P&T Committee Meeting Minutes
Medicaid Business
November 17, 2015

Present:	**Absent:**
Bret Yarczower, MD, MBA – Chair	Keith Boell, DO
Chris Abbazio – pharmacy student	John Bulger, MD, Chief Medical Officer
Kristen Bender, Pharm.D. – via phone	Dean Christian, MD
Beverly Blaisure, MD – via phone	John Flaherty, Pharm.D.
Holly Bones, Pharm.D. – via phone	Thomas Morland, MD
Kimberly Clark, Pharm.D.	Jonas Pearson, MS, RPh
Kristi Clarke, Pharm. D. – via phone	James Schuster, MD
Jamie Dodson, RPh	Richard Silbert, MD
Michael Evans, Pharm.D., B.S. – via phone	Steve Tracy, Pharm.D.
Tricia Heitzman, Pharm.D.	Lori Zaleski, RPh
Michelle Holt-Macey, Pharm.D. – via phone	
Breanna Kester – pharmacy student	
Steven Kheloussi, Pharm.D.	
Phillip Krebs, R.EEG T. – via phone	
Lisa Mazonkey, RPh – via phone	
Perry Meadows, MD	
Mariette Njei, Pharm.D., Pharmacy Resident	
Kristen Scheib, Pharm. D. – via phone	
Michael Spishock RPh – via phone	
Todd Sponenberg, Pharm.D., RPh	
Kevin Szczecina, RPh	
Elaine Tino, CRNP – via phone	
William Seavey, Pharm.D. – via phone	

Call To Order:
Bret Yarczower called the meeting to order at 1:02 p.m., Tuesday, November 17, 2015.

Review and Approval of Minutes:
A correction to the September 15, 2015 minutes were proposed by Steven Kheloussi. It was noted that discussions were had and decided upon at the last meeting to disregard quantity limits referencing the loading dose of Cresemba. It was agreed upon at the last meeting that the quantity limits would be set at 2 capsules/day for the oral product, and 1 vial/day for the injection.

Bret Yarczower for a motion or approval to accept the September 15, 2015 minutes as written with above correction. Jamie Dodson accepted the motion and Kevin Szczecina seconded the motion. None were opposed.

Bret Yarczower for a motion or approval to accept the September 15, 2015 minutes as written with above correction. Jamie Dodson accepted the motion and Kevin Szczecina seconded the motion. None were opposed.

DRUG REVIEWS:

Glatopa **Steven Kheloussi**
(glatiramer acetate)

Steven Kheloussi provided a review of Glatopa to the committee for consideration as a pharmacy benefit. Glatopa is indicated for the treatment of relapsing-forms of multiple sclerosis (RRMS).

Glatiramer acetate, the active ingredient of Glatopa, is composed of the acetate salts of synthetic polypeptides and contains four naturally occurring amino acids. The mechanism of action of Glatopa is not fully understood; however, it is thought to modify immune processes believed to be responsible for the pathogenesis of MS.

Glatopa is the only available substitutable generic for Copaxone 20 mg/ml. It is not interchangeable with Copaxone 40 mg/ml.

Formulary alternatives: Tecfidera, Gilenya, Avonex*, Betaseron, Copaxone, Rebif* (*PA required)

Proposed Clinical Recommendations: Glatopa will be a pharmacy benefit and should not be added to the GHP Family formulary at this time. There is limited experience with this agent and no clear benefit with this agent over the preferred brand Copaxone 20 mg/ml. Request for Glatopa should require prior authorization with the following criteria:

- Medical record documentation of a diagnosis of relapsing forms of multiple sclerosis.

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 recommendation as written. Triciai Heitzman seconded the motion. None were opposed.

Proposed Financial Recommendations: Glatopa will be a pharmacy benefit and should not be added to the GHP Family formulary. The following additional criteria should apply:

- Medical record documentation of a therapeutic failure on, intolerance to, or contraindication to Copaxone 20 mg/ml.

Financial Discussion: none

Financial Outcome: Perry Meadows made a motion to accept the recommendation as amended. Kevin Szczecina seconded the motion. None were opposed.

Approved Recommendations: Glatopa 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 diagnosis of relapsing forms of multiple sclerosis **AND**
- Medical record documentation of a therapeutic failure on, intolerance to, or contraindication to Copaxone 20 mg/ml.

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

Orkambi (lumacaftor/ivacaftor) **Kimberly Clark**

Kimberly Clark provided a review of Orkambi to the committee for consideration as a pharmacy benefit. Orkambi is a cystic fibrosis transmembrane conductance regulator (CFTR) potentiatior and is indicated for the treatment of cystic fibrosis (CF) in patients age 12 years and older who are homozygous for the *F508del* mutation in the *CFTR* gene. If the patient's genotype is unknown, and 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

Formulary alternatives: Acetylcysteine, sodium chloride for inhalation, Pulmozyme* (*PA required).

Proposed Clinical Recommendations: Orkambi is the first medicine approved to treat the underlying cause of cystic fibrosis (CF) in people aged 12 years and older with two copies of the F508del mutation. It is recommended that Orkambi be added to the GHP Family formulary. In order to ensure appropriate utilization the following prior authorization criteria should apply:

- Must be prescribed by a pulmonologist or cystic fibrosis specialist **AND**
- Medical record documentation of the patient being $\geq$ 12 years of age **AND**
- Medical record documentation of a diagnosis of cystic fibrosis **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 reocord documentation of a baseline FEV_1 score

Quantity limits: 4 tablets per day, 30 day supply per fill

Authorization duration: Initial approval will be for 2 months. Subsequent authorizations will be for 1 year pending documentation of adherence to therapy, improvements in FEV_1 scores and a decrease in pulmonary exacerbations.

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. Drug interactions should be greatly considered when deciding on its use. For geriatric use, CF is largely a disease of children and youg adults. Clinical trials of Orkambi did not include sufficient numbers of patients 65 years of age and over to determine whether they respond differently from younger patients.

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

Proposed Financial Recommendations: It is recommended that Orkambi is added to the GHP Family formulary. No additional criteria to apply.

Financial Discussion: none

Financial Outcome: Jamie Dodson made a motion to accept the recommendations as written. Dr. Perry Meadows seconded the motion. None were opposed.

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

- Must be prescribed by a pulmonologist or cystic fibrosis specialist **AND**
- Medical record documentation of the patient being ≥ 12 years of age **AND**
- Medical record documentation of a diagnosis of cystic fibrosis **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 reocord documentation of a baseline FEV_1 score

Quantity limits: 4 tablets per day, 30 day supply per fill

Authorization duration: Initial approval will be for 2 months. Subsequent authorizations will be for 1 year pending documentation of adherence to therapy, improvements in FEV_1 scores and a decrease in pulmonary exacerbations.

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

Zarxio (filgrastim-sndz) **Steven Kheloussi**

Steven Kheloussi provided a review of Zarxio to the committee for consideration as a medical or pharmacy benefit. Through comparative efficacy and safety trials compared to Neupogen, Zarxio is a leukocyte growth factor inhibitor indicated to: decrease the incidence of infection, as manifested by febrile neutropenia, in patients with nonmyeloid malignancies receiving myelosuppressive anticancer drugs associated with a significant incidence of severe neutropenia with fever. Through indication extrapolation, Zarxio is indicated to:

- Reduce the time to neutrophil recovery and the duration of fever, following induction or consolidation chemotherapy treatment of patients with acute myeloid leukemia.
- Reduce the duration of neutropenia and neutropenia-related clinical sequelae, e.g., febrile neutropenia, in patients with nonmyeloid malignancies undergoing myeloablative chemotherapy followed by bone marrow transplantation.
- Mobilize autologous hematopoietic progenitor cells into the peripheral blood for collection by leukapheresis.
- Reduce the incidence and duration of sequelae of severe neutropenia (e.g. fever, infections, oropharyngeal ulcers) in symptomatic patients with congenital neutropenia, cyclic neutropenia, or idiopathic neutropenia.

Zarxio is a granulocyte colony-stimulating factor (G-CSF) that acts on hematopoietic cells by binding to specific cell surface receptors and stimulating proliferation, differentiation commitment, and some end-cell functional activation. Endogenous G-CSF regulates the production of neutrophils within the bone

marrow and affects neutrophil progenitor proliferation, differentiation, and selected end-cell functions. Zarxio primarily stimulates neutrophils.

Formulary alternatives: Neupogen*&, Leukine*&, Neulasta*&(*PA required)

Proposed Clinical Recommendations: Zarxio will be a medical or pharmacy benefit. As there is no discernable differences between the reference product (Neupogen) and the biosimilar, it should not be added to the GHP Family formulary at this time. Requests will require prior authorization with the following criteria:

Neupogen, Neulasta, Zarxio, and Leukine:

- Medical record documentation of a diagnosis of cancer, and when any of the following FDA labeled indications or uses supported by clinical guidelines:

  Primary Prophylaxis: For the prevention of febrile neutropenia (FN) when the risk of FN due to the myelosuppressive chemotherapy regimen is 20% or greater. Those regimens include but are not limited to:

  - TC (paclitaxel/cisplatin, or cyclophosphamide/docetaxel or docetaxel/cisplatin or paclitaxel/carboplatin)
  - MVAC (methotrexate, vinblastine, doxorubicin, cisplatin)
  - AC (doxorubicin, cyclophosphamide, docetaxel)
  - AT (doxorubicin, paclitaxel)
  - TIC (paclitaxel, ifosfamide, mesna, cisplatin)
  - VAPEC-B (vincristine, doxorubicin, prednisolone, etopside, cyclophosphamide, bleomycin)
  - A(N)CVB (doxorubicin or mitoxantrone, cyclophosphamide, vindesine, bleomycin)
  - DHAP (dexamethasone, cisplatin, cytarabine)

  NOTE: Regimens not specified in this document must be listed on a nationally recognized guideline stating risk of FN of greater than 20%.

  OR

  For the prevention of FN when the risk of developing FN is less than 20%, but any other risk factor listed below is present:
  - Age 65 years or greater
  - Poor performance status
  - Previous history of FN
  - Extensive prior radiation or chemotherapy treatment
  - Poor nutritional status
  - Open wounds or active infection
  - Advanced cancer

  Neupogen, Neulasta, Zarxio, and Leukine:

  - Medical record documentation of any of the following FDA labeled indications or uses supported by clinical guidelines:

  Secondary Prophylaxis – prevention of FN when a previous cycle of chemotherapy resulted in a neutropenic complication and for which primary prophylaxis was not received, and a dose reduction will compromise disease-free or overall survival or treatment outcome.

Treatment of Febrile Neutropenia – as an adjunct to antibiotics in high-risk individuals with FN who are at high risk for infection related complications or when any of the following prognostic factors are documented:

- Age 65 years or greater
- Anticipated prolonged and profound neutropenia
- Uncontrolled primary disease
- Pneumonia
- Invasive fungal infection
- Hypotension
- Multi-organ dysfunction
- Hospitalized at the time of development of the fever

Dose Dense Therapy – specifically in the treatment of node positive breast cancer, small cell lung cancer, and diffuse aggressive non-Hodgkin's lymphoma.

Progenitor Cell Transplantation – to mobilize peripheral blood progenitor cell (PBPC) administration after autologous PBPC transplant. Note: Neulasta is considered off-label for this indication.

Leukemia or Myelodysplastic Syndromes – insured individuals with:

- Acute myeloid leukemia (AML) receiving induction or consolidation chemotherapy
- Acute lymphoblastic leukemia (ALL) after completion of the first few days of chemotherapy of the initial induction or the first post-remission course
- Myelodysplastic syndrome with less than 15% blasts in the bone marrow, or recurrent neutropenic infections are experienced.

Lymphoma – Age 65 years or greater treated with curative chemotherapy, e.g., CHOP (cyclophosphamide, doxorubicin, vincristine, prednisone)

Non-myeloid Malignancy – For reduction in the duration of neutropenia and related complications, including engraftment delay of transplantation failure, while undergoing myeloablative chemotherapy followed by autologous or allogenic bone marrow transplantation

Radiation therapy –

- If prolonged delays secondary to neutropenia are anticipated.
- As treatment for radiation injury secondary to doses of 3-10 Grays (Gy) or greater

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 discussed that this product is limited in distribution to a single pharmacy provider. Discussion about differences in indications between reference brand product and biosimilar. NCCN does not currently recommend the use of Zarxio for initial treatment of lower risk disease associated with symptomatic anemia, no del(5q) with or without other cytogenetic abnormalities, serum erythropoietin levels ≤500 mU/mL, and ring sideroblasts ≥15% in combination with epoetin alpha or darbepoetin alpha. NCCN also list Zarxio as a category 2B for mobilization of hematopoietic progenitor cells in the allogenic transplant setting (compared to a 2A recommendation for Neupogen).

Clinical Outcome: Kevin Szczecina made a motion to accept the recommendations as written. Dr. Perry Meadows seconded the motion. None were opposed.

Proposed Financial Recommendations: Zarxio should not be added to the GHP Family formulary at this time. Authorization duration of 6 months should apply.

Financial Discussion: Prices are currently similar to the reference brand Medicare members may request this as a lower out of pocket cost alterative.

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

Approved Recommendations: Zarxio will not be added to the GHP Family formulary at this time. Requests for coverage will require:

Neupogen, Neulasta, Zarxio, and Leukine:

- Medical record documentation of a diagnosis of cancer, and when any of the following FDA labeled indications or uses supported by clinical guidelines:

  Primary Prophylaxis: For the prevention of febrile neutropenia (FN) when the risk of FN due to the myelosuppressive chemotherapy regimen is 20% or greater. Those regimens include but are not limited to:

  - TC (paclitaxel/cisplatin, or cyclophosphamide/docetaxel or docetaxel/cisplatin or paclitaxel/carboplatin)
  - MVAC (methotrexate, vinblastine, doxorubicin, cisplatin)
  - AC (doxorubicin, cyclophosphamide, docetaxel)
  - AT (doxorubicin, paclitaxel)
  - TIC (paclitaxel, ifosfamide, mesna, cisplatin)
  - VAPEC-B (vincristine, doxorubicin, prednisolone, etopside, cyclophosphamide, bleomycin)
  - A(N)CVB (doxorubicin or mitoxantrone, cyclophosphamide, vindesine, bleomycin)
  - DHAP (dexamethasone, cisplatin, cytarabine)

  NOTE: Regimens not specified in this document must be listed on a nationally recognized guideline stating risk of FN of greater than 20%.

  OR

  For the prevention of FN when the risk of developing FN is less than 20%, but any other risk factor listed below is present:

  - Age 65 years or greater
  - Poor performance status
  - Previous history of FN
  - Extensive prior radiation or chemotherapy treatment
  - Poor nutritional status
  - Open wounds or active infection
  - Advanced cancer

  Neupogen, Neulasta, Zarxio, and Leukine:

- Medical record documentation of any of the following FDA labeled indications or uses supported by clinical guidelines:

Secondary Prophylaxis – prevention of FN when a previous cycle of chemotherapy resulted in a neutropenic complication and for which primary prophylaxis was not received, and a dose reduction will compromise disease-free or overall survival or treatment outcome.

Treatment of Febrile Neutropenia – as an adjunct to antibiotics in high-risk individuals with FN who are at high risk for infection related complications or when any of the following prognostic factors are documented:

- o Age 65 years or greater
- o Anticipated prolonged and profound neutropenia
- o Uncontrolled primary disease
- o Pneumonia
- o Invasive fungal infection
- o Hypotension
- o Multi-organ dysfunction
- o Hospitalized at the time of development of the fever

Dose Dense Therapy – specifically in the treatment of node positive breast cancer, small cell lung cancer, and diffuse aggressive non-Hodgkin's lymphoma.

Progenitor Cell Transplantation – to mobilize peripheral blood progenitor cell (PBPC) administration after autologous PBPC transplant. Note: Neulasta is considered off-label for this indication.

Leukemia or Myelodysplastic Syndromes – insured individuals with:

- o Acute myeloid leukemia (AML) receiving induction or consolidation chemotherapy
- o Acute lymphoblastic leukemia (ALL) after completion of the first few days of chemotherapy of the initial induction or the first post-remission course
- o Myelodysplastic syndrome with less than 15% blasts in the bone marrow, or recurrent neutropenic infections are experienced.

Lymphoma – Age 65 years or greater treated with curative chemotherapy, e.g., CHOP (cyclophosphamide, doxorubicin, vincristine, prednisone)

Non-myeloid Malignancy – For reduction in the duration of neutropenia and related complications, including engraftment delay of transplantation failure, while undergoing myeloablative chemotherapy followed by autologous or allogenic bone marrow transplantation

Radiation therapy –

- o If prolonged delays secondary to neutropenia are anticipated.
- o As treatment for radiation injury secondary to doses of 3-10 Grays (Gy) or greater

Authorization duration: 6 months

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

Lonsurf	**Kimberly Clark**

(trifluridine and tipiracil)

Kimberly Clark provided a review of Lonsurf to the committee for consideration as a pharmacy benefit. Lonsurf is a combination of trifluridine, a nucleoside metabolic inhibitor, and tipiracil, a thymidine phosphorylase inhibitor, and is indicated for the treatment of patients with metastatic colorectal cancer who have been previously treated with fluoropyrimidine-, oxaliplatin-, and irinotecan-based chemotherapy, an anti-VEGF biological therapy, and if RAS wild-type, an anti-EGFR therapy.

Formulary alternatives: capecitabine, Stivarga* (*PA required)

Proposed Clinical Recommendations: It is recommended that Lonsurf is added to the GHP Family drug formulary. In order to ensure appropriate utilization, the following prior authorization criteria should apply to requests for Lonsurf:

- Must be prescribed by a hematologist or oncologist **AND**
- Medical record documentation of the patient being ≥18 years of age **AND**
- Medical record documentation of a diagnosis of metastatic colorectal cancer **AND**
- Medical record documentation of previous treatment with fluoropyrimidine-, oxaliplatin-, and irinotecan-based chemotherapy, an anti-VEGF biological therapy, and if RAS wild-type, an anti-EGFR therapy

Quantity limit: 30 day supply per fill

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.

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: Perry Meadows made a motion to accept the recommendations as written. Tricia Heitzman seconded the motion. None were opposed.

Proposed Financial Recommendations: Lonsurf will be added to the GHP Family formulary. No additional criteria should apply.

Financial Discussion: none

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

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

- Must be prescribed by a hematologist or oncologist **AND**
- Medical record documentation of the patient being ≥18 years of age **AND**
- Medical record documentation of a diagnosis of metastatic colorectal cancer **AND**
- Medical record documentation of previous treatment with fluoropyrimidine-, oxaliplatin-, and irinotecan-based chemotherapy, an anti-VEGF biological therapy, and if RAS wild-type, an anti-EGFR therapy **OR**
- Medical record documentation of use for a medically accepted indication

Quantity limit: 30 day supply per fill

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.

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

Odomzo (sonidegib) **Steven Kheloussi**

Steven Kheloussi provided a review of Odomzo to the committee for consideration as a pharmacy benefit. Odomzo is indicated for the treatment of adult patients with locally advanced basal cell carcinoma (BCC) that has recurred following surgery or radiation therapy, or those who are not candidates for surgery or radiation therapy. Odomzo is an inhibitor of the Hedgehog pathway. Odomzo binds to and inhibits Smoothened, a transmembrane protein involved in the Hedgehog signal transduction

Formulary alternatives: Erivedge*^ (*PA Required, ^QL apply)

Proposed Clinical Recommendations: Odomzo will be a pharmacy benefit. Odomzo has been shown to be effective in locally advanced basal cell carcinoma, a disease state with few other systemic treatment options. It is recommended that Odomzo be added to the GHP Family formulary requiring prior authorization with the following criteria:

- Medical record documentation of a diagnosis of locally advanced basal cell carcinoma (BCC) that has recurred following surgery or radiation therapy, or those who are not candidates for surgery or radiation therapy **AND**
- medical record documentation of Odomzo treatment supported by multidisciplinary board consultation per NCCN guidelines **AND**
- Documentation that the patient is ≥ 18 years of age **AND**
- Prescription written by an oncologist or dermatologist

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. Odomzo is not novel in its delivery system or dose schedule compared to the alternative, Erivedge. The FDA-approved indication for Odomzo is more limited than Erivedge, but it may be considered within the same place in therapy. Odomzo has more documented potential drug-drug interactions than Erivedge.

Clinical Outcome: Dr. Meadows made a motion to accept the recommendations as written. Todd Sponeneberg seconded the motion. None were opposed.

Proposed Financial Recommendations: It is recommended that Odomzo is added to the brand tier on the GHP Family formulary. No additional prior authorization criteria should apply.

QL – 1 per day

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 patient 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. Dr. Perry Meadows seconded the motion. None were opposed.

Approved Recommendations: Odomzo be covered under the pharmacy benefit at the brand tier. The following prior authorization criteria will apply to requests for Odomzo:

- Medical record documentation of a diagnosis of locally advanced basal cell carcinoma (BCC) that has recurred following surgery or radiation therapy, or those who are not candidates for surgery or radiation therapy **AND**
- medical record documentation of Odomzo treatment supported by multidisciplinary board consultation per NCCN guidelines **AND**
- Documentation that the patient is $\geq$ 18 years of age **AND**
- Prescription written by an oncologist or dermatologist

QL – 1 per day

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 patient 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.

Entresto **Kimberly Clark**
(sacubitril and valsartan)

Kimberly Clark provided a review of Entresto to the committee for consideration as a pharmacy benefit. Entresto is indicated to reduce the risk of cardiovascular death and hospitalization for heart failure in patients with chronic heart failure (NYHA Class II-IV) and reduced ejection fraction. Entresto contains a neprilysin inhibitor, sacubitril, and an angiotensin receptor blocker, valsartan. Entresto inhibits neprilysin via LBQ657, the active metabolite of the prodrug sacubitril, and blocks the angiotensin II type-1 (AT_1) receptor via valsartan.

Formulary alternatives: Benazepril, Enalapril, Enalapril/HCTZ, Lisinopril, Lisinopril/HCTZ, Fosinopril, Quinapril, Ramipril, Losartan, Losartan/HCTZ, Benazepril/HCTZ, Captopril, Captopril/HCTZ, Enalapril IV, Fosinopril/HCTZ, Quinapril/HCTZ, Trandolapril, Candesartan, Candesartan/HCTZ, Eprosartan, Irbesartan, Irbesartan/HCTZ, Valsartan/HCTZ,bisoprolol, metoprolol succinate, carvedilol

Proposed Clinical Recommendations: Entresto has shown to be safe and effective in treating patients with chronic heart failure and reduced ejection fraction in place of ACE inhibitor or other ARB therapy. Entresto should be added to the GHP Family formulary with a prior authorization for members who meet the following criteria:

- Medical record documentation of NYHA Class III-IV or hospital admission due to HF within 12 months **AND**
- Medical record documentation of a left ventricular ejection fraction (LVEF) ≤ 35% **AND**
- Medical record documentation of eGFR > 30 mL/min/1.73 m^2 **AND**
- Medical record documentation of potassium level < 5 mmol/L **AND**
- Medical record documentation of systolic blood pressure ≥ 100 mmHg **AND**
- Medical record documentation that the member has tolerated an ACEi or ARB for 4 weeks prior to initiation of Entresto therapy **AND**
- Medical record documentation of age 18 years or older **AND**
- Medication is being prescribed by or in consultation with a cardiologist **AND**
- Medical record documentation that the member is currently on or was intolerant to the maximally tolerated dose of an evidence based beta blocker.

Target Doses of Evidence-based Beta-Blockers

Beta-Blocker	Low Dose	Moderate Dose	Target Dose
Bisoprolol	2.5 mg	>2.5 mg to < 7.5 mg	7.5 mg +
Carvedilol	3.125 mg	>3.125 mg to < 18.75mg	18.75 mg +
Metoprolol Succinate	25 mg	>25 mg to < 100 mg	100 mg +

Beta-Blocker Intolerance

1. Hypotension with increasing dose of eBBB
2. Significant pulmonary disease worsened by eBBB therapy

3. Significant right heart failure worsened by increasing dose of eBBB

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. Entresto showed superiority over ACEi (enalapril) in the PARADIGM-HF trial by reducing the risk of the combined endpoint of cardiovascular death or hospitalization for heart failure, based on a time-to-event analysis (21.8% vs 26.5%) (hazard ratio [HR]: 0.80, 95% confidence interval [CI], 0.73, 0.87, p <0.0001).

There was much group discussion regarding the proposed criteria. The following changes were recommended:

- Medical record documentation of NYHA Class II-IV or hospital admission due to HF within 12 months
- ~~Medical record documentation of eGFR > 30 mL/min/1.73 m^2~~ (criteria to be removed)
- ~~Medical record documentation of potassium level < 5 mmol/L~~ (criteria to be removed)
- Medical record documentation that the member has no history of angioedema with previous trials of ACEi or ARB (criteria to be added)

Clinical Outcome: Todd Sponenberg made a motion to accept the recommendations as amended. Jamie Dodson seconded the motion. None were opposed.

Proposed Financial Recommendations: It is recommended that Entresto be added to the GHP Family formulary at the brand tier. No further criteria should apply, however, a quantity limit of 2 tablets/day should apply

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: Entrestowill be added to the GHP Family formulary at the brand tier. The following criteria will apply to prior authorization requests for Entresto:

- Medical record documentation of NYHA Class II-IV or hospital admission due to HF within 12 months **AND**
- Medical record documentation of a left ventricular ejection fraction (LVEF) ≤ 35% **AND**
- Medical record documentation of systolic blood pressure ≥ 100 mmHg **AND**
- Medical record documentation that the member has tolerated an ACEi or ARB for 4 weeks prior to initiation of Entresto therapy **AND**
- Medical record documentation of age 18 years or older **AND**
- Medication is being prescribed by or in consultation with a cardiologist **AND**
- Medical record documentation that the member is currently on or was intolerant to the maximally tolerated dose of an evidence based beta blocker.
- Medical record documentation that the member has no history of angioedema with previous trials of ACEi or ARB

Target Doses of Evidence-based Beta-Blockers

Beta-Blocker	Low Dose	Moderate Dose	Target Dose
Bisoprolol	2.5 mg	>2.5 mg to < 7.5 mg	7.5 mg +
Carvedilol	3.125 mg	>3.125 mg to < 18.75mg	18.75 mg +
Metoprolol Succinate	25 mg	>25 mg to < 100 mg	100 mg +

Beta-Blocker Intolerance

1. Hypotension with increasing dose of eBBB
2. Significant pulmonary disease worsened by eBBB therapy
3. Significant right heart failure worsened by increasing dose of eBBB

QuantityLimit: 2 tablets/day

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

Repatha **Steven Kheloussi**
(evolocumab)

Steven Kheloussi provided a review of Repatha to the committee for consideration as a pharmacy benefit. Repatha is indicated as an adjunct to diet and maximally tolerated statin therapy for the treatment of adults with heterozygous familial hypercholesterolemia (HeFH) or clinical atherosclerotic cardiovascular disease (ASCVD), who require additional lowering of LDL-C. Repatha is also indicated as an adjunct to diet and other LDL-lowering therapies (e.g., statins, ezetimibe, LDL apheresis) for the treatment of patients with homozygous familial hypercholesterolemia (HoFH) who require additional lowering of LDL-C.

Limitations of use: The effect of Repatha on cardiovascular morbidity and mortality has not been determined.

Evolocumab is a human monoclonal IgG2 directed against human proprotein convertase subtilisin kexin 9 (PCSK9). Evolocumab binds to PCSK9 and inhibits circulating PCSK9 from binding to the low density lipoprotein (LDL) receptor (LDLR), preventing PCSK9-mediated LDLR degradation and permitting LDLR to recycle back to the liver cell surface. By inhibiting the binding of PCSK9 to LDLR, evolocumab increases the number of LDLRs available to clear LDL from the blood, thereby lowering LDL-C levels.

Formulary alternatives: atorvastatin, Kynamro*

Proposed Clinical Recommendations: It is recommended that Repatha not be added to the GHP Family formulary at this time. The following prior authorization criteria should apply:

- Medical record documentation of a diagnosis of:
    - Clinical atherosclerotic cardiovascular disease, including acute coronary syndromes (a history of myocardial infarction or unstable angina), coronary or other arterial revascularization, stroke, transient ischemic attack, or peripheral arterial disease presumed to

be of atherosclerotic origin **OR**
    - Heterozygous familial hypercholesterolemia **AND** either:
        - Genetic testing to confirm a mutation in the LDL receptor gene **OR**
        - Medical record documentation of definite HeFH (score > 8) on the diagnostic criteria scoring system (Table 5) as defined by the ESC/EAS guidelines and the World Health Organization **OR**
    - Homozygous familial hypercholesterolemia **AND** either:
        - Genetic testing to confirm diagnosis showing at least one LDL receptor-defective mutation **OR**
        - Diagnosis made based on a history of an untreated LDL-C > 500 mg/dL **AND** either xanthoma before 10 years of age **OR** evidence of HeFH in both parents **AND**
- Prescription must be written by a cardiologist or lipidologist **AND**
- Medical record documentation of a baseline LDL within 3 months of the start of PCSK9 therapy **AND**
- Medical record documentation that the patient is $\geq$ 18 years of age if the diagnosis is clinical ASCVD or HeFH **OR** medical record documentation that the patients is $\geq$ 13 years of age if the diagnosis is HoFH **AND**
- One of the following:
    - Medical record documentation that patient is currently on and is adherent to (taking at least 90% of prescribed doses over the past three months) high-intensity statin therapy with atorvastatin 40 mg or 80 mg or Crestor 20 mg or 40 mg, or the highest tolerable dose AND patient's most recent LDL > 70 mg/dL **OR**
    - Medical record documentation of intolerance to atorvastatin **AND** Crestor **AND** current use or intolerance to a lower dose of Crestor or atorvastatin or an alternative statin **OR**
    - Medical record documentation of a contraindication to statin therapy **AND**
- Medical record documentation that counseling of non-pharmacologic therapies has been done including cholesterol lowering diet, physical activity, and weight management strategies

Definitions:
- Therapeutic failure to statins, Zetia, and/or bile acid sequestrants – inability to reach target LDL Goals (<100 mg/dL or <70 mg/dL based on patient risk) despite a $\geq$ 3 month trial with the patient taking $\geq$ 90% of the prescribed doses.
    - Adherence calculations must be supported by claims data or physician attestation if no claims history is available (i.e., if the patient is new to the plan or did not use insurance for their statin prescriptions).
- Intolerance to statins – increased LFTs, intolerable myalgia (muscle symptoms without creatinine kinase [CK] elevations), myopathy (muscle symptoms with CK elevations), or myositis (elevations in CK without muscle symptoms)
- Contraindication to statins – active liver disease, previous history of rhabdomyolysis, or hypersensitivity

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. Repatha is the second PCSK9 inhibitor to hit the market and has been shown to be clinically efficacious, lowering LDL-C by approximately 55-60% compared to placebo in most clinical trials. No long-term outcomes data is available at this point, but ongoing studies are expected to conclude within the next few years. Repatha is administered as either a 140 mg/mL SC injection every two weeks

or as three 140 mg/mL SC injections once monthly for clinical ASCVD or HeFH, or as three 140 mg/mL SC injections once monthly for HoFH.

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

Proposed Financial Recommendations: Repatha should not be added to the GHP Family formulary at this time. The following additional prior authorization criteria should apply:

- Medical record documentation of a therapeutic failure on, intolerance to, or contraindication to a bile acid sequestrant or medical record documentation of an LDL $\geq$ 100 **AND**
- Medical record documentation of a therapeutic failure on, intolerance to, or contraindication to Zetia **AND**
- Medical record documentation of an inability to achieve and maintain an LDL cholesterol level at or below goal (< 100 mg/dL or < 70 mg/dL based on patient risk) with diet, exercise, and at least 12 weeks of combination therapy of statin with Zetia and a bile acid sequestrant if appropriate with the patient taking ≥ 90% of the prescribed doses of each medication.

Quantity Limits:

- 2 mL per 28 days if diagnosis is ASCVD or HeFH;
- 3 mL per 28 days if diagnosis is HoFH

AUTHORIZATION DURATION: Initial authorizations for Repatha will be approved for a period of 6 months for ASCVD and HeFH indications and 2 months for patients with HoFH. Reauthorizations will be for a period of 12 months each provided the following criteria are met:

- Medical record documentation of an up to date LDL cholesterol level since the date of the previous review showing the patient has had a clinically significant response to treatment with a PCSK9 inhibitor **AND**
- Medical record documentation that the patient is not experiencing any significant adverse events related to therapy **AND**
- Claims history and attestation from the provider showing the patient is adherent to PCSK9 therapy
- Claims history or attestation from the provider that the patient is staying adherent to (filling at least 90% of doses) statin therapy.

Additional Formulary Recommendations

Juxtapid:

- It is recommended that the following additional criterion be added to the existing Juxtapid policy:
    - Medical record documentation of a therapeutic failure on, intolerance to, or contraindication to Repatha.

Kynamro:

- It is recommended that the following additional criterion be added to the existing Kynamro policy:
    - Medical record documentation of a therapeutic failure on, intolerance to, or contraindication to Repatha.

PCSK9 policy update: update policy 1304.0F to the following:
ADDITIONAL DEFINITIONS:
5. Therapeutic failure to statins, Zetia, and/or bile acid sequestrants – inability to reach target LDL Goals (<100 mg/dL or <70 mg/dL based on patient risk) despite a ≥ 3 month trial with the patient taking ≥ 90% of the prescribed doses.
6. Intolerance to statins – increased LFT's, intolerable myalgia (muscle symptoms without creatinine kinase [CK] elevations) or myopathy (muscle symptoms with CK elevations), or myositis (elevations in CK without muscle symptoms)
7. Contraindication to statins – active liver disease, previous history of rhabdomyolysis, or hypersensitivity

PROCEDURE:
Prior authorization of PCSK9 Inhibitors will be made for members who meet the following criteria:
• Medical record documentation of use for an FDA approved indication (based on FDA approved indications) AND
o If indicated and being used for homozygous familial hypercholesterolemia:
 Medical record documentation of genetic testing showing at least one LDL receptor-defective mutation OR
 Diagnosis made based on a history of an untreated LDL-C > 500 mg/dL AND either xanthoma before 10 years of age OR evidence of HeFH in both parents OR
o If indicated and being used for heterozygous familial hypercholesterolemia (HeFH):
 Genetic testing to confirm a mutation in the LDL receptor gene OR
 Medical record documentation of definite HeFH (score ≥ 8) on the diagnostic criteria scoring system (Table 1) as defined by the ESC/EAS guidelines and the World Health Organization (WHO) OR
o If indicated, medical record documentation of a diagnosis clinical atherosclerotic cardiovascular disease, including acute coronary syndromes (a history of myocardial infarction or unstable angina), coronary or other arterial revascularization, stroke, transient ischemic attack, or peripheral arterial disease presumed to be of atherosclerotic origin AND
• Prescription must be written by a cardiologist or lipidologist AND
• Medical record documentation of a baseline LDL within 3 months of the start of PCSK9 therapy AND
• Medical record documentation that the patient is at a high or very high risk of cardiovascular events based on the patient's most recent LDL cholesterol level and a calculated atherosclerotic cardiovascular disease risk score of > 7.5%* AND
• Medical record documentation that the patient is at least 18 years of age (based on FDA approved age) AND
• One of the following:
o Medical record documentation that patient is currently on and is adherent to (taking at least 90% of prescribed doses over the past three months) high-intensity statin therapy with atorvastatin 40 mg or 80 mg or Crestor** 20 mg or 40 mg, or the highest tolerable dose AND patient's most recent LDL > 70 mg/dL OR
o Medical record documentation of intolerance to atorvastatin AND Crestor** AND current use or intolerance to a lower dose of Crestor** or atorvastatin or an alternative statin OR

o Medical record documentation of a contraindication to statin therapy AND
• Medical record documentation of a therapeutic failure on, intolerance to, or contraindication to Zetia AND
• Medical record documentation of a therapeutic failure on, intolerance to, or contraindication to a bile acid sequestrant or medical record documentation of an LDL > 100 AND
• Medical record documentation that non-pharmacologic therapies are in place including cholesterol lowering diet, exercise, and weight management strategies AND
• Medical record documentation of an inability to achieve and maintain an LDL cholesterol levels at or below goal (< 100 mg/dL or < 70 mg/dL based on patient risk) with diet, exercise, and at least 12 weeks of combination therapy of statin with Zetia and a bile acid sequestrant if appropriate with the patient taking ≥ 90% of the prescribed doses of each medication

Note: Risk score must be calculated based on the American College of Cardiology ASCVD risk estimator supported by the 2013 ACC/AHA Guideline on the Treatment of Blood Cholesterol to Reduce Atherosclerotic Cardiovascular Risk in Adults

Note: Adherence calculations must be supported by claims data or physician attestation if no claims history is available (i.e., if the patient is new to the plan or did not use insurance for their statin prescriptions)

**PA Required
Quantity limits will apply (based on FDA approved dosing)

Approval duration
Initial authorizations for evolocumab or alirocumab will be approved for a period of 6 months. Reauthorizations will be for a period of 12 months each provided the following criteria are met:

1. Medical record documentation of an up to date LDL cholesterol level since the date of the previous review showing the patient has had a clinically significant response to treatment with a PCSK9 inhibitor AND
2. Medical record documentation that the patient is not experiencing any significant adverse events related to therapy AND
3. Claims history and attestation from the provider showing the patient is adherent to PCSK9 therapy AND
4. Claims history or attestation from the provider that the patient is staying adherent to (filling at least 90% of doses) statin therapy.

Table 1. Diagnostic criteria for the clinical diagnosis of HeFH (WHO)

	Criteria	Score
Family history	First-degree relative known with premature CAD* and/or first-degree relative with LDL-C >95th percentile	1
	First-degree relative with Tx and/or children <18 with LDL-C >95th centile	2
Clinical history	Patient has premature CAD*	2
	Patient has premature cerebral/peripheral vascular disease	1
Physical examination	Tx	6
	Arcus cornealis below the age of 45 years	4
LDL-C	>8.5 mmol/L (more than ~330 mg/dL)	8
	6.5-8.4 mmol/L (~250-329 mg/dL)	5
	5.0-6.4 mmol/L (~190-249 mg/dL)	3
	4.0-4.9 mmol/L (~155-189 mg/dL)	1
Definite FH		Score >8
Probable FH		Score 6-8
Possible FH		Score 3-5
No diagnosis		Score <3

Tx – Tendon xanthomata; *Premature CAD: male before 55, women before 60 years of age.

Formulary alternatives: atorvastatin, Zetia, cholestyramine, Prevalite, colestipol

Praluent policy update: update policy 1316.0F to the following:
ADDITIONAL DEFINITIONS:
5. Therapeutic failure to statins, Zetia, and/or bile acid sequestrants – inability to reach target LDL Goals (<100 mg/dL or <70 mg/dL based on patient risk) despite a ≥ 3 month trial with the patient taking ≥ 90% of the prescribed doses.
6. Intolerance to statins – increased LFT's, intolerable myalgia (muscle symptoms without creatine kinase [CK] elevations) or myopathy (muscle symptoms with CK elevations), or myositis (elevations in CK without muscle symptoms)
7. Contraindication to statins – active liver disease, previous history of rhabdomyolysis, or hypersensitivity

PROCEDURE:
Prior authorization of Praluent will be made for members who meet the following criteria:
- Medical record documentation of a diagnosis of:
  - Clinical atherosclerotic cardiovascular disease, including acute coronary syndromes (a history of myocardial infarction or unstable angina), coronary or other arterial revascularization, stroke, transient ischemic attack, or peripheral arterial disease presumed to be of atherosclerotic origin OR
  - Heterozygous familial hypercholesterolemia AND either:
    - Genetic testing to confirm a mutation in the LDL receptor gene OR
    - Medical record documentation of definite HeFH (score > 8) on the diagnostic criteria scoring system (Table 1) as defined by the ESC/EAS guidelines and the World Health Organization AND
- Prescription must be written by a cardiologist or lipidologist AND
- Medical record documentation of a baseline LDL within 3 months of the start of PCSK9 therapy AND
- Medical record documentation that the patient is at least 18 years of age AND
- One of the following:
  - Medical record documentation that patient is currently on and is adherent to (taking at least 90% of prescribed doses over the past three months) high-intensity statin therapy with atorvastatin 40 mg or 80 mg or Crestor** 20 mg or 40 mg, or the highest tolerable dose AND patient's most recent LDL > 70 mg/dL OR
  - Medical record documentation of intolerance to atorvastatin AND Crestor** AND current use or intolerance to a lower dose of Crestor** or atorvastatin or an alternative statin OR

o Medical record documentation of a contraindication to statin therapy AND
• Medical record documentation that counseling of non-pharmacologic therapies has been done including cholesterol lowering diet, physical activity, and weight management strategies AND
• Medical record documentation of an inability to achieve and maintain an LDL cholesterol levels at or below goal (< 100 mg/dL or < 70 mg/dL based on patient risk) with diet, exercise, and at least 12 weeks of combination therapy of statin with Zetia and a bile acid sequestrant if appropriate with the patient taking ≥ 90% of the prescribed doses of each medication AND
• Medical record documentation of a therapeutic failure on, intolerance to, or contraindication to Zetia AND
• Medical record documentation of a therapeutic failure on, intolerance to, or contraindication to a bile acid sequestrant or medical record documentation of an LDL > 100.

**PA Required

Quantity limit: 2 mL per 28 days

Approval duration
Initial authorizations for Praluent will be approved for a period of 6 months. Reauthorizations will be for a period of 12 months each provided the following criteria are met:
1. Medical record documentation of an up to date LDL cholesterol level since the date of the previous review showing the patient has had a clinically significant response to treatment with a PCSK9 inhibitor AND
2. Medical record documentation that the patient is not experiencing any significant adverse events related to therapy AND
3. Claims history and attestation from the provider showing the patient is adherent to PCSK9 therapy AND
4. Claims history or attestation from the provider that the patient is staying adherent to (filling at least 90% of doses) statin therapy.

Note to reviewers: If approved authorization should be entered by GPID

Table 1. Diagnostic criteria for the clinical diagnosis of HeFH (WHO)

	Criteria	Score
Family history	First-degree relative known with premature CAD* and/or first-degree relative with LDL-C >95th percentile	1
	First-degree relative with Tx and/or children <18 with LDL-C >95th centile	2
Clinical history	Patient has premature CAD*	2
	Patient has premature cerebral/peripheral vascular disease	1
Physical examination	Tx	6
	Arcus cornealis below the age of 45 years	4
LDL-C	>8.5 mmol/L (more than ~330 mg/dL)	8
	6.5-8.4 mmol/L (~250-329 mg/dL)	5
	5.0-6.4 mmol/L (~190-249 mg/dL)	3
	4.0-4.9 mmol/L (~155-189 mg/dL)	1
Definite FH		Score >8
Probable FH		Score 6-8
Possible FH		Score 3-5
No diagnosis		Score <3

Tx – Tendon xanthomata; *Premature CAD: male before 55, women before 60 years of age.

Formulary alternatives: atorvastatin, Zetia, cholestyramine, Prevalite, colestipol

Financial Discussion: No questions or comments.

Financial Outcome: Tricia Heitzman made a motion to accept the recommendations for Repatha as written. Todd Sponenberg seconded the motion. None were opposed.
Perry Meadows made a motion to accept the recommendations for other formulary changes. Kevin Szczecina seconded the motion. None were opposed.

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

- Medical record documentation of a diagnosis of:
    - Clinical atherosclerotic cardiovascular disease, including acute coronary syndromes (a history of myocardial infarction or unstable angina), coronary or other arterial revascularization, stroke, transient ischemic attack, or peripheral arterial disease presumed to be of atherosclerotic origin **OR**
    - Heterozygous familial hypercholesterolemia **AND** either:
        - Genetic testing to confirm a mutation in the LDL receptor gene **OR**
        - Medical record documentation of definite HeFH (score > 8) on the diagnostic criteria scoring system (Table 5) as defined by the ESC/EAS guidelines and the World Health Organization **OR**
    - Homozygous familial hypercholesterolemia **AND** either:
        - Genetic testing to confirm diagnosis showing at least one LDL receptor-defective mutation **OR**
        - Diagnosis made based on a history of an untreated LDL-C > 500 mg/dL **AND** either xanthoma before 10 years of age **OR** evidence of HeFH in both parents **AND**
- Prescription must be written by a cardiologist or lipidologist **AND**
- Medical record documentation of a baseline LDL within 3 months of the start of PCSK9 therapy **AND**
- Medical record documentation that the patient is $\geq$ 18 years of age if the diagnosis is clinical ASCVD or HeFH **OR** medical record documentation that the patients is $\geq$ 13 years of age if the diagnosis is HoFH **AND**
- One of the following:
    - Medical record documentation that patient is currently on and is adherent to (taking at least 90% of prescribed doses over the past three months) high-intensity statin therapy with atorvastatin 40 mg or 80 mg or Crestor 20 mg or 40 mg, or the highest tolerable dose AND patient's most recent LDL > 70 mg/dL **OR**
    - Medical record documentation of intolerance to atorvastatin **AND** Crestor **AND** current use or intolerance to a lower dose of Crestor or atorvastatin or an alternative statin **OR**
    - Medical record documentation of a contraindication to statin therapy **AND**
- Medical record documentation that counseling of non-pharmacologic therapies has been done including cholesterol lowering diet, physical activity, and weight management strategies **AND**
- Medical record documentation of a therapeutic failure on, intolerance to, or contraindication to a bile acid sequestrant or medical record documentation of an LDL $\geq$ 100 **AND**
- Medical record documentation of a therapeutic failure on, intolerance to, or contraindication to Zetia **AND**
- Medical record documentation of an inability to achieve and maintain an LDL cholesterol level at or below goal (< 100 mg/dL or < 70 mg/dL based on patient risk) with diet, exercise, and at least 12 weeks of combination therapy of statin with Zetia and a bile acid sequestrant if appropriate with the patient taking $\geq$ 90% of the prescribed doses of each medication.

Quantity Limits:

- 2 mL per 28 days if diagnosis is ASCVD or HeFH;
- 3 mL per 28 days if diagnosis is HoFH

AUTHORIZATION DURATION: Initial authorizations for Repatha will be approved for a period of 6 months for ASCVD and HeFH indications and 2 months for patients with HoFH. Reauthorizations will be for a period of 12 months each provided the following criteria are met:

- Medical record documentation of an up to date LDL cholesterol level since the date of the previous review showing the patient has had a clinically significant response to treatment with a PCSK9 inhibitor **AND**
- Medical record documentation that the patient is not experiencing any significant adverse events related to therapy **AND**
- Claims history and attestation from the provider showing the patient is adherent to PCSK9 therapy
- Claims history or attestation from the provider that the patient is staying adherent to (filling at least 90% of doses) statin therapy.

Definitions:

- Therapeutic failure to statins, Zetia, and/or bile acid sequestrants – inability to reach target LDL Goals (<100 mg/dL or <70 mg/dL based on patient risk) despite a ≥ 3 month trial with the patient taking ≥ 90% of the prescribed doses.
    - Adherence calculations must be supported by claims data or physician attestation if no claims history is available (i.e., if the patient is new to the plan or did not use insurance for their statin prescriptions).
- Intolerance to statins – increased LFTs, intolerable myalgia (muscle symptoms without creatinine kinase [CK] elevations), myopathy (muscle symptoms with CK elevations), or myositis (elevations in CK without muscle symptoms)
- Contraindication to statins – active liver disease, previous history of rhabdomyolysis, or hypersensitivity

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

Technivie **Kristi Clarke**
(ombitasvir, paritaprevir and ritonavir)

Kristi Clarke provided a review of Technivie to the committee for consideration as a pharmacy benefit. Technivie is a fixed-dose combination of ombitasvir, a hepatitis C virus NS5A inhibitor, paritaprevir, a hepatitis C virus NS3/4A protease inhibitor, and ritonavir, a CYP3A inhibitor and is indicated in combination with ribavirin for the treatment of patients with genotype 4 chronic hepatitis C virus (HCV) infection without cirrhosis. Limitations of Use: TECHNIVIE is not recommended for use in patients with moderate hepatic impairment (Child-Pugh B).

Formulary alternatives: Ribavirin, Ribasphere,Viekira Pak*^, Sovaldi*, Pegasys Proclick, Pegasys, Pegintron Redipen, Pegintron (*PA required, ^ QL apply)

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

- The member is at least 18 years of age or older **AND**
- Medical record documentation of a diagnosis of hepatitis C infection **AND**
- Medical record documentation of a diagnosis of hepatitis C virus (HCV) genotype 4 infection **AND**
- Medical record documentation of F2 – F3 liver fibrosis based on METAVIR liver (not FDA approved for F4 and will not be approved) **OR**
- Medical record documentation of severe extra hepatic manifestations of hepatitis C (Such as but not limited to: a syndrome involving cryoglobulinemia, an immune complex disorder, and a lymphoproliferative disorder that produces arthralgias, fatigue, palpable purpura, renal disease, neurologic disease, and reduced complement levels, as well as symptoms or objective evidence of end-organ damage), HIV or HBV coinfection, or history of a liver transplant **AND**
- Medical record documentation of no signs and symptoms of decompensated liver disease **AND**
- Is prescribed by a board certified gastroenterology, hepatology, infectious disease or transplant specialist **AND**
- Member must be evaluated and treated by a contracted Center of Excellence in Hepatitis C management **AND**
- Medical record documentation of Genotype 4 and concurrent therapy with ribavirin **AND**
- Medical record documentation of the member receiving an Food and Drug Administration (FDA) approved medication regimen that is inside the parameters of use approved by the FDA **AND**
- Medical record documentation of appropriate duration of treatment **AND**
- Medical record documentation of previous treatment and treatment response (and if previously treated only includes peginterferon and ribavirin) **AND**
- Medical record documentation of any potential drug interactions addressed by the prescriber (such as discontinuation of the interacting drug, dose reduction of the interacting drug, or counseling of the recipient of the risks associated with the use of both medications when they interact) **AND**
- Medical record documentation of receiving the following within the past 3 months:
    - Hepatic function panel
    - Complete blood count including differential
    - Basic metabolic panel
    - Baseline HCV RNA viral load **AND**
- Medical record documentation of concurrent therapy with appropriate dose and duration of ribavirin (weight-based dosing of ribavirin 1200 mg per day if ≥ 75 kg or 1000 mg per day if < 75 kg), if indicated **AND**
- Medical record documentation of a negative pregnancy test if member is female of childbearing potential and receiving ribavirin **AND**
- When concurrent ribavirin therapy is indicated and prescribed, medical record documentation for male members that female partner is not pregnant **AND**
- If the member or their partner are of childbearing potential, medical record documentation that the member was instructed to practice effective contraception during therapy with ribavirin and for 6 months following discontinuation of ribavirin therapy **AND**
- If actively abusing alcohol or IV drugs, or has a history of abuse, has documentation of prescriber counseling regarding the risks of alcohol or IV drug abuse, and an offer of a referral for substance use disorder treatment **AND**
- Medical record documentation that member received pre-treatment readiness education about hepatitis C treatment expectations by a health care provider **AND**

- Medical record documentation that the member in writing commits to the documented planned course of treatment including anticipated blood tests and visits, during and after treatment **AND**
- Medical record documentation that member is agreeable to counseling and monitoring by representatives from GHP **AND**
- Medical record documentation that member does not have a limited life expectancy of less than 12 months due to non-liver related co-morbid conditions **AND**
- Medical record documentation of rationale for not using Sovaldi* or Harvoni*

Initial Authorization: Technivie will be approved for a time period of up to 12 weeks.

Quantity Limits: 2 tablets per day with a maximum of 28 day supply per fill (unless additional tablets are needed for dose adjustments)

Formulary Alternatives: Sovaldi (*requires PA)

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 ritonavir component of Technivie is also an HIV-1 protease inhibitor and can select for HIV-1 protease inhibitor resistance-associated substitutions. Any HCV/HIV-1 co-infected patients treated with Technivie should also be on a suppressive antiretroviral drug regimen to reduce the risk of HIV-1 protease inhibitor drug resistance.

Clinical Outcome: Dr. Meadows made a motion to accept the recommendations as ammended. Kevin Szczecina seconded the motion. None were opposed.

Proposed Financial Recommendations: It is recommended that Technivie not be added to the GHP Family formulary at this time. No further criteria should apply.

Financial Discussion: No comments or questions.

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

Approved Recommendations: Tehnivie will not be added to the GHP Family formulary. Requests for use will require the following:

- The member is at least 18 years of age or older **AND**
- Medical record documentation of a diagnosis of hepatitis C infection **AND**
- Medical record documentation of a diagnosis of hepatitis C virus (HCV) genotype 4 infection **AND**
- Medical record documentation of F2 – F3 liver fibrosis based on METAVIR liver (not FDA approved for F4 and will not be approved) **OR**
- Medical record documentation of severe extra hepatic manifestations of hepatitis C (Such as but not limited to: a syndrome involving cryoglobulinemia, an immune complex disorder, and a lymphoproliferative disorder that produces arthralgias, fatigue, palpable purpura, renal disease, neurologic disease, and reduced complement levels, as well as symptoms or objective evidence of end-organ damage), HIV or HBV coinfection, or history of a liver transplant **AND**
- Medical record documentation of no signs and symptoms of decompensated liver disease **AND**
- Is prescribed by a board certified gastroenterology, hepatology, infectious disease or transplant specialist **AND**

- Member must be evaluated and treated by a contracted Center of Excellence in Hepatitis C management **AND**
- Medical record documentation of Genotype 4 and concurrent therapy with ribavirin **AND**
- Medical record documentation of the member receiving an Food and Drug Administration (FDA) approved medication regimen that is inside the parameters of use approved by the FDA **AND**
- Medical record documentation of appropriate duration of treatment **AND**
- Medical record documentation of previous treatment and treatment response (and if previously treated only includes peginterferon and ribavirin) **AND**
- Medical record documentation of any potential drug interactions addressed by the prescriber (such as discontinuation of the interacting drug, dose reduction of the interacting drug, or counseling of the recipient of the risks associated with the use of both medications when they interact) **AND**
- Medical record documentation of receiving the following within the past 3 months:
    - Hepatic function panel
    - Complete blood count including differential
    - Basic metabolic panel
    - Baseline HCV RNA viral load **AND**
- Medical record documentation of concurrent therapy with appropriate dose and duration of ribavirin (weight-based dosing of ribavirin 1200 mg per day if ≥ 75 kg or 1000 mg per day if < 75 kg), if indicated **AND**
- Medical record documentation of a negative pregnancy test if member is female of childbearing potential and receiving ribavirin **AND**
- When concurrent ribavirin therapy is indicated and prescribed, medical record documentation for male members that female partner is not pregnant **AND**
- If the member or their partner are of childbearing potential, medical record documentation that the member was instructed to practice effective contraception during therapy with ribavirin and for 6 months following discontinuation of ribavirin therapy **AND**
- If actively abusing alcohol or IV drugs, or has a history of abuse, has documentation of prescriber counseling regarding the risks of alcohol or IV drug abuse, and an offer of a referral for substance use disorder treatment **AND**
- Medical record documentation that member received pre-treatment readiness education about hepatitis C treatment expectations by a health care provider **AND**
- Medical record documentation that the member in writing commits to the documented planned course of treatment including anticipated blood tests and visits, during and after treatment **AND**
- Medical record documentation that member is agreeable to counseling and monitoring by representatives from GHP **AND**
- Medical record documentation that member does not have a limited life expectancy of less than 12 months due to non-liver related co-morbid conditions **AND**
- Medical record documentation of rationale for not using Sovaldi* or Harvoni*

Initial Authorization: Technivie will be approved for a time period of up to 12 weeks.

Quantity Limits: 2 tablets per day with a maximum of 28 day supply per fill (unless additional tablets are needed for dose adjustments)

Formulary Alternatives: Sovaldi (*requires PA)

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

Daklinza (daclatasvir)	**Kristi Clarke**

Kristi Clarke provided a review of Daklinza to the committee for consideration as a pharmacy benefit. Daclatasvir is a hepatitis C virus (HCV) NS5A inhibitor indicated for use with sofosbuvir for the treatment of chronic HCV genotype 3 infection.

Limitations of Use: Sustained virologic response (SVR) rates are reduced in patients with cirrhosis.

Formulary alternatives: Ribavirin, Ribasphere, Viekira Pak*^, Sovaldi*, Pegasys Proclick, Pegasys, Pegintron Redipen, Pegintron (*PA required, ^QL apply)

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

- The member is at least 18 years of age or older **AND**
- Medical record documentation of a diagnosis of hepatitis C infection **AND**
- Medical record documentation of a diagnosis of hepatitis C virus (HCV) genotype 3 infection **AND**
- Medical record documentation of F2 – F3 liver fibrosis based on METAVIR liver scoring (Daklinza will not be approved for cirrhotic members (F4) due to limited efficacy) **OR**
- Medical record documentation of severe extra hepatic manifestations of hepatitis C (Such as but not limited to: a syndrome involving cryoglobulinemia, an immune complex disorder, and a lymphoproliferative disorder that produces arthralgias, fatigue, palpable purpura, renal disease, neurologic disease, and reduced complement levels, as well as symptoms or objective evidence of end-organ damage), HIV or HBV coinfection, or history of a liver transplant **AND**
- Medical record documentation of no signs and symptoms of decompensated liver disease **AND**
- Is prescribed by a board certified gastroenterology, hepatology, infectious disease or transplant specialist **AND**
- Member must be evaluated and treated by a contracted Center of Excellence in Hepatitis C management **AND**
- Medical record documentation of Genotype 3 and concurrent therapy with Sovaldi **AND**
- Medical record documentation of the member receiving an Food and Drug Administration (FDA) approved medication regimen that is inside the parameters of use approved by the FDA **AND**
- Medical record documentation of appropriate duration of treatment **AND**
- Medical record documentation of previous treatment and treatment response (and does not include previous use of Harvoni or Daklinza) **AND**
- Medical record documentation of any potential drug interactions addressed by the prescriber (such as discontinuation of the interacting drug, dose reduction of the interacting drug, or counseling of the recipient of the risks associated with the use of both medications when they interact) **AND**
- Medical record documentation of receiving the following within the past 3 months:
    - Hepatic function panel
    - Complete blood count including differential
    - Basic metabolic panel
    - Baseline HCV RNA viral load **AND**

- If actively abusing alcohol or IV drugs, or has a history of abuse, has documentation of prescriber counseling regarding the risks of alcohol or IV drug abuse, and an offer of a referral for substance use disorder treatment **AND**
- Medical record documentation that member received pre-treatment readiness education about hepatitis C treatment expectations by a health care provider **AND**
- Medical record documentation that the member in writing commits to the documented planned course of treatment including anticipated blood tests and visits, during and after treatment **AND**
- Medical record documentation that member is agreeable to counseling and monitoring by representatives from GHP **AND**
- Medical record documentation that member does not have a limited life expectancy of less than 12 months due to non-liver related co-morbid conditions

Initial Authorization: Daklinza will be approved for a time period of up to 12 weeks.

Quantity Limits: 1 tablet per day with a maximum of 28 day supply per fill (unless additional tablets are needed for dose adjustments)

Formulary Alternatives: Sovaldi (requires prior authorization)

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. Daklinza is the only FDA approved regimen for rare genotype 3 (about 10% of HCV) that is ribavirin and interferon free. Must be taken in combination with Sovaldi. Drug interactions require dose adjustments. The efficacy is limited in cirrhotic patients. The other currently available, all-oral regimen approved for treatment of genotype 3 is Sovaldi with ribavirin for 24 weeks or Sovaldi with peginterferon and ribavirin for 12 weeks.

Resistance: Cross-resistance is expected for Daklinza and other NS5A inhibitors (ledipasvir). The efficacy of Daklinza/Sovaldi has not been studied in patients who have previously failed treatment with regimens that include an NS5A inhibitor.

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

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

- Medical record documentation of rationale for not using Sovaldi used in combination with peginterferon and ribavirin if clinically appropriate

Financial Discussion: No comments or questions.

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

Approved Recommendations: Daklinza will not be added to the GHP Family formulary. The following criteria will apply to requests for Daklinza:

- The member is at least 18 years of age or older **AND**
- Medical record documentation of a diagnosis of hepatitis C infection **AND**
- Medical record documentation of a diagnosis of hepatitis C virus (HCV) genotype 3 infection **AND**
- Medical record documentation of F2 – F3 liver fibrosis based on METAVIR liver scoring (Daklinza will not be approved for cirrhotic members (F4) due to limited efficacy) **OR**
- Medical record documentation of severe extra hepatic manifestations of hepatitis C (Such as but not limited to: a syndrome involving cryoglobulinemia, an immune complex disorder, and a lymphoproliferative disorder that produces arthralgias, fatigue, palpable purpura, renal disease, neurologic disease, and reduced complement levels, as well as symptoms or objective evidence of end-organ damage), HIV or HBV coinfection, or history of a liver transplant **AND**
- Medical record documentation of no signs and symptoms of decompensated liver disease **AND**
- Is prescribed by a board certified gastroenterology, hepatology, infectious disease or transplant specialist **AND**
- Member must be evaluated and treated by a contracted Center of Excellence in Hepatitis C management **AND**
- Medical record documentation of Genotype 3 and concurrent therapy with Sovaldi **AND**
- Medical record documentation of the member receiving an Food and Drug Administration (FDA) approved medication regimen that is inside the parameters of use approved by the FDA **AND**
- Medical record documentation of appropriate duration of treatment **AND**
- Medical record documentation of previous treatment and treatment response (and does not include previous use of Harvoni or Daklinza) **AND**
- Medical record documentation of any potential drug interactions addressed by the prescriber (such as discontinuation of the interacting drug, dose reduction of the interacting drug, or counseling of the recipient of the risks associated with the use of both medications when they interact) **AND**
- Medical record documentation of receiving the following within the past 3 months:
    - Hepatic function panel
    - Complete blood count including differential
    - Basic metabolic panel
    - Baseline HCV RNA viral load **AND**
- If actively abusing alcohol or IV drugs, or has a history of abuse, has documentation of prescriber counseling regarding the risks of alcohol or IV drug abuse, and an offer of a referral for substance use disorder treatment **AND**
- Medical record documentation that member received pre-treatment readiness education about hepatitis C treatment expectations by a health care provider **AND**
- Medical record documentation that the member in writing commits to the documented planned course of treatment including anticipated blood tests and visits, during and after treatment **AND**
- Medical record documentation that member is agreeable to counseling and monitoring by representatives from GHP **AND**
- Medical record documentation that member does not have a limited life expectancy of less than 12 months due to non-liver related co-morbid conditions **AND**
- Medical record documentation of rationale for not using Sovaldi used in combination with peginterferon and ribavirin if clinically appropriate

Initial Authorization: Daklinza will be approved for a time period of up to 12 weeks.

Quantity Limits: 1 tablet per day with a maximum of 28 day supply per fill (unless additional tablets are needed for dose adjustments)

Formulary Alternatives: Sovaldi (requires prior authorization

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

Kengreal (cangrelor) **Steven Kheloussi**

Steven Kheloussi provided a review of Kengreal to the committee for consideration as a pharmacy or medical benefit. Kengreal is indicated as adjunctive treatment to percutaneous coronary intervention (PCI) to reduce the risk for periprocedural myocardial infarction (MI), repeat coronary revascularization and stent thrombosis in patients who have not been treated with $P2Y_{12}$ platelet inhibitors and are not being given a glycoprotein IIb/IIIa inhibitor. Kengreal is a direct $P2Y_{12}$ platelet receptor inhibitor that blocks adenosine diphosphate (ADP) induced platelet activation and aggregation. It binds selectively and reversibly to the $P2Y_{12}$ receptor to prevent further signaling and platelet activation. Kengreal is rapidly distributed and metabolized, reaching C_{max} within 2 minutes after administration of an IV bolus followed by infusion.

Formulary alternatives: clopidogrel, ticlopidine, Effient (requires prior authorization)

Proposed Clinical Recommendations: It is recommended that Kengreal be considered a medical benefit for GHP Family.

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 use of this product should be limited to the inpatient setting. Kengreal is the first and only intravenous $P2Y_{12}$ inhibitor that blocks platelet ADP activation and aggregation. It is dosed two-times only based on actual body weight. It is not intended for extended use and is not a replacement for maintenance antiplatelet therapy.

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

Proposed Financial Recommendations: It is recommended that Kengreal be considered a medical benefit for GHP Family. No prior authorization criteria should be put in place.

Financial Discussion: No comments or questions.

Financial Outcome: Kevin Szczecina made a motion to accept the recommendations as written. Dr. Perry Meadows seconded the motion. None were opposed.

Approved Recommendations: Kengreal should be considered a medical benefit for GHP Family.

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

Iressa **Kim Clark**
(gefitinib)

Kim Clark provided results from the electronic vote for Iressa, held on October 9, 2015. Iressa is a pharmacy benefit. Iressa is indicated for the 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.

Limitations of use: Safety and efficacy of Iressa have not been established in patients with metastatic NSCLC whose tumors have EGFR mutations other than exon 19 deletions or exon 21 (L858R) substitution mutations.

Formulary alternatives: gilotrif*, Tarceva*(*PA required)

Approved Recommendations: Iressa was approved for formulary via electronic vote on October 9, 2015. Iressa will be added to the GHP Family formulary at the brand tier, and will require prior authorization under the pharmacy benefit. The following criteria will apply to prior authorization requests:

- 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

Quantity Limits: 1 tablet/day

AUTHORIZATION DURATION: Initial approval will for **6 months**. Re-review will occur every six (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.

Electronic voting results: Twenty three (23) electronic votes to approve the recommendations as written. None were opposed.

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

FAST FACTS:

Zomig Nasal Spray **Steven Kheloussi**
(zolmitriptan)

Updated age restriction: Zomig is now indicated for the acute treatment of migraine with or without aura in adults and pediatric patients 12 years and older. Previously only indicated in adults.

New Dose and administration:
Adults and Pediatric Patients 12 years or older:

- Recommended dosage: 2.5 mg
- Maximum recommended single dose: 5 mg
- Maximum dosage in a 24-hour period: 10 mg
- If the migraine has not resolved after 2 hours or returns after transient improvement, another dose of Zomig may be administered at least 2 hours after the previous dose.
- The safety of Zomig in the treatment of an average of more than four headaches in a 30-day period has not been established.

Recommendation: It's recommended that Zomig Nasal Spray remains NF and a policy be created for with the following criteria:

- Medical record documentation of a FDA approved indication **AND**
- Medical record documentation the member is not using concurrent opioid or barbiturate therapy for migraine treatment **AND**
- Medical record documentation of a therapeutic failure on, intolerance to, or contraindication to sumatriptan for patients 18 years of age and older **OR**
- Medical record documentation of a therapeutic failure on, intolerance to, or contraindication to rizatriptan for patients 12 to 18 years of age

- QUANTITY LIMIT: 16 units per 28 days (The quantity limit of 16 units per 28 days applies to each individual nasal or injectable product however applies across all triptan oral tablet products.) (1 unit = 1 tablet = 1 injection = 1 nasal spray)

Discussion: No comments or questions.

Outcome: Dr. Meadows 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.

Dysport **Kimberly Clark**
(abobotulinumtoxinA)

New Indication: Dysport is now indicated for upper limb spasticity in post stroke and post traumatice brain injury patients.

Recommendation: It is recommended that the new indication is added to the existing Botulinum Toxin and Derivatives medical and Medicare pharmacy policies with the following wording:

- Medical record documentation that Dysport is being used for the treatment of upper limb spasticity in the following muscles: elbow flexors (biceps), wrist flexors (flexor carpi radialis and flexor carpi ulnaris), finger flexors (flexor digitorum profundus and flexor digitorum sublimis), and thumb flexors (adductor pollicis and flexor pollicis longus) AND
- Documentation that the patient is at least 18 years of age

Discussion: No questions or comments.

Outcome: Jamie Dodson 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.

Epzicom **Steven Kheloussi**
(abacavir and lamivudine**)**

New Indication: Epzicom, in combination with other antiretroviral agents, is indicated for the treatment of human immunodeficiency virus type 1 (HIV-1) infection. Epzicom was previously only indicated in adults, and is now indicated in pediatric patients weighing at least 25 kg.

Newly Added and Updated Contraindications[1]:

- Epzicom is now contraindicated in patients who have the HLA-B*5701 allele.
- Previous contraindication of "hepatic impairment" has been updated to "moderate or severe hepatic impairment."

Newly Added Warning and Precaution[1]:

- Related products that are not recommended
    - Epzicom contains fixed doses of 2 nucleoside analogue reverse transcriptase inhibitors (abacavir and lamivudine); concomitant administration with other products containing abacavir or lamivudine is not recommended. In addition, do not administer Epzicom in combination with products containing emtricitabine.

Recommendation: No changes to formulary recommended

Discussion: No comments or questions.

Outcome: Jamie Dodson made a motion to accept the recommendations as written. Perry Meadows 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.

Edurant **Kimberly Clark**
(rilpivirine)

New Indication: Edurant is now indicated for the treatment of HIV-1 in treatment-naïve patients with an HIV RNA ≤100,000 copies/mL at the start of therapy in adolescents. Patients need to be at least 12 years old and weigh at least 35 kg.

- Previously only indicated in patients 18 years of age and older
- Safety and effectiveness in pediatric patients < 12 years of age have not been established.
- **Dose:** 1 tablet (25mg) once daily with a meal.
- **If given concomitantly with rifabutin:** 2 tablets (50 mg) once daily with a meal.

Recommendation: No changes to the formulary recommended at this time.

Discussion: No questions or comments.

Outcome: Kevin Szczecina made a motion to accept the recommendations as written. Perry Meadows 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.

Reyataz **Steven Kheloussi**
(atazanavir)

New Indication: Reyataz is indicated in combination with other antiretroviral agents for the treatment of HIV-1 infection for patients 3 months and older weighing at least 5 kg.

- Previously only indicated in patients weighing at least 10 kg

Recommendation: No changes recommended to formulary at this time.

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.

Aptiom **Kimberly Clark**
(eslicarbazepine)

New Indication: Aptiom is indicated for the treatment of partial-onset seizures as monotherapy or adjunctive therapy

Recommendation: There are no formulary tiering changes recommended at this time. It is recommended that the criterion regarding concomitant use with at least one other formulary AED is removed from the drug policy as follows:

- Prescription is written by a neurologist **AND**
- Patient is at least 18 years of age **AND**
- Medical record documentation of a diagnosis of partial-onset seizures **AND**

- Medical record documentation of contraindication to, therapeutic failure on, or intolerance to 3 formulary alternatives

Quantity Limit:
600 mg tablet: 2 tablets per day
All other strengths (200 mg, 400 mg, 800 mg): 1 tablet per day

Discussion: No comments or questions

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

Keytruda **Steven Kheloussi**
(pembrolizumab)

New Indication: Keytruda is now indicated for the treatment of patients with metastatic NSCLC whose tumors expressed PD-L1 as determined by an FDA-approved test and who have disease progression on or after 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 Keytruda.

Recommendation: The policy for Keytruda should be updated to the following:

- 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

Discussion: NCCN guidelines recommend Keytruda as a preferred single-agent (if not already given) as subsequent therapy for metastatic disease following progression on a cytotoxic regimen for patients with performance status 0-2 and tumors of squamous cell histology and PD-L1 expression.

Outcome: Perry Meadows 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.

Opdivo **Steven Kheloussi**
(nivolumab)

New Indication: Opdivo is now indicated in combination with ipilimumab for the treatment of patients with BRAF V600 wild-type, unresectable or metastatic melanoma.

- This indication is approved under accelerated approval based on tumor response rate and durability of response. Continued approval for this indication may be contingent upon verification and description of clinical benefit in confirmatory trials.
- Previously only indicated as a single agent in patients with unresectable or metastatic melanoma and disease progression following ipilimumab and, if BRAF V600 mutation positive, a BRAF inhibitor.
- Opdivo is also now indicated for the treatment of patients with metastatic NSCLC with progression on or after platinum-based chemotherapy. Patients with EGFR or ALK genomic tumor aberrations should have disease progression on FDA-approved therapy for these aberrations prior to receiving Opdivo.

Recommendation: The policy for Opdivo should be updated to the following:

- Medical record documentation of a diagnosis of metastatic ~~squamous~~ non-small cell lung cancer (NSCLC) and disease progression while on or after platinum-based chemotherapy
- 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)

Discussion: NCCN guidelines recommend Opdivo as a preferred single-agent (if not already given) as subsequent therapy for metastatic disease following progression on a cytotoxic regimen for patients with performance status 0-2 (category 1 recommendation for progression following a first-line cytotoxic regimen; category 2A for further progression).

Metastatic melanoma:
NCCN recommends Opdivo for metastatic or unresectable disease as a single agent or in combination with ipilimumab as

- first-line therapy
- second-line or subsequent therapy for disease progression for patients with performance status 0-2 if not previously used

Category 1 when used as a single agent as first-line therapy; category 2A otherwise.

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

Promacta **Kimberly Clark**
(eltrombopag)

New Indication: Promacta is a thrombopoietin receptor agonist indicated for the treatment of thrombocytopenia in adult and <u>pediatric patients 1 year and older</u> with chronic immune (idiopathic) thrombocytopenia (ITP) who have had an insufficient response to corticosteroids, immunoglobulins, or splenectomy.

Recommendation: There are no formulary tiering or prior authorization changes recommended at this time. It is recommended that the following definition be added to the prior authorization criteria as follows:

Add to policy definitions:

> Chronic Immune Thrombocytopenia (ITP) – immune-mediated thrombocytopenia (platelet count less than 100,000/ μL, with no other hematologic abnormalities) persisting beyond 12 months from the time of the initial presentation of ITP

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.

CLASS REVIEW

Growth Homrone **Steven Kehloussi**

Steven Kheloussis presented a review of the growth hormone class to include the following products:

Brand Name	Generic name	Manufacturer	How Supplied		FDA Approval Date
Genotropin[1]	somatropin	Pfizer, Inc.	Cartridges for use with Pen or Mixer: 5 mg; 12 mg	MiniQuick Cartridge Device: 0.2 mg; 0.4 mg; 0.6 mg; 0.8 mg; 1.0 mg; 1.2 mg; 1.4 mg; 1.6 mg; 1.8 mg; and 2.0 mg/0.25 mL	8/24/1995
Humatrope[2]	somatropin	Eli Lilly	Vial: 5 mg	Cartridge Kits: 6 mg; 12 mg; 24 mg	3/8/1987
Norditropin FlexPro[3]	somatropin	Novo Nordisk, Inc.	FlexPro Pen: 5 mg/1.5 mL; 10 mg/1.5 mL; 15 mg/1.5 mL; 30 mg/3 mL		6/20/2000
Nutropin AQ[4]	somatropin	Genentech, Inc.	Cartridge Pen: 10 mg/2 mL; 20 mg/2 mL	NuSpin Pen: 5 mg/2 mL; 10 mg/2 mL; 20 mg/2 mL	12/29/1995
Omnitrope[5]	somatropin	Sandoz, Inc.	Vial: 5.8 mg	Pen: 5 mg/1.5 mL; 10 mg/1.5 mL	5/30/2006
Saizen[6]	somatropin	EMD Serono, Inc.	Vial: 5 mg; 8.8mg	Click.Easy Device: 8.8 mg/1.5 mL	10/8/1996
Serostim[7]	somatropin	EMD Serono, Inc.	Vial: 4 mg; 5 mg; 6 mg		8/23/1996

Zomacton[8]*	somatropin	Teva Pharmaceuticals	Vial: 5 mg; 10 mg	5/25/1995
Zorbtive[9]	somatropin	EMD Serono, Inc.	Vial: 8.8 mg	12/1/2003

FDA Approved Indications[1-9]

	Genotropin	Humatrope	Norditropin	Nutropin AQ	Omnitrope	Saizen	Serostim	Zomacton	Zorbtive
Pediatric patients									
Pediatric GHD	✓	✓	✓	✓	✓	✓		✓	
Prader-Willi Syndrome	✓				✓				
Small for Gestational Age	✓[a]	✓[b]	✓[b]		✓[a]				
Turner Syndrome	✓	✓	✓	✓	✓				
Idiopathic Short Stature	✓	✓		✓	✓				
SHOX Deficiency		✓							
Noonan Syndrome			✓						
Growth Failure Secondary to CKD				✓[c]					
Adults patients									
Adult or Childhood Onset[d] GHD	✓	✓	✓	✓	✓	✓			
Non-Growth Failure Related Indications									
Wasting or cachexia in HIV patients[e]							✓		
Short Bowel Syndrome[e]									✓

Recommendations: As there are no discernable differences between products, it is recommended no changes are made to our formulary agents at this time (for clinical reasons).:

- The following changes are recommended for the Medicaid formulary:
  - Genotropin should be removed from the formulary
  - Nutropin formulations should be added to the Brand Tier requiring prior authorization
- Prior authorization criteria should be updated to read:
  - For Norditropin and Nutropin:
    - Medical record documentation of use for an FDA-approved indication

- For all other growth hormone products
    - Medical record documentation of use for an FDA-approved indication **AND**
    - Medical record documentation of a therapeutic failure on, intolerance to, or contraindication to Norditropin and Nutropin if appropriate.

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. Class review and specialist input agree that products are interchangeable. The use of a pen device is preferred for patient compliance.

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

POLICY UPDATES:

Bethkis **Kim Clark**

At the July P&T meeting, it was recommended and approved that an age-related criterion be added to the policy. However, the indicated age is below some of the formulary alternatives. The criteria should be updated to reflect this.

Recommendation: No changes recommended at this time.

Discussion: In the absence of an acute pulmonary exacerbation, we generally suggest **not** administering chronic or intermittent systemic antibiotics to patients with cystic fibrosis (CF), EXCEPT for the following:

- For patients six years and older with persistent P. aeruginosa infection and moderate or severe lung disease, we recommend chronic treatment with inhaled tobramycin (Grade 1A). We also suggest this treatment for patients with mild lung disease and persistent P. aeruginosa infection (Grade 2B). Inhaled aztreonam lysine is a reasonable alternative, as is inhaled colistin. The inhaled antibiotics are typically cycled between 28 days on and 28 days off treatment."[1]

In general there is no clinical difference in the efficacy of the inhaled tobramycin products. In clinical trials, the frequency of cough was higher with the powdered form (25.3%) compared with the nebulized liquid (4.3%) < which lead to a higher rate of drug discontinuation. The powdered preparation is advantageous in that is significantly reduces the time required to administer each dose compared with the aerosolized form.

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.

Kalydeco **Kevin Szczecina**

Recommendation: Kalydeco is now approved for use in patients age 2 and older with the *R117H* mutation in the *CFTR* gene. The Kalydeco policy should be updated to reflect this change

Discussion: no questions or comments

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

GHP Family Quantity Limits **Kevin Szczecina**

Recommendation: The following Quantity Limit updates were recommended by Pennsylvania Department of Human Services (DHS) and should be updated for GHP Family:

Sylatron	4 injections per 28 days
Morphine 20 mg/5 mL	45 mL per day
Morphine 10 mg/5 mL	90 mL per day
Morphine 100 mg/5 mL	9 mL per day
Naloxone Syringe	Quantity limit was removed

Discussion: No questions or comments.

Outcome: Jamie Dodson 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.

Synthroid **Kevin Szczecina**

Recommendation: Currently there are no branded levothyroxine products on the GHP Family Formulary. As a result, there is only one alternative to costlier branded products such as Tirosint. It is recommended that Synthroid be added to the GHP Family Formulary.

Discussion: no questions or comments

Outcome: Jamie Dodson 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.

Praluent Policy 1316.0F **Kevin Szczecina**

Recommendation: The following changes were made to the Praluent policy at the request of DHS. It is recommended they be approved by the committee (additions are underlined, strikethroughs indicate removal):

- Medical record documentation that counseling of non-pharmacologic therapies are in place has been done including cholesterol lowering diet, exercise physical activity, and weight management strategies AND
- Medical record documentation an inability to achieve and maintain an LDL cholesterol levels at or below goal (< 100 mg/dL or < 70 mg/dL based on patient risk) with a combination of medications, diet and exercise physical activity

It is recommended the committee approve these changes.

Discussion: No questions or comments.

Outcome: Steven Kheloussi 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.

Nasacort OTC **Kevin Szczecina**

Recommendation: The only manufacturer of Nasacort OTC is not a covered labeler by DHS. It is recommended it be reomoved from the GHP Family formulary to avoid confusion.

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.

Quarterly case audit results **Todd Sponenberg**

A quarterly case audit meeting ws held on 9/14/15. No formulary changes recommended.

Meeting adjourned at 4:07 pm.

Future Scheduled Meetings

January 19, 2015 at 1:00 HCSRLL 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.