P&T Committee Meeting Minutes
GHP Family Business
March 15, 2016

Present:	**Absent:**
Bret Yarczower, MD, MBA – Chair	Kristen Bender, Pharm.D.
Olivia Andersen – pharmacy student	Keith Boell, DO
Beverly Blaisure, MD – via phone	John Bulger, MD, Chief Medical Officer
Holly Bones, Pharm.D. – via phone	Dean Christian, MD
Kimberly Clark, Pharm.D.	Michael Evans, Pharm.D. B.S.
Kristi Clarke, Pharm. D. – via phone	John Flaherty, Pharm.D.
Jamie Dodson, RPh – via phone	Perry Meadows, MD
Tricia Heitzman, Pharm.D.	Thomas Morland, MD
Michelle Holt-Macey, Pharm.D. – via phone	Jonas Pearson, MS, RPh
Erica Kaczmarczyk – pharmacy student	William Seavey, Pharm.D.
Steven Kheloussi, Pharm.D.	James Schuster, MD
Jeffrey Kinney – pharmacy student	Steve Tracy, Pharm.D.
Phillip Krebs, R.EEG T. – via phone	
Lisa Mazonkey, RPh – via phone	
Mariette Njei, Pharm.D., Pharmacy Resident	
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 1:02 p.m., Tuesday, March 15, 2016.

Review and Approval of Minutes:
Dr. Bret Yarczower asked for a motion or approval to accept the January 19, 2016 minutes as written. Tricia Heitzman accepted the motion and Kimberly Clark seconded the motion. None were opposed.

DRUG REVIEWS:

TRESIBA **Steven Kheloussi**
(insulin degludec)

Steven Kheloussi provided a review of Tresiba to the committee for consideration as a pharmacy benefit. Tresiba is indicated to improve glycemic control in adults with diabetes mellitus.

Limitations of use: Not recommended for treating diabetic ketoacidosis.

Tresiba is a long-acting insulin analog indicated to improve glycemic control in adults with diabetes mellitus. Tresiba is different from other long acting insulins because it has a longer duration of action than other basal insulin products, and can therefore does not need to be taken at the same time every day. When using the U200 formulation, Tresiba allows more units of insulin to be given in a concentrated dose, allowing patients to administer the same amount of insulin required in half of the volume that they would need with current U100 formulations. Tresiba is administered SC once daily and should be dosed based on the patient's individual needs. In patients with inadequate blood sugar control, Tresiba provided reductions in HbA1c in line with alternative, previously approved long-acting insulin therapies.

Formulary alternatives: Lantus Solostar, Lantus Vial, Toujeo Solostar, Levemir Flextouch, Levemir Vial

Proposed Clinical Recommendations: It is recommended that Tresiba is not added to the GHP Family formulary at this time.

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. Kevin Szczecina seconded the motion. None were opposed.

Proposed Financial Recommendations: It is recommended that Tresiba is not added to the GHP Family formulary at this time. The following criteria should apply to requests for Tresiba:

- Medical record documentation of a therapeutic failure on, intolerance to, or contraindication to:
  - Lantus OR Toujeo **AND**
  - Levemir

Financial Discussion: No questions or comments.

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

Approved Recommendations: Tresiba will not be added to the GHP Family formulary, and will require prior authorization under the pharmacy benefit. The following criteria will apply to prior authorization requests:

- Medical record documentation of a therapeutic failure on, intolerance to, or contraindication to:
  - Lantus OR Toujeo **AND**
  - Levemir

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

ADDYI **Kimberly Clark**
(flibanserin)

Kimberly Clark provided a review of Addyi to the committee for consideration as a pharmacy benefit. Addyi is indicated for the treatment of premenopausal women with acquired, generalized hypoactive sexual desire disorder (HSDD) as characterized by low sexual desire that causes marked distress or interpersonal difficulty and is not due to: a coexisting medical or psychiatric condition, problems within the relationship, or the effects of a medication or other drug substance.

Limitations of use: Addyi is not indicated for the treatment of HSDD in postmenopausal women or in men, and is not indicated to enhance sexual performance.

Addyi is the first medication to be FDA approved for premenopausal women diagnosed with Hypoactive Sexual Desire Disorder. Although clinical trials demonstrated modest efficacy of this medication, there are serious adverse events associated with Addyi. This drug is only available through the REMs program due to these adverse events and only physicians and pharmacies enrolled in this program may prescribe and dispense Addyi. Addyi is contraindicated with alcohol, and it may be difficult for some women to abstain. Addyi also must be taken every day at bedtime instead of situationally like with medications such as Viagra.

Formulary alternatives: none

Proposed Clinical Recommendations: Because Addyi is used to treat sexual dysfunction, it is excluded from the GHP Family formulary.

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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. The risk of severe hypotension and syncope when Addy is used in combination with alcohol must be considered prior to prescribing. There was additional discussion regarding making Addyi a contractual exclusion in the future as it is considered a lifestyle medication. These changes have been proposed to BRT. If approved it will be necessary to update all applicable prescription drug riders.

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

Proposed Financial Recommendations: Because Addyi is used to treat sexual dysfunction, it is excluded from the GHP Family formulary.

Financial Discussion: No comments or questions.

Financial Outcome: Steven Kheloussi made a motion to accept the recommendations as written. Mariette Njei seconded the motion. None were opposed.

Approved Recommendations: Because Addyi is used to treat sexual dysfunction, it is excluded from 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.

ALECENSA **Steven Kheloussi**
(alectinib)

Steven Kheloussi provided a review of Alecensa to the committee for consideration as a pharmacy benefit. Alecensa is indicated for the treatment of patients with anaplastic lymphoma kinase (ALK)-positive, metastatic non-small cell lung cancer (NSCLC) who have progressed on or are intolerant to crizotinib.

This indication 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 a confirmatory trial.

Alecensa is indicated as a twice daily oral capsule for the treatment of patients with anaplastic lymphoma kinase (ALK)-positive, metastatic non-small cell lung cancer (NSCLC) who have progressed on or are intolerant to crizotinib. The only medication similar in MOA and FDA-approved and NCCN-supported indication is Zykadia (ceritinib). The overall response rate in two clinical trials was 38% and 44%, with a median duration of response of 7.5 months and 11.2 months in Studies 1 and 2, respectively. Fatal adverse reactions occurred in 2.8% of patients in the clinical trials and included hemorrhage, intestinal perforation, dyspnea, pulmonary embolism, and endocarditis.

Formulary alternatives: Zykadia* (*PA required)

Proposed Clinical Recommendations: Alecensa should be added to the GHP Family formulary at this time. The following prior authorization criteria should apply:

- Prescription written by a hematologist/oncologist **AND**
- Medical record documentation of a diagnosis of ALK-positive, metastatic non-small cell lung cancer **AND**
- Medical record documentation that Alecensa is being used as subsequent therapy after documented failure on, intolerance to, or contraindication to Xalkori (crizotinib) therapy.

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: Kimberly Clark made a motion to accept the recommendations as written. Todd Sponenberg seconded the motion. None were opposed.

Proposed Financial Recommendations: Alecensa should be added to the brand tier of the GHP Family formulary. The following quantity limit and authorization duration should apply:

QUANTITY LIMIT: 8 capsules per day

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 unacceptable toxicity or worsening of disease.

Financial Discussion: No comments or questions.

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

Approved Recommendations: Alecensa will be added to the brand tier of the GHP Family formulary. The following prior authorization criteria will apply:

- Prescription written by a hematologist/oncologist **AND**
- Medical record documentation of a diagnosis of ALK-positive, metastatic non-small cell lung cancer **AND**
- Medical record documentation that Alecensa is being used as subsequent therapy after documented failure on, intolerance to, or contraindication to Xalkori (crizotinib) therapy.

QUANTITY LIMIT: 8 capsules per day

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 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.

SEEBRI NEOHALER/UTIBRON NEOHALER **Kimberly Clark**
(glycopyrrolate/glycopyrrolate & indacaterol)

Kimberly Clark provided a review of Seebri Neohaler and Utibron Neohaler to the committee for consideration as a pharmacy benefit. Seebro Neohaler and Utibron Neohaler are indicated for the long-term maintenance treatment of airflow obstruction in patients with chronic obstructive pulmonary disease (COPD), including chronic bronchitis and/or emphysema.

Seebri may be useful as a new long acting muscarinic agent to help improve lung function in COPD patients. Utibron shows more promise as a combination of a long acting muscarinic agent and a long acting beta agonist that has shown to improve lung function in clinical trials. It is possible that this combination agent may improve adherence to medication therapies. Use of these medications may lead to an increased risk of upper respiratory tract infections and oropharyngeal or back pain. Both Seebri and Utibron are dosed twice daily and require no dose adjustments for age, renal or hepatic impairment, although caution should be used in severe renal impairment. Utibron should not be used in patients with asthma due to a boxed warning about increased risk of death.

Formulary alternatives: Anoro Ellipta, Spiriva Handihaler, Spiriva Respimat

Proposed Clinical Recommendations: It is recommended that Seebri Neohaler and Utribron Neohaler are not added to the GHP Family formulary at this time due to similarity to existing formulary alternative: Spiriva, Spiriva Respimat, Tudorza, and Anoro Ellipta.

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. Kevin Szczecina seconded the motion. None were opposed.

Proposed Financial Recommendations: It is recommended that neither Seebri Neohaler nor Utibron Neohaler are added to the GHP Family formulary at this time. The following prior authorization criteria should apply to requests:

Seebri Neohaler

- Medical record documentation of a diagnosis of COPD **AND**
- Medical record documentation of therapeutic failure on, intolerance to, or contraindication to Spiriva

Utibron Neohaler

- Medical record documentation of a diagnosis of COPD **AND**
- Medical record documentation of therapeutic failure on, intolerance to, or contraindication to Anoro Ellipta

Financial Discussion: No comments or questions.

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

Approved Recommendations: Seebri Neohaler and Utibron Neohaler will not be added to the GHP Family formulary at this time. The following prior authorization criteria will apply to requests:

Seebri Neohaler

- Medical record documentation of a diagnosis of COPD **AND**
- Medical record documentation of therapeutic failure on, intolerance to, or contraindication to Spiriva

Utibron Neohaler

- Medical record documentation of a diagnosis of COPD **AND**
- Medical record documentation of therapeutic failure on, intolerance to, or contraindication to Anoro Ellipta

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

NUCALA **Steven Kheloussi**
(mepolizumab)

Steven Kheloussi provided a review of Nucala to the committee for consideration as a medical benefit. Nucala is indicated as add-on maintenance therapy for patients with severe asthma aged 12 years and older, and with an eosinophilic phenotype.

Nucala is an IL-5 antagonist monoclonal antibody indicated for add-on maintenance treatment of patients with severe asthma aged 12 years and older, and with an eosinophilic phenotype. Nucala is dosed 100 mg SC once every 4 weeks. Nucala, when studied in randomized, double-blind, placebo-controlled trials, reduced the annual number of clinically significant asthma exacerbations. The exacerbations were defined as those requiring oral steroids, hospitalization, or a visit to an emergency department. Nucala compared to placebo also increased the time to first asthma exacerbation. In a randomized, double-blind, placebo-controlled trial, Nucala patients with eosinophilic asthma (compared to placebo) achieved greater reductions in daily maintenance oral steroid doses, while maintaining asthma control. Nucala has not yet been incorporated into the NHLBI asthma guidelines.

Formulary alternatives: Xolair (Medical benefit, PA required)

Proposed Clinical Recommendations: Nucala is a medical benefit and should not be placed on the GHP Family formulary at this time. Requests for Nucala should require prior authorization with the following criteria:

- Documentation of patient age ≥ 12 years **AND**
- Prescription written by an allergist or pulmonologist **AND**
- Medical record documentation of a blood eosinophil count of either ≥ 300 cells/mcL during the 12-month period before screening and/or ≥ 150 cells/mcL within 3 months of the start of therapy **AND**
- Medical record documentation of:
    - Intolerance to or not well controlled or very poorly controlled symptoms* despite at least a 3 month trial of: high-dose inhaled corticosteroids and/or oral systemic corticosteroids plus a long-acting beta agonist **OR**
    - Two or more exacerbations in the previous 12 months requiring additional medical treatment (oral corticosteroids, emergency department or urgent care visits, or hospitalization) despite current therapy with high-dose inhaled corticosteroids plus a long-acting beta agonist **AND**
- Insured individual must be adherent with current therapeutic regimen and must demonstrate appropriate inhaler technique **AND**
- Known environmental triggers within the member's control have been eliminated **AND**
- Medical record documentation that Nucala is not being used in combination with Xolair

*****Measures of disease severity

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

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. Specialist input from Dr. Simonelli indicated that blood eosinophils are an adequate way to justify using Nucala, but are not a good way to measure improved control. He stated that it is possible for a member to have both eosinophilic and allergic asthma so it is possible that Nucala could be used in combination with Xolair but this should be the absolute last line. He states that every pharmacologic agent (including Xolair) should be tried before progressing to Nucala. There was concern regarding the inclusion of use with Xolair as an exclusion from approval. This requirement was added to ensure that the prescribing physician would consult with a medical director prior to approval.

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

Proposed Financial Recommendations: Nucala is a medical benefit and should not be placed on the GHP Family formulary at this time. The following authorization duration should apply to requests for Nucala:

> **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.

Financial Discussion: No questions or comments.

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

Approved Recommendations: Nucala will be covered as a medical benefit for GHP Family members. The following prior authorization criteria will apply to requests for Nucala:

- Documentation of patient age ≥ 12 years **AND**
- Prescription written by an allergist or pulmonologist **AND**
- Medical record documentation of a blood eosinophil count of either ≥ 300 cells/mcL during the 12-month period before screening and/or ≥ 150 cells/mcL within 3 months of the start of therapy **AND**
- Medical record documentation of:
    - Intolerance to or not well controlled or very poorly controlled symptoms* despite at least a 3 month trial of: high-dose inhaled corticosteroids and/or oral systemic corticosteroids plus a long-acting beta agonist **OR**
    - Two or more exacerbations in the previous 12 months requiring additional medical treatment (oral corticosteroids, emergency department or urgent care visits, or hospitalization) despite current therapy with high-dose inhaled corticosteroids plus a long-acting beta agonist **AND**
- Insured individual must be adherent with current therapeutic regimen and must demonstrate appropriate inhaler technique **AND**
- Known environmental triggers within the member's control have been eliminated **AND**
- Medical record documentation that Nucala is not being used in combination with Xolair

*****Measures of disease severity

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

AUTHORIZATION DURATION: Initial approval will be for 12 months 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.

VIBERZI **Kimberly Clark**
(eluxadoline)

Kimberly Clark provided a review of Viberzi to the committee for consideration as a pharmacy benefit. Viberzi is indicated in adults for the treatment of abdominal pain and diarrhea in irritable bowel syndrome with diarrhea (IBS-D).

Viberzi is a mixed mu-opioid receptor agonist, delta opioid receptor antagonist, and kappa opioid receptor agonist, which all act locally to reduce abdominal pain and diarrhea in patients with IBS-D without constipating side effects. Viberzi is dosed 100mg by mouth twice daily. Viberzi, when studied in a randomized, multi-center, multi-national, double-blind, placebo-controlled trial, showed a reduction in a composite responder primary endpoint (compared to placebo). The primary endpoint was defined by the simultaneous improvement in the daily worst abdominal pain score by ≥30% as compared to the baseline weekly average AND a reduction in the Bristol Stool Scale to <5 on at least 50% of the days within a 12-week time interval. Results for endpoints were based on electronic daily diary entries by patients. Viberzi has not yet been incorporated into the American Gastroenterological Association guidelines for irritable bowel syndrome.

Formulary alternatives: dicyclomine, diphenoxylate-atropine, loperamide, Xifaxan*

Proposed Clinical Recommendations: Based on the clinical information available it is not recommended that Viberzi be placed on the formulary at this time. There is no existing guideline recommendation for this agent. IBS-D is a very patient oriented, subjective, disease state with available formulary alternatives with similar efficacy data to Viberzi. Requests for Viberzi should require prior authorization with the following criteria:

- Documentation of patient age ≥ 18 years **AND**
- Prescription written by gastroenterologist **AND**
- Medical record documentation of irritable bowel syndrome with diarrhea (IBS-D) **AND**

- Medical record documentation of inadequate response or intolerance to two of the following:
    - Loperamide
    - Antispasmodics (dicyclomine, hyoscyamine)
    - Alosetron (if female) **AND**
- Medical record documentation patient does not have:
    - History of severe constipation or sequelae from constipation; **OR**
    - Biliary duct obstruction or sphincter of Oddi dysfunction; **OR**
    - History of pancreatitis or structural disease of the pancreas; **OR**
    - Excessive alcohol intake (more than 3 alcoholic beverages per day); **OR**
    - Severe hepatic impairment (Child-Pugh Class C).

QUANTITY LIMIT: 2 tablets 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.

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

Proposed Financial Recommendations: Based on the cost analysis and clinical information presented it is not recommended the Viberzi be placed on the formulary at this time.

Financial Discussion: No comments or questions.

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

Approved Recommendations: Viberzi will no be added to the GHP Family formulary at this time. The following criteria will apply to prior authorization requests for Viberzi:

- Documentation of patient age ≥ 18 years **AND**
- Prescription written by gastroenterologist **AND**
- Medical record documentation of irritable bowel syndrome with diarrhea (IBS-D) **AND**
- Medical record documentation of inadequate response or intolerance to two of the following:
    - Loperamide
    - Antispasmodics (dicyclomine, hyoscyamine)
    - Alosetron (if female) **AND**
- Medical record documentation patient does not have:
    - History of severe constipation or sequelae from constipation; **OR**
    - Biliary duct obstruction or sphincter of Oddi dysfunction; **OR**
    - History of pancreatitis or structural disease of the pancreas; **OR**
    - Excessive alcohol intake (more than 3 alcoholic beverages per day); **OR**
    - Severe hepatic impairment (Child-Pugh Class C).

QUANTITY LIMIT: 2 tablets per day

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

PORTRAZZA **Steven Kheloussi**
(necitumumab)

Steven Kheloussi provided a review of Portrazza to the committee for consideration as a medical benefit. Portrazza is indicated, in combination with gemcitabine and cisplatin, for first-line treatment of patients with metastatic squamous non-small cell lung cancer (NSCLC).

Limitation of use: Portrazza is not indicated for treatment of non-squamous NSCLC.

Portrazza must not be used in non-squamous NSCLC as it did not improve overall survival, progression-free survival, or overall response rate when added on to pemetrexed and cisplatin, and actually led to increased mortality and increased thromboembolic events. It's mechanism of action (EGFR antagonist) is similar to Erbitux, which is used off-label for NSCLC as subsequent therapy for ALK-positive tumors. It has a Category 3 recommendation from NCCN and is expected to improve overall survival in metastatic squamous NSCLC by approximately 2 months. There are black box warnings for cardiopulmonary arrest and hypomagnesemia. Other serious adverse reactions include venous and arterial thromboembolic events and infusion reactions.

Formulary alternatives: etoposide (oral)

Proposed Clinical Recommendations: Portrazza is a medical benefit and should not be added to the GHP Family formulary at this time. The following prior authorization criteria should apply:

- Prescription written by a hematologist/oncologist **AND**
- Medical record documentation of a diagnosis of metastatic squamous non-small cell lung cancer **AND**
- Medical record documentation that Portrazza will be used in combination with gemcitabine and cisplatin **AND**
- Medical record documentation of disease progression on or intolerance to an alternative Category 1 or Category 2 recommended regimen per NCCN

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. Portrazza currently holds a category 3 recommendation in combination with cisplatin and gemcitabine for the treatment for recurrence or metastasis in patients with squamous NSCLC with performance status 0-2 as:

- First-line therapy
- Subsequent therapy for sensitizing EGFR mutation-positive tumors and prior erlotinib, afatinib, or gefitinib therapy
- Subsequent therapy for ALK-positive tumors and prior crizotinib therapy

A Category 3 recommendation means: Based upon any level of evidence, there is major NCCN disagreement that the intervention is appropriate.

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

Proposed Financial Recommendations: Portrazza should be covered under the medical benefit requiring prior authorization. It should be considered a medical drug for GHP Family. The following authorization duration should apply to requests for Portrazza:

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 unacceptable toxicity or worsening of disease.

Financial Discussion: No questions or comments.

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

Approved Recommendations: Portrazza will be covered under the medical benefit for GHP Family members. The following prior authorization criteria will apply:

- Prescription written by a hematologist/oncologist **AND**
- Medical record documentation of a diagnosis of metastatic squamous non-small cell lung cancer **AND**
- Medical record documentation that Portrazza will be used in combination with gemcitabine and cisplatin **AND**
- Medical record documentation of disease progression on or intolerance to an alternative Category 1 or Category 2 recommended regimen per NCCN

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 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.

VARUBI **Kimberly Clarke**
(rolapitant)

Kimberly Clark provided a review of Varubi to the committee for consideration as a pharmacy benefit. Varubi is indicated in combination with other antiemetic agents in adults for the prevention of delayed nausea and vomiting associatd with initial and repeat courses of emetogenic cancer chemotherapy, including, but not limited to, highly emetogenic chemotherapy.

Varubi is a long acting NK-1 antagonist used similarly to Emend in the NCCN guidelines. In clinical trials it showed an improvement in preventing nausea and vomiting. Varubi has a longer half-life than Emend and only needs to be dosed on the first day of each chemotherapy cycle. Due to the longer half-life it may help to prevent nausea and vomiting in the delayed nausea of chemotherapy.

Formulary alternatives: Emend (^ QL apply)

Proposed Clinical Recommendations: It is recommended that Varubi be added to the GHP Family formulary with the following criteria:

- Medical record documentation of use for the prevention of chemotherapy induced nausea and vomiting in patients who are receiving moderately or highly emetogenic chemotherapy and there is medical record documentation of use in combination with other antiemetic agents. This includes, but is not limited to:

1. AC combination defined as either doxorubicin or epirubicin with cyclophosphamide
2. Busulfan
3. Carmustine
4. Cisplatin/Carboplatin
5. Clofarabine
6. Cyclophosphamide (1000mg/m2 or greater
7. Dacarbazine
8. Dactinomycin
9. Doxorubicin (20mg/m2 or greater)
10. Epirubicin (50mg/m2 or greater)
11. FOLFIRINOX, FOLFOX , FOLFIRI
12. HDAC (Cytarabine 3g/m2 or greater)
13. Ifosfamide
14. Irinotecan (125mg/m2 6 cycles/6 weeks)
15. Mechlorethamine
16. Methotrexate (1g/m2 or greater)
17. Streptozotocin

QUANTITY LIMIT: 4 tablets per 28 days

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. There was discussion around the fact that Varubi did not show a difference when compared to the control regimen in the extension trial. Because the extension was voluntary, it's possible that there was a selection bias because it is unlikely that patients who received no response from the medication would have continued it for future cycles. This would indicate that only responders would have continued on in the trial.

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

Proposed Financial Recommendations: It is recommended that Varubi be added to the brand tier of the GHP Family formulary.

Financial Discussion: No comments or questions.

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

Approved Recommendations: Varubi will be added to the brand non-preferred tier of the GHP Family formulary with the following quantity limit:

- Medical record documentation of use for the prevention of chemotherapy induced nausea and vomiting in patients who are receiving moderately or highly emetogenic chemotherapy and there

is medical record documentation of use in combination with other antiemetic agents. This includes, but is not limited to:

2. AC combination defined as either doxorubicin or epirubicin with cyclophosphamide
2. Busulfan
3. Carmustine
4. Cisplatin/Carboplatin
5. Clofarabine
6. Cyclophosphamide (1000mg/m2 or greater
7. Dacarbazine
8. Dactinomycin
9. Doxorubicin (20mg/m2 or greater)
10. Epirubicin (50mg/m2 or greater)
11. FOLFIRINOX, FOLFOX , FOLFIRI
12. HDAC (Cytarabine 3g/m2 or greater)
13. Ifosfamide
14. Irinotecan (125mg/m2 6 cycles/6 weeks)
15. Mechlorethamine
16. Methotrexate (1g/m2 or greater)
17. Streptozotocin

QUANTITY LIMIT: 4 tablets per 28 days

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

PRAXBIND **Steven Kheloussi**
(idarucizumab)

Steven Kheloussi provided a review of Praxbind to the committee for consideration as a medical benefit. Praxbind is indicated in patients treated with Pradaxa when reversal of the anticoagulant effects of dabigatran is needed:

- For emergency surgery/urgent procedures
- In life-threatening or uncontrolled bleeding

Praxbind (idarucizumab) is specifically in emergency surgery/urgent procedures or in life-threatening or uncontrolled bleeding. This is the first and only reversal agent for Pradaxa and was shown in clinical trials to quickly and with 100% effectiveness reduce the anticoagulant effect of dabigatran.

Formulary alternatives: none

Proposed Clinical Recommendations: Praxbind is a medical benefit and would not be included on the GHP Family formulary. Since Praxbind is only indicated for emergent situations, it should not be utilized on an outpatient basis and therefore should require prior authorization with the following criteria for outpatient use only:

- Medical record documentation that Praxbind is being used in a patient treated with Pradaxa when reversal of the anticoagulant effects of dabigatran is needed for emergency surgery/urgent procedures or in life-threatening or uncontrolled bleeding.

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. Praxbind will be available without restriction for us in an inpatient environment. A prior authorization review will only be required when Praxbind is used in an outpatient setting to ensure that it is not being used inappropriately.

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

Proposed Financial Recommendations: Praxbind should be covered under the medical benefit requiring prior authorization for outpatient use. It will not be included on the GHP Family formulary.

Financial Discussion: No comments or questions.

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

Approved Recommendations: Praxbind will be covered under the medical benefit for GHP Family members. The following prior authorization criteria will apply to outpatient utilization of Praxbind:

- Medical record documentation that Praxbind is being used in a patient treated with Pradaxa when reversal of the anticoagulant effects of dabigatran is needed for emergency surgery/urgent procedures or in life-threatening or uncontrolled bleeding.

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

STRENSIQ **Kimberly Clark**
(asfotase alfa)

Kimberly Clark provided a review of Strensiq to the committee for consideration as a pharmacy benefit. Strensiq is a tissue nonspecific alkaline phosphatase indicated for the treatment of patients with perinatal/infantile- and juvenile-onset hypophosphatasia (HPP).

Strensiq is the first therapy approved in the United States for the treatment of patients with HPP. Strensiq has the potential to alter the natural history of severe perinatal and infantile HPP cases and lead to longer more productive lives for those afflicted with this condition.

Formulary alternatives: none

Proposed Clinical Recommendations: As the first medication approved for the treatment of Perinatal/infantile- and juvenile-onset HPP it is recommended that Strensiq is added to the GHP Family formulary. In order to ensure appropriate utilization, it is recommended that the following prior authorization criteria apply:

- Must be prescribed by an endocrinologist **AND**
- Medical record documentation of a diagnosis of perinatal/infantile- or juvenile-onset hypophosphatasia (HPP) **AND**
- Medical record documentation of low total serum alkaline phosphatase activity (see chart below for typical lowest normal reference values) **AND**
- Medical record documentation that member will receive a weight and diagnosis appropriate dosing regimen

Table 2. Typical Lowest Normal Reference Values for Serum Alkaline Phosphatase Activity in North America

Age	Lowest Normal Total Serum or Plasma Alkaline Phosphatase Activity (U/L)	
	Male	Female
0-30 days	60	60
1-11 months	70	70
1-3 years	125	125
4-11 years	150	150
12-13 years	160	110
14-15 years	130	55
16-19 years	60	40
>20 years	40	40

NOTE:

- Perinatal/Infantile-Onset HPP
  - Recommended dosage regimen is 2 mg/kg administered subcutaneously three times per week, or 1 mg/kg administered six times per week. Injection site reactions may limit the tolerability of the six times per week regimen.
  - The dose may be increased to 3 mg/kg three times per week for insufficient efficacy.
- Juvenile-Onset HPP
  - Recommended dosage regimen is 2 mg/kg administered subcutaneously three times per week, or 1 mg/kg administered six times per week. Injection site reactions may limit the tolerability of the six times per week regimen.

DAY SUPPLY LIMIT: A maximum of 30 day supply per fill will be approved.

AUTHORIZATION DURATION: Initial approval will be for a period of 3 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.

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. It was recommended that metabolic specialists were included in the list of approved providers.

Clinical Outcome: Steven Kheloussi made a motion to accept the recommendations as amended. Tricia Heitzman seconded the motion. None were opposed.

Proposed Financial Recommendations: It is recommended that Strensiq is added to the brand tier of the GHP Family formulary.

Financial Discussion: No comments or questions.

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

Approved Recommendations: Strensiq will be added to the brand tier of the GHP Family formulary. The following prior authorization criteria will apply to requests for Strensiq:

- Must be prescribed by an endocrinologist or metabolic specialist **AND**
- Medical record documentation of a diagnosis of perinatal/infantile- or juvenile-onset hypophosphatasia (HPP) **AND**
- Medical record documentation of low total serum alkaline phosphatase activity (see chart below for typical lowest normal reference values) **AND**
- Medical record documentation that member will receive a weight and diagnosis appropriate dosing regimen

Table 2. Typical Lowest Normal Reference Values for Serum Alkaline Phosphatase Activity in North America

Age	Lowest Normal Total Serum or Plasma Alkaline Phosphatase Activity (U/L)	
	Male	Female
0-30 days	60	60
1-11 months	70	70
1-3 years	125	125
4-11 years	150	150
12-13 years	160	110
14-15 years	130	55
16-19 years	60	40
>20 years	40	40

NOTE:

- Perinatal/Infantile-Onset HPP
  - Recommended dosage regimen is 2 mg/kg administered subcutaneously three times per week, or 1 mg/kg administered six times per week. Injection site reactions may limit the tolerability of the six times per week regimen.
  - The dose may be increased to 3 mg/kg three times per week for insufficient efficacy.
- Juvenile-Onset HPP
  - Recommended dosage regimen is 2 mg/kg administered subcutaneously three times per week, or 1 mg/kg administered six times per week. Injection site reactions may limit the tolerability of the six times per week regimen.

DAY SUPPLY LIMIT: A maximum of 30 day supply per fill will be approved.

AUTHORIZATION DURATION: Initial approval will be for a period of 3 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.

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

FAST FACTS:

KEYTRUDA **Steven Kheloussi**
(pembrolizumab)

New Indication: Melanoma: Keytruda is now indicated for the treatment of patients with unresectable or metastatic melanoma.

Previously indicated as subsequent therapy following ipilimumab and, if BRAF V600 mutation positive, a BRAF inhibitor.

Current Formulary Status:
Medical benefit requiring the following prior authorization (related to 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.

Recommendation:
No changes are recommended at this time.

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.

KYPROLIS **Kimberly Clark**
(carfilzomib)

New Indication: Kyprolis is indicated in combination with dexamethasone or with lenalidomide plus dexamethasone for the treatment of patients with relapsed or refractory multiple myeloma who have received one to three lines of therapy.

Previously only indicated as a single agent for the treatment of patients with relapsed or refractory multiple myeloma who have received one or more lines of therapy.

Current Formulary Status:
Medical benefit requiring the following prior authorization (related to multiple myeloma):

- Kyprolis (carfilzomib) is prescribed by a hematologist/oncologist; and
- Documentation of a diagnosis of multiple myeloma; and
- Physician documentation of therapeutic failure on, intolerance to, or contraindication to:
    - Bortezomib (Velcade); and
    - An immunomodulatory agent (e.g., Thalidomide (Thalomid) or Lenalidomide (Revlimid)) and

- Medical record documentation of progression on or within 60 days of completion of the last therapy

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.

Recommendation:
Medical benefit requiring the following prior authorization (related to multiple myeloma):

- Kyprolis (carfilzomib) is prescribed by a hematologist/oncologist; and
- Documentation of a diagnosis of multiple myeloma; and
- Physician documentation of therapeutic failure on, intolerance to, or contraindication to:
    - Bortezomib (Velcade); and
    - An immunomodulatory agent (e.g., Thalidomide (Thalomid) or Lenalidomide (Revlimid)); or
- Physician documentation that Kyprolis will be used in combination with Lenalidomide (Revlimid); and
- Medical record documentation of progression on or within 60 days of completion of the last therapy

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

Discussion: No questions or comments.

Outcome: 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.

HALAVEN **Steven Kheloussi**
(eribulin**)**

New Indication: Halaven is now indicated for the treatment of unresectable or metastatic liposarcoma in patients who have received a prior anthracycline-containing regimen.

Recommendation: It is recommended that the following criteria be added to the medical benefit policy for Halaven (MBP88.0):

- Medical record documentation of a diagnosis of unresectable or metastatic liposarcoma AND
- Medical record documentation of a previous trial of an anthracycline-containing regimen

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.

HARVONI **Kristi Clarke**
(ledipasvir/sofosbuvir)

New Indication: Harvoni is now indicated for genotype 4, 5, and 6. It also has included dosing recommendations for HCV/HIV coinfection and an alternative for genotype 1 cirrhotics who are previously treated. It also includes those with chronic hepatitis C virus genotype 1, infection who are liver transplant recipients, genotype 4 infection who are liver transplant recipients without cirrhosis, or with compensated cirrhosis, and genotype 1 infection with decompensated cirrhosis.

New Dosing Instructions:

Recommended Treatment Regimen and Duration for HARVONI in Patients with Genotype 1, 4, 5 or 6 HCV

	Patient Population	Treatment Regimen and Duration
Genotype 1	Treatment-naïve without cirrhosis or with compensated cirrhosis (Child-Pugh A)	HARVONI 12 weeks*
	Treatment-experienced** without cirrhosis	HARVONI 12 weeks
	Treatment-experienced** with compensated cirrhosis (Child-Pugh A)	HARVONI 24 weeks†
	Treatment-naïve and treatment-experienced** with decompensated cirrhosis (Child-Pugh B or C)	HARVONI + ribavirin‡ 12 weeks
Genotype 1 or 4	Treatment-naïve and treatment-experienced** liver transplant recipients without cirrhosis, or with compensated cirrhosis (Child-Pugh A)	HARVONI + ribavirin§ 12 weeks
Genotype 4, 5 or 6	Treatment-naïve and treatment-experienced**, without cirrhosis or with compensated cirrhosis (Child-Pugh A)	HARVONI 12 weeks

* HARVONI for 8 weeks can be considered in treatment-naïve genotype 1 patients without cirrhosis who have pre-treatment HCV RNA less than 6 million IU/mL *[see Clinical Studies (14.2)]*.

** Treatment-experienced patients include those who have failed a peginterferon alfa + ribavirin based regimen with or without an HCV protease inhibitor.

† HARVONI+ribavirin for 12 weeks can be considered in treatment-experienced genotype 1 patients with cirrhosis who are eligible for ribavirin *[see Clinical Studies (14.2)]*. See footnote § for ribavirin dosage recommendations.

‡ In patients with decompensated cirrhosis, the starting dosage of ribavirin is 600 mg and can be titrated up to 1000 mg for patients <75 kg and 1200 mg for those ≥75 kg in two divided doses with food. If the starting dosage of ribavirin is not well tolerated, the dosage should be reduced as clinically indicated based on hemoglobin levels.

Recommendation: Update current policy criteria to the following (underline indicates new criteria):

- Medical record documentation of a diagnosis of hepatitis C virus (HCV) genotype 1, 4, 5, or 6 infection **AND**
- Medical record documentation of Genotype 1: as monotherapy OR Concurrent therapy with ribavirin if treatment experienced with cirrhosis, OR Concurrent therapy with ribavirin if treatment naïve or experienced with decompensated cirrhosis, OR Concurrent therapy with ribavirin if treatment naïve or experienced with or without compensated cirrhosis in liver transplant recipients **AND**
- Medical record documentation of Genotype 4: as monotherapy, OR Concurrent therapy with ribavirin if treatment naïve or experienced with decompensated cirrhosis, OR Concurrent therapy with ribavirin if treatment naïve or experienced with or without compensated cirrhosis in liver transplant recipients **AND**
- Medical record documentation of Genotype 5 as monotherapy **AND**
- Medical record documentation of Genotype 6 as monotherapy **AND**

Treatment Duration: Genotype 4, 5, 6: Harvoni will be approved for a time period or 12 weeks

Discussion: No questions or comments.

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

OLYSIO **Kristi Clarke**
(simeprevir)

New Indication: Olysio is now including dosing recommendations for the treatment of HCV/HIV-1 coinfection and to expand the indications and usage to include genotype 4 infection.

New Dosing Instructions:

The recommended dosage regimens and treatment duration for genotype 1 and HCV/HIV-1 co-infected patients was added to the following table:

Table 1: Recommended Dosage Regimens and Treatment Duration for OLYSIO, Peg IFN alfa, and RBV Combination Therapy for Treatment of CHC Infection in HCV Genotype 1 or 4 Mono infected and HCV/HIV 1 Co infected Patients

Patient Population	Treatment Regimen and Duration
Treatment naïve patients and prior relapsers*	
• with or without cirrhosis, who are not co infected with HIV	12 weeks of OLYSIO in combination with Peg IFN alfa and RBV followed by an additional 12 weeks of Peg IFN alfa and RBV (total treatment duration of 24 weeks)†
• without cirrhosis, who are co infected with HIV	
with cirrhosis, who are co infected with HIV	12 weeks of OLYSIO in combination with Peg-IFN-alfa and RBV followed by an additional 36 weeks of Peg IFN alfa and RBV (total treatment duration of 48 weeks)†
Prior non responders (including partial‡ and null responders#), with or without cirrhosis, with or without HIV co infection	12 weeks of OLYSIO in combination with Peg-IFN-alfa and RBV followed by an additional 36 weeks of Peg IFN alfa and RBV (total treatment duration of 48 weeks)†

†HIV = human immunodeficiency virus.
* Prior relapser: HCV RNA not detected at the end of prior IFN based therapy and HCV RNA detected during follow up [see Clinical Studies (14)].
‡† Recommended duration of treatment if patient does not meet stopping rules (see Table 3).
#‡ Prior partial responder: prior on-treatment ≥ 2 log10 IU/mL reduction in HCV RNA from baseline at Week 12 and HCV RNA detected at end of prior IFN based therapy [see Clinical Studies (14)].
§# Prior null responder: prior on treatment < 2 log10 reduction in HCV RNA from baseline at Week 12 during prior IFN based therapy [see Clinical Studies (14)].

Recommendation: No changes recommended to current policies based on the AASLD/IDSA guidelines recommendations at this time.

Discussion: No questions or comments.

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.

LETAIRIS & ADCIRCA **Steven Kheloussi**
(ambrisentan & tadalafil)

Background:

- Historically, there has been uncertainty of the value of combination therapy for pulmonary arterial hypertension (PAH), especially the combination of phosphodiesterase-5 (PDE5) inhibitors and endothelin receptor antagonists (ERAs).
- Previous study data showed no increase benefit in exercise capacity when combining sildenafil with bosentan. A more recent clinical trial, COMPASS-2, followed 334 patients on stable sildenafil therapy randomized to placebo or bosentan 125 mg twice daily. The study concluded

that adding bosentan to stable sildenafil therapy was not superior to sildenafil monotherapy in delaying the time to the first morbidity/mortality event.

- The recently published AMBITION trial shows quite different results. The AMBITION trial randomized 605 patients to Letairis plus tadalafil or to ambrisentan or tadalafil monotherapy. The AMBITION trial supports the rationale for targeting multiple pathways in pulmonary arterial hypertension and showed that early combination therapy can be beneficial.

New Indication:

- Appropriately, the indication for Letairis has been updated to reflect the results of the AMBITION trial. The indication has been updated to:
    - Letairis is indicated for the treatment of pulmonary arterial hypertension (PAH) (WHO Group 1) in combination with tadalafil to reduce the risks of disease progression and hospitalization for worsening PAH, and to improve exercise ability.
- The indication of Adcirca has not been updated to this point.

Recommendation:

Current Policies with recommended updates (proposed updates underlined):

- Adcirca (1043.0F)
    - Prescription must be written by a cardiologist or pulmonologist **AND**
    - Medical record documentation of a diagnosis of functional class 2, 3, or 4 pulmonary arterial hypertension **AND**
    - <u>Medical record documentation of one of the following:</u>
        - Therapeutic failure on, intolerance to, or contraindication to Revatio* **OR**
        - <u>Use as first line therapy in combination with Letairis in patients with WHO Group I, functional class II or III symptoms.</u>
- Letairis (1029.0F)
    - Prescription is written by a pulmonologist or cardiologist AND
    - Diagnosis of functional class 2 or 3 pulmonary arterial hypertension **AND**
    - <u>Medical record documentation of one of the following:</u>
        - Therapeutic failure on, intolerance to, or contraindication to sildenafil* **<u>OR</u>**
        - <u>Use as first line therapy in combination with Adcirca in patients with WHO Group I, functional class II or III symptoms.</u>

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.

Class Review

Erythropoietin Stimulating Agents (ESA) Class Review **Mariette Njei**

Mariette Njei presented an update to the Erythrompoietin Stimulating Agents class review which was originally presented at the Januart 2016 P&T Committee meeting. The review included the following agents:

Brand	Generic name	How supplied				Manufacturer	FDA approval date[5]
Epogen	Epoetin Alfa	Single-dose vial: 2000, 3000, 4000, and 10,000 Units/1 mL		Multidose vial containing benzyl alcohol: 20,000 Units/2 mL and 20,000 Units/1 mL		Amgen	1989
Procrit	Epoetin Alfa	Single-dose, Preservative-free Vial: Each 1 mL of solution contains 2000, 3000, 4000 or 10,000	Single-dose, Preservative-free Vial: 1 mL (40,000 Units/mL)	Multidose, Preserved Vial: 2 mL (20,000 Units, 10,000 Units/mL)	Multidose, Preserved Vial: 1 mL (20,000 Units/mL	Amgen	2008
Aranesp	Darbepoetin Alfa	Single-dose vials: 25, 40, 60, 100, 200, 300, and 500 mcg/1 mL, and 150 mcg/0.75 mL		Single-dose prefilled syringes: 10 mcg/0.4mL, 25 mcg/0.42mL, 40 mcg/0.4mL, 60 mcg/0.3 mL, 100 mcg/0.5 mL, 150 mcg/0.3 mL, 200 mcg/0.4 mL, 300 mcg/0.6 mL, and 500 mcg/1 mL		Amgen	2001
Mircera	Methoxy Polyethylene glycol-Epoetin Beta			Single use prefilled syringes: 50, 75, 100, 150, 200, or 250 mcg in 0.3 mL		Hoffmann-La Roche Inc.	2007

FDA Approved Indications:

	Epogen	Procrit	Aranesp	Mircera
Anemia due to chronic renal failure	✓	✓	✓	✓
Treatment of Anemia in Zidovudine-treated HIV-infected Patients	✓	✓		
Treatment of Anemia in Cancer Patients on Chemotherapy	✓	✓	✓	
Reduction of Allogeneic Blood Transfusion in Patients undergoing elective, non-cardiac, nonvascular Surgery	✓	✓		

Non FDA Approved Indications:

	Epogen	Procrit	Aranesp	Mircera
Anemia - Hepatitis C, In patients being treated with a combination of ribavirin and interferon alfa or ribavirin and peginterferon alfa	✓	✓		
Anemia - Myelodysplastic syndrome	✓	✓	✓	
Anemia - Multiple myeloma	✓	✓		
Anemia - Rheumatoid arthritis	✓	✓		
Anemia - Congestive heart failure	✓	✓		
Anemia due to radiation	✓	✓		
Anemia during the puerperium	✓	✓		
Anemia – Myelofibrosis	✓	✓		
Anemia of prematurity	✓	✓		
Beta Thalassemia	✓	✓		
Blood unit collection for autotransfusion	✓	✓		

Epoetin alfa and Darbepoetin alfa have similar efficacy and safety profiles. Darbepoetin offers the advantage of less frequent dosing but has fewer FDA approved indications compared to epoetin alfa. Compared to other ESA's Micera has a longer half-life and been shown to be as safe and effective as other ESA's in the treatment of anemia in patients with CKD on or not on dialysis.

Recommendations based on clinical review: It is recommended that the following updates be made:

Epogen, Procrit, Aranesp:

1. Treatment of symptomatic anemia of chronic renal insufficiency, chronic renal failure, including end stage renal disease either requiring or not requiring dialysis when all of the following criteria are met:
    - Hgb less than or equal to 10 g/dL for new starts and less than 11 g/dL for continuation of therapy OR medical record documentation that the dose will be reduced or interrupted if Hgb exceeds 11g/dL and
    - Ferritin greater than or equal to 100 ng/mL or transferrin saturation level greater than or equal to 20%, or a history of chelation therapy for iron

2. Treatment of anemia secondary to myelosuppressive chemotherapy in non-myeloid malignancies when all of the following criteria are met:
   - Insured individual is currently on anemia-inducing chemotherapy and there is a minimum of two additional months of planned chemotherapy.
   - Hgb less than or equal to 10 g/dL for new starts and less than 12 g/dL for continuation of therapy and
   - Ferritin greater than or equal to 100 ng/mL or transferrin level saturation greater than or equal to 20% or a history of chelation therapy for iron

   Note: Non-myeloid malignancies include all types of carcinoma, sarcoma, melanoma, multiple myeloma, lymphoma and lymphocytic leukemia

3. Treatment of symptomatic anemia in zidovudine-treated HIV infected insured individuals when all of the following criteria are met:
   - Endogenous erythropoietin levels of 500 MU/mL or less; and
   - Ferritin greater than or equal to 100 ng/mL or transferrin level saturation greater than or equal to 20% or a history of chelation therapy for iron; and
   - Zidovudine doses of 4200 mg or less per week; and
   - Hgb less than or equal to 10 g/dL for new starts and less than 12 g/dL for continuation of therapy.

   Note: Treatment should not last longer than 3 months following the discontinuation of zidovudine

4. Treatment of symptomatic anemia secondary to myelodysplastic syndrome (MDS) when all of the following criteria are met:
   - Hgb less than or equal to 10 g/dL for new starts and less than 12 g/dL for continuation of therapy and
   - Ferritin greater than or equal to 100ng/dL or transferrin level saturation greater than or equal to 20% OR a history of chelation therapy for iron; and
   - Baseline endogenous erythropoietin levels of 500 MU/mL or less (NCCN Clinical Practice Guidelines in Oncology – Myelodysplastic Syndromes v2.2010)

5. Treatment of symptomatic anemia of chronic disease (rheumatoid arthritis, inflammatory bowel disease, systemic lupus erythematosis) when all of the following criteria are met:
   - Hgb less than or equal to 10g/dL for new starts and less than 12g/dL for continuation of therapy and
   - Ferritin greater than or equal to 100ng/dL or transferrin level saturation greater than or equal to 20% or a history of chelation therapy for iron; and
   - Insured individual has a severe comorbidity (e.g. severe angina, pulmonary disease, heart failure, cerebrovascular disease causing transient ischemic attacks, lymphoma, myeloma etc.); OR
   - Insured individual's anemia is manifested by impairments such as, but not limited to, exercise intolerance, tachycardia or shortness of breath with minimal activity, or inability to perform activities of daily living

6. Reduction of allogeneic blood transfusion in anemic insured individuals undergoing surgery when all of the following criteria are met:
   - Hgb less than 13 g/dL and
   - Ferritin greater than or equal to 100ng/dL or transferrin level saturation greater than or equal to 20% or a history of chelation therapy for iron; and
   - Anemia is related to chronic disease state (limited to rheumatoid arthritis, inflammatory bowel disease, systemic lupus erythematosis, and hepatitis C undergoing treatment); and
   - Insured individual is scheduled to undergo elective, non-cardiac, non-vascular surgery in which anticipated blood loss is greater than 2 units and the need for allogeneic blood transfusion is anticipated.
   - Authorization will be for a duration of 1 month. Request for use beyond 4 weeks will require medical record documentation indicating medical necessity.

   Note: Erythropoietin therapy (epoetin alfa) is not indicated for anemic patients who are able and willing to donate autologous blood.

   AUTHORIZATION DURATION FOR ALL INDICATIONS:
   Except for the indication of use in anemic surgical patients, approval for Epogen, Procrit or Aranesp therapy will be given for an initial duration of 12 months. Subsequent authorizations will be considered based on the stated criteria.

Discussion: FDA Approved Indications, Dosing Schedule, Clinical Evidence of Safety and Efficacy, Black Box Warnings, Contraindications, Warnings and Precautions, Adverse Reactions, Special Population Precautions and Patent Life were discussed.

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

Recommendations based on financial review:
Epogen, Procrit and Aranesp: No changes recommended to current formulary status

Mircera: Will not be added to formulary at this time due to limited commercial distribution.

Discussion: No questions or comments

Outcome: Kimberly 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.

POLICY UPDATES:

AFINITOR **Steven Kheloussi**
(everolimus)

Background: In a recent clinical trial, Opdivo (nivolumab) was shown to improve overall survival rates (25.0 months vs 19.6 months) compared to everolimus in advanced renal cell carcinoma (RCC). The hazard ratio for death (from any cause) with nivolumab versus everolimus was 0.73 (P=0.002). The overall response rate was also reported to be 5 times greater with nivolumab (25% vs 5%; odds ratio, 5.98 [95% CI, 3.68 to 9.72; P < 0.001]). The incidence of adverse events was also shown to be less in the nivolumab group.

NCCN Recommendation: Due to the OS advantage shown by nivolumab over everolimus in the second-line setting, nivolumab is the preferred choice over everolimus in the second-line setting for advanced RCC after an antiangiogenic agent.

Recommendation: It is recommended that the following additions be made to the Afinitor policy (underlined language is new):

- Prescription is written by an oncologist **AND**
- Medical record documentation of a diagnosis of renal cell cancer **AND**
- Medical record documentation of a therapeutic failure on, intolerance to, or contraindication to Sutent (sunitinib) or Nexavar (sorafenib) **AND**
- Medical record documentation of a therapeutic failure on, intolerance to, or contraindication to Opdivo.

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.

SUBOXONE, BUPRENORPHINE, & BUPRENORPHINE/NALOXONE **Kimberly Clark**

Background: Current GHP Family Suboxone and buprenorphine policies require the following:

- If on buprenorphine and buprenorphine/naloxone therapy for > 1 year and total daily buprenorphine dose is > 8 mg rationale must be provided for dose.

It has been brought to our attention that this is generating a high number of peer-to-peer reviews, all of which have been overturned when the prescribing physician spoke to a Health Plan Medical Director and provided additional information justifying the dose.

Recommendation: Based on this information and in order to decrease the number of peer-to-peer reviews generated, it is recommended that the above criterion is removed from existing policies (Commercial Policy 1018.0F).

Discussion: No comments or questions.

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

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

YERVOY **Steven Kheloussi**
(ipilimumab)

Background: At the January 2016 P&T meeting, a new indication for Yervoy was added to the Yervoy policy. A question arose about specific criteria in the policy prior to the January 2016 meeting and how to incorporate the new criteria. This update serves to clarify the correct wording of how the policy should currently read.

Current Formulary Status:
Criteria prior to January P&T:

- For Metastatic Melanoma
    - Physician provided medical documentation of unresectable stage III or IV melanoma; **AND**
    - No current autoimmune disease **AND**
    - Not currently receiving immunosuppression for organ transplantation **AND**
    - Current ECOG performance status of 0 and 1

New indication added at January P&T:

- Medical record documentation of use as a single agent for adjuvant therapy for Stage IIIA with metastases > 1 mm, or Stage IIIB or Stage IIIC cutaneous melanoma with nodal metastases following a complete lymph node dissection or resection **OR**
- Following complete lymph node dissection and/or complete resection of nodal recurrence

Recommendation: It is recommended that the following wording replace current wording in the Yervoy policy:

- Prescription written by a hematologist/oncologist

AND

- Medical record documentation of unresectable stage III or IV melanoma **AND**
- One of the following:
    - Medical record documentation of use in combination with nivolumab for first line therapy **OR**
    - Medical record documentation of use as a single agent or in combination with nivolumab as second-line or subsequent therapy for disease progression if not previously used **OR**
    - Medical record documentation of use as a single-agent reinduction therapy in select patients who experienced no significant systemic toxicity during prior ipilimumab therapy and who relapse after initial clinical response or progress after stable disease >3 months

OR

- Medical record documentation of use as a single agent for adjuvant therapy:
    - For Stage IIIA with metastases > 1 mm, or Stage IIIB or Stage IIIC cutaneous melanoma with nodal metastases following a complete lymph node dissection or resection **OR**
    - Following complete lymph node dissection and/or complete resection of nodal recurrence

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.

GUANFACINE ER **Kevin Szczecina**

Background: Guanfacine ER is an extended release, selective alpha2A-adrenoreceptor agonist that reduces sympathetic nerve impulses, resulting in reduced sympathetic outflow and a subsequent decrease in vasomotor tone and heart rate. In addition, guanfacine preferentially binds postsynaptic alpha2A-adrenoreceptors in the prefrontal cortex and has been theorized to improve delay-related firing of prefrontal cortex neurons. As a result, underlying working memory and behavioral inhibition are affected, thereby improving symptoms associated with ADHD. Guanfacine is not a CNS stimulant. It is indicated for treatment of attention deficit hyperactivity disorder (ADHD) as monotherapy and as adjunctive therapy to stimulant medications.

Currently guanfacine ER is on the Marketplace Formulary on the Generic Non-Preferred Tier requiring prior authorization and the Generic Tier requiring prior authorization for the Commercial formulary, which has resulted in numerous requests from prescribers to have a non-stimulant treatment for ADHD added.

Recommendation: It is recommended that the prior authorization requirement be lifted for the GHP Family formulary.

Discussion: No comments or questions.

Outcome: Kimberly 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.

HEPATITIS C POLICY UPDATE **Kevin Szczecina**

Background: The American Association for the Study of Liver Diseases (AASLD) recently updated its recommendations for patients with decompensated cirrhosis to include treatment with Harvoni [daily fixed-dose combination ledipasvir (90 mg)/sofosbuvir (400 mg)] with low initial dose of ribavirin (600 mg, increased as tolerated) for 12 weeks as a recommended regimen for patients with HCV genotype 1 or 4 with decompensated cirrhosis and daily Daklinza [daclatasvir (60 mg*)] plus Sovaldi [sofosbuvir (400 mg)] with low initial dose of ribavirin (600 mg, increased as tolerated) for 12 weeks as a recommended

regimen for patients with HCV genotype 1 or 4 with decompensated cirrhosis (*The dose of daclatasvir may need to increase or decrease when used concomitantly with cytochrome P450 3A/4 inducers and inhibitors, respectively. Please refer to the prescribing information for daclatasvir).

Recommendation: As a result of the above recommendations it is recommended that the following criterion be removed from Commercial policies 1246.0F Sovaldi, 1284.0F Harvoni and 1334.0F Daklinza:

- Medical record documentation of no signs and symptoms of decompensated liver

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.

PRALUENT FORMULARY UPDATE — Steven Kheloussi

Background: Praluent and Repatha are very similar in their effectiveness and safety. Currently, we have a generous offer on Praluent without having to prefer one product over the other. Further, our criteria need not be altered to be compliant with the contract. Instead, our only requirement is to place Praluent on the brand preferred tier.

Recommendation: It is recommended that Praluent is placed on the brand preferred tier (effective immediately for all LOB) with no changes to our current prior authorization criteria, QL, authorization duration, or reauthorization criteria.

Discussion: The effective date of the change will be confirmed with contracting prior to implementation.
Outcome: Kimberly 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.

LINEZOLID FORMULARY UPDATE — Steven Kheloussi

Background: DHS commented that our current criteria in our linezolid policy were relatively incomplete. They brought up points related to specific isolates mentioned in the FDA-approved indication that are not mentioned in our policy.

Recommendation: It is recommended that the current linezolid policy be updated to the criteria shown in the right column below.

Coverage of Zyvox will be restricted to those who meet one of the following criteria:

Old GHP Family Criteria	Updated Criteria
Medical record documentation of Vancomycin-Resistant *Enterococcus* (VRE) *faecium* infection which has been	Medical record documentation of Vancomycin-Resistant *Enterococcus* (VRE) *faecium* infection which has been

diagnosed and documented with Infectious Disease consultation.	diagnosed and documented with Infectious Disease consultation.
Medical record documentation of a diagnosis of nosocomial pneumonia caused by Methicillin Resistant *Staphylococcus aureus* (MRSA) or Multidrug-resistant Strains of *Streptococcus pneumoniae* (MDRSP) which has been diagnosed and documented with Infectious Disease consultation.	Medical record documentation of a diagnosis of nosocomial pneumonia caused by *Staphylococcus aureus* (MSSA and MRSA) or *Streptococcus pneumoniae* which has been diagnosed and documented with Infectious Disease consultation.
Medical record documentation of a diagnosis of complicated skin and structure infections caused by MRSA which has been diagnosed and documented with Infectious Disease consultation.	Medical record documentation of a diagnosis of complicated skin and structure infections, without concomitant osteomyelitis, caused by *Staphylococcus aureus* (MSSA and MRSA), *Streptococcus pyogenes*, or *Streptococcus agalactiae* which has been diagnosed and documented with Infectious Disease consultation.
Medical record documentation of a diagnosis of uncomplicated skin and skin structure infections caused by *Staphylococcus aureus* (methicillin-susceptible only) which has been diagnosed and documented with Infectious Disease consultation.	Medical record documentation of a diagnosis of uncomplicated skin and skin structure infections caused by *Staphylococcus aureus* (MSSA only) or *Streptococcus pneumoniae* which has been diagnosed and documented with Infectious Disease consultation.
Medical record documentation of a diagnosis of Community-acquired pneumonia caused by Multidrug-resistant strains of *Streptococcus pneumoniae* (MDRSP), including cases with concurrent bacteremia.	Medical record documentation of a diagnosis of community-acquired pneumonia caused by *Streptococcus pneumoniae* or *Staphylococcus aureus* (MSSA only) which has been diagnosed and documented with Infectious Disease consultation.
	AND for all indications – Medical record documentation of a culture and sensitivity showing the patient's infection is not susceptible to alternative antibiotic treatments **OR** a documented history of previous intolerance to or contraindication to other antibiotics shown to be susceptible on the culture and sensitivity **OR** medical record documentation that linezolid therapy was started during an inpatient setting

Discussion: There was a great deal of discussion about whether it is necessary to require an infectious disease consultion prior to approval. Holly Bones confirmed that this drug is limited to only infectious disease physicians within Geisinger Health System. It was determined that the language would be approved as presented but we would reach out to infectious disease for their input on the subject. The cost of linezolid was also discussed with Holly Bones and Lori Zaleski and the large discrepancy between the AWP cost and the actual acquisition cost. The pricing will also be investigated after the meeting.

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.

Flovent HFA **Kevin Szczecina**

Background: On January 1, 2016 an edit restricting its use in members age 11 years old and younger without prior authorization took effect for GHP Family members. The result of this edit was that there was no inhaled corticosteroid meter dose inhaler on the formulary without restriction for members age 12 and older. The Plan received numerous complaints from pediatricians and pulmonologist who requested access to an ICS MDI be available without restriction to their adolescent patients

Recommendation: It is recommended that the edit on Flovent HFA be changed as to be effective for members age 18 years old and greater, thus allowing access to a formulary MDI for all members age 17 years old and younger

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.

Orkambi **Kevin Szczecina**

Background: At the November, 2016 Pharmacy and Therapeutics Committee meeting the following reauthorization criteria for Orkambi was approved: Subsequent authorizations will be for 1 year pending documentation of adherence to therapy, improvement in FEV1 scores and a decrease in pulmonary exacerbations.However, based on feedback DHS received from their expert opinion, which stated that FEV1 scores are a poor indicator of lung function in those with Cystic Fibrosis, it was requested that the reauthorization criteria be changed to: Subsequent authorizations will be for 1 year pending documentation of adherence to therapy and a decrease or stabilization in cystic fibrosis exacerbations

Recommendation: It is recommended that this change to the GHP Family policy be approved.

Discussion: No questions or comments

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

Daklinza **Kevin Szczecina**

Background: At the November, 2016 Pharmacy and Therapeutics Committee meeting the following criterion for Daklinza was approved: Medical record documentation of rationale for not using Sovaldi used in combination with peginterferon and ribavirin if clinically appropriate. However DHS does not allow plans to require regimens that include peginterferon and ribavirin if alternatives are available. Since the only Daklinza treatment regimen that requires peginterferon and ribavirin is when treating Genotype 3 in members with cirrhosis, the criterion was changed to: Medical record documentation of rationale for not using Sovaldi used in combination with peginterferon and ribavirin if clinically appropriate in those with genotype 3 cirrhosis (F4 Metavir score)

Recommendation: It is recommended that this change to the GHP Family policy be approved.

Discussion: No questions or comments

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

Xyrem (informational only)	**Kevin Szczecina**

Formulary alternatives for Xyrem erroneously included methylphenidate ER and amphetamine-dextroamphetamine ER in the GHP Family policy. However, only the immediate-release versions are indicated for narcolepsy. This has since been corrected.

Meeting adjourned at 4:12 pm.

Future Scheduled Meetings

May 17, 2016 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.