policy:

For Rheumatoid Arthritis:
A formulary exception for coverage of Kineret may be made for members who meet all the following criteria:

- 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
- Member must be at least 18 years of age AND
- Must be prescribed by a rheumatologist AND
- Medical record documentation of an intolerance to, contraindication to, or therapeutic failure on a minimum 3 month trial of Humira* and Enbrel*

For Neonatal-Onset Multisystem Inflammatory Disease
A formulary exception for coverage of Kineret may be made for members who meet all of the following criteria:

- Medical record documentation of diagnosis of Neonatal-Onset Multisystem Inflammatory Disease AND
- Must be prescribed by an immunologist, rheumatologist, or allergist

Indication: Kineret has been given orphan drug designation for the treatment of cryopyrin-associated periodic syndromes. This was approved August 19, 2010.

Recommendations from National Agencies or Organizations: Per UpToDate, there are three types of cryopyrin-associated periodic syndromes: Familial Cold Autoinflammatory Syndrome (FCAS), Muckle-Wells Syndrome, and Neonatal-Onset Multisystem Inflammatory Disease. The medications used for cryopyrin-associates periodic syndromes (CAPS) includes anakinra, rilonacept, canakinumab. For patients with FCAS, anakinra given subcutaneously once daily can prevent cold-induced attacks and reduce daily symptoms. Anakinra has led to reductions in proteinuria and stabilized serum creatinine in patients who have renal secondary amyloidosis due to CAPS. Anakinra also can control systemic inflammation in Muckle-Wells Syndrome and potentially has an impact on amyloid risk through normalization of serum amyloid A protein. For Neonatal-Onset Multisystem Inflammatory Disease, anakinra has improved signs and symptoms related to inflammation in some cases. Bone and joint abnormalities are less responsive to anakinra.

Specialist's Feedback: Dr. David Bulbin, DO, rheumatologist, stated that Kineret is as effective as Arcalyst and Ilaris for CAPS. He mentioned that some patients may want fewer injections and Kineret is administered daily. Arcalyst is administered weekly and Ilaris is administered every 8 weeks. He also mentioned that adenosine deaminase deficiency may be an exception to Kineret use, however this is very rare. Dr. Peter Nigrovic wrote the UpToDate article regarding CAPS. He mentioned that failure on Kineret and/or Ilaris is appropriate before treating a patient with Arcalyst. We discussed preferring Kineret to Ilaris and he mentioned that it is hard to require failure on Kineret given that the injections are daily compared to Ilaris injections, which are administered every 2 to 3 months. He said in most cases

therapy is lifelong and daily injections are difficult, especially for children. Ilaris injection frequency is patient specific and is determined by monitoring (e.g. clinical symptoms, MRI, inflammatory markers). He mentioned a study recently published by the NIH which suggests that Kineret may be more effective for CNS manifestations.

Recommendations to Kineret Policies:
It is recommended that the criteria in the Kineret policy be updated to include the following indication:

- Medical record documentation of diagnosis of Cryopyrin–Associated Periodic Syndrome (CAPS), including Familial Cold Autoinflammatory Syndrome (FCAS), and Muckle-Wells Syndrome (MWS) supported by documentation of genetic testing to identify the CIAS1/NLRP-3 gene mutation AND
- Must be prescribed by an immunologist, rheumatologist, or allergist

Authorization Duration: The initial approval will be for a time period of 12 weeks, requiring medical record documentation of improvement in signs and symptoms of CAPS. Kineret will then require approval on a yearly basis.

Recommendations to Ilaris Policies:
GHP Family: It is recommended that the criteria for CAPS in the Ilaris Policy MBP77.0 be updated to include the following:

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

Recommendations to Arcalyst Policies:
GHP Family: It is recommended that the criteria in the Arcalyst Policy 1145.0F be updated to include the following:

- Medical record documentation of therapeutic failure on, intolerance to, or contraindication to Kineret AND Ilaris

The following should be **removed** from the current policy: **For a NOMID Diagnosis, the Geisinger Health Plan would require failure on Anakinra and Ilaris, in that order, prior to approval of Arcalyst**

AUTHORIZATION DURATION: The initial approval will be for a time period of 12 weeks, requiring medical record documentation of improvement in signs and symptoms of CAPS. Arcalyst will then require approval on a yearly basis.

Discussion: No comments or questions.

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

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

Spinosad **Kevin Szczecina**

Recommendation: Add Spinosad to the formulary without restriction.

Discussion: No comments or questions.

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

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

Meeting adjourned at 4:27 pm.

Future Scheduled Meetings
July 18, 2017 at 1:00 HCN3A & 3B Conference room

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