GHP FAMILY MINUTES

P&T MEETING

NOVEMBER 15, 2016

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

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

Call to Order:
Bret Yarczower called the meeting to order at 1:02 p.m., Tuesday, November 15, 2016.

Review and Approval of Minutes:
Dr. Bret Yarczower asked for a motion or approval to accept the September 20, 2016 minutes as written. Todd Sponenberg made a motion to accept the minutes as written and Tricia Heitzman seconded the motion. None were opposed.

DRUG REVIEWS:

EPCLUSA **Kristi Clarke**
(velpatasvir/sofosbuvir)

Kristi Clarke provided a review of Epclusa to the committee for consideration as a pharmacy benefit. Epclusa is a fixed-dosed combination of sofosbuvir, a hepatitis C virus (HCV) nucleotide analog NS5B polymerase inhibitor, and velpatasvir, an HCV NS5A inhibitor, and is indicated for the treatment of adult patients with chronic HCV genotype 1, 2, 3, 4, 5, or 6 infection: without cirrhosis or with compensated cirrhosis and with decompensated cirrhosis for use in combination with ribavirin.

Formulary alternatives: ribavirin, ribasphere, Pegasys, PegIntron, Harvoni*, Sovaldi*, Zepatier* (*prior authorization required)

Proposed Clinical Recommendations: A prior authorization with the following 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, 2, 3, 4 5 or 6 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**
- 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 1, 2, 3, 4, 5, 6
        - As monotherapy if treatment-naïve or peginterferon alfa + ribavirin based regimen experienced **OR**
        - Concurrent therapy with ribavirin if decompensated cirrhosis **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 (1000 mg per day for patients less than 75 kg and 1200 mg for those weighing at least 75 kg), 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 that member does not have severe renal impairment (estimated glomerular filtration rate < 30 mL/min/1.73 m^2) or end stage renal disease requiring hemodialysis **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 does not have a limited life expectancy of less than 12 months due to non-liver related co-morbid conditions

TREATMENT DURATION: 12 weeks

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

Epclusa is a single tablet, once daily, pangenotypic HCV direct acting antiviral that has been FDA approved to treat genotypes 1 through 6 without the need for accompanying agents including peginterferon or ribavirin (unless decompensated cirrhosis). Epclusa is especially useful for genotype 2 and 3 and as the alternatives contain more complicated regimens or longer treatment durations.

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

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

- **For genotype 1 or 4**: Medical record documentation of a therapeutic failure on, intolerance to, or contraindication to formulary alternatives

Financial Discussion: No questions or comments.

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

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

- 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, 2, 3, 4 5 or 6 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**
- 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 1, 2, 3, 4, 5, 6
        - As monotherapy if treatment-naïve or peginterferon alfa + ribavirin based regimen experienced **OR**
        - Concurrent therapy with ribavirin if decompensated cirrhosis **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 (1000 mg per day for patients less than 75 kg and 1200 mg for those weighing at least 75 kg), 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 that member does not have severe renal impairment (estimated glomerular filtration rate < 30 mL/min/1.73 m^2) or end stage renal disease requiring hemodialysis **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 does not have a limited life expectancy of less than 12 months due to non-liver related co-morbid conditions
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  - **For genotype 1 or 4**: Medical record documentation of a therapeutic failure on, intolerance to, or contraindication to formulary alternatives

    TREATMENT DURATION: 12 weeks

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

BEVESPI AEROSPHERE **Keith Hunsicker**
(glycopyrrolate/formoterol fumarate)

Keith Hunsicker provided a review of Bevespi Aerosphere to the committee for consideration as a pharmacy benefit. Bevespi Aerosphere is indicated for long-term maintenance of airflow obstruction in patients with chronic obstructive pulmonary disease (COPD).

Limitation of Use: Bevespi Aerosphere is not indicated for the relief of acute bronchospasm or for the treatment of asthma.

Formulary alternatives: Advair Diskus*, Anoro Ellipta, Atrovent HFA, Breo Ellipta, Serevent Diskus, Spiriva (*prior authorization required)

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

- Medical record documentation of a diagnosis of COPD

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.

Bevespi is an inhaled LAMA/LABA indicated to treat patients with symptoms of COPD. It is a combination of two independently marketed products, glycopyrrolate (Seebri Neohaler) and formoterol fumarate (Perforomist and previously Foradil Aerolizer); however, Bevespi leverages different dosages than the other marketed products. There are two other medications within the same medication class as Bevespi, Anoro Ellipta and Utibron. Of the three medications, Bevespi requires the most inhalations per day at four inhalations, and Anoro Ellipta requires the least inhalations per day at one inhalation. There is currently no published data supporting the use of one medication within the class over another. Bevespi should not be used in patients with asthma due to a boxed warning citing a risk of increased death in this population.

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

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

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

Financial Discussion: No questions or comments.

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

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

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

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

RELISTOR **Aubrielle Prater**
(methylnaltrexone bromide)

Aubrielle Prater provided a review of Relistor tablets to the committee for consideration as a pharmacy benefit. Relistor tablets are indicated for the treatment of opioid-induced constipation (OIC) in adults with chronic non-cancer pain.

Note: Relistor injection is indicted for the treatment of OIC in adults with chronic non-cancer pain AND for the treatment of OIC in adults with advanced illness who are receiving palliative care, when response to laxative therapy has not been sufficient. Use beyond 4 months has not been studied in advanced illness population.

Formulary alternatives: polyethylene glycol (PEG), lactulose, magnesium sulfate, senna, bisacodyl

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

- Medical record documentation of a diagnosis of chronic non-cancer pain **AND**
- Medical record documentation of opioid-induced constipation **AND**
- Medical record documentation that member is currently on opioid therapy
  QUANTITY LIMIT: 3 tablets per day

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

Relistor tablets are indicated for the treatment of OIC in adults with chronic non-cancer pain. Methylnaltrexone is a selective antagonist at the mu-opioid receptor. Methylnaltrexone does not cross the blood brain barrier. The recommended dose of Relistor is 450 mg orally once daily with water, on an empty stomach, and at least 30 minutes before the first meal of the day. The trial within the package insert showed that Relistor significantly improved spontaneous bowel movement frequency compared to placebo. Relistor should not be used in patients with known or suspected GI obstruction and those at risk of recurrent obstruction. The most common adverse reactions included: abdominal pain, diarrhea, headache, abdominal distention, vomiting, hyperhidrosis, anxiety, muscle spasms, rhinorrhea, and chills. In patients with creatinine clearance <60 mL/min or Child-Pugh Class B or C hepatic impairment, the recommended dose of Relistor is 150 mg once daily in the morning. Clinicians use Movantik, Amitiza, and Relistor as options for those who fail first line therapy (stimulant laxatives and osmotic laxatives).

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

Proposed Financial Recommendations: It is recommended that Relistor tablets should not be added to the GHP Family formulary. Relistor tablets should require a prior authorization on the pharmacy benefit with the following criteria:

- Medical record documentation of therapeutic failure on, intolerance to, or contraindication to Amitiza **AND** Movantik

Additional Formulary Recommendations:

- Recommend adding Movantik and Amitiza to the GHP Family formulary and require prior authorization. Change the criterion which called for therapeutic failure on, intolerance to or contraindication to one formulary alternative from three different classes to one osmotic agent and one stimulant laxative.
- Recommend requiring failure on, intolerance to, or contraindication to Movantik and Amitiza instead of four alternative therapies for the treatment of opioid-induced constipation in adults with chronic noncancer pain in the Relistor Injection policy.

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

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

- Medical record documentation of a diagnosis of chronic non-cancer pain **AND**
- Medical record documentation of opioid-induced constipation **AND**
- Medical record documentation that member is currently on opioid therapy **AND**
- Medical record documentation of therapeutic failure on, intolerance to, or contraindication to Amitiza **AND** Movantik

Additional Formulary Recommendations – Relistor Injection:

1. Medical record documentation of a diagnosis of chronic non-cancer pain **AND**
2. Medical record documentation that the member is currently on opioid therapy **AND**
3. Medical record documentation of therapeutic failure on, intolerance to or contraindication to Amitiza* **AND** Movantik*

OR

1. Medical record documentation of advanced illness receiving palliative care **AND**
2. Medical record documentation that member is currently on opioid therapy **AND**
3. Medical record documentation of therapeutic failure on four alternative laxative/bowel therapies.

QUANTITY LIMIT: Quantity Limit: 12 mg dose = 1 per day, 8 mg dose = 15 per 30 days

Additional Formulary Recommendations – Amitiza:

- Medical record documentation of the member being ≥ 18 **AND**
- Medical record documentation of a diagnosis of chronic idiopathic constipation **OR**
- Medical record documentation of a diagnosis of being a female with irritable bowel syndrome with constipation **AND**
- Medical record documentation of therapeutic failure on, intolerance to, or contraindication to one formulary alternative from three different classes

OR

- Medical record documentation of opioid-induced constipation **AND**
- Medical record documentation of therapeutic failure on, intolerance to, or contraindication to one osmotic agent and one stimulant laxative

Additional Formulary Recommendations – Movantik:

- Medical record documentation of the member being ≥ 18YOA **AND**
- Medical record documentation of a diagnosis of chronic non-cancer pain **AND**
- Medical record documentation of opioid-induced constipation **AND**
- Medical record documentation of current opioid medication use for ≥4 weeks **AND**
- Medical record documentation of therapeutic failure on, intolerance to, or contraindication to one osmotic agent AND one stimulant laxative.

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

AFSTYLA **Keith Hunsicker**
(antihemophilic factor (recombinant), single chain)

Keith Hunsicker provided a review of Afstyla to the committee for consideration as a pharmacy or medical benefit. Afstyla is a recombinant, antihemophilic factor indicated in adults and children with

hemophilia A (congenital Factor VIII deficiency) for: On-demand treatment and control of bleeding episodes, routine prophylaxis to reduce the frequency of bleeding episodes, and perioperative management of bleeding.

Limitations of Use: Afstyla is not indicated for the treatment of von Willebrand disease.

Formulary alternatives: Advate*, Eloctate*, Helixate FS*, Kogenate FS*, Novoeight*, Obizur*, Recombinate*, Xyntha*, Xyntha Solofuse* (*prior authorization required)

Proposed Clinical Recommendations: Afstyla is a pharmacy or medical benefit. It is recommended that Afstyla be covered as a medical benefit without prior authorization. It is recommended that Afstyla be added to the GHP Family formulary with a prior authorization. In order to ensure appropriate utilization, the following prior authorization criteria should apply:

- Medical record documentation of a diagnosis of hemophilia (a documented Factor VIII or IX deficiency) **AND**
- Medical record documentation that the antihemophilic agent will be self-administered at home

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.

Afstyla is a recombinant, antihemophilic factor indicated in adults and children with hemophilia A. It should not be used for the treatment of von Willebrand disease. Afstyla is one of many in its class, but is the only single chain recombinant factor VIII therapy on the market. It is available as a powder for reconstitution using the Mix2Vial filter transfer set, and once dosing is determined and proper education is provided to the patient by a medical professional, the patient is able to self-administer this medication at home. The World Federation of Hemophilia recommends the use of Factor VIII products but does not prefer one medication over another.

The single chain make-up of Afstyla has a longer half-life in the body which may eliminate the need for one injection per week compared to traditional factor products.

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

Proposed Financial Recommendations: Afstyla is a pharmacy or medical benefit. It is recommended that Afstyla be covered as a medical benefit without prior authorization. It is recommended that Afstyla be added to the GHP Family formulary on the brand tier with a prior authorization.

Financial Discussion: No comments or questions.

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

Approved Recommendations: Afstyla will be covered as a medical benefit without prior authorization. When self-administered in the home Afstyla will be covered as a pharmacy benefit on the brand tier. The following prior authorization criteria will apply to pharmacy benefit Afstyla requests:

- Medical record documentation of a diagnosis of hemophilia (a documented Factor VIII or IX deficiency) **AND**
- Medical record documentation that the antihemophilic agent will be self-administered at home

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

OCALIVA **Aubrielle Prater**
(obeticholic acid)

Aubrielle Prater provided a review of Ocaliva to the committee for consideration as a pharmacy benefit. Ocaliva is indicated for the treatment of primary biliary cholangitis (PBC) in combination with ursodeoxycholic acid (UDCA) in adults with inadequate response to UDCA, or as monotherapy in adults unable to tolerate UDCA.

This is an accelerated approval based on a reduction in alkaline phosphatase. An improvement in survival or disease-related symptoms has not been established. Continued approval for this indication may be contingent upon verification and description of clinical benefit in confirmatory trials.

Formulary alternatives: ursodiol

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

- Medical record documentation of primary biliary cholangitis (primary biliary cirrhosis) **AND**
- Prescription is written by a board certified gastroenterologist, hepatologist, or liver transplant specialist **AND**
- Medical record documentation that Ocaliva is not being used in members with complete biliary obstruction **AND**
    - Medical record documentation of contraindication to or intolerance to UDCA (ursodiol tablets, Urso Forte, or Urso 250) **OR**
    - Medical record documentation of inadequate biochemical response* to an appropriate dose** of UDCA for at least 1 year **AND** that Ocaliva will be prescribed in combination with UDCA

QUANTITY LIMIT: 1 tablet per day

AUTHORIZATION DURATION: The initial approval period will be for 6 months

REAUTHORIZATION CRITERIA: The following documentation is required for reauthorization:

- Medical record documentation of monitoring liver function tests, including alkaline phosphatase and bilirubin **AND**
- Medical record documentation of HDL-C **AND**
- Medical record documentation of a positive response to Ocaliva based on reduction in alkaline phosphatase and bilirubin

If approved, reauthorization will be for one year. Reevaluation will be every one (1) year requiring medical record documentation of continued or sustained improvement of primary biliary cholangitis defined by alkaline phosphatase and bilirubin levels.

* Inadequate response: ALP ≥ 1.67 times the upper limit of normal (ULN) and/or if total bilirubin was between 1 and 2 times the ULN.
ULN for females: ALP is 118 U/L and bilirubin is 1.1 mg/dL
ULN for males: ALP is 124 U/L and bilirubin is 1.5 mg/dL

**Appropriate dose of UDCA: Dose is 13 to 15 mg/kg/day in 2 to 4 divided doses

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.

Obeticholic acid is an agonist for farnesoid X receptor. After FXR becomes activated, there is a decrease in intracellular hepatocyte concentrations of bile acids. Ocaliva is indicated for the treatment of PBC either as combination with UDCA in adults with inadequate response to UDCA, or as monotherapy in adults unable to tolerate UDCA. Ocaliva is the second approved treatment for PBC. The starting dose of Ocaliva is 5 mg orally once daily. If ALP and/or total bilirubin does not adequately reduce after 3 months of Ocaliva therapy, the dose of Ocaliva should be increased to 10 mg once daily. Ocaliva has been shown to reduce ALP in clinical trials. Response in clinical trials was defined as ALP < 1.67-times ULN, total bilirubin ≤ ULN, and an ALP decrease of at least 15%. The ULN of ALP was defined as 118 U/L for females and 124 U/L for males. The ULN for total bilirubin was defined as 1.1 mg/dL for females and 1.5 mg/dL for males. However, an improvement in survival or disease-related symptoms has not been established. Ocaliva is contraindicated in patients with complete biliary obstruction. Most common adverse reactions (≥ 5%) were: pruritus, fatigue, abdominal pain and discomfort, rash, oropharyngeal pain, dizziness, constipation, arthralgia, thyroid function abnormality, and eczema. The recommended starting dose of Ocaliva for Child-Pugh Class B and Child-Pugh Class C hepatic impairment is 5 mg once weekly. If ALP and/or total bilirubin has not adequately reduced after 3 months of the once weekly dosing, and the patient is tolerating the drug, the dose of Ocaliva can be increased to 5 mg twice weekly (at least three days apart). Depending on response and tolerability, Ocaliva could further be increased to 10 mg twice weekly (at least three days apart).

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

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

Financial Discussion: No questions or comments.

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

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

- Medical record documentation of primary biliary cholangitis (primary biliary cirrhosis) **AND**
- Prescription is written by a board certified gastroenterologist, hepatologist, or liver transplant specialist **AND**

- Medical record documentation that Ocaliva is not being used in members with complete biliary obstruction **AND**
    - Medical record documentation of contraindication to or intolerance to UDCA (ursodiol tablets, Urso Forte, or Urso 250) **OR**
    - Medical record documentation of inadequate biochemical response* to an appropriate dose** of UDCA for at least 1 year **AND** that Ocaliva will be prescribed in combination with UDCA

QUANTITY LIMIT: 1 tablet per day

AUTHORIZATION DURATION: The initial approval period will be for 6 months

REAUTHORIZATION CRITERIA: The following documentation is required for reauthorization:

- Medical record documentation of monitoring liver function tests, including alkaline phosphatase and bilirubin **AND**
- Medical record documentation of HDL-C **AND**
- Medical record documentation of a positive response to Ocaliva based on reduction in alkaline phosphatase and bilirubin

If approved, reauthorization will be for one year. Reevaluation will be every one (1) year requiring medical record documentation of continued or sustained improvement of primary biliary cholangitis defined by alkaline phosphatase and bilirubin levels.

* Inadequate response: ALP $\geq$ 1.67 times the upper limit of normal (ULN) and/or if total bilirubin was between 1 and 2 times the ULN.

ULN for females: ALP is 118 U/L and bilirubin is 1.1 mg/dL

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

PROBUPHINE **Keith Hunsicker**
(buprenorphine hydrochloride)

Keith Hunsicker provided a review of Probuphine to the committee for consideration as a medical benefit. Probuphine is a partial opioid agonist indicated for the maintenance treatment of opioid dependence in patients who have achieved and sustained prolonged clinical stability on low-to-moderate doses of a transmucosal buprenorphine containing product (i.e. doses of no more than 8 mg per day of Subutex or Suboxone sublingual tablet or generic equivalent).

Limitations of Use: Probuphine is not appropriate for new entrants to treatment and patients who have not achieved and sustained prolonged clinical stability, while being maintained on buprenorphine 8 mg per day or less of a Subutex or Suboxone sublingual tablet equivalent or generic equivalent.

Formulary alternatives: buprenorphine HCl*, buprenorphine/naloxone HCl*, naltrexone HCl, Suboxone Film* (*prior authorization required)

Proposed Clinical Recommendations: Probuphine should be covered as a medical benefit with the following prior authorization criteria:

- Prescriber must have a unique identification number issued by the Drug Enforcement Agency (DEA) certifying prescribing authority for buprenorphine agents **AND**
- Prescriber must have enrolled, trained, and demonstrated competency in Probuphine procedures as described by the Probuphine REMS Program **AND**
- Probuphine must be prescribed by a participating provider or a provider who participates in the plan's designated behavioral health benefit program **AND**
- Medical record documentation of a diagnosis of opioid dependence **AND**
- Medical record documentation that patient is clinically stable by verifying **ALL** of the following:
    - No reports of significant withdrawal symptoms
    - Reports of low to no desire/need to use illicit opioids
    - No episodes of hospitalizations (for addiction or mental health issues), emergency room visits, or crisis interventions in the past 90 days
    - Consistent compliance with clinic visit requirements as evidenced by documentation of attendence to all scheduled appointments **at least** 6 months prior to the ordering of Probuphine **AND**
- Medical record documentation that patient is stable for at least the last 6 months on low-to-moderate doses of a transmucosal buprenorphine containing product (i.e., doses of no more than 8 mg per day of Subutex or Suboxone sublingual tablets or generic equivalent) **AND**
- Medical record documentation that the member is compliant with oral buprenorphine therapy as documented by a urine drug screen (dated within 28 days of request date) for opiates and buprenorphine. The drug screen must be positive for buprenorphine and norbuprenorphine. Presence of controlled substances other than buprenorphine must be addressed **AND**
- Medical record documentation of member abstinence from alcohol **AND**
- Medical record documentation that the member will not be receiving supplemental sublingual buprenorphine after implant insertion **AND**
- Member must be actively involved in formal counseling with a licensed behavioral health provider. Must provide the name of counselor and/or facility or rationale for non-participation **AND**
- Member must attest that a behavioral health vendor and/or plan case managers may contact prescriber, member, or counselor/facility to ensure compliance with these requirements **AND**

- For re-authorization:
    - Member must be adherent to buprenorphine and must not be using opiates. Must be verified by lab screen (dated within 28 days of request date) for opiates and buprenorphine. The presence of controlled substances other than buprenorphine must be addressed **AND**
    - Medical record documentation of continued member abstinence from alcohol **AND**
    - Member is cooperative with behavioral health vendor and/or plan case managers who are in contact **AND**
    - Medical record documentation that Probuphine has **NOT** been used for greater than one year **AND**
    - Medical record documentation that the new implants will be inserted into the contralateral arm **AND**
    - Medical record documentation that member will not be receiving supplemental sublingual buprenorphine after implant insertion

QUANTITY LIMIT: Four (4) implants (one kit) every 180 days

AUTHORIZATION DURATION: If approved, initial authorization duration will be six (6) months. If approved, one subsequent authorization duration will be six (6) months.

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.

Probuphine is a first-in-class implantable form of buprenorphine. It is available in one strength as four implantable devices, which release the drug evenly across six months of therapy. The implants must be removed after six months. The Probuphine dose is unable to be titrated. Probuphine must be prescribed and implanted/removed by a qualified physician as described by the Probuphine REMS program. The warnings and precautions are similar to those of alternate buprenorphine therapies with the addition of implantation site adverse reactions. In clinical trials, Probuphine was as effective as sublingual buprenorphine/naloxone; however, Probuphine was insufficient for about 37% of the studied patients.

There was extensive discussion regarding the appropriate use of Probuphine. Unanswered questions included why was the product not studied beyond a year, is there a way to abuse the product, what happens if the patient is lost to follow-up and the implant is not removed, how do we avoid patients receiving oral buprenorphine in conjunction with Probuphine.

In order to support stabilization on Probuphine the following criteria will be added:
Initial Review:

- Medical record documentation that member does not have any urine drug screens positive for controlled substances other than buprenorphine within 90 days of the request date

Reauthorization:

- Medical record documentation that patient has not had any positive urine drug screens within the past 6 months for controlled substances other than buprenorphine

Additionally, a note will be added to the policy regarding not data to support use of Probuphine beyond one year of therapy.

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

Proposed Financial Recommendations: Probuphine should be covered as a medical benefit requiring prior authorization for GHP Family members.

Financial Discussion: No comments or questions.

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

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

- Prescriber must have a unique identification number issued by the Drug Enforcement Agency (DEA) certifying prescribing authority for buprenorphine agents **AND**
- Prescriber must have enrolled, trained, and demonstrated competency in Probuphine procedures as described by the Probuphine REMS Program **AND**

- Probuphine must be prescribed by a participating provider or a provider who participates in the plan's designated behavioral health benefit program **AND**
- Medical record documentation of a diagnosis of opioid dependence **AND**
- Medical record documentation that patient is clinically stable by verifying **ALL** of the following:
    - No reports of significant withdrawal symptoms
    - Reports of low to no desire/need to use illicit opioids
    - No episodes of hospitalizations (for addiction or mental health issues), emergency room visits, or crisis interventions in the past 90 days
    - Consistent compliance with clinic visit requirements as evidenced by documentation of attendence to all scheduled appointments **at least** 6 months prior to the ordering of Probuphine **AND**
- Medical record documentation that patient is stable for at least the last 6 months on low-to-moderate doses of a transmucosal buprenorphine containing product (i.e., doses of no more than 8 mg per day of Subutex or Suboxone sublingual tablets or generic equivalent) **AND**
- Medical record documentation that the member is compliant with oral buprenorphine therapy as documented by a urine drug screen (dated within 28 days of request date) for opiates and buprenorphine. The drug screen must be positive for buprenorphine and norbuprenorphine. Presence of controlled substances other than buprenorphine must be addressed **AND**
- Medical record documentation that member does not have any urine drug screens positive for controlled substances other than buprenorphine within 90 days of the request date **AND**
- Medical record documentation of member abstinence from alcohol **AND**
- Medical record documentation that the member will not be receiving supplemental sublingual buprenorphine after implant insertion **AND**
- Member must be actively involved in formal counseling with a licensed behavioral health provider. Must provide the name of counselor and/or facility or rationale for non-participation **AND**
- Member must attest that a behavioral health vendor and/or plan case managers may contact prescriber, member, or counselor/facility to ensure compliance with these requirements **AND**

- For re-authorization:
    - Member must be adherent to buprenorphine and must not be using opiates. Must be verified by lab screen (dated within 28 days of request date) for opiates and buprenorphine. The presence of controlled substances other than buprenorphine must be addressed **AND**
    - Medical record documentation that patient has not had any positive urine drug screens within the past 6 months for controlled substances other than buprenorphine **AND**
    - Medical record documentation of continued member abstinence from alcohol **AND**
    - Member is cooperative with behavioral health vendor and/or plan case managers who are in contact **AND**
    - Medical record documentation that Probuphine has **NOT** been used for greater than one year **AND**
    - Medical record documentation that the new implants will be inserted into the contralateral arm **AND**
    - Medical record documentation that member will not be receiving supplemental sublingual buprenorphine after implant insertion

QUANTITY LIMIT: Four (4) implants (one kit) every 180 days

AUTHORIZATION DURATION: If approved, initial authorization duration will be six (6) months. If approved, one subsequent authorization duration will be six (6) months. Note: studies of Probuphine use past one year have not be assessed.

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

FAST FACTS:

Viekira XR **Kristi Clarke**
(dasabuvir, ombitasvir, paritaprevir, and ritonavir)

New Formulation: A new long acting formulation of Viekira called Viekira XR has been FDA approved. It includes dasabuvir, a hepatitis C virus non-nucleoside NS5B palm polymerase inhibitor, ombitasvir, a hepatitis C virus NS5A inhibitor, paritaprevir, a hepatitis C virus NS3/4A protease inhibitor, and ritonavir, a CYP3A inhibitor and is indicated for the treatment of adult patients with chronic hepatitis C virus (HCV) genotype 1b infection without cirrhosis or with compensated cirrhosis OR genotype 1a infection without cirrhosis or with compensated cirrhosis for use in combination with ribavirin.

Viekira XR differs from Viekira Pak in that all of the HCV antiviral drugs are now combined in one fixed dose combination tablet for once daily dosing.

Clinical discussion: New Dosing Instructions, Dosage Form, Drug Interactions, Adverse Reactions, Clinical Trials and Recommendations from National Agencies/Organizations were discussed.

Recommendation: It is recommended that Viekira XR not be added to the GHP Family formulary and should be reviewed using the Viekira policy. A quantity limit of three tablets per day, 84 tablets per 28 day be added.

Discussion: No comments or questions.

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

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

TROKENDI XR **Aubrielle Prater**
(topiramate)

Updated Indication: Trokendi XR is now indicated as initial monotherapy in patients ≥ 6 years of age with partial onset or primary generalized tonic-clonic seizures.

Note: Trokendi XR was previously indicated as adjunctive therapy in patients ≥ 6 years of age with partial onset, primary generalized tonic-clonic seizures, or seizures associated with Lennox-Gastaut syndrome.

Clinical discussion: Updated Dosing for New Indication, Clinical Studies, Adverse Reactions and Cost were discussed.

Recommendation: The current policy does not specify that Trokendi XR must be used as adjunct therapy, which was the previous indication. No changes should be made to the policy. However, ethosuximide should be removed as a formulary alternative. Phenobarbital should be added as a formulary alternative. Currently Trokendi XR is nonformulary for GHP Family. No formulary changes should be made.

Discussion: No comments or questions.
Outcome: Keith Hunsicker 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.

DYSPORT **Keith Hunsicker**
(abobotulinumtoxinA)

Updated Indication: Dysport is now indicated for the treatment of lower limb spasticity in pediatric patients 2 years of age and older.

Previously only indicated for the treatment of adults with cervical dystonia, the temporary improvement in the appearance of moderate to severe glabellar lines associated with procerus and corrugator muscle activity in adult patients <65 years of age, and the treatment of upper limb spasticity in adults.

Clinical discussion: Updated Dosing for New Indication, Formulary Alternatives, Clinical Studies and Adverse Reactions were discussed.

Recommendation: No changes to the formulary are recommended at this time. The following should be added to the Medical Benefit Policy:
Pediatric Lower Limb Spasticity

- Medical record documentation that Dysport is being used for the treatment of the lower limb(s) **AND**
- Documentation that the member is between 2 and 17 years of age

Note: Adult lower limb spasticity is indicated under Botox Only, **NOT Dysport.

It is recommended that the following Botulinum Toxin policy investigational verbiage be changed to the following to account for the new indication:

Botulinum toxin is considered **investigational** for:

- headache or migraine other than chronic migraine
- myofascial pain syndrome
- tremors such as benign essential tremor, chronic motor tic disorder, and tics associated with Tourette syndrome
- treatment of upper limb spasticity in pediatric patients
- treatment of lower limb spasticity pediatric patients (with exception of Dysport)
- treatment of hyperhidrosis in body areas other an axillary

As treatment of wrinkles or other cosmetic indications. Cosmetic procedures are an exclusion per the "Exclusions" section of the applicable benefit documents.

It is recommended that the following limitations be added to apply to ALL Dysport authorizations for GHP Family:

- **Quantity Limit**: One (1) treatment every 90 days.
- **Authorization Duration:** Initial approval will be six (6) months or less if the reviewing provider feels it is medically appropriate. Subsequent approvals should be six (6) months or less if the reviewing provider feels it is medically appropriate and will require medical record documentation of continued disease improvement or lack of disease progression. The medication will no longer be covered if patient experiences toxicity or worsening of disease.

Discussion: No comments or questions.

Outcome: Keith Hunsicker 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.

DIFFERIN 0.1% GEL **Aubrielle Prater**
(adapalene)

New Product: Differin 0.1% gel is now approved as an OTC product, however it is not commercially available. Differin 0.1 % cream and lotion is Rx. Differin 0.3% gel is Rx. All of the generic formulations are Rx

Discussion: Cost and Current Formulary Status was discussed.

Recommendation: No changes are recommended at this time.

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.

ARZERRA **Keith Hunsicker**
(ofatumumab)

Updated Indication: Arzerra is now indicated for the treatment of patients with relapsed chronic lymphocytic leukemia (CLL) in combination with fludarabine and cyclophosphamide.

Previously, Arzerra was approved for the following indications: 1) in combination with chlorambucil, for the treatment of previously untreated patients with CLL for whom fludarabine-based therapy is

considered inappropriate, 2) for extended treatment of patients who are in complete or partial response after at least two lines of therapy for recurrent or progressive CLL, and 3) for the treatment of patients with CLL refractory to fludarabine and alemtuzumab.

Clinical discussion: Updated Dosing and Administration for New Indication, Clinical Studies, Adverse Reactions, Recommendations from National Agencies or Organizations and Cost were discussed.

Recommendation: No formulary changes are recommended at this time. The following criterion should be added to the Medical Benefit Policy:
o Medical record documentation of relapsed chronic Lymphocytic Leukemia/Small Lymphocytic Lymphoma (CLL/SLL) AND
o Medical record documentation that Arzerra is being used in combination with fludarabine and cyclophosphamide

Discussion: No comments or questions.

Outcome: Keith Hunsicker 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.

DEXILANT **Aubrielle Prater**
(dexlansoprazole)

Updated Indication: Dexilant capsules are now indicated for patients ≥ 12 years old for:
- Healing of all grades of erosive esophagitis (EE) for up to 8 weeks
- Maintenance of healed EE and relief of heartburn for up to 6 months in adults and 16 weeks in patients 12 to 17 years of age
- Treatment of symptomatic non-erosive GERD for 4 weeks

Dexilant SoluTab is now indicated in patients ≥ 12 years old for:
- Maintenance of healed EE ad relief of heartburn for up to 6 months in adults and 16 weeks in patients 12 to 17 years of age
- Treatment of symptomatic non-erosive GERD for 4 weeks

Note: Previously these indications only applied to adult patients.

Clinical discussion: Updated Dosing for New Indication, Clinical Studies and Adverse Reactions were discussed.

Recommendation: There are no current age restrictions in the policies for Dexilant within the Dexilant, Esomeprazole, Zegerid policy for Commercial and Medicaid. Also there are no age restrictions in the policy for Dexilant within the Aciphex Sprinkles, Dexilant, Prevacid SoluTabs, Prilosec Suspension Packets, Zegerid for Medicare. Therefore, no formulary or policy updates are recommended at this time. Since, Dexilant SoluTab is not commercially available, it will not be added to formulary at this time.

Discussion: No comments or questions.

Outcome: Jamie Dodson made a motion to accept the recommendations as written. Kristi Clarke 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.

TEFLARO **Keith Hunsicker**
(ceftaroline fosamil)

Updated Indication: Teflaro is an antibacterial cephalosporin indicated to treat acute bacterial skin and skin structure infections (ABSSSI) and community-acquired bacterial pneumonia (CABP) caused by susceptible bacteria in patients 2 months of age and older.

Previously, Teflaro was only indicated for patients ages 18 years of age and older.

Clinical discussion: Updated Dosing for New Indication, Clinical Studies, Warnings and Precautions and Adverse Reactions were discussed.

Recommendation: Currently Teflaro is a medical benefit. No formulary changes are recommended at this time.

Discussion: No comments or questions.

Outcome: Kristen Scheib 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.

CRESTOR **Aubrielle Prater**
(rosuvastatin)

Updated Indication: Crestor is now indicated as an adjunct to diet to reduce Total-C, LDL-C, ApoB and nonHDL-C in children and adolescents 7 to 17 years of age with homozygous familial hypercholesterolemia, either alone or with other lipid-lowering treatments (e.g. LDL apheresis).

Note: Crestor was previously approved for treatment in adult patients with homozygous familial hypercholesterolemia and in children and adolescents 8 to17 years of age with heterozygous familial hypercholesterolemia

Clinical discussion: Updated Dosing, Clinical Studies, and Adverse Reactions were discussed.

Recommendation: Currently Crestor in nonformulary and rosuvastatin is formulary for GHP Family. No changes are recommended at this time.

Discussion: No comments or questions.

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

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

BLINCYTO **Keith Hunsicker**
(blinatumomab)

Updated Indication: Blincyto is a bispecific CD19-directed CD3 T-cell engager indicated for the treatment of Philadelphia chromosome-negative relapsed or refractory B-cell precursor acute lymphoblastic leukemia (ALL). This indication is approved under accelerated approval. Continued approval for this indication may be contingent upon verification of clinical benefit in subsequent trials

Clinical discussion: Updated Dosing, Clinical Trials, Warnings and Precautions, and Recommendations from National Agencies or Organizations were discussed.

Recommendation: Blincyto is currently considered a medical benefit requiring prior authorization. No changes to the formulary are recommended at this time. It is recommended that the existing prior authorization criteria are modified to the following:
Blincyto will be considered medically necessary when all of the following criteria are met:

- Prescription written by an oncologist/hematologist **AND**
- Medical record documentation of a diagnosis of Philadelphia chromosome-**negative** relapsed or refractory B-cell precursor acute lymphoblastic leukemia (ALL)

AUTHORIZATION DURATION: Initial approval will be limited to one lifetime 5 cycle (8 month) course. Subsequent approval for treatment past the initial 5 cycle course will require documentation of well-controlled, peer-reviewed literature with evidence to support this request.

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.

HUMIRA **Kristen Scheib**
(adalimumab)

Updated Indication: Treatment of non-infectious intermediate, posterior and panuveitis in adult patients.

Clinical discussion: Updated Dosing, Clinical Trials and Recommendations from National Agencies or Organizations were discussed.

Recommendation: Humira is currently on the GHP Family formulary at the Brand Tier with a prior authorization. Recommend no changes at this time and addition of following prior authorization criteria to existing policy:

- Medical record documentation of a diagnosis of non-infectious intermediate, posterior or panuveitis AND
- Medical record documentation of age 18 years and older AND
- Medical record documentation prescription is written by ophthalmologist AND
- Medical record documentation of therapeutic failure on, contraindication to, or intolerance to one antimetabolite (methotrexate, azathioprine, or mycophenolate) and one calcineurin antagonist (cyclosporine or tacrolimus)

Auth Duration: Approval will be given for an initial duration of six (6) months. For continuation of coverage, medical record documentation of clinical improvement or lack of progression in signs and symptoms of uveitis on six (6) months of adalimumab therapy is required.
After the initial six (6) month approval, subsequent approvals will be for a duration of one (1) year, requiring medical record documentation of continued or sustained improvement in the signs and symptoms of uveitis while on adalimumab therapy.

Quantity Limits:
Initial Auth: One-week auth for QL of 4 syringes per 28 days; Remainder of the 6 month auth duration, QL of 2 syringes per 28 days

Reauthorization: QL of 2 syringes per 28 days

Discussion: No comments or questions.

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

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

POLICY/FORMULARY UPDATES:

DICLEGIS (doxylamine succinate/pyridoxine hcl) **Kevin Szczecina**

Diclegis (doxylamine succinate/pyridoxine hcl) is indicated for the treatment of nausea and vomiting of pregnancy in women who do not respond to conservative management. It is recommended that the requirement that members be between 7 and 14 weeks gestation be removed from the policies for all lines of business. It is also recommended that the authorization duration be changed from four weeks to nine months.

Discussion: No comments or questions.

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

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

APTIOM **Kevin Szczecina**
(eslicarbazepine acetate)

The recommended maintenance dose of Aptiom (eslicarbazepine acetate) is now 800 mg to 1600 mg daily. It is recommended that the quantity limit of Aptiom 800 mg tablets be increased to two tablets daily.

Discussion: No comments or questions.

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

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

FORMULARY ADDITIONS **Kevin Szczecina**

It is recommended that dipyridamole oral tablets and valsartan oral tablets be added to the GHP Family formulary on the generic tier.

Discussion: No comments or questions.

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

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

HEPATITIS C POLICIES **Kristi Clarke**

It is recommended that the following criterion be removed from all GHP Family Hepatitis C Policies:

- Medical record documentation that the member is agreeable to counseling and monitoring by representatives from GHP

Discussion: No comments or questions.

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

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

Meeting adjourned at 4:08 pm.

Future Scheduled Meetings

January 17, 2017 at 1:00 HCN3A & 3B Conference room

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