P&T Committee Meeting Minutes
GHP Family Business
May 17, 2016

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

Call To Order:
Bret Yarczower called the meeting to order at 1:02 p.m., Tuesday, May 17, 2016.

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

DRUG REVIEWS:

ODEFSEY **Steven Kheloussi**
(emtricitabine/rilpivirine/tenofovir alafenamide)

Steven Kheloussi provided a review of Odefsey to the committee for consideration as a pharmacy benefit. Odefsey is indicated as a complete regimen for the treatment of HIV-1 infection in patients > 12 years of age as initial therapy in those with no antiretroviral treatment history with HIV-1 RNA < 100,000 copies per mL; or to replace a stable antiretroviral regimen in those who are virologically-suppressed (HIV-1 RNA < 50 copies per mL) for at least six months with no history of treatment failure and no known substitutions associated with resistance to the individual components of Odefsey.

Formulary alternatives: Atripla, Complera, Genvoya, Stribild, Triumeq

Proposed Clinical Recommendations: It is recommended that Odefsey be added to the GHP Family formulary

Clinical Discussion: FDA Approved Indications, Pharmacology/MOA, Clinical Evidence of Safety and Efficacy, Adverse Reactions, Dosing Schedule, Monitoring, Safety Profile, Black Box Warnings, Contraindications, Warnings and Precautions, Drug Interactions, Patent Life, Unique Therapeutic Features, Recommendations of National Agencies and Organizations, and Special Population Precautions were discussed. For geriatric use, no differences in safety or efficacy have been observed between elderly subjects and those 12 to 65 years of age.

Odefsey is an "all-in-one" combination therapy formulation to treat HIV-1 infection in patients ≥ 12 years of age. It is indicated as initial therapy for treatment-naive patients or to replace a stable antiretroviral regimen in those who are virologically-suppressed. Odefsey is composed of two nucleoside/nucleotide reverse transcriptase inhibitors, FTC and TAF and a non-nucleoside reverse transcriptase inhibitor, RPV. This formulation is similar to Complera, which has the same three medications with the difference that Complera contains TDF. The TAF component of Odefsey, reduces the renal toxicity compared to Complera making it possible to be used in patients with reduced renal function (CrCL > 30 mL/min). A clinical study where patients were switched from FTC+TDF to FTC+TAF demonstrated that the rates of virological suppression were maintained with a lower incidence of side effects.

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

Proposed Financial Recommendations: It is recommended that Odefsey be added to the GHP Family formulary.

Financial Discussion: No questions or comments.

Financial Outcome: Kristen Bender made a motion to accept the recommendation as written. Kim Clark seconded the motion. None were opposed.

Approved Recommendations: Odefsey will be added to the GHP Family formulary on the Brand tier.

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

DESCOYV **Steven Kheloussi**
(emtricitabine/tenofovir alafenamide))

Steven Kheloussi provided a review of Descovy to the committee. Descovy is indicated, in combination with other antiretroviral agents, for the treatment of HIV-1 infection in adults and pediatric patients 12 years of age and older.

Limitations of use: Descovy is not indicated for use as pre-exposure prophylaxis (PrEP) to reduce the risk of sexually acquired HIV-1 in adults at high risk.

Formulary alternatives: lamivudine/zidovudine, abacavir/lamivudine, zidovudine, Epzicom ,Truvada, Trizivir

Proposed Clinical Recommendations: Based on the available safety and efficacy data, it is recommended that Descovy be added to the GHP Family formulary.

Clinical Discussion: FDA Approved Indications, Pharmacology/MOA, Clinical Evidence of Safety and Efficacy, Adverse Reactions, Dosing Schedule, Monitoring, Safety Profile, Black Box Warnings, Contraindications, Warnings and Precautions, Drug Interactions, Patent Life, Unique Therapeutic Features, Recommendations of National Agencies and Organizations, and Special Population Precautions were discussed. For geriatric use, no differences in safety or efficacy have been observed between elderly subjects and those 12 to 65 years of age.

Descovy is composed of two nucleoside/nucleotide reverse transcriptase inhibitors, FTC and TAF. This formulation is similar to Truvada, which has the same two medications with the difference that Truvada contains TDF.

Different studies have shown that TAF does not accumulate in the renal proximal tubules, providing higher renal safety than TDF.[3] In another study, TAF has been shown to be absorbed in a higher amount by peripheral blood mononuclear cells compared with TDF, while maintaining lower plasma tenofovir exposure.[4] The safer renal profile of Descovy allows for it to be used without dose reduction in patients with CrCl $\geq$ 30 mL/min. This differs slightly from Truvada, which must be dose reduced (every 48 hour dosing) for CrCl < 50 mL/min and should also not be used in patients with CrCL < 30 mL/min.

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

Proposed Financial Recommendations: It is recommended that Descovy be added to the GHP Family formulary.

Financial Discussion: No comments or questions.

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

Approved Recommendations: Descovy will be added to the GHP Family formulary on the Brand Tier.

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

Belbuca **Kim Clark**
(buprenorphine)

Kim Clark provided a review of Belbuca to the committee for consideration as a pharmacy benefit. Belbuca buccal film contains buprenorphine, a partial opioid agonist. Belbuca is indicated for the management of pain severe enough to require daily, around-the-clock, long-term opioid treatment and for which alternative treatment options are inadequate.

Limitations of Use: Because of the risks of addiction, abuse, and misuse with opioids, even at recommended doses, and because of the greater risks of overdose and death with long-acting opioid formulations, reserve Belbuca for use in patients for whom alternative treatment options (e.g., non-opioid analgesics, or immediate-release opioids) are ineffective, not tolerated, or would be otherwise inadequate to provide sufficient management of pain. Belbuca is not indicated as an as-needed (PRN) analgesic.

Formulary alternatives: fentanyl patches, morphine sulfate ER, tramadol ER

Proposed Clinical Recommendations: Belbuca should not added to the GHP Family formulary at this time. The following prior authorization criteria should apply:

- Must be prescribed by a pain management specialist **AND**
- Medical record documentation of pain severe enough to require daily, around-the-clock, long-term opioid treatment and for which alternative treatment options are inadequate **AND**
- Medical record documentation of therapeutic failure on, intolerance to, or contraindication to 3 formulary alternatives, one of which must be morphine sulfate ER

Quantity Limit: 2 films per day

Clinical Discussion: FDA Approved Indications, Pharmacology/MOA, Clinical Evidence of Safety and Efficacy, Adverse Reactions, Dosing Schedule, Monitoring, Safety Profile, Black Box Warnings, Contraindications, Warnings and Precautions, Drug Interactions, Patent Life, Unique Therapeutic Features, Recommendations of National Agencies and Organizations, and Special Population Precautions were discussed. For geriatric use, of the total number of patients that were treated with Belbuca in controlled and open-label chronic pain trials (2,127), 340 patients were 65 years and older. Of those, 49 patients were aged 75 years and older. The incidences of selected Belbuca-related adverse effects were higher in older subjects. No notable differences in pharmacokinetics were observed from population pharmacokinetic analysis in subjects aged 65 compared to younger subjects. Other reported clinical experience with buprenorphine has not identified differences in responses between the elderly and younger patients. Although specific dose adjustments on the basis of advanced age are not required for pharmacokinetic reasons, use caution in the elderly population to ensure safe use.clinical studies of Alecensa did not include a sufficient number of subjects aged 65 and older to determine whether they respond differently from younger subjects.

Belbuca is the first and only buprenorphine formulation developed with a dissolving film that is absorbed through the inner lining of the check for chronic pain management. Belbuca utilizes buccal film technology for improved absorption of buprenorphine, which may help reduce the potential for misuse and potentially lessen the incidence of certain side effects.

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

Proposed Financial Recommendations: Belbuca should not be added to the GHP Family formulary at this time. No additiona1 critiera should apply.

Financial Discussion: No comments or questions.

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

Approved Recommendations: Belbuca will not be added to the GHP Family formulary. Request for coverage will require the following:

- Must be prescribed by a pain management specialist **AND**
- Medical record documentation of pain severe enough to require daily, around-the-clock, long-term opioid treatment and for which alternative treatment options are inadequate **AND**
- Medical record documentation of therapeutic failure on, intolerance to, or contraindication to 3 formulary alternatives, one of which must be morphine sulfate ER

Quantity Limit: 2 films per day

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

VELTASSA **Steven Kheloussi**
(patiromer)

Steven Kheloussi provided a review of Veltassa to the committee for consideration as a pharmacy benefit. Veltassa is a potassium binder indicated for the treatment of hyperkalemia.

Limitation of Use: Veltassa should not be used as an emergency treatment for life-threatening hyperkalemia because of its delayed onset of action.

Formulary alternatives: sodium polystyrene sulfonate

Proposed Clinical Recommendations: It is recommended that Veltassa is added to the GHP Family formulary. The following prior authorization criteria should apply to requests for Veltassa:
- Medical record documentation of a diagnosis of mild to moderate hyperkalemia (serum potassium ≥ 5.1 mEq/L and < 6.5 mEq/L) **AND**
- Medical record documentation of age >18 years **AND**
- Medical record documentation that attempt has been made to identify and correct the underlying cause of the patient's hyperkalemia **OR** rationale as to why the underlying cause cannot be corrected **AND**
- For mild hyperkalemia (serum potassium > 5.1 mEq/L to < 5.5 mEq/L): Medical record documentation that a low potassium diet has been tried and was unsuccessful at controlling the patient's serum potassium level.

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.

Veltassa is indicated for the treatment of hyperkalemia. The active ingredient of Veltassa is a non-absorbable polymer that sequesters potassium from the digestive tract and is discarded in the stool. Patients on renin-angiotensin-aldosterone system inhibitors (i.e., ACE inhibitors, ARB, or aldosterone antagonists) have the tendency to suffer from hyperkalemia. Clinical trials that included these patients have demonstrated the efficacy of Veltassa in reducing the plasma concentration of potassium to values within normal limits. Those studies have also shown that when used for extended periods of time, Veltassa can maintain the potassium concentration within normal limits.

The mechanism of action of Veltassa is similar to that of another polymer, sodium polystyrene sulfonate, brand names Kionex or Kayexalate. Both polymers are similarly effective in reducing potassium levels at the indicated dosages. Unlike sodium polystyrene sulfonate, Veltassa does not swell appreciably when exposed to water and it does not require a laxative to reach the distal colon. The most common side effect of these two medicines is hypomagnesemia. Both Veltassa and sodium polystyrene sulfonate can cause GI discomfort. Sodium polystyrene sulfonate has been associated with incidence of bowel obstruction and serious GI complications including fatal colonic perforation. Studies with Veltassa have not shown these side effects

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

Proposed Financial Recommendations: It is recommended that Veltassa be added to the Brand tier on the GHP Family formulary. The following additional prior authorization criteria should apply to requests:

- Medical record documentation of a therapeutic failure on, intolerance to, or contraindication to loop diuretic or thiazide diuretic therapy.

Quantity limits: approved by GPID with a quantity limit of 1 packet per day for each strength.

Financial Discussion: No comments or questions.

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

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Approved Recommendations: Veltassa will be added to the GHP Family formulary on the Brand tier requiring prior authorization. The following prior authorization criteria will apply to requests:

Medical record documentation of a diagnosis of mild to moderate hyperkalemia (serum potassium $\geq$ 5.1 mEq/L and < 6.5 mEq/L) **AND**
- Medical record documentation of age >18 years **AND**
- Medical record documentation that attempt has been made to identify and correct the underlying cause of the patient's hyperkalemia **OR** rationale as to why the underlying cause cannot be corrected **AND**
- For mild hyperkalemia (serum potassium > 5.1 mEq/L to < 5.5 mEq/L): Medical record documentation that a low potassium diet has been tried and was unsuccessful at controlling the patient's serum potassium level **AND**

-Medical record documentation of a therapeutic failure on, intolerance to, or contraindication to loop diuretic or thiazide diuretic therapy.

Quantity limits: approved by GPID with a quantity limit of 1 packet per day for each strength

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

Kanuma (mepolizumab) **Kim Clark**

Kim Clark provided a review of Kanuma to the committee for consideration as a medical or pharmacy benefit. Kanuma is a hydrolytic lysosomal cholesteryl ester and triacylglycerol-specific enzyme indicated for the treatment of patients with a diagnosis of Lysosomal Acid Lipase deficiency.

Lysosomal Acid Lipase Deficiency LAL-D is a rare autosomal recessive genetic disorder caused by mutations of the "lipase A lysosomal acid type" gene (LIPA). Lysosomal Acid Lipase LAL is the enzyme responsible for metabolizing lipids in the lysosomes of cells. A deficiency or absence of LAL leads to an accumulation of cholesteryl esters, LDL, and triglycerides in the following cells and tissues: spleen, liver, bone marrow, small intestine, adrenal glands, blood vessels and lymph nodes. LAL-D may cause bloating, abdominal distention, malabsorption, vomiting, fibrosis of the liver, and hepatosplenomegaly. The diagnosis of LAL-D is confirmed by identification of either pathogenic variants in *LIPA* or deficient LAL in peripheral blood leukocytes, fibroblasts, or dried blood spots.

LAL-D can manifest in two different ways. Wolman disease is a rare (1-2 infants per million births) and rapidly progressive disease which presents during infancy. Patients with Wolman disease rarely survive beyond the first year of life due to the serious digestive abnormalities, hepatic dysfunction, severe anemia, and adrenal gland stenosis. Cholesteryl ester storage disease CESD is a milder form of LAL-D and presents during childhood or early adulthood. Life expectancy of patients with CESD depends on the severity of the disease and associated complications. CESD affects 25 individuals per million births. Most disease management therapies aim to treat symptoms not the underlying cause of LAL-D. Lipid lowering medications, liver transplantation, and hematopoietic stem cell transplantation are currently used to manage LAL-D.

Formulary alternatives: none

Proposed Clinical Recommendations: Kanuma is a medical benefit for GHP Family and should not be added to the formulary. Requests for Kanuma should require a medical prior authorization with the following criteria:

- Must be prescribed by a provider specializing in genetics or metabolism **AND**
- Medical record documentation of Lysosomal Acid Lipase deficiency as either Wolman disease **OR** Cholesteryl ester storage disease (CESD) **AND**
- Medical record documentation of confirmed diagnosis in one of three ways: Dried Blood Spot (DBS) test*, leucocyte testing, genetic testing **AND**
- Medical record documentation that the member will receive a weight and diagnosis appropriate dosing regimen

Rapidly progressing/ Wolman disease: Patients 0-6 months of age Kanuma will initially be approved for quantity sufficient for up to 3 mg/kg once weekly. These requests should be approved for a total of 4 visits per month (medical benefit).

Late onset/ CESD: Patients 4 years of age and older will be approved for 1 mg/kg every other week. These requests should be approved for a total of 2 visits per month (medical benefit).

Authorization duration: Initial approval will be for a period of 3 months or less if the reviewing provider feels it is medically appropriate. Subsequent approvals will be for an additional 12 months or less if the reviewing provider feels it medically appropriate and will require medical record documentation of continued disease improvement or lack of disease progression.

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

Bret Yarczower summarized input from specialists regarding the use of this medication. The exact role of this medications remains unclear at this time. Other medical therapy which could be considered as curative such as liver transplantation and hematopoetic stem cell therapy transplants need to be evaluated. This medications role may be considered for bridge therapy until such other treatments are evaluated.

Clinical Outcome: Kim Clark propsed changing the recommendations to make Kanuma a medical benefit but to table the specific prior authorization criteria until the exact role in therapy could be fully evaluated. Steve Kheloussi made a motion to accept the modified recommendations. Tricia Heitzman seconded the motion. None were opposed.

Proposed Financial Recommendations: Kanuma is a medical benefit and should not be added to the GHP Family formulary at this time.

Financial Discussion: No questions or comments.

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

Approved Recommendations: Kanuma will be a medical benefit requiring prior authorization for GHP Family.

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

VIVLODEX **Steven Kheloussi**
(meloxicam)

Steven Kheloussi provided a review of Vivlodex to the committee for consideration as a pharmacy benefit. Vivlodex is a non-steroidal anti-inflammatory drug indicated for management of osteoarthritis (OA) pain

Formulary alternatives: Celecoxib*, choline sal/mag salicylate, diclofenac potassium, diclofenac sodium, diclofenac sodium/misoprostol, diflunisal, etodolac, fenoprofen, flurbiprofen, ibuprofen, indomethacin, ketoprofen, meclofenamate, mefenamic acid, meloxicam, nabumetone, naproxen sodium, naproxen, oxaprozin, piroxicam, sulindac, tolmetin

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Proposed Clinical Recommendations: Based on the clinical information available it is not recommended that Vivlodex be placed on the formulary at this time. The following criteria should apply to requests for Vivlodex:
- Medical record documentation of a diagnosis of osteoarthritis **AND**
- Documentation of patient age > 18 years

A quantity limit of one capsule per day should apply. Requests should be approved by GPID.

Clinical Discussion: FDA Approved Indications, Pharmacology/MOA, Clinical Evidence of Safety and Efficacy, Adverse Reactions, Dosing Schedule, Monitoring, Safety Profile, Black Box Warnings, Contraindications, Warnings and Precautions, Drug Interactions, Patent Life, Unique Therapeutic Features, Recommendations of National Agencies and Organizations, and Special Population Precautions were discussed. For geriatric use, elderly patients are at greater risk for NSAID-associated cardiovascular, gastrointestinal, and/or renal adverse reactions.

NSAIDs, like meloxicam, are intended to be administered in the lowest amount for the shortest time possible to decrease the possibility of side effects. The new formulation of meloxicam in Vivlodex is intended to do that. Vivlodex is formulated as capsules using SoluMatrix Fine Particle Technology. This technology produces drug particles that are approximately 20 times smaller than conventional formulations leading to increased surface area and faster dissolution.This claim was demonstrated in a study that compared the absorption of 10 mg Vivlodex capsules with traditional 15 mg meloxicam capsules.The maximum plasma concentration of both formulations was similar, while the systemic exposure was 33% lower for Vivlodex compared to meloxicam. The mean time to maximum plasma concentrations was lower for Vivlodex (2h) than for regular meloxicam (4h). While this study demonstrates the faster bioavailability of the new formulation, there is no clinical evidence that this reduction in systemic exposure correlates to lower side effects.

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

Proposed Financial Recommendations: Based on the cost analysis and clinical information presented it is not recommended that Vivlodex be placed on the formulary at this time. The following additional criterion should apply:

- Medical record documentation of a therapeutic failure on, intolerance to, contraindication to three generic formulary NSAIDs, one of which must be meloxicam.

Financial Discussion: No comments or questions.

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

Approved Recommendations: Vivlodex will not be added to the GHP Family formulary at this time. The following criteria will apply to prior authorization requests for Vivlodex:

- Medical record documentation of a diagnosis of osteoarthritis **AND**
- Documentation of patient age > 18 years **AND**
- Medical record documentation of a therapeutic failure on, intolerance to, contraindication to three generic formulary NSAIDs, one of which must be meloxicam.

A quantity limit of one capsule per day should apply. Requests should be approved by GPID.

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

NARCAN **Kim Clark**
(naloxone HCl)

Kim Clark provided a review of Narcan to the committee for consideration as a pharmacy benefit. Narcan Nasal Spray is indicated for the emergency treatment of known or suspected opioid overdose, as manifested by respiratory and/or central nervous system depression.

Narcan is intended for immediate administration as emergency therapy in settings where opioids may be present.

Formulary alternatives: naloxone syringes for injection

Proposed Clinical Recommendations: It is recommended that Narcan be added to the GHP Family formulary.

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

Clinical Outcome: Recommendations were made to add a quantity limit of 4 nasal devices (2 boxes, each containing 2 units) per month should be applied. Jamie Dodson made a motion to accept the recommendations as written. Kristen Bender seconded the motion. None were opposed

Proposed Financial Recommendations: Narcan should be added to the GHP Family formulary on the brand tier without prior authorization.

Quantity Limit: 4 nasal devices (2 boxes, each contining 2 units) per moth

Financial Discussion: No questions or comments.

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

Approved Recommendations: Narcan will be added to the GHP Family formulary at the brand tier without prior authorization.

Quantity Limit: 4 nasal devices (2 boxes, each contining 2 units) per moth

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

VRAYLAR **Steven Kheloussi**
(cariprazine)

Steven Kheloussi provided a review of Vraylar to the committee for consideration as a pharmacy benefit. Vraylar is indicated for the treatment of schizophrenia, and for the acute treatment of manic or mixed episodes associated with bipolar I disorder.

Formulary alternatives: aripiprazole, clozapine, olanzapine, quetiapine, risperidone, ziprasidone

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

- Medical record documentation that patient is > 18 years of age
AND
- Medical record documentation Vraylar is being used for:
o Schizophrenia **OR**
o Acute treatment of manic or mixed episodes associated with bipolar I disorder

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.

Vraylar is a second generation (atypical) antipsychotic currently approved for the treatment of schizophrenia and acute treatment of manic or mixed episodes associated with bipolar I disorder. In a post hoc analysis, Vraylar was also seen to be more affective at modifying aggressive and hostile behavior in comparison to placebo. Vraylar has a similar mechanism of action to Abilify and Rexulti, but it differs from these atypical antipsychotics due to its high affinity for the D3 receptor. Vraylar's partial agonist activity at the D3 receptor is theorized to give the drug the benefit of improving cognitive function, over other atypical antipsychotics. Whether this would be clinically relevant requires additional randomized controlled trials. Vraylar's most common side effects include drug-induced extrapyramidal reaction, parkinsonian-like syndrome, akathisia, headache, insomnia, and nausea. Unlike other atypical antipsychotics on the market, in short-term randomized controlled trials, Vraylar does not appear to adversely impact metabolic variables, prolactin, or the electrocardiogram (ECG) QT interval.

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

Proposed Financial Recommendations: It is recommended that Vrylar 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 three generic formulary alternatives (aripiprazole, olanzapine, quetiapine, ziprasidone, or risperidone).

Quantity limits: Requests should be approved by GPID with a quantity limit of 1 capsule per day

Financial Discussion: No comments or questions.

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

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

- Medical record documentation that patient is > 18 years of age
AND
- Medical record documentation Vraylar is being used for:
o Schizophrenia **OR**
o Acute treatment of manic or mixed episodes associated with bipolar I disorder
AND
- Medical record documentation of a therapeutic failure on, intolerance to, or contraindication to three generic formulary alternatives (aripiprazole, olanzapine, quetiapine, ziprasidone, or risperidone).

Quantity limits: Requests should be approved by GPID with a quantity limit of 1 capsule per day

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

VENCLEXTA **Kim Clark**
(ventoclax)

Kim Clark provided a review of Venclexta to the committee for consideration as a pharmacy benefit. Venclexta is indicated for the treatment of patients with chronic lymphocytic leukemia (CLL) with 17p deletion, as detected by an FDA approved test, who have received at least one prior therapy.

This indication is approved under accelerated approval based on overall response rate. Continued approval for this indication may be contingent upon verification and description of clinical benefit in a confirmatory trial

Formulary alternatives: Imbruvica, Revlimid

Proposed Clinical Recommendations: It is recommende that Venclexta be added to the GHP Family formulary. The following criteria should apply to requests:

- Must be prescribed by a hematologist/oncologist **AND**
- Medical record documentation of patient age ≥ 18 years **AND**
- Medical record documentation of chronic lymphocytic leukemia (CLL) with 17p deletion, as detected by an FDA approved test **AND**
- Medical record documentation of disease progression following treatment with at least one prior therapy

NOTE: The FDA approved test for detection of 17-p deletion in patients to be treated with Venclexta is the Vysis CLL Fish Probe Kit.

AUTHORIZATION DURATION: Initial approval will be for six (6) months. Subsequent approvals will be for an additional 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.

QUANTITY LIMIT: Starter Pack: 42 tablets per 28 days
Ongoing therapy: 4 tablets per day, 30 day supply per fill

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.

Venclexta is the first approved therapy designed to trigger a natural process that helps cells self-destruct, and is a new way to help people who have been previously treated and have this high-risk form of disease.

Clinical Outcome: Kim Clark made a recommendation to change the quantity limits of the bulk tablets to 1/day for the 50 mg strength, and 2/day for the 10 mg/day. Jamie Dodson made a motion to accept the recommendations as written. Tricia Heitzman seconded the motion. None were opposed.

Proposed Financial Recommendations: It is recommended that Venclexta be added to the brand tier for GHP Family

Financial Discussion: No comments or questions.

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

Approved Recommendations: Venclexta will be added to the GHP Family formulay's brand tier. The following prior authorization criteria will apply to request for Venclexta:

- Must be prescribed by a hematologist/oncologist **AND**
- Medical record documentation of patient age ≥ 18 years **AND**
- Medical record documentation of chronic lymphocytic leukemia (CLL) with 17p deletion, as detected by an FDA approved test **AND**
- Medical record documentation of disease progression following treatment with at least one prior therapy **OR**
- Medical record documentation of use for a medically accepted indication

NOTE: The FDA approved test for detection of 17-p deletion in patients to be treated with Venclexta is the Vysis CLL Fish Probe Kit.

AUTHORIZATION DURATION: Initial approval will be for six (6) months. Subsequent approvals will be for an additional 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.

QUANTITY LIMIT: Starter Pack: 42 tablets per 28 days; 10 mg tablets: 2/day; 50 mg tablets: 1/day: 100 mg tablets: 4/day. 30 day supply per fill

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

UPTRAVI **Steven Kheloussi**
(selexipag)

Steven Kheloussi provided a review of Uptravi to the committee for consideration as a pharmacy benefit. Uptravi is indicated for the treamtent of pulmonary arterial hypertension (PAH), WHO Group I to delay disease progression and reduce the risk of hospitalization for PAH.

- Effectiveness was established in a long-term study in PAH patients with WHO Functional Class (FC) II-III symptoms.

Selexipag is an oral prostacyclin receptor (IP receptor) agonist that is structurally distinct from prostacyclin. Selexipag is hydrolyzed by carboxylesterase 1 to yield its active metabolite, which is approximately 37-fold as potent as selexipag. Selexipag and the active metabolite are selective for the IP receptor versus other prostanoid receptors (EP1-4, DP, FP and TP). Prostacyclin is one of three key pathways that are targeted with PAH therapy, the others being nitric oxide and endothelin

Formulary alternatives: sildenafil, Letairis, Tracleer

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

- Prescription written by a cardiologist or pulmonologist **AND**
- Medical record documentation of a diagnosis of WHO Group I, functional class II or III pulmonary hypertension

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.

Uptravi is the first in a new class of PAH drugs. While it is mechanistically similar to the prostanoids (treprostinil [Orenitram, Remodulin, Tyvaso], epoprostenol [Flolan, Veletri], and iloprost [Ventavis]), it is "chemically distinct from prostacyclin with a different pharmacology." Uptravi targets one particular prostacyclin receptor (the IP receptor), which is proposed to reduce the risk of side effects mediated by activation of other prostanoids receptors, such as peripheral pain, nausea, vomiting, and the slowing of gastric emptying and gastric transport.

The only other oral agent that is similar in mechanism is Orenitram (oral treprostinil). Other prostacyclin analogs are inhaled (Tyvaso [treprostinil], Ventavis [iloprost]) or must be administered through continuous infusion (Remodulin [SC or IV treprostinil], Flolan or Veletri [IV epoprostenol]). Orenitram is

dosed one tablet every 8 or 12 hours depending on the strength used, while Uptravi is an easy-to-follow, once daily oral regimen. Additionally, Orenitram has not shown clinical benefit in combination therapy.

Specialist Feedback: GHS pulmonology report that "Switching from one agent to another may be indicated in certain patients especially if they develop side effects to a certain class of drug or are unable to use IV for some reason. Switching is usually not done from one oral to another to increase efficacy." It was also reported that Tracleer has fallen out of favor due to less favorable dosing (twice daily dosing compared with Letairis and Opsumit's once daily dosing) as well as fewer adverse events with the newer ERAs.

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

Proposed Financial Recommendations: It is recommended that Uptravi be considered nonformulary for GHP Family. The following prior authorization criteria should apply to requests for Uptravi:

- Medical record documentation of use in combination with, or failure on, intolerance to, or contraindication to sildenafil and/or an endothelin receptor antagonist (Tracleer [bosentan], Letairis [ambrisentan], or Opsumit [macitentan])

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: Uptravi will not be added to the GHP Family formulary. The following prior authorization critieria will apply:
- Prescription written by a cardiologist or pulmonologist **AND**
- Medical record documentation of a diagnosis of WHO Group I, functional class II or III pulmonary hypertension **AND**
- Medical record documentation of use in combination with, or failure on, intolerance to, or contraindication to sildenafil and/or an endothelin receptor antagonist (Tracleer [bosentan], Letairis [ambrisentan], or Opsumit [macitentan])

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

ZEPATIER **Kristin Scheib**
(elbasvir/grazoprevir)

Kristin Scheib provided a review of Zepatier to the committee for consideration as a pharmacy benefit. Zepatier is a fixed-dose combination product containing elbasvir, a hepatitis C virus (HCV) NS5A inhibitor, and grazoprevir, an HCV NS3/4A protease inhibitor, and is indicated with or without ribavirin for treatment of chronic HCV genotypes 1 or 4 infection in adults.

Zepatier combines two direct-acting antiviral agents to target HCV at multiple steps in the viral lifecycle. Elbasvir: inhibitor of HCV NS5A, which is essential for viral RNA replication and virion assembly. Grazoprevir: inhibitor of the HCV NS3/4A protease which is necessary for the proteolytic cleavage of the HCV encoded polyprotein (into mature forms of the NS3, NS4A, NS4B, NS5A, and NS5B proteins)

Formulary alternatives: Ribavirin, Ribasphere, Viekira, Sovaldi, Pegasys, Pegintron

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Proposed Clinical Recommendations: Zepatier is a pharmacy benefit and is recommended to be added to the GHP Family formulary at this time. The following prior authorization criteria should apply:

- 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 the member's hepatitis C genotype **AND**
- Medical record documentation of a diagnosis of hepatitis C virus (HCV) genotype 1 or 4 infection **AND**
- Medical record documentation of F2 - F4 liver fibrosis based on METAVIR liver scoring **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 a hepatocellular carcinoma screening in those with cirrhosis (METAVIR score F4) **AND**
- Medical record documentation that the member does not have moderate or severe hepatic impairment (Child-Pugh B or C) **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 the member receiving an Food and Drug Administration (FDA) approved medication regimen that is inside the parameters of use approved by the FDA or supported in the widely used compendia available **AND**
- Medical record documentation of:
    - Genotype 1a
        - As monotherapy if treatment-naïve or peginterferon alfa + ribavirin experienced without baseline NS5A polymorphisms **OR**
        - Concurrent therapy with ribavirin if treatment-naïve or peginterferon alfa + ribavirin experienced with baseline NS5A polymorphisms **OR**
        - Concurrent therapy with ribavirin if peginterferon alfa + ribavirin + HCV NS3/4A protease inhibitor experienced **OR**
    - Genotype 1b
        - As monotherapy if treatment-naïve or peginterferon alfa + ribavirin experienced **OR**
        - Concurrent therapy with ribavirin if peginterferon alfa + ribavirin + HCV NS3/4A protease inhibitor experienced **OR**
    - Genotype 4
        - As monotherapy if treatment naive **OR**
        - Concurrent therapy with ribavirin if treatment experienced with peginterferon alfa + ribavirin **AND**
- Medical record documentation of appropriate duration of treatment **AND**
- Medical record documentation of previous treatment and treatment response **AND**

- Medical record documentation of concurrent therapy with appropriate dose and duration of ribavirin (less than 66 kg = 800 mg per day, 66 to 80 kg = 1000 mg per day, 81 to 105 kg = 1200 mg per day, greater than 105 kg = 1400 mg per day), if indicated **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 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 their 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 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

TREATMENT DURATION:

- Genotype 1a:
    - Zepatier will be approved for a time period of 12 weeks if NS5A- OR
    - Zepatier will be approved for a time period 16 weeks if NS5A+ OR
- Genotype 1b:
    - Zepatier will be approved for a time period of 12 weeks OR
- Genotype 4:
    - Zepatier will be approved for a time period of 12 weeks OR
    - Zepatier will be approved for a time period 16 weeks if peginterferon and ribavirin treatment experienced

QUANTITY LIMIT: One (1) tablet per day, 28 day supply per fill

FORMULARY ALTERNATIVES
Viekira Pak, Sovaldi

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

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

Proposed Financial Recommendations: It is recommended that Zepatier be added to the formulary on the Brand tier. No additional prior authorization criteria should apply.

Financial Discussion: No comments or questions.

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

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

- 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 the member's hepatitis C genotype **AND**
- Medical record documentation of a diagnosis of hepatitis C virus (HCV) genotype 1 or 4 infection **AND**
- Medical record documentation of F2 - F4 liver fibrosis based on METAVIR liver scoring **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 a hepatocellular carcinoma screening in those with cirrhosis (METAVIR score F4) **AND**
- Medical record documentation that the member does not have moderate or severe hepatic impairment (Child-Pugh B or C) **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 the member receiving an Food and Drug Administration (FDA) approved medication regimen that is inside the parameters of use approved by the FDA or supported in the widely used compendia available **AND**
- Medical record documentation of:
    - Genotype 1a
        - As monotherapy if treatment-naïve or peginterferon alfa + ribavirin experienced without baseline NS5A polymorphisms **OR**
        - Concurrent therapy with ribavirin if treatment-naïve or peginterferon alfa + ribavirin experienced with baseline NS5A polymorphisms **OR**

        - Concurrent therapy with ribavirin if peginterferon alfa + ribavirin + HCV NS3/4A protease inhibitor experienced **OR**
    - Genotype 1b
        - As monotherapy if treatment-naïve or peginterferon alfa + ribavirin experienced **OR**
        - Concurrent therapy with ribavirin if peginterferon alfa + ribavirin + HCV NS3/4A protease inhibitor experienced **OR**
    - Genotype 4
        - As monotherapy if treatment naive **OR**
        - Concurrent therapy with ribavirin if treatment experienced with peginterferon alfa + ribavirin **AND**
- Medical record documentation of appropriate duration of treatment **AND**
- Medical record documentation of previous treatment and treatment response **AND**
- Medical record documentation of concurrent therapy with appropriate dose and duration of ribavirin (less than 66 kg = 800 mg per day, 66 to 80 kg = 1000 mg per day, 81 to 105 kg = 1200 mg per day, greater than 105 kg = 1400 mg per day), if indicated **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 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 their 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 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

TREATMENT DURATION:

- Genotype 1a:
    - Zepatier will be approved for a time period of 12 weeks if NS5A- OR
    - Zepatier will be approved for a time period 16 weeks if NS5A+ OR
- Genotype 1b:
    - Zepatier will be approved for a time period of 12 weeks OR

- Genotype 4:
    - Zepatier will be approved for a time period of 12 weeks OR
    - Zepatier will be approved for a time period 16 weeks if peginterferon and ribavirin treatment experienced

QUANTITY LIMIT: One (1) tablet per day, 28 day supply per fill

FORMULARY ALTERNATIVES
Viekira Pak, Sovaldi

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

FAST FACTS:

IBRANCE **Steven Kheloussi**
(palbociclib)

New Indication: Ibrance is now indicated for the treatment of ER-positive, HER2-negative advanced or metastatic breast cancer in combination with:
- Letrozole as initial endocrine based therapy in postmenopausal women, or
- Fulvestrant in women with disease progression following endocrine therapy

The previous indication included the use of Ibrance in combination with only letrozole for postmenopausal women with ER-positive, HER2-negative advanced breast cancer as initial endocrine-based therapy.

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

Recommendation:
It is recommended that the Ibrance policy be updated to reflect the new indication. The following should be added to the Ibrance policy:
- … **OR** Medical record documentation that Ibrance is being used in combination with fulvestrant after disease progression on endocrine therapy.

Note – No changes are recommended for the quantity limits or authorization duration.

Discussion: No comments or questions.

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

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

BOTOX **Kimberly Clark**
(onabotulinumtoxin A)

New Indication:

Lower Limb Spasticity: Botox is an acetylcholine release inhibitor and a neuromuscular blocking agent indicated for the treatment of lower limb spasticity in adult patients to decrease the severity of increased muscle tone in ankle and toe flexors (gastrocnemius, soleus, tibialis posterior, flexor hallucis longus, and flexor digitorum longus).

Current Formulary Status:
Medical benefit requiring PA

Recommendation:
It is recommended that the following criteria be added to the medical benefit policy:

- Medical record documentation that Botox is being used for the treatment of lower limb spasticity to decrease the severity of increased muscle tone in ankle and toe flexors (gastrocnemius, soleus, tibialis posterior, flexor hallucis longus, and flexor digitorum longus) **AND**
- Documentation that patient is at least 18 years of age **AND**
- Medical record documentation of failure to control spasticity with conventional therapies, e.g., physical therapy, splinting/bracing, or systemic antispasticity medication

Discussion: Tricia Heitzman asked if there was a clinical need to know the specific muscle for injection. Recommended eliminating identification of muscle for injection as a requirement. Will look for diagnosis only. No other questions or comments.

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

XEOMIN **Kim Clark**
(incobotulinumtoxin A)

New Indication:

Upper Limb Spasticity: Xeomin is an acetylcholine release inhibitor and neuromuscular blocking agent indicated for the treatment or improvement of adult patients with upper limb spasticity.

Current Formulary Status:
Medical benefit requiring PA

Recommendation: It is recommended that the following Xeomin specific criteria be added to the medical benefit policy):

- Medical record documentation that Xeomin is being used for the treatment of upper limb spasticity in the following muscles: clenched fist (flexor digitorum superficialis, flexor digitorum profundus), flexed wrist (flexor carpi radialis, flexor carpi ulnaris), flexed elbow (brachioradialis,

biceps, brachialis), pronated forearm (pronator quadratus, pronator teres), and thumb-in-palm (flexor pollicis longus, adductor pollicis, flexor pollicis brevis/opponens pollicis) **AND**

• Documentation that patient is at least 18 years of age

Discussion: Tricia Heitzman asked if there was a clinical need to know the specific muscle for injection. Recommended eliminating identification of muscle for injection as a requirement. Will look for diagnosis only. No other questions or comments.

Outcome: Jamie Dodson made a motion to accept the recommendations as modified. Tricia Heitzman seconded the motion. None were opposed.

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

PRADAXA **Steve Kheloussi**
(dabigatran)

Updated indication: Pradaxa is now indicated for the prophylaxis of deep vein thrombosis (DVT) and pulmonary embolism (PE), in patients who have undergone hip replacement surgery.
Previously indicated for the:

- Reduction of stroke and systemic embolism in patients with non-valvular atrial fibrillation;
- Treatment of DVT and PE in patients who have been treated with a parenteral anticoagulant for 5-10 days; and
- Risk reduction of recurrence of DVT and PE in patients who have been previously treated

Updated Dosing Instructions: For the new indication:

- CrCl > 30 mL/min: 110 mg for first day, then 220 mg once daily (see below for full instructions)
- CrCl < 30 mL/min or on dialysis: Dosing recommendations cannot be provided
- Concomitant use of P-gp inhibitors
    - CrCl < 50 mL/min: Avoid co-administration
    - CrCl > 50 mL/min: Separate the timing of administration by several hours

For patients with CrCl >30 mL/min, the recommended dose of Pradaxa is 110 mg taken orally 1-4 hours after surgery and after hemostasis has been achieved, then 220 mg taken once daily for **28-35 days**. If Pradaxa is not started on the day of surgery, after hemostasis has been achieved initiate treatment with 220 mg once daily.

Recommendation: It is recommended that the Pradaxa policy be updated to include this new indication.

The following underlined addition should be made to the policy:

1. Medical record documentation of one of the following: • Medical record documentation of a diagnosis of treatment to reduce the risk of stroke and systemic embolism in patients with non-valvular atrial fibrillation **OR**
• Medical record documentation of treatment of deep vein thrombosis, pulmonary embolism, or for the reduction in the risk of recurrence of deep vein thrombosis and/or pulmonary embolism **OR**

• Medical record documentation of use for the prophylaxis of deep vein thrombosis and pulmonary embolism in patients who have undergone hip replacement surgery **AND**

2. Medical record documentation of a therapeutic failure on, intolerance to, or contraindication to Eliquis and Xarelto

An authorization duration of 2 months should apply for all LOB for approved requests for Pradaxa for the updated indication.

Discussion: Todd Sponenberg recommended extending auth duration for this indication from 2 months to 3 months. No other questions or comments.

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

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

AFINITOR **Kim Clark**
(everolimus)

New Indication[1]: Neuroendocrine tumors of gastrointestinal (GI) or lung origin: Afinitor is a kinase inhibitor indicated for the treatment of adults with progressive, well-differentiated, non-functional neuroendocrine tumors (NET) of gastrointestinal origin (GI) or lung origin that are unresectable, locally advanced, or metastatic.

New Dosing instructions[1]:
- 10 mg once daily with or without food

Current Formulary Status:
Specialty tier requiring prior authorization

Recommendation: It is recommended that the following criteria be added to the existing drug policy within the neuroendocrine tumors section:
• Medical record documentation of a diagnosis of progressive, well-differentiated, non-functional neuroendocrine tumors (NET) of gastrointestinal origin (GI) or lung origin that are unresectable, locally advanced, or metastatic

AUTHORIZATION DURATION: Each treatment period will be defined as 3 months. Re-review will occur every 3 months. Afinitor will no longer be covered if there is medical record documentation of disease progression. No changes recommended to current policies based on the AASLD/IDSA guidelines recommendations at this time.

Discussion: No questions or comments.

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

GAZYVA **Steven Kheloussi**
(obinutuzumab)

Updated indication: Gazyva is now indicated, in combination with bendamustine followed by Gazyva monotherapy, for the treatment of patients with follicular lymphoma (FL) who relapsed after, or are refractory to, a rituximab-containing regimen.

- Previously, Gazyva was only indicated in combination with chlorambucil, for the treatment of patients with previously untreated chronic lymphocytic leukemia (CLL).

Dosing: Each dose of Gazyva is 1000 mg administered IV according to Table 1. Patients who achieve stable disease, complete response, or partial response to the initial 6 cycles of Gazyva in combination with bendamustine should continue on Gazyva 1000 mg as monotherapy for two years.

Recommendation: It is recommended that current Gazyva medical policy be updated to include the new indication as follows:

For Follicular Lymphoma:

- Medical record documentation of a diagnosis of follicular lymphoma **AND**
- Medical record documentation that Gazyva is being used in combination with bendamustine **OR** that the patient was previously treated with 6 cycles of Gazyva + bendamustine **AND**
- Medical record documentation that the patient has relapsed after, or is refractory to, a rituximab-containing regimen.

Note – Authorization duration should be 6 months for this indication. The following criteria should apply to reauthorization requests for Gazyva:

- Medical record documentation that the patient achieved a complete response, partial response, or has stable disease after 6 cycles of Gazyva + bendamustine therapy **AND**
- Documentation that Gazyva will be used as monotherapy.

Subsequent authorization duration should be 24 months as data does not extend past this point.

Discussion: There was discussion regarding the differences between the FDA approved indications and the NCCN recommendations (acceptable NCCN recommendation is also for monotherapy, although strength of evidence is low). It was questioned how a patient who previously failed a bendamustine containing therapy would be handled. It was decided that those would need to be handled on a case by case basis. No other comments or questions

Outcome: Tricia Heitzman 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.

FASLODEX **Kim Clark**
(fulvestrant)

New Indication[1]**:** Faslodex is an estrogen receptor antagonist indicated for the treatment of hormone receptor (HR)-positive, human epidermal growth factor receptor 2 (HER2)-negative advanced or metastatic breast cancer in combination with palbociclib in women with disease progression after endocrine therapy.

Current formulary status: Medical benefit, or pharmacy on specialty tier (currently with PA)

Recommendation: No changes to existing policy are recommended at this time (Faslodex will be further discussed as part of the Medical Benefit Policy Updates).

Discussion: No comments or questions

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

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

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TRUVADA **Steven Kheloussi**
(emtricitabine/tenofovir DF)

Updated indication: Truvada is indicated in combination with other antiretroviral agents for the treatment of HIV-1 infection in adults and pediatric patients **weighing at least 17 kg**.

- Truvada was previously indicated for adults and pediatric patients 12 years of age and older.

New Dosage Forms

- Truvada is now available in four different strength tablets
  - 100 mg FTC/150 mg TDF
  - 133 mg FTC/200 mg TDF
  - 167 mg FTC/200 mg TDF
  - 200 mg FTC/300 mg TDF (historically, this was the only available strength)

Updated Dosing Information

- For adults and pediatric patients weighing > 35 kg
  - One tablet (200 mg FTC and 300 mg of TDF) orally once daily.

- For pediatric patients weighing > 17 kg to < 35 kg and able to swallow a whole tablet
  - weight based dosing.

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

Discussion: No comments or questions

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

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

COMPLERA **Steven Kheloussi**
(emtricitabine/tenofovir DF/rilpivirine)

Updated indication: Complera is indicated for use as a complete regimen for the treatment of HIV-1 infection in patients **12 years of age and older** with no antiretroviral treatment history and with HIV-1 RNA < 100,000 copies/mL at the start of therapy, and in certain virologically-suppressed (HIV-1 RNA < 50 copies/mL) patients on a stable antiretroviral regimen at the start of therapy in order to replace their current antiretroviral treatment regimen.

- Complera was previously only indicated in adult patients.

Dosage
As previously recommended in adult patients, the recommended dose of Complera in patients 12 years of age and older and weighing at least 35 kg is one tablet taken orally once daily with food.

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

Discussion: No comments or questions

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

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

SOMATULINE DEPOT **Kim Clark**
(lanreotide)

New Indication[1]: Somatuline Depot Injection is a somatostatin analog indicated for the treatment of patients with unresectable, well- or moderately-differentiated, locally advanced or metastatic gastroenteropancreatic neuroendocrine tumors (GEP-NETs) to improve progression-free survival. Previously indicated for the long-term treatment of acromegalic patients who have had an inadequate response to or cannot be treated with surgery and/or radiotherapy.

Dosage and Administration[1]:

- Somatuline Depot should be administered by healthcare professionals.
- The recommended dose for the treatment of GEP-NETs is Somatuline Depot 120 mg administered every 4 weeks by deep subcutaneous injection.

Current formulary status: Brand tier requiring pior authorization OR medical benefit without prior authorization.

Recommendation: Based on the low utilization, it is recommended that the prior authorization requirement be lifted and be covered as a medical benefit only.

Discussion: No comments or questions

Outcome: Kristen Bender 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

XALKORI **Steven Kheloussi**
(crizotinib)

Updated indication: Xalkori is now indicated for the treatment of patients with metastatic non-small cell lung cancer (NSCLC) whose tumors are ROS1-positive.

- Previously only indicated for patients with metastatic NSCLC whose tumors are anaplastic lymphoma kinase (ALK)-positive as detected by an FDA-approved test.

Patient selection: Select patients for the treatment of metastatic NSCLC based on the presence of ALK or ROS1 positivity in tumor specimens. An FDA-approved test for the detection of ROS1 rearrangements in NSCLC is not currently available. Refer to the clinical trial for information on the tests used in the clinical study to identify patients with ROS1 rearrangements in NSCLC.

Recommendation: It is recommended that the Xalkori policy be updated to reflect the new indication for GHP Family. The following should be added to the Xalkori policy:

- … **OR** Medical record documentation of a diagnosis of metastatic non-small cell lung cancer (NSCLC) that is ROS1-positive.

Note – quantity limits and authorization duration do not require updating. It is recommended that current

Discussion: No comments or questions

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

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

CRESTOR **Steven Kheloussi**
(rosuvastatin)

Updated indication: Crestor is now indicated as an adjunct to diet to reduce total cholesterol (TC), LDL cholesterol (LDL-C), and ApoB levels in children and adolescents **8 to 17 years of age** with heterozygous familial hypercholesterolemia (HeFH) if after an adequate trial of diet therapy the following findings are present: LDL-C > 190 mg/dL or > 160 mg/dL and there is a positive family history of premature cardiovascular disease (CVD) or two or more other CVD risk factors.

- Crestor previously had this indication for adolescent boys and girls, who are at least one year post-menarche, 10 to 17 years of age.

Recommendation:

It is recommended that generic rosuvastatin is added to the generic tier. Requests for brand Crestor should be reviewed under the Brand Coverage when AB-rated Generic Available policy. No prior authorization should apply to generic rosuvastatin.

Discussion: No comments or questions

Outcome: Kristen Bender 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

POLICY UPDATES:

MISCELLANEOUS MEDICAL POLIC\IES **Tricia Heitzman**

The following policies are informational only policies which are viewable on our website. There is no Prior Authorization requirement on these medications and the policies often cause confusion by providers who see them listed on our website and assume they require prior authorization. It is recommended to retire them at this time.

- MBP 32.0 Kepivance (palifermin)
- MBP 14.0 Meningococcal vaccine
- MBP 20.0 Faslodex (fulvestrant Injection)
- MBP 103.0 Ondansetron/ Metoclopramide subcutaneous micro-infusion pump
- MBP 107.0 Zostavax

Recommendation to remove the Prior Authorization requirement for use and retire the following policies:

The following chemotherapeutic agents result in a large number of Prior Authorization requests, with a 100% approval rating over the past 6 months of claims reviewed. To improve provider and member satisfaction and to improve Prior Authorization efficiencies it is recommended to remove the Prior Authorization requirement on these medications and retire associated policies under the Medical Benefit.

- MBP 26.0 Oxaliplatin
- MBP 72.0 Treanda (bendamustine)
- MBP 30.0 Avastin (bevacizumab)
- MBP 98.0 Perjeta (pertuzumab)
- MBP 31.0 Erbitux (cetuximab)

Discussion: No other comments or questions.

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

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

PCSK9 INHIBITORS **Steven Kheloussi**

The following updates reflect requested changes to the policy from GWV Cardiology, as well as the GHS familial hypercholesterolemia clinic.

The major changes include:
- Adding fibrates as an alternative to bile acid sequestrants for Medicaid
  - LDL goals were added:
    - < 100 mg/dL for HeFH (and HoFH for Repatha) when being used for primary prevention
    - < 70 mg/dL for ASCVD or HeFH/HoFH for secondary prevention
- Specific gene mutations for HeFH have been updated
- Added a requirement that the requested PCSK9 is not being used in combination with another PCSK9 inhibitor, Juxtapid, or Kynamro for both initial and reauthorization criteria
- Fibrates have been added to the formulary alternatives list
- "Intolerance" definition has been updated to include, symptoms that "…persist after two retrials of with a different dose or different dosing strategy (i.e. every other day administration) of alternative moderate- or high-intensity statin."
- Statin failure criteria have been updated for GHP Family

Recommendation: Modify policies for Praluent and Repatha as stated below. Also recommended to add Repatha to the Brand tier with this UM criteria and a quantity limit.

Recommended Praluent policy:

- Medical record documentation of a diagnosis of:

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

o Heterozygous familial hypercholesterolemia AND either:

 Genetic testing to confirm a mutation in the LDL receptor, PCSK9, or ApoB 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 drawn within three months of the start of PCSK9 therapy showing:

o LDL > 100 if the patient has a diagnosis of HeFH and is using Praluent for primary prevention OR

o LDL > 70 if the patient has a diagnosis of ASCVD or HeFH and is using Praluent for secondary prevention AND

- Medical record documentation that the patient is at least 18 years of 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 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 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 for primary prevention in HeFH or < 70 mg/dL for ASCVD or secondary prevention in HeFH) with diet, physical activity, and at least 12 weeks of combination therapy of statin with Zetia and either a bile acid sequestrant or fibrate 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 either a bile acid sequestrant or fibrate medical record documentation of and LDL > 100 AND

• Medical record documentation that Praluent is not being used in combination with another PCKS9 inhibitor, Juxtapid, or Kynamro.

**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 AND

5. Medical record documentation that Praluent continues to not be used in combination with another PCSK9 inhibitor, Juxtapid, or Kynamro.

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

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

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

Formulary alternatives: atorvastatin, rosuvastatin, Zetia, cholestyramine, Prevalite, colestipol, fenofibrate, fenofibric acid, gemfibrozil

Recommended Repatha policy:

- Medical record documentation of a diagnosis of:
o 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
o Heterozygous familial hypercholesterolemia AND either:
 Genetic testing to confirm a mutation in the LDL receptor, PCSK9, or ApoB 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 OR
o 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 drawn within 3 months of the start of PCSK9 therapy showing:
o LDL > 100 if the patient has a diagnosis of HeFH or HoFH and is using Repatha for primary prevention OR
o LDL > 70 if the patient has a diagnosis of ASCVD or either HeFH or HoFH and is using Repatha for secondary prevention AND
- Medical record documentation that the patient is > 18 years of age if the diagnosis is clinical ASCVD or HeFH OR medical record documentation that the patients is > 13 years of age if the diagnosis is HoFH 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 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 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 either a bile acid sequestrant or fibrate or medical record documentation of an LDL > 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 for primary prevention in HeFH or HoFH or < 70 mg/dL for ASCVD or secondary prevention in HeFH or HoFH) with diet, physical activity, and at least 12 weeks of combination therapy of statin with Zetia and either a bile acid sequestrant or fibrate if appropriate with the patient taking ≥ 90% of the prescribed doses of each medication AND
- Medical record documentation that Repatha is not being used in combination with another PCSK9 inhibitor, Juxtapid, or Kynamro.

**PA Required

Quantity limit:
- 2 mL per 28 days if diagnosis is ASCVD or HeFH;
- 3 mL per 28 days if diagcnosis is HoFH

Approval 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 AND
- Claims history or attestation from the provider that the patient is staying adherent to (filling at least 90% of doses) statin therapy AND
- Medical record documentation that Repatha continues to not be used in combination with another PCSK9 inhibitor, Juxtapid, or Kynamro.

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

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

Formulary alternatives: atorvastatin, Zetia, cholestyramine, Prevalite, colestipol, fenofibrate, fenofibric acid, gemfibrozil

Discussion: No comments or questions.

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

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

HEPATITIS C POLICY UPDATE — Kristen Scheib

Harvoni (ledipasvir/sofosbuvir)

Harvoni is not FDA approved for use in genotype 3.[1] AASLD/IDSA guidelines no longer recommend Harvoni to be used in Genotype 3**.**

It is recommended to remove the following from the Harvoni policy:

Genotype 3

- Concurrent therapy with ribavirin if treatment naïve OR
- Concurrent therapy with ribavirin if treatment experienced without cirrhosis

Discussion: No comments or questions.

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

Sovaldi (sofosbuvir)

Based on the AASLD/IDSA recommendations:

ADD (underlined): Medical record documentation of:

Genotype 3

- Concurrent therapy with peginterferon and ribavirin if cirrhotic **OR**
- Concurrent therapy with Daklinza if peginterferon ineligible* and noncirrhotic **OR**

Discussion: No comments or questions.

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

For all HCV policies, revise and apply reauthorization criteria for use beyond 12 weeks to be:

- Medical record documentation that the member is compliant with hepatitis C medications as evidenced by HCV RNA viral load and medication claims AND
- Medical record documentation of the member receiving a Food and Drug Administration (FDA) approved medication regimen and duration that is inside the parameters of use approved by the FDA or supported in the widely used compendia available.

Discussion: No comments or questions.

Outcome: Steve 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.

HIV MEDICATION QUANTITY LIMITS — Steve Kheloussi

GHP Family does not require prior authorization for the use of HIV medications. In order to deter fraud and waste, we are recommending add quantity limits to this class of medications.

The following quantity limits are recommended:

Brand Name	Generic Name	Dosage	QL to be added
NRTIs			
Ziagen 300 mg tablet	abacavir	600 mg daily	60/30 days
Ziagen 20 mg/mL solution (240 mL package)	abacavir	600 mg daily (30 mL daily)	900 mL/30 days
Videx 10 mg/mL solution^ (2 G or 4 G bottles)	didanosine	400 mg daily or 250 daily BOW*	1200 mL/30 days
Videx EC (125, 200, 250, or 400 mg capsules)	didanosine	1 capsule daily BOW	1 per day
Emtriva 200 mg capsules	emtricitabine	200 mg daily	30/30 days
Emtriva 10 mg/mL solution (170 mL bottle)	emtricitabine	240 mg (24 mL) once daily	720 mL/30 days
Epivir 300 mg tablets	lamivudine	300 mg once daily	30/30 days
Epivir 150 mg tablets	lamivudine	150 mg twice daily	60/30 days
Epivir 10 mg/mL solution (240 mL bottle)	lamivudine	300 mg (30 mL) daily	900 mL/30 days
Zerit capsules	stavudine	Dose BOW every 12 hours	60/30 days
Zerit 1 mg/mL solution^ (200 mL bottle)	stavudine	Max – 40 mg (40 mL) every 12 hours	1200 mL/30 days
Viread tablets	tenofovir disoproxil fumarate (TDF)	300 mg once daily	30/30 days
Viread 40mg/gram powder^ (60 Gram Bottle)	tenofovir disoproxil fumarate (TDF)	Max – 300 mg once daily	240 grams/30 days
Retrovir 100 mg capsule	zidovudine	300 mg twice daily	180/30 days
Retrovir 10 mg/mL solution (240 mL bottle)	zidovudine	300 mg twice daily	1800 mL/30 days

NNRTIs			
Rescriptor	delavirdine	400 mg TID	180/30 days
Sustiva 600 mg tablet	efavirenz	600 mg once daily	30/30 days
Sustiva 200 mg capsule	efavirenz	Based on weight	60/30 days
Sustiva 50 mg capsule	efavirenz	Based on weight	90/30 days
Intelence 25 mg tablet	etravirine	Based on weight	60/30 days
Intelence 100 mg tablet	etravirine	Based on weight	30/30 days
Intelence 200 mg tablet	etravirine	200 mg twice daily	60/30 days
Viramune 200 mg tablet	nevirapine	Up to 400 mg daily	60/30 days
Viramune 10 mg/mL solution (240 mL bottle)	nevirapine	Up to 400 mg daily	1200 mL/30 days
Viramune XR 100 mg tab	nevirapine	Up to 300 mg daily	90/30 days
Viramune XR 400 mg tab	nevirapine	400 mg daily	30/30 days
Edurant 25 mg tablet	rilpivirine	25 mg once daily (50 mg once daily when used with rifabutin)	60/30 days
Protease Inhibitors			
Reyataz 150 mg capsule	atazanavir	Cost of 150 mg BID = 300 mg once daily	60/30 days
Reyataz 200 mg capsule	atazanavir	Up to 400 mg daily	60/30 days
Reyataz 300 mg capsule	atazanavir	300 mg once daily	30/30 days
Reyataz 50 mg powder pack	atazanavir	Up to 6 packs per day	180 packs/30 days
Prezista 800 mg tablet	darunavir	800 mg once daily	30/30 days
Prezista 600 mg tablet	darunavir	600 mg twice daily	60/30 days
Prezista 100 mg/mL susp^ (200 mL bottle)	darunavir	Up to 600 mg twice daily	400 mL/30 days
Lexiva 700 mg tablet	fosamprenavir	1,400 mg daily	60/30 days
Lexiva 50 mg/mL solution (225 mL bottle)	fosamprenavir	1,400 mg (28 mL) daily	840 mL/30 days
Crixivan 400 mg caps	indinavir	800 mg every 8 hrs	180/30 days
Crixivan 200 mg caps	indinavir	600 (400 + 200) or 1000 mg ((2*400) + 200) every 8 hrs	90/30 days
Viracept 250 mg tablet	nelfinavir	750 mg TID	270/30 days
Viracept 625 mg tablet	nelfinavir	1,250 mg BID	120/30 days
Norvir 100 mg tab or cap	ritonavir	600 mg twice daily	360/30 days
Norvir 80 mg/mL solution^	ritonavir	600 mg twice daily	480 mL/30 days
Invirase 500 mg tablet	saquinavir	1000 mg BID	120/30 days
Invirase 200 mg capsule	saquinavir	1000 mg BID	300/30 days
Aptivus 250 mg capsule	tipranavir	500 mg BID	120/30 days
Aptivus 100 mg/mL solution (95 mL bottle)	tipranavir	500 mg BID	300 mL/30 days
Fusion Inhibitors			
Fuzeon 90 mg SC solution	enfuvirtide	90 mg twice daily	60 vials/30 days
Entry Inhibitors			
Selzentry 150 mg tablet	maraviroc	150 mg BID with potent CYP3A inducers	60/30 days
Selzentry 300 mg tablet	maraviroc	300 mg BID (600 mg BID with potent CYP3A inducers)	120/30 days
Integrase Inhibitors			
Tivicay	dolutegravir	Up to 50 mg BID	60/30 days
Vitekta	elvitegravir	Once daily	30/30 days
Isentress 400 mg tablet	raltegravir	400 mg BID (800 mg BID with rifampin)	120/30 days
Isentress 100 mg chew tab	raltegravir	300 mg BID	180/30 days

Isentress 25 mg chew tab	raltegravir	Up to 4 daily	120/30 days
Isentress 100 mg oral pack	raltegravir	Up to 100 mg BID	60/30 days
Pharmacokinetic Enhancers			
Tybost	cobicistat	1 tablet once daily	30/30 days
Combination HIV Medications			
Epzicom	abacavir/lamivudine	1 tablet once daily	30/30 days
Triumeq	abacavir/dolutegravir/lamivudine	1 tablet once daily	30/30 days
Trizivir	abacavir/lamivudine/zidovudine	1 tablet twice daily	60/30 days
Evotaz	atazanavir/cobicistat	1 tablet once daily	30/30 days
Prezcobix	darunavir/cobicistat	1 tablet once daily	30/30 days
Atripla	efavirenz/emtricitabine/TDF	1 tablet once daily	30/30 days
Genvoya	elvitegravir/cobicistat/emtricitabine/TAF	1 tablet once daily	30/30 days
Stribild	elvitegravir/cobicistat/emtricitabine/TDF	1 tablet once daily	30/30 days
Odefsey	emtricitabine/rilpivirine/TAF	1 tablet once daily	30/30 days
Complera	emtricitabine/rilpivirine/TDF	1 tablet once daily	30/30 days
Truvada	emtricitabine/TDF	1 tablet once daily	30/30 days
Descovy	emtricitabine/TAF	1 tablet once daily	30/30 days
Combivir	Lamivudine/zidovudine	1 tablet twice daily	60/30 days
Kaletra 100/25 mg	lopinavir/ritonavir	Up to 4 BID (5 BID when used with certain HIV meds)	300/30 days
Kaletra 200/50 mg	lopinavir/ritonavir	Up to 4 once daily	120/30 days
Kaletra 400/100 mg per 5 mL (160 mL bottle)	lopinavir/ritonavir	400/100 mg BID (533/133 mg BID when used with certain HIV meds)	420 mL/30 days

*Based on weight

^Must be stored/dispensed in original container

Discussion: Recommended quantity limits are set at max dosing limits. No other questions or comments.

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

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

BUPRENORPHINE POLICY UPDATES — Kimberly Clark

Summary of changes to policy: At the March P&T meeting, it was recommended that the following language be removed from GHP Suboxone/buprenorphine policies:

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

Upon review by DHS they were in disagreement with our recommendation to remove this criterion as their specialists stated that it was appropriate to expect a taper. Upon further discussion, the following criteria was recommended in place of the existing policy language:

- If on buprenorphine and buprenorphine/naloxone therapy for > 1 year, documentation of a clinical assessment of effectiveness and dosage is required.

Discussion: No questions or comments

Outcome: Steven Kheloussi 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.

SYMBICORT POLICY UPDATE — Kristen Bender

Summary of changes to policy: It is recommended that the following be added to the Advair policy to ensure consistency when reviewing request for Symbicort:

And for Symbicort:
- Member is age 12 years or older **AND**
- Member has medical record documentation of a diagnosis of Asthma **AND** medical record documentation of therapeutic failure on, intolerance to, or contraindication to Dulera **OR**
- Member has medical record documentation of a diagnosis of COPD **AND** medical record documentation of a therapeutic failure on, intolerance to, or contraindication to Breo Ellipta

(Note: only Symbicort 160/4.5 is indicated for COPD)

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.

STRATTERA POLICY UPDATE — Steven Kheloussi

Summary of changes to policy: Given that providers often request the use of Strattera for patients with ADHD primarily as an alternative to stimulant medications, it is recommended that a non-stimulant formulary alternative is added to the medications that should be tried prior to approving Strattera. There was also some concern that patients with a substance abuse history were being inappropriately denied Strattera for a lack of failure on the formulary stimulants, which are controlled substances. The recommendation is that the GHP Family policy for Strattera should be updated from:

- Medical record documentation of a therapeutic failure on, intolerance to, or contraindication to Methylphenidate ER* **AND** Amphetamine-Dextroamphetamine ER*

To:

- Medical record documentation of a therapeutic failure on, intolerance to, or contraindication to Methylphenidate ER* **AND** Amphetamine-Dextroamphetamine ER* **OR** prior history of substance abuse **AND**

- For members 6 - 17 years of age: Medical record documentation of a therapeutic failure on, intolerance to, or contraindication to guanfacine ER.

Discussion: No questions or comments

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

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

GHP FAMILY FORMULARY UPDATE **Kristen Bender**

Summary of changes: It is recommended that eszopiclone be added to the GHP Family formulary on the generic tier with a quantity limit of one tablet daily

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.

Meeting adjourned at 4:12 pm.

Future Scheduled Meetings

May 17, 2016 at 1:00 HCN3A & 3B Conference room

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