GHP FAMILY MINUTES

P&T Meeting Minutes

January 17, 2017

P&T Committee Meeting Minutes
GHP Family Business
January 17, 2017

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

Call to Order:
Bret Yarczower called the meeting to order at 1:01 p.m., Tuesday, January 17, 2017.

Review and Approval of Minutes:
Dr. Bret Yarczower asked for a motion or approval to accept the November 15, 2016 minutes as written. Kevin Szczecina accepted the motion and Todd Sponenberg seconded the motion. None were opposed.

DRUG REVIEWS:

LARTRUVO **Kim Clark**
(olaratumab)

Kim Clark provided a review of Lartruvo to the committee for consideration as a pharmacy and medical benefit. Lartruvo is a platelet-derived growth factor receptor alpha (PDGFR-α) blocking antibody indicated, in combination with doxorubicin, for the treatment of adult patients with soft tissue sarcoma (STS) with a histologic subtype for which an anthracycline-containing regimen is appropriate and which is not amendable to curative treatment with radiotherapy or surgery. This indication is approved under accelerated approval. Continued approval for this indication may be contingent upon verification and description of clinical benefit in confirmatory trials.

Proposed Clinical Recommendations: Lartruvo will be considered a medical benefit for GHP Family. In order to ensure appropriate utilization, it is recommended that the following prior authorization criteria apply:

- Must be prescribed by an oncologist/hematologist **AND**
- Medical record documentation of age greater than or equal to 18 years **AND**
- Medical record documentation of a diagnosis of soft tissue sarcoma with a histologic subtype for which an anthracycline-containing regimen is appropriate and which is not amenable to curative treatment with radiotherapy or surgery **AND**
- Medical record documentation that Lartruvo will be administered in combination with doxorubicin for the first eight (8) treatment cycles

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.

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.

Lartruvo is the first new therapy approved by the FDA for the initial treatment of soft tissue sarcoma since doxorubicin's approval more than 40 years ago.

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

Proposed Financial Recommendations: It is recommended that Lartruvo be considered a medical benefit. No further prior authorization criteria recommended

Financial Discussion: No questions or comments.

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

Approved Recommendations: Lartruvo will be considered a medical benefit with GHP Family with the following prior authorization:

- Must be prescribed by an oncologist/hematologist **AND**
- Medical record documentation of age greater than or equal to 18 years **AND**
- Medical record documentation of a diagnosis of soft tissue sarcoma with a histologic subtype for which an anthracycline-containing regimen is appropriate and which is not amenable to curative treatment with radiotherapy or surgery **AND**
- Medical record documentation that Lartruvo will be administered in combination with doxorubicin for the first eight (8) treatment cycles

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.

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

XIIDRA **Aubrielle Prater**
(lifitegrast ophthalmic solution)

Aubrielle Prater provided a review of Xiidra to the committee for consideration as a pharmacy benefit. Xiidra is indicated for the treatment of the signs and symptoms of dry eye disease (DED).

Formulary alternatives: OTC lubricating drops and ointments

Proposed Clinical Recommendations: Xiidra will not be added to the GHP Family formulary and will be considered non-formulary.

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.

Xiidra is the first drug approved to treat the signs and symptoms of dry eye disease. Restasis is the only other prescription agent that is indicated for the treatment of dry eyes. The indication of Restasis is to increase tear production in patients whose tear production is presumed to be suppressed due to ocular inflammation associated with keratoconjunctivitis sicca. The trials for the FDA-approval of Restasis analyzed the signs of dry eye disease, not the symptoms. The primary efficacy outcome was the Schirmer

wetting test and found significant improvement at 6 months with Restasis. The significance was observed in patients who had tear production that was suppressed by ocular inflammation. Increased tear production was not observed in patients currently taking topical anti-inflammatory drugs or using punctal plugs. A 158 patients with dry eye symptoms (mild, moderate, severe) despite the use of artificial tears were included in a prospective cohort to evaluate the use of Restasis. Patients showed improvement in symptoms, Schirmer scores, and mean tear breakup times compared to baseline.

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

Proposed Financial Recommendations: It is recommended that Xiidra not be added to the GHP Family formulary.

Financial Discussion: No questions or comments.

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

Approved Recommendations: Xiidra will not be added to the GHP Family formulary.

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

EXONDYS 51 **Keith Hunsicker**
(eteplirsen)

Keith Hunsicker provided a review of Exondys 51 to the committee for consideration as both a pharmacy and medical benefit. Exondys 51 is indicated for the treatment of Duchenne muscular dystrophy (DMD) in patients who have a confirmed mutation of the DMD gene that is amenable to exon 51 skipping. This indication is approved under accelerated approval based on an increase in dystrophin in skeletal muscle observed in some patients treated with Exondys 51. A clinical benefit of Exondys 51 has not been established. Continued approval for this indication may be contingent upon verification of a clinical benefit in confirmatory trials.

Exondys 51 will be available by limited distribution only to two specialty/home infusion pharmacies, Orsini Healthcare and Option Care.

Formulary alternatives: none

Proposed Clinical Recommendations:
Exondys 51 is a medical benefit for GHP Family. The following prior authorization criteria should apply.

- Medical record documentation of interdisciplinary team involvement including, at a minimum, neurology, cardiology, pulmonology, and a genetic specialist (e.g. geneticist, genetic counselor, etc.) **AND**
- Medical record documentation of Duchenne's Muscular Dystrophy (DMD) confirmed by genetic testing **AND**
- Medical record documentation that the member has a confirmed mutation of the DMD gene that is amenable by exon 51 skipping confirmed by a genetic counselor (including, but not limited to mutation numbers: 45-50, 48-50, 49-50, 50, and 52) **AND**

- Medical record documentation that Exondys 51 is being given concurrently with oral corticosteroids **AND**
- Medical record documentation that the patient is ambulatory (e.g. able to walk with assistance, not wheelchair bound, does not have full-time dependence on motorized wheelchairs or scooters for mobility) **AND**
- Medical record documentation of a baseline 6-Minute Walk Test Distance (6MWT) of at least 200 meters within 3 months of initiation of Exondys 51.

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. For geriatric use, Exondys 51 has not been studied in patients 65 years of age or older. The pharmacokinetics of eteplirsen has been only evaluated in pediatric DMD patients.

Exondys 51 is the only medication indicated for the treatment of DMD. Exondys 51 is not a curative treatment as it functions to alter protein production to produce a partially functioning component rather than "fix" the underlying problem causing the lack of dystrophin.

A clinical discussion occurred regarding the required for ambulatory status and 6MWT. Specialist feedback was also reviewed. Bret Yarczower explained that skeletal muscle reserve is needed for this medication to have a chance at being effective. 200 meters what was used in the study. It was recommended that the last 2 bullet points of the authorization criteria be modified as follows:

- Medical record documentation that the patient is ambulatory (e.g. able to walk with assistance, not wheelchair bound, does not have full-time dependence on motorized wheelchairs or scooters for mobility) as proven by documentation of a 6-Minute Walk Test Distance (6MWT) within the past 3 months of initiation of Exondys 51.

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

Proposed Financial Recommendations: Exondys 51 is a medical benefit for GHP Family. No additional prior authorization criteria should apply. The following authorization duration and reauthorization criteria should apply:

Authorization Duration: If approved, Exondys 51 should be approved for an authorization duration of **6 months**. Subsequent authorizations will be for **6 months** and require medical record documentation of the following:

- Medical record documentation that Exondys 51 is being given concurrently with oral corticosteroids **AND**
- Medical record documentation that the patient remains ambulatory (e.g. able to walk with assistance, not wheelchair bound, does not have full-time dependence on motorized wheelchairs or scooters for mobility) as proven by documentation of a follow-up 6-Minute Walk Test Distance (6MWT) within the past 6 months

Financial Discussion: No comments or questions.

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

Approved Recommendations: Exondys 51 will be considered a medical benefit with the following prior authorization requirements:

- Medical record documentation of interdisciplinary team involvement including, at a minimum, neurology, cardiology, pulmonology, and a genetic specialist (e.g. geneticist, genetic counselor, etc.) **AND**
- Medical record documentation of Duchenne's Muscular Dystrophy (DMD) confirmed by genetic testing **AND**
- Medical record documentation that the member has a confirmed mutation of the DMD gene that is amenable by exon 51 skipping confirmed by a genetic counselor (including, but not limited to mutation numbers: 45-50, 48-50, 49-50, 50, and 52) **AND**
- Medical record documentation that Exondys 51 is being given concurrently with oral corticosteroids **AND**
- Medical record documentation that the patient is ambulatory (e.g. able to walk with assistance, not wheelchair bound, does not have full-time dependence on motorized wheelchairs or scooters for mobility) as proven by documentation of a 6-Minute Walk Test Distance (6MWT) within the past 3 months of initiation of Exondys 51. Additional evidence of the criteria used to make this decision can be found in the drug review presented to the committee.

Authorization Duration: If approved, Exondys 51 should be approved for an authorization duration of **6 months**. Subsequent authorizations will be for **6 months** and require medical record documentation of the following:

- Medical record documentation that Exondys 51 is being given concurrently with oral corticosteroids **AND**
- Medical record documentation that the patient remains ambulatory (e.g. able to walk with assistance, not wheelchair bound, does not have full-time dependence on motorized wheelchairs or scooters for mobility) as proven by documentation of a follow-up 6-Minute Walk Test Distance (6MWT) within the past 6 months

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

ZURAMPIC **Aubrielle Prater**
(Lesinurad)

Aubrielle Prater provided a review of Zurampic to the committee for consideration as a pharmacy benefit. Zurampic is indicated in combination with a xanthine oxidase inhibitor for the treatment of hyperuricemia associated with gout in patients who have not achieved target serum uric acid levels with a xanthine oxidase inhibitor.

Limitations of use: Zurampic is not recommended for the treatment of asymptomatic hyperuricemia and should not be used as monotherapy.

Formulary alternatives: allopurinol, probenecid

Proposed Clinical Recommendations:
Zurampic will be a pharmacy benefit. It is recommended that Zurampic not be added to the GHP Family formulary. Zurampic should require a prior authorization with the following criteria:

- Medical record documentation of age greater than or equal to 18 years AND
- Medical record documentation of symptomatic hyperuricemia associated with gout AND
- Medical record documentation that patient has been on a stable dose of allopurinol of at least 300 mg (or at least 200 mg in patients with estimated creatinine clearance (eCLcr < 60 mL/min)) or febuxostat and did not achieve target serum uric acid levels AND
- Medical record documentation that Zurampic will be co-administered with a xanthine oxidase inhibitor (allopurinol or febuxostat) AND
- Medical record documentation of an estimated creatinine clearance (eCLCr) ≥ 45 mL/min AND
- Medical record documentation that Zurmapic is not being used in tumor lysis syndrome, Lesch-Nyhan syndrome, and kidney transplant recipients.

Quantity Limit: 1 tablet per day

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.

Zurampic is indicated in combination with a xanthine oxidase inhibitor for the treatment of hyperuricemia associated with gout in patients who have not achieved target serum uric acid levels with a xanthine oxidase inhibitor. Zurampic is not recommended for the treatment of asymptomatic hyperuricemia and should not be used as monotherapy. Zurampic is supplied as 200 mg tablets. The recommended dose of Zurampic is 200 mg once daily, by mouth, in the morning with food and water. The maximum dose is Zurampic 200 mg once daily. Lesinurad reduces serum uric acid levels by inhibiting the function of transporter proteins (URAT1 and OAT4) responsible for the reabsorption of uric acid in the kidney. In the clinical trials, Zurampic and allopurinol had a significant decrease in uric acid levels < 6 mg/dL by Month 6 compared to allopurinol alone. However, there was no statistically significant difference in gout flares from the end of Month 6 to the end of Month 12. When comparing Zurampic and febuxostat to febuxostat alone, there was no statistically significant difference in uric levels < 5 mg/dL by Month 6 and gout flares from the end of Month 6 to the end of Month 12. There was also no statistically significant difference in resolution of 1 or more tophi between Zurampic and febuxostat verses febuxostat monotherapy. Zurampic has a Black Box Warning for acute renal failure, most common when used as monotherapy. The most common adverse reactions in patients taking Zurampic in combination with xanthine oxidase inhibitor (≥ 2%) were headache, influenza, blood creatinine increased, and GERD. Zurampic is contraindicated in patients with severe renal impairment (CrCl < 30 mL/min), end stage renal disease, kidney transplant recipients, or on dialysis. It is also contraindicated in patients with tumor lysis syndrome or Lesch-Nyhan syndrome. Zurampic should not be initiated in patients with a CrCl < 45 mL/min. No dose adjustment is recommended in patients with CrCl 45 to < 60 mL/min, but more frequent renal monitoring is

recommended. Zurampic should be discontinued when CrCl is persistently < 45 mL/min. Zurampic is not recommended for use in patients with severe hepatic impairment.

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

Proposed Financial Recommendations: It is recommended that Zurampic not be added to the GHP Family formulary. The following additional prior authorization criteria should apply to requests:

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

Financial Discussion: No comments or questions.

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

Approved Recommendations: Zurampic will not be added to the GHP Family formulary. The following prior authorization criteria will apply to requests:

- Medical record documentation of age greater than or equal to 18 years AND
- Medical record documentation of symptomatic hyperuricemia associated with gout AND
- Medical record documentation that patient has been on a stable dose of allopurinol of at least 300 mg (or at least 200 mg in patients with estimated creatinine clearance (eCLcr < 60 mL/min)) or febuxostat and did not achieve target serum uric acid levels AND
- Medical record documentation that Zurampic will be co-administered with a xanthine oxidase inhibitor (allopurinol or febuxostat) AND
- Medical record documentation of an estimated creatinine clearance (eCLCr) ≥ 45 mL/min AND
- Medical record documentation that Zurmapic is not being used in tumor lysis syndrome, Lesch-Nyhan syndrome, and kidney transplant recipients AND
- Medical record documentation of a therapeutic failure on, intolerance to, or contraindication to probenecid.

Quantity limits: 1 tablet/day

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

AMELUZ **Kim Clark**
(aminolevulinic acid hydrochloride)

Kim Clark provided a review of Ameluz to the committee for consideration as a medical benefit. Ameluz gel, a porphyrin precursor, in combination with photodynamic therapy using BF-RhodoLED lamp, is indicated for the lesion-directed and field-directed treatment of actinic keratosis (AK) of mild-to-moderate severity on the face and scalp.

Formulary alternatives: fluorouracil 5% cream/solution, imiquimod 5% cream

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Proposed Clinical Recommendations:
Ameluz will be considered a medical benefit for Geisinger GHP Family. The manufacturer of Ameluz does not participate with the Medicare program at this time and is therefore not eligible for coverage under the Medicaid benefit. In the event that Ameluz becomes eligible for coverage it is recommended that it be covered as a medical benefit for GHP Family. The following prior authorization criteria should apply to requests for Ameluz:

- Must be prescribed by a dermatologist **AND**
- Medical record documentation of a diagnosis of actinic keratosis of mild-to-moderate severity on the face and/or scalp **AND**
- Medical record documentation of age greater than or equal to 18 years **AND**
- Medical record documentation of therapeutic failure on, intolerance to, or contraindication to topical fluorouracil **AND**
- Medical record documentation that Ameluz will be used in conjunction with the BF-RhodoLED lamp

Quantity Limit: 2 grams (1 tube) per application

Authorization duration: Initial approval will be for a period of 3 months. One additional 3 month approval may be granted if there is medical record documentation that lesions have not completely resolved within 3 months after the initial treatment

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.

Clinical Outcome: Todd Sponenberg made a motion to accept the recommendations as written. Lisa Mazonkey seconded the motion. None were opposed.

Proposed Financial Recommendations: Ameluz will be considered a medical benefit requiring prior authorization for Geisinger GHP Family in the event that Ameluz becomes eligible for coverage.

Financial Discussion: No questions or comments.

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

Approved Recommendations: Ameluz will be considered a medical benefit requiring prior authorization for GHP Family in the event that Ameluz becomes eligible for coverage with the following utilization management requirements:

- Must be prescribed by a dermatologist **AND**
- Medical record documentation of a diagnosis of actinic keratosis of mild-to-moderate severity on the face and/or scalp **AND**
- Medical record documentation of age greater than or equal to 18 years **AND**

- Medical record documentation of therapeutic failure on, intolerance to, or contraindication to topical fluorouracil **AND**
- Medical record documentation that Ameluz will be used in conjunction with the BF-RhodoLED lamp

Quantity Limit: 2 grams (1 tube) per application

Authorization duration: Initial approval will be for a period of 3 months. One additional 3 month approval may be granted if there is medical record documentation that lesions have not completely resolved within 3 months after the initial treatment

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

SUSTOL **Keith Hunsicker**
(granisetron ER)

Keith Hunsicker provided a review of Sustol to the committee for consideration as medical benefit. Sustol is indicated in combination with other antiemetics in adults for the prevention of acute and delayed nausea and vomiting associated with initial and repeat courses of moderately emetogenic chemotherapy (MEC) or anthracycline and cyclophosphamide (AC) combination chemotherapy regimens.

Formulary alternatives: ondansetron, ondansetron ODT, ondansetron solution

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Proposed Clinical Recommendations:
Sustol is a medical benefit for GHP Family formulary. The following prior authorization criteria should apply.

- Medical record documentation of a diagnosis that Sustol is being used for the prevention of acute or delayed nausea and vomiting associated with initial or repeat courses of moderately emetogenic chemotherapy (MEC) or anthracycline and cyclophosphamide (AC) combination chemotherapy regimens **AND**
- Medical record documentation that Sustol is being given in combination with dexamethasone **AND**
- Medical record documentation that member has a treatment failure or contraindication to Aloxi.

OR

- Medical record documentation that Sustol is being used for prevention of acute or delayed chemotherapy induced nausea and vomiting from low, or minimally emetogenic chemotherapy for members who have a treatment failure or contraindication to Aloxi (palonosetron) **AND** ondansetron OR granisetron **AND**
- Medical record documentation that Sustol is being given in combination with dexamethasone.

The following antineoplastic agents are considered MODERATELY emetogenic (not a complete list):

- Aldesleukin >12-15 million IU/m^2
- Amifostine >300 mg/m^2
- Arsenic trioxide
- Azacitidine
- Bendamustine
- Busulfan
- Carboplatin
- Carmustine $\leq$ 250 mg/m^2
- Clofarabine
- Cyclophosphamide $\leq$ 1500mg/m^2
- Cytarabine >200mg/m^2
- Dactinomycin
- Daunorubicin
- Dinutuximab
- Doxorubicin <60 mg/m^2
- Epirubicin $\leq$ 90 mg/m^2
- Idarubicin
- Ifosfamide <2 g/m^2 per dose
- Interferon alfa $\geq$ 10 million IU/m^2
- Irinotecan
- Melphalan
- Methotrexate $\geq$250 mg/m^2
- Oxaliplatin
- Temozolomide
- Trabectedin

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.

Sustol (granisetron ER) is a first in class extended-release 5-HT_3 antagonist given via subcutaneous injection no more frequent than every 7 days. It is indicated for the treatment of prevention of acute and delayed nausea and vomiting associated with initial and repeat courses of moderately emetogenic chemotherapy (MEC) or anthracycline and cyclophosphamide (AC) combination chemotherapy regimens. In clinical trials, Sustol was proven to be noninferior to palonosetron (Aloxi) for this indication. The most common adverse events reported are injection site reactions, constipation, and headache. There are not currently NCCN recommendations for the use of Sustol.

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

Proposed Financial Recommendations: Sustol will be considered a medical benefit for GHP Family. No additional prior authorization criteria should apply, however, the following auth duration and quantity limits were recommended:

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

Quantity Limit: One 10mg syringe per 7 days (FDA Max Dosing)

Financial Discussion: No comments or questions.

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

Approved Recommendations: Sustol will be considered a medical benefit for GHP Family. The following criteria will apply to prior authorization requests for Sustol:

- Medical record documentation of a diagnosis that Sustol is being used for the prevention of acute or delayed nausea and vomiting associated with initial or repeat courses of moderately emetogenic chemotherapy (MEC) or anthracycline and cyclophosphamide (AC) combination chemotherapy regimens **AND**
- Medical record documentation that Sustol is being given in combination with dexamethasone **AND**
- Medical record documentation that member has a treatment failure or contraindication to Aloxi.

OR

- Medical record documentation that Sustol is being used for prevention of acute or delayed chemotherapy induced nausea and vomiting from low, or minimally emetogenic chemotherapy for members who have a treatment failure or contraindication to Aloxi (palonosetron) **AND** ondansetron OR granisetron **AND**
- Medical record documentation that Sustol is being given in combination with dexamethasone.

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

Quantity Limit – All LOB: One 10mg syringe per 7 days (FDA Max Dosing)

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

FAST FACTS:

INVOKAMET XR **Aubrielle Prater**
(canagliflozin/metformin)

Updated Formulation: Invokamet is now available as extended-release tablets.

Clinical discussion: FDA Approved Indications, Clinical Evidence of Safety and Efficacy, Dosing Schedule, Warnings and Precautions, and Recommendations of National Agencies and Organizations were discussed.

Current Formulary Status/Prior Authorization Criteria:
Invokamet is a pharmacy benefit at Brand Preferred tier requiring ST. The following criteria applies to Invokamet:

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

Quantity Limit: 2 tablets per day

Recommendation:
It is recommended to add Invokamet XR to formulary at the same Tier as Invokamet. The same criteria and quantity limits will also apply.

Discussion: No comments or questions.

Outcome: Jamie Dodson made a motion to accept the recommendations as written. Lisa Mazonkey 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[1]: Keytruda is now indicated in patients:

1. With metastatic non-small cell lung cancer (NSCLC) whose tumors have high PD-L1 expression (Tumor Proportion (TPS) greater than or equal to 50%) as determined by an FDA-approved test, with no EGFR or ALK genomic tumor aberrations.
2. With metastatic NSCLC whose tumors express PD-L1 (TPS greater than or equal to 1%) as determined by an FDA-approved test, with disease progression on or after platinum-containing chemotherapy. Patients with EGFR or ALK genomic tumor aberrations should have clinical progression on FDA-approved therapy for these aberrations prior to receiving Keytruda.

Updated Dosing for New Indication[1]:

- Select patients for treatment of metastatic NSCLC with Keytruda based on the presence of positive PD-L1 expression.
- Keytruda 200mg IV over 30 minutes every 3 weeks until disease progression, unacceptable toxicity, or up to 24 months in patients without disease progression.

Current Formulary Status:
Medical benefit requiring PA.

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 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 non-small cell lung cancer (NSCLC) with tumor expression of PD-L1 as determined by an FDA-approved test and disease progression while on or after platinum-based chemotherapy.

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 the member experiences toxicity or worsening of disease.

Recommendation:
Keytruda is currently a medical benefit requiring prior authorization. No changes are recommended at this time.

It is recommended that the policy be changed to read the following:

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 (NSCLC)**
    - Prescription written by a hematologist/oncologist **AND**
    - Medical record documentation that patient is ≥ 18 years of age **AND**
    - Medical record documentation of a diagnosis of metastatic NSCLC meeting one of the following situations:
        - Medical record documentation 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 the member experiences toxicity or worsening of disease.

No changes are recommended to the unresectable/metastatic melanoma, head and neck squamous cell carcinoma, or authorization duration sections.

Discussion: No comments or questions.

Outcome: Kevin Szczecina made a motion to accept the recommendations as modified. Jamie Dodson 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.

DARZALEX **Aubrielle Prater**
(daratumumab)

Updated Indication[1]: Darzalex is now indicated in combination with lenalidomide and dexamethasone, or bortezomib and dexamethasone, for the treatment of patients with multiple myeloma who have received at least one prior therapy.

Note: Darzalex was previously approved as monotherapy for the treatment of patients with multiple myeloma who have received at least three prior lines of therapy including a proteasome inhibitor (PI) and an immunomodulatory agent or who are double-refractory to a PI and an immunomodulatory agent.

Current Formulary Status/Prior Authorization criteria:
Medical benefit requiring PA.

- Prescription written by a hematologist/oncologist AND
- Medical record documentation of a diagnosis of multiple myeloma AND
- One of the following:
  - Medical record documentation of therapeutic failure on, intolerance to, or contraindication to at least three prior lines of therapy including a proteasome inhibitor (including but not limited

to Velcade*, Kyprolis*, or Ninlaro*) and an immunomodulatory agent (including but not limited to Pomalyst*, Revlimid*, Thalomid*) OR
    - Medical record documentation that the patient is double-refractory to a proteasome inhibitor (including but not limited to Velcade*, Kyprolis*, or Ninlaro*) and an immunomodulatory agent (including but not limited to Pomalyst*, Revlimid*, Thalomid*)

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.

Recommendation:
There are no changes to the tiering status at this time.

The following changes are recommended to the current prior authorization criteria:
- Prescription written by a hematologist/oncologist AND
- Medical record documentation of a diagnosis of multiple myeloma AND
- One of the following:
    - Medical record documentation of therapeutic failure on, intolerance to, or contraindication to at least three prior lines of therapy including a proteasome inhibitor (including but not limited to Velcade*, Kyprolis*, or Ninlaro*) and an immunomodulatory agent (including but not limited to Pomalyst*, Revlimid*, Thalomid*) OR
    - Medical record documentation that the patient is double-refractory to a proteasome inhibitor (including but not limited to Velcade*, Kyprolis*, or Ninlaro*) and an immunomodulatory agent (including but not limited to Pomalyst*, Revlimid*, Thalomid*) OR
    - Medical record documentation of therapeutic failure on, intolerance to, or contraindication to at least 1 prior therapy including a proteasome inhibitor (including but not limited to Velcade*, Kyprolis*, or Ninlaro*) or an immunomodulatory agent (including but not limited to Pomalyst*, Revlimid*, Thalomid*) AND one of the following:
        - Medical record documentation that Darzalex will be prescribed in combination with lenalidomide and dexamethasone OR
        - Medical record documentation that Darzalex will be prescribed in combination with bortezomib and dexamethasone

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

Discussion: Todd Sponenberg asked for clarification of the criteria and to explain their differences. Tricia Heitzman clarified that the first bullet point was a trial or contraindication of 3 medications (therapy could have been discontinued due to side effects), bullet point 2 is that patients needed to have received and were refractory to one agent from each class. No other questions or comments.

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

TECENTRIQ **Keith Hunsicker**
(atezolizumab)

Updated Indication[1]: Tecentriq is now indicated for the treatment of patients with 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.

Previously, Tecentriq was approved under accelerated process for the treatment of patients with locally or metastatic 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.

Current Formulary Status/Prior Authorization Criteria:
Medical benefit requiring PA.

The following prior authorization criteria are in place:

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

AUTHORIZATION DURATION: Initial approval will be for 6 months. Subsequent approvals will be for an additional 6 months and will require medical record documentation of continued disease improvement or lack of disease progression. The medication will no longer be covered if the member experiences unacceptable toxicity or worsening of disease.

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

It is recommended that the following changes are made to the existing prior authorization criteria so that the criteria read as follows:

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

    OR

2. Medical record documentation of a diagnosis of non-small cell lung cancer AND medical record documentation that the patient has had either:
    i. Disease progression during or following platinum-containing chemotherapy OR
    ii. 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. Subsequent approvals will be for an additional 12 months and will require medical record documentation of continued disease improvement or lack of disease progression. The medication will no longer be covered if the member experiences unacceptable toxicity or worsening of disease.

Discussion: No other questions or comments.

Outcome: Lisa Mazonkey made a motion to accept the recommendations as modified. 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.

ZEMPLAR **Aubrielle Prater**
(paricalcitol)

Updated Indication: Zemplar is now indicated in adults and pediatric patients 10 years and older for the prevention and treatment of secondary hyperparathyroidism associated with: chronic kidney disease (CKD) Stages 3 and 4, and Stage 5 (in patients on hemodialysis (HD) or peritoneal dialysis (PD)).

Note: Zemplar was previously only indicated for use in adult patients for the prevention and treatment of secondary hyperparathyroidism associated with CKD Stages 3,4, and 5 (in patients on HD or PD). The intravenous formulation of paricalcitol is only indicated for CKD Stage 5 in patients 5 years and older.

Current Formulary Status/Prior Authorization Criteria:
Paricalcitol and Zemplar are pharmacy benefits and are NF.

Recommendations:
Paricalcitol should be added to the GHP Family formulary on the generic tier since calcitriol is not appropriate for pediatric patients with ESRD on dialysis.

Discussion: No questions or comments.

Outcome: Kevin Szczecina 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.

TARCEVA **Keith Hunsicker**

(erlotinib)

Updated Indication[1]: Tarceva is indicated for the treatment of patients with metastatic non-small cell lung cancer (NSCLC) whose tumors have epidermal growth factor receptor (EGFR) exon 19 deletions or exon 21 (L858R) substitution mutations as detected by an FDA-approved test receiving first-line, maintenance, or second or greater line treatment after progression following at least one prior chemotherapy regimen.

Tarceva is also indicated as first-line treatment of patients with locally advanced, unresectable, or metastatic pancreatic cancer in combination with gemcitabine.

Limitation of use: Safety and efficacy of Tarceva have not been established in patient with NSCLC whose tumors have other EGFR mutations, and Tarceva is not recommended for use in combination with platinum-based chemotherapy.

Previously, Tarceva was indicated for first-line treatment of patients as:

1) First-line treatment of patients with metastatic non-small cell lung cancer (NSCLC) whose tumors have epidermal growth factor receptor (EGFR) exon 19 deletions or exon 21 (L858R) substitution mutations as detected by an FDA-approved test,
2) Maintenance treatment of patients with locally advanced or metastatic NSCLC whose disease has not progressed after four cycles of platinum-based first-line chemotherapy,
3) Treatment of locally advanced or metastatic NSCLC after failure of at least one prior chemotherapy regimen, and
4) First-line treatment of patients with locally advanced, unresectable or metastatic pancreatic cancer, in combination with gemcitabine.

Tarceva is not recommended for use in combination with platinum-based therapy, and the safety and efficacy of Tarceva have not been established as first-line treatment in patients with metastatic NSCLC whose tumors have EGFR mutations other than exon 19 deletions or exon 21 (L858R) substitution.

Current Formulary Status/Prior Authorization Criteria:
Pharmacy benefit on the Brand tier requiring a prior authorization.

The following prior authorization criteria are in place:

Non-Small Cell Lung Cancer

- Must be prescribed by a hematologist/oncologist **AND**
- Medical record documentation of metastatic non-small cell lung cancer **AND**
- Medical record documentation of **one** of the following EGFR mutations as detected by an FDA approved test
    - Exon 19 deletion
    - Exon 21 (L858R) substitution

OR

- Must be prescribed by a hematologist/oncologist **AND**
- Medical record documentation of locally advanced or metastatic non-small cell lung cancer after failure on at least one prior chemotherapy regimen

OR

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

- Medical record documentation of Tarceva being used for maintenance treatment of locally advanced or metastatic non-small cell lung cancer whose disease has not progressed after four cycles on a platinum based chemotherapy regimen

Pancreatic Cancer

- Must be prescribed by a hematologist/oncologist **AND**
- Medical record documentation of locally advanced, unresectable, or metastatic pancreatic cancer **AND**
- Medical record documentation of Tarceva being prescribed in combination with gemcitabine

QUANTITY LIMIT: 25 mg tablets: Three (3) tablets per day
100 mg and 150 mg tablets: One (1) tablet per day

AUTHORIZATION DURATION: If approved, approval will be for a period of six (6) months. Re-review will be every six (6) months. Tarceva will no longer be covered if there is medical record documentation of disease progression.

Recommendations:

Tarceva is currently a pharmacy benefit on the Brand tier requiring a prior authorization. No changes to tiering are recommended at this time

It is recommended that the existing NSCLC prior authorization criteria are changed to the following:

Non-Small Cell Lung Cancer

- Must be prescribed by a hematologist/oncologist **AND**
- Medical record documentation of metastatic non-small cell lung cancer **AND**
- Medical record documentation that Tarceva is being used as first line treatment OR maintenance treatment **OR** second line or greater treatment after progression on at least one prior chemotherapy regimen **AND**
- Medical record documentation of one of the following EGFR mutations as detected by an FDA approved test
    - Exon 19 deletion **OR**
    - Exon 21 (L858R) substitution

No changes are recommended to the existing Pancreatic Cancer prior authorization criteria, quantity limits, or authorization durations.

Discussion: Tricia Heitzman questioned the removal of locally advanced has been removed from our indications. What is the difference. Question could not successfully be answered during the meeting so it was decided to pend the determination of this medication until further investigation could be made.

Outcome: Decision pended. Awaiting further investigation of need or removal of "locally advanced" from the policy. None were opposed.

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

SELZENTRY **Aubrielle Prater**
(maraviroc)

Updated Indication[1]: Selzentry is a CCR5 co-receptor antagonist now indicated in combination with other antiretroviral agents for the treatment of only CCR5-tropic HIV-1 infection in patients 2 years of age and older weighing at least 10 kg.

Limitations of use: Not recommended in patients with dual/mixed- or CXCR4-tropic HIV-1.

Note: Previously only indicated for adult patients.

Updated Dosage Form[1]: Approved as an oral solution (20 mg/mL) and tablets (25 mg, 75 mg, 150 mg, and 300 mg). However, Selzentry 150 mg and 300 mg tablets are the only commercially available formulations.

Current Formulary Status/Prior Authorization Criteria:
pharmacy benefit available on the Brand tier without a PA.

Quantity Limits: 2 tablets/day for the 150 mg tablet and 4 tablets/day for the 300 mg tablet

Recommendations: Selzentry is to remain available without PA

The following Quantity Limits should all to all lines of business when the formulations are commerically available:
Selzentry 25 mg tablet: 4 tablets/day
Selzentry 75 mg tablet: 2 tablets/day
Selzenty 150 mg tablet: 2 tablets/day
Selzentry 300 mg tablet: 4 tablets/day
Selzentry 20 mg/mL oral solution: 30 mL/day

Discussion: Todd Sponenberg made a recommendation to increase the quantity limit of the 25 mg tablets to 8/day. This will allow dosing for pediatric patients weighing between 30-40 kg, without the need for 2 required prescriptions. No other comments or questions

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

OPDIVO **Keith Hunsicker**
(nivolumab)

Updated Indication[1]: Opdivo is now indicated for the treatment of patients with recurrent or metastatic squamous cell carcinoma of the head and neck (SCCHN) with disease progression on or after a platinum-based therapy.

Previously, Opdivo was indicated for BRAF V600 wildtype and mutation positive metastatic melanoma, metastatic melanoma in combination with ipilimumab, metastatic non-small cell lung cancer after progression on or after platinum-based chemotherapy, advanced renal cell carcinoma, and Classical Hodgkin lymphoma.

Current Formulary Status/Prior Authorization Criteria:
Medical Benefit requiring PA

The following prior authorization criteria are in place:
1. 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 Opdivo is not being used in combination with any other agents for the treatment of unresectable or metastatic melanoma (with the exception of ipilimumab).

2. Metastatic Squamous Non-Small Cell Lung Cancer (NSCLC)
- Prescription written by a hematologist/oncologist **AND**
- Medical record documentation that patient is ≥ 18 years of age **AND**
- Medical record documentation of a diagnosis of metastatic non-small cell lung cancer (NSCLC) with disease progression while on or after platinum-based chemotherapy **AND**
- Medical record documentation that Opdivo is not being used in combination with any other agents for the treatment of metastatic non-small cell lung cancer (NSCLC)

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

4. Classical Hodgkin Lymphoma (CHL)
- 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 classical Hodgkin lymphoma (CHL) that has relapsed or progressed after autologous hematopoietic stem cell transplantation and post-transplantation brentuximab vedotin (Adcetris).

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: It is recommended that the prior authorization criteria of applicable policies are changed to include the following:

5. **Squamous Cell Carcinoma of the Head and Neck (SCCHN)**

- 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 recurrent or metastatic squamous cell carcinoma of the head and neck **AND**
- Medical record documentation of disease progression while on or after receiving a platinum-based therapy

No changes are recommended for the Metastatic Melanoma, Metastatic Squamous Non-Small Cell Lung Cancer, Metastatic Renal Cell Carcinoma, or Classical Hodgkin Lymphoma indications or the current authorization duration recommendations.

Discussion: No comments or questions

Outcome: Kevin Szczecina 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

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ORKAMBI **Aubrielle Prater**
(lumacaftor/ivacaftor)

Updated Indication: Orkambi is a cystic fibrosis transmembrane conductance regulator (CFTR) potentiator, indicated for the treatment of cystic fibrosis (CF) in patients 6 years and older who are homozygous for the *F508del* mutation on the *CFTR* gene. If the patient's genotype is unknown, an FDA-cleared CF mutation test should be used to detect the presence of the *F508del* mutation on both alleles of the *CFTR* gene.

Limitations of use: The efficacy and safety of Orkambi have not been established in patients with CF other than those homozygous for the *F508del* mutation.

Note: Orkambi was previously indicated for the treatment of CF in patients age 12 years and older.

Current Formulary Status/Prior Authorization Criteria:

GHP Family: A pharmacy benefit, on the Brand tier, with prior authorization.

- Must be prescribed by a pulmonologist or cystic fibrosis specialist AND
- Medical record documentation of patient age ≥ 12 years AND
- Medical record documentation of a diagnosis of cystic fibrosis (CF) AND
- Medical record documentation that the member is homozygous for the F508del CFTR mutation as documented by an FDA-cleared CF mutation test AND

- Medical record documentation of a baseline FEV1 score

Recommendations: It is recommended that the Orkambi policy be updated to reflect the updated age requirements. The following statement should replace the current age criteria in the Orkambi policy: …AND Medical record documentation of the patient being ≥ 6 years of age.

Discussion: No comments or questions

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

AVASTIN **Aubrielle Prater**
(bevacizumab)

Updated Indication[1]: Avastin is now indicated recurrent epithelial ovarian, fallopian tube, or primary peritoneal cancer that is platinum-sensitive in combination with carboplatin and paclitaxel or in combination with carboplatin and gemcitabine, followed by Avastin as a single agent.

Note: Avastin was previously only indicated for platinum-resistant recurrent epithelial ovarian, fallopian tube or primary peritoneal cancer, in combination with paclitaxel, pegylated liposomal doxorubicin or topotecan.

Updated Dosing[1]:
Platinum-sensitive recurrent epithelial ovarian, fallopian tube, or primary peritoneal cancer:
- 15 mg/kg IV every 3 weeks in combination with carboplatin and paclitaxel for 6 to 8 cycles, followed by 15 mg/kg IV every 3 weeks as a single agent.
- 15 mg/kg IV every 3 weeks in combination with carboplatin and gemcitabine for 6 to 10 cycles, followed by 15 mg/kg IV every 3 weeks as a single agent.

Current Formulary Status/Prior Authorization Criteria:
GHP Family: Medical benefit without a PA

Recommendations: Avastin is available without restriction for all LOBs. No changes recommended.

Discussion: No comments or questions

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

POLICY UPDATES:

2017 GHP Family Formulary **Kevin Szczecina**

The 2017 GHP Family Formulary was presented to the committee for approval.

Discussion: No comments or questions.

Outcome: Janie Dodson made a motion to accept the formulary as presented. Keith Hunsicker seconded the motion. None were opposed

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

Meeting adjourned at 3:52 pm.

Future Scheduled Meetings
March 21, 2017 at 1:00 HCN3A & 3B Conference room

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