P&T Committee Meeting Minutes
GHP Family
July 17, 2018

Present:	**Absent:**
Bret Yarczower, MD, MBA – Chair	Kenneth Bertka, MD
Kristen Bender, PharmD – via phone	Beverly Blaisure, MD
Holly Bones, PharmD – via phone	Kim Castelnovo, RPh
Rajneel Chohan Pharm.D	Dean Christian, MD
Alyssa Cilia, RPh – via phone	Michael Evans, RPh
Kimberly Clark, PharmD	Sandra Garrett, RPh, MBA
Kristi Clarke, PharmD, MHA – via phone	Tricia Heitzman, Pharm.D
Patrick Ferguson, RPh, MBA – via phone	Jason Howay, Pharm.D.
Keith Hunsicker, Pharm.D.	Perry Meadows, MD
Kelli Hunsicker, Pharm.D. – via phone	Stephen Moscello, RPh
Steven Kheloussi, PharmD – via phone	Jonas Pearson, RPh
Phillip Krebs, R.EEG T.	Ginnetta Reed
Jamie Miller, RPh	William Seavey, Pharm.D
Aubrielle Prater Pharm.D.	
Kristen Scheib, Pharm. D. – via phone	
Richard Silbert, MD – via phone	
Michael Spishock, RPh – via phone	
Todd Sponenberg, Pharm.D.	
Kevin Szczecina, RPh	
Lori Zaleski, RPh – via phone	
Emily Kneeream, Pharmacy Student	
Leslie Shumlas, Pharmacy Student	

Call to Order:
Dr. Bret Yarczower called the meeting to order at 1:04 p.m., Tuesday, July 17, 2018.

Review and Approval of Minutes:
Dr. Bret Yarczower asked for a motion or approval to accept the May 15, 2018 minutes as written. Keith Hunsicker pointed out that there was discussion (financial) during the May P&T meeting to require failure of two different intra-articular steroids prior to Zilretta rather than one. This was questioned and recommended by Dr. Yarczower and agreed upon by the committee. Todd Sponenberg made a motion to accept the amended minutes and Kevin Szczecina seconded the motion. None were opposed.

DRUG REVIEWS

FIASP (insulin aspart)

Review: Fiasp (insulin aspart) is a rapid-acting insulin with excipients added to increase its response time once taken. Fiasp may be taken at the start of a meal or up to 20 minutes after the start of a meal, compared to the other insulin aspart product, NovoLog, which must be taken 5-10 minutes before a meal. It has been shown to be non-inferior to NovoLog, with a similar adverse event profile and similar warnings and precautions. Another major difference between Fiasp and NovoLog is that Fiasp is indicated only in patients 18 and older for both Type I and Type II diabetes, while NovoLog is FDA-approved for patients 2 years of age and older with Type I diabetes and for patients 18 and older in Type II diabetes. Finally, NovoLog may be used in an insulin pump, while Fiasp is not labeled for use in that way.

A Clinical Review including Clinical Information, Efficacy Evidence, Safety Evidence, Other Considerations and a Financial Review Based on Cost Analysis were presented.

Clinical Discussion: No questions or comments. Jamie Miller made a motion to accept the criteria as written. Kevin Szczecina seconded the motion. None were opposed.

Financial Discussion: No questions or comments. Keith Hunsicker made a motion to accept the criteria as written. Kevin Szczecina seconded the motion. None were opposed.

Outcome: For GHP Family, Fiasp will be a pharmacy benefit and will not be added to the formulary. The following criteria will apply:
- Medical record documentation that the patient is 18 years of age or older
- Medical record documentation of a therapeutic failure on, contraindication to, or intolerance to NovoLog

Additional Recommendations
The Lilly Insulin policy should be updated to the following:
- Medical record documentation of a therapeutic failure on, contraindication to, or intolerance to comparable Novo Nordisk brand insulin **(with the exception of Fiasp).**

No questions or comments. Kevin Szczecina made a motion to accept the recommendation as presented. Keith Hunsicker seconded the motion. None were opposed.

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

ADMELOG (insulin lispro)

Review: Admelog (insulin lispro) is the first FDA-approved follow-on rapid-acting insulin product and is indicated in patients 3 years and older with Type 1 diabetes and for adults with Type 2 diabetes. It has been shown to have non-inferior HbA1c lowering effects when compared to another insulin lispro product in clinical trials for both type 1 diabetes mellitus and type 2 diabetes mellitus. Admelog is available as a 10 mL multiple-dose vial or a 3 mL SoloStar prefilled pen. Dosing of Admelog should be based on patient

weight and patient-specific metabolic needs and glycemic goals. The most common adverse effects seen with Admelog are hypoglycemia, nasopharyngitis, and upper respiratory tract infections. Similar to Humalog, Admelog may be diluted, but should not be diluted if being used in an insulin pump. Novolog and Fiasp cannot be diluted for subcutaneous injection. There are no clinically meaningful differences between this drug and Humalog.

A Clinical Review including Clinical Information, Efficacy Evidence, Safety Evidence, Other Considerations and a Financial Review Based on Cost Analysis were presented.

Clinical Discussion: No questions or comments. Kevin Szczecina made a motion to accept the recommendations as presented. Kim Clark seconded the motion. None were opposed.

Financial Discussion: No questions or comments. Aubrielle Prater made a motion to accept the recommendations as presented. Kevin Szczecina seconded the motion. None were opposed.

Outcome: For GHP Family, Admelog will not be added to the formulary. Criteria will be as follows:
- Medical record documentation of a therapeutic failure on, intolerance to, or contraindication to comparable Novo Nordisk brand insulin **OR**
- Medical record documentation that the requested insulin requires dilution

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

SYMFI/SYMFI LO (efavirenz/lamivudine/tenofovir disoproxil fumarate)

Review:

Symfi and Symfi Lo are very similar medications with the only difference being the strength of efavirenz that they contain. Symfi contains 600 mg of efavirenz, 300 mg of lamivudine, and 300 mg of tenofovir disoproxil fumarate while Symfi Lo contains 400 mg of efavirenz, 300 mg of lamivudine, and 300 mg of tenofovir disoproxil fumarate. Both medications have been deemed equally effective in clinical trials with Symfi Lo offering a lower dose of efavirenz to help lower side effects. Symfi and Symfi Lo are complete single-tablet regimens containing a non-nucleoside analog reverse-transcriptase inhibitor (NNRTI) with two nucleoside analog reverse transcriptase inhibitors (NRTI) as the backbone.

The recommended dosage of Symfi/Symfi Lo in HIV-1-infected adults is one tablet taken orally once daily. Symfi/Symfi Lo tablets should be taken on an empty stomach, preferably at bedtime. Dosing at bedtime may improve the tolerability of nervous system symptoms.

Symfi/Symfi Lo have a black box warning for post-treatment acute exacerbations of Hepatitis B, consistent with other tenofovir containing medications. Additionally, Symfi/Symfi Lo shares the majority of their warnings and precautions with Atripla. Symfi/Symfi Lo have warnings and precautions for:

- • Lactic Acidosis/Severe Hepatomegaly with Steatosis
- • New Onset or Worsening Renal Impairment
- • Serious Psychiatric Symptoms
- • Nervous System Symptoms (NSS)
- • Rash
- • Hepatotoxicity

- • Pancreatitis
- • Convulsions
- • Lipids
- • Immune Reconstitution Syndrome
- • Redistribution/Accumulation of Body Fat

The most common adverse reactions occurring in >5% of patients on Symfi Lo were rash and dizziness.
In Study 903, the most common adverse reactions were mild to moderate gastrointestinal events and dizziness.

Trial 903 evaluated the efficacy of a three-drug regimen including EFV 600 mg, 3TC 300 mg and TDF 300 mg. In study 903 achievement of plasma HIV-1 RNA concentrations of less than 400 copies/mL at Week 144 was similar between the two treatment groups. ENCORE 1 evaluated the comparability of 400 mg of EFV in a triple drug regimen to a 600-mg dose of EFV in a triple drug regimen. The trial showed similar response rates among both strengths of medications. The side effect profile did not drastically differ with Symfi Lo compared to Symfi.

Based on a large database of clinical trials supporting these characteristics of INSTIs, the Department of Health and Human Services (DHHS) updated its guidelines to recommend INSTI-based three-drug regimens as initial treatment for most patients with HIV. Efavirenz-based regimens may be recommended in certain clinical situations but are not expected to be highly utilized given the widespread availability of more tolerable alternatives.

A Clinical Review including Clinical Information, Efficacy Evidence, Safety Evidence, Other Considerations and a Financial Review Based on Cost Analysis were presented.

Clinical Discussion: No comments or questions. Kim Clark made a motion to accept the recommendations as written. Kevin Szczecina seconded the motion. None were opposed

Financial Discussion: No comments or questions. Todd Sponenberg made a motion to accept the recommendations as written. Kevin Szczecina seconded the motion. None were opposed.

Outcome: For GHP Family, Symfi and Symfi Lo will be added to the formulary on the brand tier. A quantity limit of one tablet daily will apply.

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

CIMDUO (lamivudine/tenofovir disoproxil fumarate))

Review: Cimduo is a two-drug combination of lamivudine (3TC) and tenofovir disoproxil fumarate (TDF), both nucleo(t)side reverse transcriptase inhibitors and is indicated in combination with other antiretroviral agents for the treatment of human immunodeficiency virus type 1 (HIV-1) infection in adult and pediatric patients weighing at least 35 kg. Cimduo containing 2 NRTIs and serving as the 2-drug backbone is similar to Truvada which is single tablet composed of emtricitabine and tenofovir disoproxil fumarate.

The approval of Cimduo was based on data from a double-blind, active-controlled multicenter clinical trial comparing efavirenz [EFV] 600 mg + 3TC 300 mg + TDF 300 mg vs. EFV 600 mg + 3TC 300 mg + stavudine (d4T) 40 mg in 600 antiretroviral-naïve adult patients with HIV-1 infection. Seventy-nine percent of patients were responders (HIV-1 RNA < 400 copies/mL) in the EFV/3TC/TDF group vs. 82% in the EFV/3TC/d4T group at week

48, and 68% of patients were responders in the EFV/3TC/TDF group vs. 62% in the EFV/3TC/d4T group at week 144. Through 144 weeks of therapy, 62% and 58% of patients in the TDF and d4T groups, respectively, achieved and maintained confirmed HIV-1 RNA < 50 copies/mL. Cimduo carries a boxed warning for post-treatment acute exacerbations of hepatitis B. Other warnings and precautions include lactic acidosis and severe hepatomegaly with steatosis, new onset or worsening renal impairment, risk of hepatic decompensation when used with interferon- and ribavirin-based regimens, pancreatitis, bone effects, immune reconstitution syndrome, fat redistribution, and early virologic failure. The most common adverse reactions (> 10%) with Cimduo use were headache, pain, depression, diarrhea, and rash. The recommended dose of Cimduo is one tablet taken orally once daily with or without food. Cimduo is not a complete drug regimen and should be taken with other antiretroviral medication for proper treatment of a HIV-1 infection.

Prior to initiation of Cimduo, patients should be tested for hepatitis B virus infection. Serum creatinine, serum phosphorous, estimated creatinine clearance (CrCL), urine glucose, and urine protein should be assessed before initiating Cimduo and during therapy in all patients as clinically appropriate. Use is not recommended in patients with CrCL less than 50 mL/min or patients with end-stage renal disease requiring hemodialysis.

A Clinical Review including Clinical Information, Efficacy Evidence, Safety Evidence, Other Considerations and a Financial Review Based on Cost Analysis were presented.

Clinical Discussion: No questions or comments. Kim Clark made a motion to accept the recommendations as written. Todd Sponenberg seconded the motion. None were opposed.

Financial Discussion: No comments or questions. Kevin Szczecina made a motion to accept the recommendations as written. Todd Sponenberg seconded the motion. None were opposed.

Outcome: For GHP Family, Cimduo will be added to the formulary on the brand tier with a quantity limit of one tablet per day.

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

AIMOVIG (erenumab-aooe)

Review: Aimovig is indicated for the preventive treatment of migraine in adults. Aimovig was evaluated in both episodic and chronic migraine populations. Episodic migraines are characterized by headaches occurring ≤14 days per month whereas chronic migraines are characterized by headaches occurring for ≥15 days per month for >3 months with features of a migraine headache occurring ≥8 days per month.
Aimovig is the first calcitonin gene-related peptide (CGRP) receptor antagonist approved for the preventive treatment of migraine in adults. CGRP is a 37-amino acid neuropeptide that is expressed in trigeminal ganglia nerves and is a potent vasodilator of cerebral and dural vessels. In patients who have migraines, stimulation of the trigeminal ganglion induces the release of CGRP and CGRP infusion can trigger a migraine attack.
Aimovig is available as a 70mg/mL single-dose prefilled autoinjector or two pack autoinjector for subcutaneous self-administration. The recommended dosage is 70 mg once monthly; some patients may benefit from a dosage of 140 mg once monthly, which is administered once monthly as two consecutive injections of 70 mg each.
The safety and efficacy of Aimovig was evaluated as a preventive treatment of episodic or chronic migraine in three randomized, double-blind, placebo-controlled studies: two studies in patients with episodic migraine (4 to 14 migraine days per month)) and one study in patients with chronic migraine (≥

15 headache days per month with ≥ 8 migraine days per month). All trials excluded patients who received botulinum toxin 4 months prior to baseline. The STRIVE Study studied a total of 955 patients with a history of episodic migraine. Patients were randomized to receive either Aimovig 70 mg, Aimovig 140 mg, or placebo once monthly for 6 months. The ARISE Study studied a total of 577 patients with a history of episodic migraine. Patients were randomized to receive either Aimovig or placebo once monthly for 3 months. Study 3 included a total of 667 patients with a history of chronic migraine with or without aura. Patients were randomized to receive Aimovig 70 mg, Aimovig 140 mg, or placebo once monthly for 3 months. For all three trials, Aimovig demonstrated statistically significant improvements change from baseline in mean monthly migraine days, ≥50% reduction in mean monthly migraine days, and mean monthly acute migraine-specific medication days, compared to placebo. Migraine Physical Function Impact Diary (MPFID) was analyzed in STRIVE and ARISE studies. MPFID measures the impact of migraine on everyday activities and physical impairment using a daily electronic diary. Higher scores indicate worse impact on everyday activities and physical impairment. In the STRIVE study, Aimovig showed statistically significant reductions from baseline in mean monthly MPFID every day activity and physical impairment scores compared to placebo. For the ARISE study, the analysis for MPFID was based on at least a 5-point reduction. Aimovig once monthly was not significantly better than placebo for everyday activity and physical impairment. In an exploratory analysis for MPFID, patients treated with Aimovig compared to placebo, showed significantly greater reductions in physical impairment scores, but not everyday activities scores.

There are no black box warnings, warnings/precautions, or contraindications associated with the use of Aimovig. The most common adverse reactions reported in clinical studies (incidence ≥ 3%) are injection site reactions and constipation. The safety and effectiveness of Aimovig in pediatric patients have not been established.

The following agents are currently FDA-approved for migraine prevention: propranolol, timolol, valproic acid/divalproex sodium, topiramate and onabotulinumtoxinA (Botox). Botox is indicated for preventive treatment of chronic migraines only. Aimovig has some potential advantages over current migraine prophylaxis agents: Its less frequent dosing (once-monthly), minimizes the potential for non-adherence that may be associated with the daily administration required for most of the currently used prophylactic medications. Additionally, Aimovig may have a more favorable safety profile, since it acts preferentially in the periphery, a minimal amount crosses the blood brain barrier, thereby reducing the potential for adverse CNS side effects associated with beta-blockers and anticonvulsants. However, there is a concern for an increase the risk of serious cardiovascular or cerebrovascular events.

Dr. Sana Ghafoor recommends that Aimovig should be reserved for end of line therapy and should only be prescribed by a neurologist. Aimovig should not be initiated in patients who received an injection of Botox within 3 months of starting Aimovig.

According to American Academy of Neurology the following is recommended for episodic migraine prevention in adults:

- Established as effective (level A):
  - Divalproex sodium/sodium valproate
  - Topiramate
  - Metoprolol
  - Propranolol
  - Timolol
- Probably effective (level B)
  - Amitriptyline
  - Venlafaxine
  - Atenolol
  - Nadolol
- Possibly effective (Level C)
  - Candesartan

o Lisinopril
o Clonidine
o Guanfacine
o Carbamazepine
o Nebivolol
o Pindolol

A Clinical Review including Clinical Information, Efficacy Evidence, Safety Evidence, and Other Considerations and a Financial Review Based on Cost Analysis were presented**.**

Clinical Discussion: Keith Hunsicker made the recommendation to remove criterion regarding the use of botulinum toxin within 3 months of using Aimovig. Kevin Szczecina made a motion to accept the recommendations as amended. Kim Clark seconded the motion. None were opposed.

Financial Discussion: No comments or questions. Kevin Szczecina made a motion to accept the recommendations as written. Keith Hunsicker seconded the motion. None were opposed.

Outcome: Aimovig will not be added to the GHP Family formulary. The following prior authorization criteria should apply:

- Medical record documentation that Aimovig is prescribed by a neurologist AND
- Medical record documentation of patient age greater than or equal to 18 years AND
- Medical record documentation of a diagnosis of migraine with or without aura, based on the ICHD-III diagnostic criteria AND
- Medical record documentation of number of baseline migraine or headache days per month AND
- Medical record documentation that Aimovig will not be used in combination with botulinum toxin AND
- Medical record documentation of therapeutic failure on, intolerance to, or contraindication to at least three (3) of the following:
    - One (1) beta blocker (metoprolol, propranolol, timolol, atenolol, nadolol)
    - Topiramate
    - Divalproex/Sodium Valproate
    - Amitriptyline
    - Venlafaxine

ICHD-III Diagnostic Criteria [3]	
Migraine without Aura:	**Migraine with Aura:**
A) At least five (5) attacks fulfilling criteria B through D below:	A) At least two (2) attacks fulfilling criteria B through C below:
B) Headache lasting 4 to 72 hours (untreated or unsuccessfully treated)	B) One (1) or more of the following fully reversible aura symptoms: o Visual o Sensory o Speech and/or language o Motor o Brainstem o Retinal
C) Headache with at least two (2) of the following characteristics: o unilateral location o pulsating quality o moderate to severe pain intensity	C) At least three (3) of the following: o at least one (1) aura symptom spreads over 5 or more minutes o two (2) or more aura symptoms occur in succession o each individual aura symptom lasts 5 to 60 minutes[1]

o aggravation by or causing avoidance of routine physical activity (e.g. walking or climbing stairs)	o at least one (1) aura symptom is unilateral[2] o at least one (1) aura symptom is positive[3] o the aura is accompanied, or followed within 60 minutes, by a headache
D) At least one of the following during the headache: o nausea and/or vomiting o photophobia and phonophobia	D) Not better accounted for by another ICHD-3 diagnosis
E) Not better accounted for by another ICHD-3 diagnosis	

1. Example, if three symptoms occur during an aura, the acceptable maximal duration is 3 x 60 minutes. Motor symptoms may last up to 72 hours.
2. Aphasia (impairment of language) is always a unilateral symptom; dysarthria (slurred or slowed speech) may or may not be.
3. Scintillations (flash of light) and pins and needles are positive symptoms of aura

Quantity Limit: 2 mL per 30 days
Authorization Duration: Initial approval will be for six (6) months and subsequent approvals will be for twelve (12) months.
Reauthorization Criteria:

- Medical record documentation of continued or sustained reduction in migraine or headache frequency AND
- Medical record documentation that Aimovig is not being used concurrently with botulinum toxin.

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

LONHALA MAGNAIR (glycopyrrolate)

Review: Lonhala Magnair (glycopyrrolate) is the first FDA-approved nebulized long-acting muscarinic antagonist (LAMA) for the treatment of airflow obstruction in adults with COPD, including chronic bronchitis and/or emphysema. Glycopyrrolate is also available as an inhaler (Seebri Neohaler). Lonhala is also the first use of the Magnair portable nebulizer device. Lonhala Magnair is available as a Starter Kit containing 60 unit-dose vials packaged with one Magnair, and a Refill Kit containing 60 unit-dose vials packaged with a Magnair handset refill. The recommended dosing of Lonhala Magnair is 25 mcg (one vial) twice daily. The most common adverse effects seen with Lonhala Magnair are dyspnea and urinary tract infections.

A Clinical Review including Clinical Information, Efficacy Evidence, Safety Evidence, and Other Considerations and a Financial Review Based on Cost Analysis were presented.

Clinical Discussion: No comments or questions. Kevin Szczeicna made a motion to accept the recommendations as written. Jamie Miller seconded the motion. None were opposed.

Financial Discussion: No comments or questions. Tricia Heitzman made a motion to accept the recommendations as written. Kevin Szczecina seconded the motion. None were opposed.

Outcome: Lonhala Magnair will not be added to the GHP Family formulary. The following prior authorization criteria will be applied:

- Medical record documentation of a diagnosis of chronic obstructive pulmonary disease (COPD) **AND**
- Medical record documentation that the patient is at least 18 years of age **AND**
- Medical record documentation of therapeutic failure on, intolerance to, or contraindication to Spiriva **OR**
- Medical record documentation of inability to perform proper inhaler technique

Quantity Limit: 60 vials per 30 days

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

HEMLIBRA (emicizumab-kxwh)

Review: Hemlibra is a bispecific factor IXa- and factor X-directed antibody indicated for routine prophylaxis to prevent or reduce the frequency of bleeding episodes in adult and pediatric patients with hemophilia A (congenital VIII [FVIII] deficiency) with FVIII inhibitors. Since Hemlibra has no structural relationship or sequence homology to FVIII, it does not promote the formation of FVIII inhibitors, or neutralizing antibodies. Hemlibra is the second bypassing agent approved for routine prophylaxis in hemophilia A patients with FVIII inhibitors, joining Feiba. The recommended dose of Hemlibra for adults and pediatric patients is 3 mg/kg via subcutaneous (SC) injection once weekly for the first 4 weeks, followed by 1.5 mg/kg once weekly.

The efficacy of Hemlibra for routine prophylaxis in previously treated patients with hemophilia A with FVIII inhibitors was established in two clinical trials, HAVEN 1 (for adults and adolescents) and HAVEN 2 (for pediatric patients). In HAVEN 1, patients treated with Hemlibra had a significantly lower annualized rate of bleeding than patients without prophylaxis, and administration of Hemlibra resulted in a statistically significant reduction in bleed rate in intra-patient analysis. In HAVEN 2, use of Hemlibra resulted in a 99% reduction in bleed rate, and 84.6% of patients using Hemlibra had zero treated bleeds.

Hemlibra has a black box warning for thrombotic microangiopathy and thromboembolism, and patients should be monitored for symptom development if activated prothrombin complex concentrate (aPCC) is administered. Hemlibra also interferes with intrinsic pathway clotting-base laboratory tests, so certain testing should not be used to monitor Hemlibra activity or determine dosing. The most common adverse events reported are injection site reaction, headache, arthralgia, pyrexia, diarrhea, and myalgia.

Hemlibra is available through several authorized specialty distributors as 30 mg/mL, 60 mg/0.4 mL, 105 mg/0.7 mL, and 150 mg/mL single-dose vials for injection. No hemophilia guidelines have been updated yet to include specific recommendations regarding Hemlibra.

A Clinical Review including Clinical Information, Efficacy Evidence, Safety Evidence, and Other Considerations and a Financial Review Based on Cost Analysis were presented.

Clinical Discussion: No comments or questions. Kevin Szczecina made a motion to accept the recommendations as written. Keith Hunsicker seconded the motion. None were opposed.

Financial Discussion: No comments or questions. Aubrielle Prater made a motion to accept the recommendations as written. Kevin Szczecina seconded the motion. None were opposed.

Outcome: If Hemlibra is not self-administered, it will be a medical benefit. If Hemlibra is selfadministered, it will be a pharmacy benefit covered on the Brand Tier. Prior authorization with the following criteria will apply:

- Medical record documentation of a diagnosis of hemophilia A (a documented Factor VIII deficiency) **AND**
- Medical record documentation that Hemlibra is being used for routine prophylaxis **AND**
- Medical record documentation that the antihemophilic agent will be for outpatient use **AND**

• Medical record documentation that the member has clotting factor

In addition to the recommendations for Hemlibra, it is also recommended that the current GHP Family antihemophilic agent policy be separated into four policies dependent on indication.

For requests for antihemophilic agents indicated for hemophilia B (Alphanine SD, Alprolix, Bebulin, BeneFIX, Idelvion, Ixinity, Mononine, Profilnine, Rebinyn, Rixubis), the following prior authorization criteria should apply:

- Medical record documentation of a diagnosis of hemophilia B (a documented Factor IX deficiency) **AND**
- Medical record documentation that the antihemophilic agent will be for outpatient use **AND**
- Medical record documentation that the antihemophilic agent will be used appropriately for routine prophylaxis, on-demand treatment/control of bleeding episodes, **OR** perioperative management of bleeding

	Routine Prophylaxis	**On-Demand/ Perioperative**
Alphanine SD		X
Alprolix	X	X
Bebulin		X
BeneFIX		X
Idelvion	X	X
Ixinity		X
Mononine		X
Profilnine		X
Rebinyn		X
Rixubis	X	X

For requests for antihemophilic agents indicated for hemophilia A (Advate, Adynovate, Afstyla, Eloctate, Helixate FS, Hemofil M, Koate, Koate-DVI, Kogenate FS, Kovaltry, Monoclate-P, Novoeight, Nuwiq, Obizur, Recombinate, Tretten, Xyntha, Xyntha Solofuse), the following prior authorization criteria should apply:

- Medical record documentation of a diagnosis of hemophilia A (a documented Factor VIII deficiency) **AND**
- Medical record documentation that the antihemophilic agent will be for outpatient use **AND**
- Medical record documentation that the antihemophilic agent will be used appropriately for routine prophylaxis, on-demand treatment/control of bleeding episodes, **OR** perioperative management of bleeding

	Routine Prophylaxis	**On-Demand/ Perioperative**
Advate	X	X
Adynovate	X	X
Afstyla	X	X
Eloctate	X	X
Helixate FS	X	X
Hemofil M		X
Koate/Koate-DVI		X
Kogenate FS	X	X
Kovaltry	X	X
Monoclate-P		X
Novoeight	X	X
Nuwiq	X	X
Obizur		X
Recombinate		X
Tretten	X	
Xyntha/Xyntha Solofuse		X

For requests for Novoseven, the following prior authorization criteria should apply:

- Medical record documentation of a diagnosis of hemophilia A or B with inhibitors, congenital Factor VII deficiency, **OR** Glanzmann's thrombasthenia with refractoiness to platelet transfusions, with or without antibodies to platelets **AND**
- Medical record documentation that the antihemophilic agent will be for outpatient use **AND**
- Medical record documentation that the antihemophilic agent will be used for on-demand treatment/control of bleeding episodes **OR** perioperative management of bleeding

AND

- For hemophilia A or B with inhibitors, medical record documentation that the member has factor inhibitors (neutralizing antibodies), confirmed by laboratory testing (ie. Bethesda assay)

AND

- For hemophilia A with inhibitors, medical record documentation of therapeutic failure on, intolerance to, or contraindication to Feiba

For requests for Feiba, the following prior authorization criteria should apply:

- Medical record documentation of a diagnosis of hemophilia A (a documented Factor VIII deficiency) **AND**
- Medical record documentation that the antihemophilic agent will be for outpatient use **AND**
- Medical record documentation that the member has factor inhibitors (neutralizing antibodies), confirmed by laboratory testing (ie. Bethesda assay) **AND**
- Medical record documentation that the antihemophilic agent will be used for on-demand treatment or perioperative management of bleeds

OR

- Medical record documentation that the antihemophilic agent will be used for routine prophylaxis **AND** medical record documentation of therapeutic failure on, intolerance to, or contraindication to Hemlibra

Keith Hunsicker made a motion to accept the additional recommendations as presented. 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.

NOCTIVA (desmopressin acetate)

Review: Noctiva is desmopressin acetate nasal spray indicated for nocturia caused by nocturnal polyuria for patients over 50 who average 2 or more nocturia episodes a night. It is dosed as one 1.66 mcg spray once daily approximately 30 minutes before bed. It is also available as a 0.83 mcg spray, but two sprays of the 0.83 mcg and one spray of the 1.66 mcg strengths are noted to not be interchangeable. Each 3.8 g bottle contains 35 sprays, enough for a 30 day supply. In clinical trials, Noctiva was shown to have a modest benefit in reduction of the number of nocturic episodes (-0.3 fewer episodes per night versus placebo) and increase in the number of nights with one or fewer nocturic episodes from baseline (47% of Noctiva-treated patients versus 27% of placebo-treated patients).

While other desmopressin products are available, Noctiva is currently one of only two drugs available on the market with this indication. The other, Nocdurna, is a subcutaneous form of desmopressin that was granted FDA approval on 6/21/18. There is a black box warning concerning the risk of hyponatremia and many contraindications:

hyponatremia or a history of hyponatremia, polydipsia, primary nocturnal enuresis (childhood bedwetting), concomitant use with loop diuretics or systemic or inhaled glucocorticoids, eGFR below 50 mL/min/1.73 m2, syndrome of inappropriate antidiuretic hormone (SIADH) secretion, use during illnesses that can cause fluid or electrolyte imbalance, New York Heart Association (NYHA) Class II-IV congestive heart failure, and uncontrolled hypertension. Adverse effects include nasal discomfort, nasopharyngitis, nasal congestion, sneezing, hypertension/blood pressure increased, back pain, epistaxis, bronchitis, and dizziness. Patient age plays an important role with this medication. Patients under the age of 50 have not been studied, use in those under 18 is contraindicated due to reports of hyponatremic-related seizures in pediatric patients, and patients over the age of 65 are at an increased risk of hyponatremia. As a result, patients over the age of 65 should be initiated on 0.83 mcg once daily, which may be titrated up to 1.66 mcg once daily after 1 week.

A Clinical Review including Clinical Information, Efficacy Evidence, Safety Evidence, and Other Considerations and a Financial Review Based on Cost Analysis were presented.

Clinical Discussion: No comments or questions. Kevin Szczecina made a motion to accept the recommendations as written. Phil Krebs seconded the motion. None were opposed

Financial Discussion: No comments or questions. Rajneel Chohan made a motion to accept the recommendations as written. Kevin Szczecina seconded the motion. None were opposed.

Outcome: Noctiva will not be added to the GHP Family formulary at this time. The following prior authorization criteria will apply:

- Medical record documentation of a diagnosis of nocturia due to nocturnal polyuria, as defined by a night-time urine production exceeding one-third of the 24-hour urine production confirmed with a 24-hour urine frequency/volume chart **AND**
- Medical record documentation that the patient is waking at least 2 times per night to void **AND**
- Medical record documentation that the patient is 50 years of age or older AND
- Medical record documentation that the patient is not currently hyponatremic (serum sodium < 135 meq/L) and does not have a history of hyponatremia **AND**
- Medical record documentation of an eGFR >50 ml/min/1.73m$_2$ **AND**
- Medical record documentation that the patient has no diagnosis of syndrome of inappropriate antidiuretic hormone (SIADH) secretion, New York Heart Association (NYHA) class II-IV congestive heart failure, or uncontrolled hypertension **AND**
- Medical record documentation that Noctiva is not being used in combination with a loop diuretic or systemic or inhaled glucocorticoids.

Authorization Duration: Initial authorizations will be for a period of 6 months**.**
Quantity Limit: A QL of 3.8 g per 30 days should apply.
Reauthorization Info: Reauthorizations will also be for 6 months and will require the following:
- Medical record documentation the individual is experiencing clinical benefit from the use of Noctiva **AND**
- Medical record documentation that the patient is not currently hyponatremic (serum sodium

< 135 meq/L) and does not have a history of hyponatremia AND
- Medical record documentation of an eGFR >50 ml/min/1.73m$_2$ **AND**
- Medical record documentation that the patient has no diagnosis of syndrome of inappropriate antidiuretic hormone (SIADH) secretion, New York Heart Association (NYHA) class II-IV congestive heart failure, or uncontrolled hypertension **AND**

- Medical record documentation that Noctiva is not being used in combination with a loop diuretic or systemic or inhaled glucocorticoids.

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

SYMDEKO (tezacaftor/ivacaftor)

Review: Symdeko is indicated for the treatment of patients with cystic fibrosis (CF) aged 12 years and older who are homozygous for the F508del mutation or who have at least one mutation in the cystic fibrosis transmembrane conductance regulator (CFTR) gene that is responsive to tezacaftor/ivacaftor based on in vitro data and/or clinical evidence, see table 1. The recommended dose is one tablet (containing tezacaftor 100 mg/ivacaftor 150 mg) in the morning and one tablet (containing ivacaftor 150 mg) in the evening, approximately 12 hours apart. Dose adjustments are recommended in patients with moderate and severe hepatic impairment as well as when co-administered with drugs that are moderate CYP3A4 inhibitors or strong CYP3A inhibitors

Symdeko (tezacaftor/ivacaftor) is the third FDA-approved cystic fibrosis transmembrane regulator (CFTR) modulator after Orkambi (lumacaftor/ivacaftor) and Kalydeco (ivacaftor). These agents vary by indication and target population: Both Symdeko and Orkambi are indicated for patients who are homozygous for the F508del mutation in the CFTR gene. However, Symdeko offers an additional treatment option for patients with at least one copy of a responsive mutation. In contrast, Kalydeco is not indicated in patients with the F508del mutation, but is indicated in those who have at least one responsive mutation. All the mutations responsive to Symdeko are also responsive to Kalydeco, except for homozygous F508del mutation. There are additional mutations that are responsive to Kalydeco and not listed in the labeling for Symdeko (e.g. G1069R, G1244E, R1070Q). Symdeko is approved for patients 12 years of age or older, Orkambi is approved for patients 6 years of age and older, and Kalydeco is approved for patients 2 years of age and older. Symdeko may offer a potentially more favorable safety profile. For instance, Symdeko has not been associated with an increased incidence of respiratory events or an acute post-dose decline in the percentage of the predicted FEV1, which have been reported with Orkambi. The Cystic Fibrosis Foundation (CFF) treatment guidelines have not yet been updated to include Symdeko.

The efficacy of Symdeko in CF patients aged 12 years and older was evaluated in three Phase 3, double-blind, placebo-controlled trials (Trials 1, 2, and 3). Trial 1 was a 24-week randomized, double-blind, placebo-controlled, two-arm study in CF patients who were homozygous for the *F508del* mutation in the *CFTR* gene. The primary efficacy endpoint was change in lung function as determined by absolute change from baseline in ppFEV1 through Week 24. Treatment with Symdeko resulted in a statistically significant improvement in ppFEV1. Also, there was a lower rate of pulmonary exacerbations noted in the Symdeko group compared to placebo.

Trial 2 was a randomized, double-blind, placebo-controlled, 2-period, 3-treatment, 8-week crossover study in CF patients who were heterozygous for the *F508del* mutation and a second mutation predicted to be responsive to Symdeko. Patients were randomized to treatment that included Symdeko, ivacaftor, and placebo. Treatment with Symdeko compared to placebo resulted in significant improvement in ppFEV1 and CFQ-R Respiratory Domain Score. Treatment with Kalydeco compared to placebo resulted in significant improvement in ppFEV1 and CFQ-R Respiratory Domain Score. Treatment with Symdeko compared to Kalydeco resulted in significant improvement in ppFEV1. There was no clinically significant difference in CFQ-R score change between tezacaftor/ivacaftor and ivacaftor groups**.**

Trial 3 was a 12-week randomized, double-blind, placebo-controlled, two-arm study in CF patients who were heterozygous for the *F508del* mutation and a second *CFTR* mutation predicted to be unresponsive to Symdeko.

There was no clinically significant difference in ppFEV$_1$ change between Symdeko and placebo. This study was terminated following the planned interim analysis because the pre-specified futility criteria were met.

There are no black box warnings or contraindications associated with the use of Symdeko. The most common adverse drug reactions to Symdeko (occurring in ≥3% of patients) were headache, nausea, sinus congestion, and dizziness. The safety and efficacy of Symdeko in patients < 12 years of age have not been studied.

Table 1. List of CFTR Gene Mutations that Produce CFTR Protein and are Responsive to Symdeko– *(from Symdeko Prescribing Information*

E56K	*R117C*	*A455E*	*S945L*	*R1070W*	*3272-26A→G*
P67L	*E193K*	*F508del**	*S977F*	*F1074L*	*3849+10kbC→T*
R74W	*L206W*	*D579G*	*F1052V*	*D1152H*	
D110E	*R347H*	*711+3A→G*	*K1060T*	*D1270N*	
D110H	*R352Q*	*E831X*	*A1067T*	*2789+5G→A*	

*A patient must have two copies of the F508del mutation or at least one copy of a responsive mutation presented in Table 1 to be indicated.
This list is based on a clinical FEV$_1$ response and/or *in vitro* data.
Note: *CFTR* gene mutations that are not responsive to ivacaftor alone are not expected to respond to Symdeko except for F508del homozygotes.

A Clinical Review including Clinical Information, Efficacy Evidence, Safety Evidence, and Other Considerations and a Financial Review Based on Cost Analysis were presented.

Clinical Discussion: No comments or questions. Todd Sponenberg made a motion to accept the recommendations as written. Jamie Miller seconded the motion. None were opposed.

Financial Discussion: No comments or questions. Todd Sponenberg made a motion to accept the recommendations as written. Keith Hunsicker seconded the motion. None were opposed.

Outcome: Symdeko will be a pharmacy benefit. It is recommended that Symdeko be added to the GHP Family formulary on the Brand Tier. The following prior authorization criteria should apply.

- Medical record documentation that Symdeko is prescribed by a pulmonologist or cystic fibrosis specialist AND
- Medical record documentation of patient age greater than or equal to 12 years AND
- Medical record documentation of a diagnosis of cystic fibrosis (CF) AND
- One of the following, as detected by an FDA cleared CF mutation test:
    - Medical record documentation that the member is homozygous for the *F508del* CFTR mutation OR
    - Medical record documentation that the member has at least one mutation in the CFTR gene that is responsive to tezacaftor/ivacaftor per product labeling

Note to reviewer: List of CFTR gene mutations that are responsive to Symdeko:

E56K	*R117C*	*A455E*	*S977F*	*F1074L*	*3849+10kbC→T*
P67L	*E193K*	*D579G*	*F1052V*	*D1152H*	
R74W	*L206W*	*711+3A→G*	*K1060T*	*D1270N*	
D110E	*R347H*	*E831X*	*A1067T*	*2789+5G→A*	
D110H	*R352Q*	*S945L*	*R1070W*	*3272-26A→G*	

Quantity Limit: 2 tablets per day, 28 day supply per fill

Authorization Duration: Initial approval will be for four (4) months and subsequent approvals will be for twelve (12) months. Additional authorizations will require medical record documentation of improvement or stabilization in the signs and symptoms of cystic fibrosis. The medication will no longer be covered if the member experiences worsening of disease.

Policy Recommendations:
It is recommended update the Medicaid (1329.0F) Orkambi policy to remove the following:

- Medical record documentation of a baseline forced expiratory volume in 1 second (FEV_1) score

It is recommended to update the authorization duration for the Medicaid (1329.0F) Orkambi policy to the following:

Authorization Duration: Initial approval will be for four (4) months and subsequent approvals will be for twelve (12) months. Additional authorizations will require medical record documentation of improvement or stabilization in the signs and symptoms of cystic fibrosis. The medication will no longer be covered if the member experiences worsening of disease.

Policy Recommendations:
It is recommended to update the criteria in the Medicaid (1054.0F) Kalydeco policy to the following:

- Medical record documentation that Kalydeco is prescribed by a pulmonologist or **cystic fibrosis specialist** AND
- Medical record documentation of age greater than or equal to 2 years AND
- Medical record documentation of one mutation in the CFTR gene that is responsive to ivacaftor potentiation **per product labeling** as evidenced by an FDA cleared mutation test AND
- Medical record documentation that the patient is not homozygous for the F508del mutation in the CFTR gene

Discussion: No comments or questions. Kevin Szczecina 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.

BONJESTA (doxylamine succinate and pyridoxine hydrochloride)

Review: Bonjesta is an extended-release form of doxylamine succinate (20mg) and pyridoxine hydrochloride (20mg), indicated for the treatment of pregnancy-associated nausea and vomiting in women who are not responsive to conservative management. Bonjesta is dosed one tablet in the evening on Day 1 and may be increased to one tablet in the morning and one tablet in the evening on Day 2 if symptoms are not controlled with one tablet. No new safety or efficacy clinical trials are presented by the Bonjesta package insert with the introduction of the new dose form. The clinical trial presented is the same as Diclegis and is accompanied by a pharmacokinetic analysis indicating Bonjesta's bioequivalence to Diclegis.

Bonjesta is contraindicated in women with a known hypersensitivity to doxylamine succinate (or other ethanolamine derivative antihistamines), pyridoxine hydrochloride, or any inactive ingredient in the formulation and

is contraindicated in combination with MAO inhibitors. Warnings and precautions are significant for somnolence, concomitant medication conditions, and interference with urine screens. Bonjesta is intended for use in pregnant patients, and no increased risk for congenital malformations has been reported in pregnant women (the older formulation of this drug is Pregnancy Category A). Bonjesta has not been studied in patients less than 18 years of age.

Other forms of doxylamine and pyridoxine include the over-the-counter "individually available" products and Diclegis (delayed release doxylamine-pyridoxine (10mg-10mg)). Bonjesta requires a less frequent dosing-schedule and maintains a lower pill burden than Diclegis; however, there are no known efficacy or safety advantages between the products. According to UpToDate, management of pregnancy-associated nausea and vomiting generally begins with conservative management (trigger avoidance, small meals/snacks, etc.). After conservative management, medications are added in a stepwise fashion, starting with pyridoxine and doxylamine

A Clinical Review including Clinical Information, Efficacy Evidence, Safety Evidence, and Other Considerations and a Financial Review Based on Cost Analysis were presented.

Clinical Discussion: No comments or questions. Rajneel Chohan made a motion to accept the recommendations as written. Aubrielle Prater seconded the motion. None were opposed.

Financial Discussion: No comments or questions. Rajneel Chohan made a motion to accept the recommendations as written. Kevin Szczecina seconded the motion. None were opposed.

Outcome: Bonjesta will be a pharmacy benefit. It is recommended that Bonjesta be added to the brand tier of the formulary with a quantity limit of 2 tablets per day and a maximum 9 month supply per year.

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

YONSA (abiraterone acetae)

Review:

Yonsa is a CYP17 inhibitor indicated in combination with methylprednisolone for the treatment of patients with metastatic castration-resistant prostate cancer. Another formulation of abiraterone acetate, Zytiga, has been FDA approved to treat metastatic prostate cancer since 2011. However, Zytiga is indicated in combination with prednisone for the treatment of patients with metastatic castration-resistant prostate cancer and metastatic castration-sensitive prostate cancer. Yonsa is available in a SoluMatrix Fine Particle Technology tablets, a proprietary process that results in much smaller particles of drug that can be given in lower doses. The submicron-sized particles allow more drug to be absorbed in the duodenum. Higher steady-state trough may reduce the risk of suboptimal exposure and treatment failure and lower peak concentrations may reduce the risk of toxicity. In the STARR and STARR-E clinical trials, patients taking methylprednisolone and Yonsa at half the dose of abiraterone acetate experienced similar efficacy and safety as those who took prednisone and Zytiga. The recommended dose of Yonsa is 500 mg (four 125 mg tablets) administered orally once daily in combination with methylprednisolone 4 mg administered orally twice daily. In contrast, Zytiga is administered as 1,000 mg orally once daily with prednisone 5 mg twice daily. Similar to Zytiga, Yonsa also requires dose adjustments for patients with moderate to severe hepatic impairment and those taking strong CYP3A4 inducers. In patients with moderate hepatic impairment (Child-Pugh Class B), the recommended dose is 125 mg once daily. Yonsa should not be used in patients with severe hepatic impairment (Child-Pugh Class C).

The efficacy and safety of abiraterone acetate was demonstrated in two randomized, placebo-controlled, multicenter phase 3 clinical trials from the previously approved active ingredient, abiraterone acetate. There were two bioavailability studies, food-effect study, drug interaction study with methylprednisolone, fasting patient studies, and on-going extension trials for comparative evidence.
Study 1 included 1195 patients with metastatic castration-resistant prostate cancer (CRPC) who had received prior docetaxel chemotherapy. Patients were randomized to receive either abiraterone acetate at a dose equivalent to 500 mg of Yonsa once daily in combination with a different corticosteroid orally twice daily (N=797) or placebo once daily plus a different corticosteroid orally twice daily (N=398). The protocol pre-specified interim analysis was conducted after 552 deaths and showed a statistically significant improvement in overall survival in patients treated with abiraterone acetate compared to patients in the placebo arm. Study 2 included 1088 patients with metastatic CRPC who had not received prior cytotoxic chemotherapy. Patients were randomized 1:1 to receive either abiraterone acetate at a dose equivalent to 500 mg of Yonsa once daily (N=546) or placebo once daily (N=542). Both arms were given a different corticosteroid twice daily. The planned final analysis for OS, conducted after 741 deaths demonstrated a statistically significant OS improvement in patients treated with abiraterone acetate compared to those treated with placebo.

Zytiga and Yonsa share the same contraindications and warnings and precautions. Both medications are contraindicated in pregnancy. Both medications share warnings for mineralocorticoid excess, adrenocortical insufficiency, and hepatotoxicity. The most common adverse reactions (≥ 10%) are fatigue, joint swelling or discomfort, edema, hot flush, diarrhea, vomiting, cough, hypertension, dyspnea, UTI, and contusion. The most common laboratory abnormalities (> 20%) are anemia, elevated alkaline phosphatase, hypertriglyceridemia, lymphopenia, hypercholesterolemia, hyperglycemia, elevated AST, hypophosphatemia, elevated ALT and hypokalemia.
The NCCN guidelines have not been updated to include Yonsa. For M0 or M1 CRPC, it is recommended to continue LHRH agonist or antagonist to maintain castrate levels of testosterone < 50 ng/dL and can add either Erleada (apalutamide) for M0 (category 1), Xtandi (enzalutamide) for M1 (category 1), Zytiga (abiraterone) + prednisone for M1 (category 1).

A Clinical Review including Clinical Information, Efficacy Evidence, Safety Evidence, and Other Considerations and a Financial Review Based on Cost Analysis were presented.

Clinical Discussion: No comments or questions. Rajneel Chohan made a motion to accept the recommendations as written. Todd Sponenberg seconded the motion. None were opposed.

Financial Discussion: No comments or questions. Todd Sponenberg made a motion to accept the recommendations as written. Keith Hunsicker seconded the motion. None were opposed.

Outcome: Yonsa will be a pharmacy benefit. It is recommended that Yonsa be added to the Brand Tier. The following prior authorization criteria should apply.
- Medical record documentation that Yonsa is prescribed by an oncologist or urologist AND
- Medical record documentation of diagnosis of prostate cancer with evidence of metastatic disease AND
- Medical record documentation that the member is no longer responding to castration or is hormone resistant AND
- Medical record documentation that methylprednisolone will be administered concomitantly with Yonsa

Quantity Limit: 120 tablets per 30 days

Authorization Duration: Each treatment period will be defined as 12 months. Re-review will occur every 12 months. Yonsa will no longer be covered if there is medical record documentation of disease progression.

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

CLENPIQ (Sodium Picosulfate/Magnesium Oxide/Citric Acid)

Review: Clenpiq is a combination of sodium picosulfate, magnesium oxide, and citric acid indicated for the cleansing of the colon as a preparation for colonoscopy in adults. Clenpiq is a ready-to-use formulation and does not require reconstitution or dilation by the patient prior to administration. Clenpiq is preferred to be given as a "split-dose;" however, can be given the "day-before" if needed. Clenpiq is a new formulation of the already existing product, Prepopik, which requires reconstitution by the patient immediately before administration.

The Clenpiq prescribing information utilizes the same clinical trials as Prepopik, which compared sodium picosulfate, magnesium oxide, and citric acid to PEG plus electrolytes. In these clinical trials the two arms were found to be non-inferior to each other.

Clenpiq's safety profile is comparable to Prepopik and contains contraindications in patients with severe renal impairment, gastrointestinal obstruction or ileus, bowel perforation, toxic colitis or megacolon, gastric retention, or a hypersensitivity to any of Clenpiq's ingredients. In addition to the listed contraindications, Clenpiq maintains warnings and precautions surrounding electrolyte abnormalities and gastrointestinal disorders. Clenpiq should be used cautiously with other co-administered drugs due to the possible decreased absorption of the co-administered drugs. Clenpiq should also be used cautiously with drugs that can cause electrolyte abnormalities or can increase the risk of renal impairment, seizures, arrhythmias, or QT prolongation.
The selection of colonoscopy preparation products is tailored to the individual patient taking into consideration product tolerability, comorbid conditions, and product affordability. The ASGE guidelines comment that sodium picosulfate, magnesium oxide, and citric acid products should be avoided in patients with renal insufficiency.

A Clinical Review including Clinical Information, Efficacy Evidence, Safety Evidence, and Other Considerations and a Financial Review Based on Cost Analysis were presented.

Clinical Discussion: No questions or comments. Todd Sponenberg made a motion to accept the recommendations as amended. Kevin Szczecina seconded the motion. None were opposed.

Financial Discussion: No comments or questions. Kevin Szczecina made a motion to accept the recommendations as written. Todd Sponenberg seconded the motion. None were opposed.

Outcome: Clenpiq will be a pharmacy benefit for GHP Family members. It is recommended that Clenpiq not be added to the GHP Family pharmacy formulary at this time. Prior authorization should apply.

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

OPIOID CLASS REVIEW

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Long-Acting Opioid Products Included in the Review (all products are pharmacy benefits)

Generic Name	Brand Name	Generic Available	Manufacturer	How Supplied
Buprenorphine	Butrans	Yes	Purdue Pharma	Transdermal patch (mcg/hr): 5, 7.5, 10, 15, 20
	Belbuca	No	Endo Pharmaceuticals	Buccal film (mcg): 75, 150, 300, 450, 600, 750, 900
Fentanyl	Duragesic	Yes	Janssen	Transdermal patch (mcg/hr): 12, 25, 37.5, 50, 62.5, 75, 87.5, 100
Hydrocodone ER	Hysingla ER	No	Purdue Pharma	Oral tablet ER (mg): 20, 30, 40, 60, 80, 100, 120
	Zohydro ER	No	Pernix Therapeutics	Oral capsule ER (mg): 10, 15, 20, 30, 40, 50
Hydromorphone ER	Exalgo	Yes	Mallinckrodt Pharmaceuticals	Oral tablet ER (mg): 8, 12, 16, 32
Methadone	Dolophine	Yes	West-Ward	Oral tablet (mg): 5, 10
Morphine Sulfate ER[%]	Kadian	Yes	Allergan USA	Oral capsule ER (mg): 10, 20, 30, 40, 45, 50, 60, 75, 80, 90, 100, 200
	MorphaBond ER	No	Inspirion Delivery Services	Oral tablet ER (mg): 15, 30, 60, 100
	MS Contin	Yes	Purdue Pharma	Oral tablet ER (mg): 15, 30, 60, 100, 200
	Arymo ER	No	Egalet US	Oral tablet ER (mg): 15, 30, 60
Oxycodone ER	OxyContin	Yes	Purdue Pharma	Oral tablet ER (mg): 10, 15, 20, 30, 40, 60, 80
	Xtampza ER	No	Patheon Pharmaceuticals	Oral capsule ER (mg): 9, 13.5, 18, 27, 36
Oxycodone/naltrexone	Troxyca ER	No	Pfizer	Oral capsule ER (mg-mg): 10-1.2, 20-2.4, 30-3.6, 40-4.8, 60-7.2, 80-9.6
Oxymorphone ER	-	Yes	Various	Oral tablet ER (mg): 5, 7.5, 10, 15, 20, 30, 40
Morphine sulfate/naltrexone	Embeda	No	Pfizer	Oral capsule ER (mg): 20-0.8, 30-1.2, 50-2, 60-2.4, 80-3.2, 100-4
Tapentadol	Nucynta ER	No	Depomed Inc	Oral tablet ER (mg): 50, 100, 150, 200, 250
Tramadol ER tablets	Ultram ER	Yes	Janssen	Oral tablet ER (mg): 100, 200, 300
Tramadol ER capsules	Conzip	Yes	Vertical Pharmaceuticals	Oral capsule ER (mg): 100, 150, 200, 300 (brand only)

Abuse-Deterrent Formulations

The FDA has approved these opioids with labeling describing abuse-deterrent properties consistent with the FDA's Guidance for Industry: Abuse-Deterrent Opioids – Evaluation and Labeling. However, abuse of each of these agents is still possible via the IV, intranasal, or oral routes.

Long-Acting Abuse-Deterrent Agents

Generic Name	Brand Name	Abuse-Deterrent Properties to Reduce Abuse Via?	Abuse-Deterrent Property Clinical Study Summary
Hydrocodone ER	Hysingla ER	Intravenous Intranasal Oral (when chewed)	When dissolved, forms a viscous gel that is difficult to inject through a hypodermic needle.
Morphine Sulfate ER	MorphaBond ER	Injection Intranasal	Formulated with inactive ingredients that make the tablet harder to adulterate while maintaining ER characteristics if the tablet is subjected to physical manipulation or chemical extraction.
	Arymo ER	Injection	A polymer matrix tablet technology with controlled-release properties as well as physical and chemical barriers that resist manipulation. The technology results in a viscous hydrogel on contact with liquid, making the product very difficult to draw into a syringe.
Oxycodone ER	OxyContin	Injection Intranasal	When dissolved, forms a viscous gel that is difficult to inject through a hypodermic needle.
	Xtampza ER	Injection Intranasal Oral (when chewed)	Capsules containing microspheres formulated with oxycodone base and inactive ingredients that make the formulation harder to manipulate.
Oxycodone/naltrexone	Troxyca ER	Intranasal Oral[14]	Contains pellets that consist of oxycodone that surround sequestered naltrexone. When taken orally, the naltrexone is intended to remain sequestered and patients receive ER oxycodone. When the pellets are crushed, the naltrexone is released and counteracts the effects of oxycodone.
Morphine sulfate/naltrexone	Embeda	Intranasal Oral	Capsules of ER morphine pellets that contain a sequestered core of naltrexone; if the pellets are swallowed, the morphine is gradually released and absorbed, while the naltrexone core passes through the gut intact. If the pellets are crushed, chewed, or dissolved, the naltrexone is released, blocking morphine-induced euphoria.

Short-Acting Abuse Deterrent Agents

Generic Name	Brand Name	Abuse-Deterrent Properties to Reduce Abuse Via?	Abuse-Deterrent Property Clinical Study Summary
Oxycodone	RoxyBond	Injection Intranasal	Includes inactive ingredients that make the tablets harder to misuse by physical manipulation, chemical extraction, or both; in vitro data suggest physicochemical properties that are expected to make abuse through injection difficult.

Review: All long-acting opioid products have an identical indication – 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. The only exceptions are Exalgo (hydromorphone ER) and fentanyl patches, which are indicated only in opioid tolerant patients; and Nucynta ER, which is also indicated for severe neuropathic pain associated with diabetic peripheral neuropathy. OxyContin is currently the only product indicated for pediatric patients at least 11 years of age or older.

While numerous long-acting opioid products are available on the market, only 6 have been designated by the FDA as abuse deterrent. These include Hysingla ER (hydrocodone), MorphaBond ER and Arymo ER (morphine sulfate), OxyContin and Xtampza ER (oxycodone), and Embeda (morphine sulfate/naltrexone). In addition, one short-acting opioid, RoxyBond (oxycodone) has also been deemed abuse-deterrent by the FDA. Evidence is limited at this time if these products offer value in meaningful, real-world outcomes, as the majority of evidence focuses on surrogate endpoints, such as "likeability." The only agent with real-world data is OxyContin, which was shown to reduce sales of higher doses of controlled-release oxycodone but increase sales of other oxycodone formulations. In all, ICER ranks the evidence for the net health impact of the long-acting abuse-deterrent formulations of opioids for the whole population as insufficient.

Four medications included in this review have never been presented at P&T, including Exalgo, MorphaBond ER, Arymo ER, and Troxyca ER. Each of these, except Exalgo, have abuse-deterrent properties. Outside of these abuse-deterrent claims of potentially reducing abuse by injection or intranasal routes (MorphaBond ER), injection (Arymo ER), and intranasal and oral routes (Troxyca ER), these agents offer nothing new over existing morphine sulfate ER and oxycodone ER products, respectively. Exalgo offers a long-acting version of hydromorphone but does not have any other unique properties worth highlighting.

Recommendations based on clinical review:

- In order to comply with the state guidance, it is recommended that the current opioid use policy be updated as follows as of 9/1/18:
  - The hard-stop MED threshold should be lowered from 120 to 90. Then, as of 7/1/19, the soft-stop threshold should be eliminated, and the hard-stop MED threshold should be lowered to 50.
  - The following update to the duration of use hard-stop should be incorporated.
    - **DURATION OF OPIOID USE PROGRAM OVERVIEW**
      Any claim for a short-acting opioid greater than a **3 day** supply for a child under the age of 18 years old or greater than a **5 day** supply for an adult, **or any claim for a long-acting opioid** will block at point of sale and require prior authorization.
  - Failure on all long-acting opioids should require the following additional prior authorization criteria:
    - Medical record documentation of therapeutic failure on, intolerance to, or contraindication to a short-acting opioid.
- It is recommended that the Actiq policy (1046.0 F) be retired and Actiq be incorporated under the opioid use policy (1382.0F).
- These changes and additional language updates are noted in the updated opioid use policy
- Arymo ER, Troxyca ER, MorphaBond ER, and hydromorphone ER should not be added to the GHP Family formulary. These agents should be considered non-preferred long-acting opioids and follow the language proposed in the opioid use policy (Appendix 2) for non-preferred long-acting opioids.

- As oxycodone ER (OxyContin) is the only FDA-approved long-acting opioid for children aged 11-18, the following additional language (currently reflected in Appendix 2) should be added:
  - "**OR** Medical record documentation that the patient is 11 to < 18 years of age"

Clinical Discussion: No comments or questions. Kevin Szczecina made a motion to accept the recommendations as written. Jamie Miller seconded the motion. None were opposed.

Recommendations based on financial review:

- Arymo ER, Troxyca ER, MorphaBond ER, and hydromorphone ER should not be added to the GHP Family formulary. As previously stated they should be considered non-preferred long-acting opioids and follow the language of the non-preferred long-acting opioids

- All non-preferred short-acting opioid requests should require failure on, intolerance to, or contraindication to oxycodone (updated from morphine sulfate IR).

Financial Discussion: No comments or questions. Keith Hunsicker made a motion to accept the recommendations as written. Todd Sponenberg seconded the motion. None were opposed.

Outcome: Arymo ER, Troxyca ER, MorphaBond ER, and hydromorphone ER should not be added to the GHP Family formulary. As previously stated they should be considered non-preferred long-acting opioids and follow the language of the non-preferred long-acting opioids, all non-preferred short-acting opioid requests should require failure on, intolerance to, or contraindication to oxycodone. The following prior authorization criteria shall apply to all opioids:

METHODOLOGY FOR ENROLLMENT

1. Inclusion criteria:
   a. All active, approved prescription claims meeting the following criteria will be counted for total cumulative MED for a plan beneficiary:
      i. Opioid drug has a defined dose-normalization factor in the POS system, and
      ii. Opioid is configured as program-eligible in the edit.
   b. The hard-stop MED threshold, at or above which claims will hard-stop reject, will be: 50
   c. The minimum prescriber number threshold will be: 1
2. Exclusion criteria:
   a. Claims identified by the OCDP as overlapping refills of existing therapy will not be included in the cumulative MED calculation.
   b. History of a prior authorization override will prevent OCDP rejections as described in the Procedure section below
   c. Member is defined as a hospice member
   d. Member has active claims history of cancer medication in the last 180 days
   e. Member has a diagnosis of Sickle cell disease
3. Reject code/POS Denial Language:

a. POS Notification: "Cumulative morphine equivalent dose of (patient's current MED) =/exceeds threshold of (MED threshold value) per day"

DURATION OF OPIOID USE PROGRAM OVERVIEW

Any claim for a short-acting opioid greater than a 3 day supply for a child under the age of 18 years old or greater than a 5 day supply for an adult, or any claim for a long-acting opioid will block at point of sale and require prior authorization.

PROCEDURE:

Prior authorization of opioids will be made for members who meet the following criteria:

- Diagnosis of active cancer or palliative care **OR**
- Diagnosis of sickle cell disease **OR**
- Member is receiving hospice care

Note: Authorizations will be entered for an opioid class override for members who meet these criteria

For members who do not meet the above criteria, the following documentation will be required:

- Medical record documentation of therapeutic failure on, intolerance to, or contraindication to first line drug and non-drug treatments for pain **AND**
- Prescriber has assessed the patient's pain, cause of pain, and documented the anticipated duration of therapy **AND**
- Medical record documentation that the member is:
  - being treated for chronic non-cancer pain **AND**
    - the prescription is written by a Pain Management Specialist **OR** the member has been referred to a Pain Management Specialist for the same condition within the previous 24 months **OR**
    - the member has a signed pain contract in place

OR

- the member requires more than a 3 day supply of a short-acting opioid if under the age of 18 or more than a 5 day supply of a short-acting opioid if an adult to stabilize an acute medical condition or the member is being tapered off opioids AND the duration of treatment is stated

AND

- The prescriber will conduct urine drug screening (UDS), which includes testing for the prescribed opioid per the CDC Guideline for Prescribing Opioids for Chronic Pain – United States 2016 **AND**
- Provider has evaluated member for risk of opioid use disorder using CAGE-AID, Opioid Risk Tool, or a similar screening tool upon initiation of opioids and every 3 months or as needed **AND**
- There is a plan for the tapering of benzodiazepines or rationale for continued use (if applicable) **AND**

- The prescriber has queried the State's Prescription Drug Monitoring System with every controlled substance written to ensure controlled substance history is consistent with prescribing record **AND**
- The prescriber has discussed the risks of addiction and overdose with the minor and parent, guardian or authorized adult if under the age of 18 **AND**
- If under the age of 18, the prescriber has obtained written consent for the prescription from the minor's parent/guardian/authorized adult on a standardized consent form **AND**
- There is medical record documentation that that the member or parent/guardian has been educated on the potential adverse effects of opioid analgesics, including the risk for misuse, abuse and addiction **AND** the member will receive a prescription for naloxone if dose of opioid is 120 MEDs (50 MEDs for minors) or greater and member is not being treated for end of life **OR** if the prescriber determines the member is at risk for an overdose at any MED.

AND

<u>For a long-acting opioid</u>:

- Medical record documentation of therapeutic failure on, intolerance to, or contraindication to a short-acting opioid.

<u>OR if the above criteria are not met:</u>

- The Plan will work with the prescriber and provide authorization for the requested medication during a period of tapering in accordance with accepted standards of care. During this tapering process, referral will be made to case management to offer assistance to the member during the transition process.

AND for non-preferred opioids:

<u>For non-preferred short-acting opioids:</u>

- Medical record documentation of a therapeutic failure on, intolerance to or contraindication to three preferred short-acting formulary alternatives, one of which must be oxycodone **OR**
- If the request is for an abuse-deterrent formulation (RoxyBond), medical record documentation that the patient is at high risk of abusing opioids (e.g., past history of abuse, untreated psychiatric disorders, social or family environments that encourage misuse, or positive CAGE-AID screen).

<u>For fentanyl citrate oral lozenge (generic Actiq)</u>

- Medical record documentation that the member is at least 16 years old **AND**
- Medical record documentation that the member has a diagnosis of cancer and is receiving scheduled opioid therapy **AND**
- Medical record documentation of a therapeutic failure on, intolerance to, or contraindication to immediate release morphine sulfate OR immediate release oxycodone

For Abstral, Lazanda, Fentora, Subsys

- Medical record documentation of age greater than or equal to 18 years **AND**
- Medical record documentation that the member has a diagnosis of cancer and is receiving scheduled opioid therapy **AND**
- Medical record documentation of therapeutic failure on, intolerance to, or contraindication to fentanyl lozenges* (generic Actiq) **AND** immediate-release morphine sulfate **OR** immediate-release oxycodone

For non-preferred long acting opioids:

- Medical record documentation of a therapeutic failure on, intolerance to or contraindication to three preferred long-acting opioid formulary alternatives, one of which must be morphine ER **OR**
- If the request is for an abuse-deterrent formulation (see table below), medical record documentation that the patient is at high risk of abusing opioids (e.g., past history of abuse, untreated psychiatric disorders, social or family environments that encourage misuse, or positive CAGE-AID screen).

For Nucynta ER for neuropathic pain:

- Medical record documentation of a therapeutic failure on, intolerance to or contraindication to three preferred long-acting opioid formulary alternatives, one of which must be morphine sulfate ER **AND** Lyrica*

For oxycodone ER or OxyContin:

- Medical record documentation of a therapeutic failure on, intolerance to or contraindication to three preferred long-acting opioid formulary alternatives, one of which must be morphine ER **OR**
- Medical record documentation that the patient is 11 to < 18 years of age **OR**
- For OxyContin (brand) – Medical record documentation that the patient is at high risk of abusing opioids (e.g., past history of abuse, untreated psychiatric disorders, social or family environments that encourage misuse, or positive CAGE-AID screen).

AUTHORIZATION DURATION:

- For chronic non-cancer pain, active cancer or palliative care, and hospice care: 1 year
- For sickle cell disease: lifetime
- For stabilization of an acute medical condition: stated duration of treatment
- For tapering the member off opioids: 1 year or the time requested by the prescriber for tapering, whichever is less

Note: Authorizations will be entered by GPID for each drug meeting the above criteria

Quantity Limits: see below

Formulary alternatives:

Non-steroidal anti-inflammatory drugs: diclofenac gel, celecoxib, choline magnesium salicylate, diclofenac, diclofenac extended release, diflunisal, etodolac, etodolac extended release, fenoprofen,

flurbiprofen, ibuprofen, indomethacin, indomethacin sustained release, ketoprofen, ketorolac, meclofenamate, meloxicam, nabumetone, naproxen, naproxen sodium, naproxen EC, oxaprozin, piroxicam, salsalate, sulindac, tolmetin

Skeletal muscle relaxers: chlorzoxazone, cyclobenzaprine, methocarbamol, tizanidine

Short-acting opioids: acetaminophen/codeine, hydrocodone/acetaminophen, hydrocodone/ibuprofen, hydromorphone, meperidine, morphine IR, oxycodone, oxycodone/acetaminophen, pentazocine/naloxone, tramadol

Long-acting opioids: buprenorphine patch*, fentanyl patch*, methadone*, morphine ER*, tramadol ER*

Additional Alternatives for Nucynta ER: Lyrica*, duloxetine

Additional Alternatives for Abstral, Lazanda, Fentora, Subsys: fentanyl lozenges (generic Actiq)*

(* requires prior authorization)

Reference Table: Abuse-Deterrent Opioids and Routes of Abuse Each is Intended to Deter

	Drug Deters Abuse Via This Route		
Drug	IV/injection	Intranasal	Oral
Arymo ER	X		
Embeda		X	X
Hysingla ER	X	X	X
MorphaBond ER	X	X	
OxyContin (oxycodone ER)	X	X	
Troxyca ER		X	X
Xtampza ER	X	X	X
RoxyBond	X	X	

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

FAST FACTS

TRUVADA (emtricitabine/tenofovir disoproxil fumarate)

Updated Indication: Truvada is now indicated in combination with safer sex practices for pre-exposure prophylaxis (PrEP) to reduce the risk of sexually-acquired HIV-1 infection in at-risk adults and adolescents weighing at least 35 kg. Truvada was previously approved for this indication in adults only.

Recommendation: No changes are recommended at this time.

Discussion: No comments or questions.

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

BRIVIACT (brivaracetam)

Updated Indication: Briviact is now indicated for the treatment of partial-onset seizures in patients 4 years of age and older. The safety of Briviact injection in pediatric patients has not been established, thus Briviact injection is indicated for the treatment of partial-onset seizures only in adult patients (16 years of age and older). Briviact was previously indicated for treatment of partial-onset seizures in patients 16 years of age and older with epilepsy.

Recommendation: No changes to the formulary are recommended at this time. The following update should be made to the Briviact policy:

- Medical record documentation of age greater than or equal to 4 years for oral tablets or oral solution

The following update should be made to formulary alternatives:

- For patients > 4 years of age: carbamazepine, gabapentin, lamotrigine IR, levetiracetam IR, oxcarbazepine, phenobarbital, phenytoin, topiramate IR, topiramate ER*
- Additional formulary alternatives for patients over certain ages:
  - Divalproex (10+), levetiracetam ER (12+), Gabitril (12+), felbamate (14+), and zonisamide (16+)

(*Prior authorization required)

Additional policy update:
Aptiom shares the exact same FDA-approved indication, including use in patients 4 years of age and older. Therefore, the formulary alternatives for Aptiom should be updated to match that of Briviact

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.

TAGRISSO (osimertinib)

Updated Indication: Pediatric use: Tagrisso is now indicated for the first-line treatment of patients with metastatic non-small cell lung cancer (NSCLC) whose tumors have epidermal growth factor receptor (EGFR) exon 19 deletions or exon 21 L858R mutations, as detected by an FDA-approved test. Previously, Tagrisso was only indicated for the treatment of patients with metastatic epidermal growth factor receptor (EGFR) T790M mutation-positive NSCLC, as detected by an FDA-approved test, whose disease has progressed on or after EGFR TKI therapy.

Recommendation: No changes are recommended to the formulary placement of Tagrosso at this time. It is recommended that the policy be updated to:

- Prescription written by a hematologist/oncologist **AND**
- Medical record documentation of metastatic non-small cell lung cancer (NSCLC) **AND**
- Medical record documentation of an EGFR exon 19 deletion, EGFR exon 21 L858R mutation, or EGFR T790 mutation **AND**
- Medical record documentation of one of the following:
    - If patient has EGFR exon 19 deletions or exon 21 L858R mutations: Documentation that Tagrisso is being used as <u>first-line</u> treatment **OR**
    - If patient has EGFR T790 mutation positive disease: Documentation of failure on or intolerance to prior tyrosine kinase inhibitor therapy with Iressa (gefitinib), Gilotrif (afatinib), or Tarceva (erlotinib)

For GHP Family, it is recommended that the policy be updated so that authorizations are entered by HICL.

Discussion: No comments or questions.

Outcome: Jamie Miller made a motion to accept the recommendations as written. Phil Krebs 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.

LUZU (luliconazole)

Updated Indication: Pediatric use: Used to treat fungal infections: topical treatment of interdigital tinea pedis (athletes foot), tinea cruris (jock itch), and tinea corporis (ring worm) caused by Trichophyton rubrum and Epidermophyton floccosum. <u>Now indicated for use in patients 12 years of age and older</u>.

Recommendation: No changes are recommended to the formulary placement of Luzu at this time. It is recommended that the Luzu policy be updated to reflect the expanded indication:

- Medical record documentation of age greater than or equal to 12 years

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.

FERAHEME (ferumoxytol)

Updated Indication: Feraheme is now indicated for the treatment of iron deficiency anemia (IDA) in adult patients who have intolerance to oral iron or have had unsatisfactory response to oral iron. Previously, Feraheme was only indicated for the treatment of IDA in adult patients who have chronic kidney disease.

Recommendation: Feraheme is currently a medical benefit and does not require prior authorization. No changes are recommended at this time despite Feraheme's new indication

Discussion: No questions or comments.

Outcome: Kim Clark made a motion to accept the recommendations as presented. 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.

TRULANCE (plecanatide)

Updated Availability: Trulance is now indicated in adults for the treatment of chronic idiopathic constipation AND irritable bowel syndrome with constipation (IBS-C). Note: Trulance was previously only indicated for the treatment of chronic idiopathic constipation.

Recommendation: There are no changes recommended to formulary status at this time. It is recommended to update the policy to the following:
Note: Amitiza is indicated for IBS-C in adult women only.

Chronic Idopathic Constipation:
- Medical record documentation of diagnosis of chronic idiopathic constipation AND
- Medical record documentation of age greater than or equal to 18 years AND
- Medical record documentation of therapeutic failure on, intolerance to, or contraindication to Linzess AND Amitiza

Irritable Bowel Syndrome with Constipation (IBS-C)
- Medical record documentation of diagnosis of IBS-C AND
- Medical record documentation of age greater than or equal to 18 years AND
- Medical record documentation of therapeutic failure on, intolerance to, or contraindication to Linzess

Quantity Limit: 1 tablet per day

Discussion: No comments or questions.

Outcome: Kevin Szczecina made a motion to accept the recommendations as presented. Phil Krebs 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.

ALIMTA (pemetrexed)

Updated Indication: Alimta is now indicated in combination with cisplatin for the initial treatment of patients with locally advanced or metastatic, non-squamous, non-small cell lung cancer (NSCLC).
Alimta maintains its previous indications for the initial treatment of metastatic, non-squamous, NSCLC in combination with carboplatin and pembrolizumab, for the maintenance treatment of locally advanced or metastatic, non-squamous NSCLC as a single agent, and for the treatment of mesothelioma in combination with cisplatin.

Recommendation: Alimta is currently available without restriction as a medical benefit. Although the average Alimta paid claim is about $5,344.50, there has been little to no "experimental" use of Alimta (large majority of claims were for lung cancer or mesothelioma). Because the utilization of Alimta appears to be appropriate, no changes are recommended at this time

Discussion: No questions or comments.

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.

AMITIZA (lubiprostone)

Updated Indication: Amitiza is indicated for the treatment of:

- Chronic idiopathic constipation in adults
- Opioid-induced constipation (OIC) in adults with chronic, non-cancer pain, <u>including patients with chronic pain related to prior cancer or its treatment who do not require frequent (e.g. weekly) opioid dosage escalation.</u>
    - Limitations of use: effectiveness of Amitiza in the treatment of OIC in patients taking diphenylheptane opioids (e.g. methadone) has not been established.
- Irritable bowel syndrome with constipation (IBS-C) in women ≥ 18 years old**.**

Recommendation: There are no changes to formulary status at this time. The current GHP Family Amitiza policy does not define the type of pain for OIC, therefore there are no recommendations to the current criteria based on the updated language for OIC. However, gender specific language has been removed from all our policies. Therefore, the following criterion should be updated and "being a female with" should be removed from the policy.

- Medical record documentation of a diagnosis of being a female with irritable bowel syndrome with constipation AND

Discussion: No questions or comments.

Outcome: Kevin Szczecina made a motion to accept the recommendations as written. Jamie Miller 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.

AVYCAZ (ceftazidime/avibactam)

Updated Indication: Avycaz is now indicated for the treatment of patients 18 years and older with hospital-acquired bacterial pneumonia and ventilator-associated bacterial pneumonia (HABP/VABP) caused by designated susceptible gram-negative microorganisms. Previously, Avycaz was indicated for complicated intra-abdominal infections (cIAI) in combination with metronidazole when caused by designated susceptible gram-negative microorganisms and for complicated urinary tract infections (cUTI), including pyelonephritis, caused by designated susceptible gram-negative microorganisms.

Recommendation: No changes are recommended to the formulary status of Avycaz at this time. It is recommended that the current criteria be updated to account for the updated indication, as well as labeling changes surrounding susceptible microorganisms for the existing indications (as recommended by DHS).

- Prescribed by or in consultation with an infectious disease specialist **AND**
- Medical record documentation of one of the following:
    - A diagnosis of complicated intra-abdominal infection caused by caused by the following susceptible microorganisms: *Escherichia coli, Klebsiella pneumoniae, Proteus mirabilis, Providencia stuartii, Enterobacter cloacae, Klebsiella oxytoca, Citrobacter freundii* complex, and *Pseudomonas aeruginosa* **OR**
    - A diagnosis of complicated urinary tract infections (cUTI) including pyelonephritis caused by the following susceptible microorganisms: *Escherichia coli, Klebsiella pneumoniae, Citrobacter koseri, Enterobacter aerogenes, Enterobacter cloacae, Citrobacter freundii* complex, *Proteus spp., Proteus mirabilis*, and *Pseudomonas aeruginosa* **OR**
    - A diagnosis of Hospital-acquired Bacterial Pneumonia and Ventilator-associated Bacterial Pneumonia (HABP/VABP) caused by the following susceptible microorganisms: *Enterobacter cloacae, Escherichia coli, Haemophilus influenzae, Klebsiella pneumoniae, Proteus mirabilis, Pseudomonas aeruginosa* and, *Serratia marcescens*

AND

- Medical record documentation of a creatinine clearance > 50 mL/min **AND**
- Documentation of patient age > 18 years **AND**
- Medical record documentation of culture and sensitivity showing the patient's infection is not susceptible to alternative antibiotic treatments **OR** a documented history of previous intolerance to or contraindication to other antibiotics shown to be susceptible on the culture and sensitivity

Discussion: No questions or comments.

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.

LYRICA (pregabalin)

Updated Indication: Lyrica is now indicated as adjunctive treatment of partial onset seizures in patients 4 years of age and older. Lyrica was previously approved for this indication in adults only

Recommendation: No changes are recommended to the current criteria of Policy 1066.0F and the formulary placement of the capsules for GHP Family. It is recommended that the solution be added to the formulary on the Brand tier with a quantity limit of 30mL per day.

Discussion: No questions or comments.

Outcome: Rajneel Chohan made a motion to accept the recommendations as presented. Keith Hunsicker seconded the motion. None were opposed.

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

DARZALEX (daratumumab)

Updated Dosing: Darzalex is now indicated in combination with bortezomib, melphalan, and prednisone for the treatment of patients with newly diagnosed multiple myeloma who are ineligible for autologous stem cell transplant.

Recommendation: No changes are recommended to the formulary status of Darzalex at this time. It is recommended that the applicable policy be updated to account for the new indication as outlined below.

- Prescription written by a hematologist/oncologist **AND**
- Medical record documentation a diagnosis of multiple myeloma **AND**

<u>If newly diagnosed multiple myeloma:</u>

- Medical record documentation that the member is <u>not</u> eligible for stem-cell transplantation (e.g. coexisting conditions, age greater than 65, etc.) **AND**
- Medical record documentation that Darzalex will be given in combination with bortezomib (Velcade), melphalan, AND prednisone [VMP] **OR**

<u>If relapsed/refractory multiple myeloma:</u>

- One of the following:
  - Medical record documentation of therapeutic failure on, intolerance to, or contraindication to at least three prior lines of therapy including a proteasome inhibitor (including but not limited to Velcade*, Kyprolis*, or Ninlaro*) and an immunomodulatory agent (including but not limited to Pomalyst*, Revlimid*, Thalomid*) **OR**
  - Medical record documentation that the patient is double-refractory to a proteasome inhibitor (including but not limited to Velcade*, Kyprolis*, or Ninlaro*) and an immunomodulatory agent (including but not limited to Pomalyst*, Revlimid*, Thalomid*) **OR**
  - Medical record documentation of therapeutic failure on, intolerance to, or contraindication to at least 1 prior therapy including a proteasome inhibitor (including but not limited to Velcade*, Kyprolis*, or Ninlaro*) or an immunomodulatory agent (including but not limited to Pomalyst*, Revlimid*, Thalomid*) **AND** one of the following:

- Medical record documentation that Darzalex will be prescribed in combination with lenalidomide and dexamethasone **OR**
- Medical record documentation that Darzalex will be prescribed in combination with bortezomib and dexamethasone

Discussion: No questions or comments

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

TAFINLAR (dabrafenib) and MEKINIST (trametinib)

Updated Indication: Tafinlar and Mekinist are now indicated in combination for the adjuvant treatment of patients with melanoma with BRAF V600E or V600K mutations as detected by an FDA-approved test, and involvement of lymph node(s), following complete resection AND the treatment of patients with locally advanced or metastatic anaplastic thyroid cancer (ATC) with BRAF V600E mutation and with no satisfactory locoregional treatment options.

Limitations of Use:
Tafinlar is not indicated for treatment of patients with wild-type BRAF melanoma, wild-type BRAF NSCLC, or wild-type BRAF ATC.
Mekinist is not indicated for treatment of patients with melanoma who have progressed on prior BRAF-inhibitor therapy.

Previous Indications:
Mekinist
- BRAF V600E or V600K mutation-positive unresectable or metastatic melanoma as a single agent or in combination with Tafinlar
- BRAF V600E mutation-positive metastatic non-small cell lung cancer in combination with Mekinist

Tafinlar
- BRAF V600E mutation-positive unresectable or metastatic melanoma as a single agent
- BRAF V600E or V600K mutation-positive unresectable or metastatic melanoma in combination with Mekinist
- BRAF V600E mutation-positive metastatic non-small cell lung cancer in combination with Mekinist

Recommendation: There are no changes to formulary placement recommended at this time. It is recommended to combine the Tafinlar and Mekinist policy into one (1) policy for all lines of business and update the criteria to include the new indications. Tafinlar/Mekinist will require a prior authorization with the following criteria:
Unresectable or Metastatic Melanoma
- Medical record documentation that requested medication is prescribed by a hematologist, oncologist, or dermatologist AND
- Medical record documentation of unresectable or metastatic melanoma AND
- One of the following:
    - Medical record documentation that the requested medication is being used as single therapy AND

- If the request is for Mekinist as a single agent, medical record documentation of no prior therapeutic failure with a BRAF inhibitor therapy (e.g. (Zelboraf (vemurafenib),Tafinlar (dabrafenib), or Braftovi (encorafenib))
  OR
- Medical record documentation that Mekinist and Tafinlar will be used in combination AND

- Medical record documentation of BRAF V600E or V600K mutations as detected by an FDA-approved test
- Medical record documentation of a medically accepted indication

Metastatic Non-Small Cell Lung Cancer
- Prescription written by a hematologist or oncologist AND
- Medical record documentation of metastatic non-small cell lung cancer AND
- Medical record documentation that Mekinist and Tafinlar will be used in combination AND
- Medical record documentation of BRAF V600E mutation as detected by an FDA-approved test
- Medical record documentation of a medically accepted indication

Adjuvant Treatment of Melanoma
- Prescription written by an oncologist or dermatologist or hematologist AND
- Medical record documentation of melanoma with involvement of lymph node(s) AND
- Medical record documentation of BRAF V600E or V600K as detected by an FDA-approved test AND
- Medical record documentation that the requested medication(s) will be used as adjuvant treatment following complete resection AND
- Medical record documentation that Mekinist and Tafinlar will be used in combination
- Medical record documentation of a medically accepted indication

Anaplastic Thyroid Cancer
- Prescription written by an oncologist or hematologist AND
- Medical record documentation of locally advanced or metastatic anaplastic thyroid cancer AND
- Medical record documentation of BRAF V600E mutation AND
- Medical record documentation that Mekinist and Tafinlar will be used in combination AND
- Medical record documentation of a medically accepted indication

Authorization Duration (for Adjuvant Treatment of Melanoma): Approval will be for 12 months or less if the reviewing provider feels it is medically appropriate. The FDA-approved treatment duration is for 12 months only. For requests exceeding the above limit, medical record documentation of the following is required:
- Peer-reviewed literature citing well-designed clinical trials to indicate that the member's healthcare outcome will be improved by dosing beyond the FDA-approved treatment duration

Authorization Duration (for all other indications):
Each treatment period will be defined as 12 months. Re-review will occur every 12 months. The requested medication(s) will no longer be considered medically necessary if there is medical record documentation of disease progression.

Quantity Limits:
Tafinlar: 120 capsules per 30 days
Mekinist 1 mg and 2 mg: 30 tablets per 30 days
Mekinist 0.5 mg: 90 tablets per 30 days

Discussion: No questions or comments.

Outcome: Phil Krebs made a motion to accept the recommendations as presented. 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.

KEYTRUDA (pembrolizumab)

Updated Indication: Keytruda is now indicated under the accelerated approval process for the treatment of patients with recurrent or metastatic cervical cancer with disease progression on or after chemotherapy whose tumors express PD-L1 (CPS≥1) as determined by an FDA-approved test**.**

Recommendation: No changes are recommended to the formulary status of Keytruda at this time. It is recommended that the current policy be updated to account for the new indication as outlined below.

Cervical Cancer

- Prescription written by a hematologist/oncologist **AND**
- Medical record documentation of recurrent or metastatic cervical cancer **AND**
- Medical record documentation that tumors express PD-L1 (CPS≥1) **AND**
- Medical record documentation of disease progression after receiving at least one prior line of therapy

Discussion: Keith Hunsicker suggested adding the following limitation: treatment of patients with multiple myeloma with a PD-1 or PD-L1 blocking antibody in combination with a thalidomide analogue plus dexamethasone is not recommended outside of controlled clinical trials.

Outcome: Jamie Miller made a motion to accept the amended recommendation. 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.

VENCLEXTA (venetoclax)

Updated Indication: Venclexta is now indicated for the treatment of patients with chronic lymphocytic leukemia (CLL) or small lymphocytic lymphoma (SLL), with or without 17p deletion, who have received at least one prior therapy. Venclexta was previously approved 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.

Recommendation: No changes are recommended to the formulary status of Venclexta at this time. It is recommended that the prior authorization criteria be updated to account for the new indication as listed below.

- 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) or small lymphocytic lymphoma (SLL), with or without 17p deletion **AND**
- Medical record documentation of disease progression following treatment with at least one prior therapy

Discussion: No comments or questions.

Outcome: Jamie Miller made a motion to accept the recommendations as presented. 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.

RITUXAN (rituximab)

Updated Indication: Rituxan is now indicated for the treatment of adult patients with moderate to severe Pemphigus Vulgaris (PV). Rituxan maintains its previous indications of Non-Hodgkin's Lymphoma (NHL), Chronic Lymphocytic Leukemia (CLL), Rheumatoid Arthritis (RA), and Granulomatosis with Polyangiitis (GPA) (Wegener's Granulomatosis) and Microscopic Polyangiitis (MPA).

Recommendation: No changes are recommended to the formulary status of Rituxan at this time. It is recommended that the prior authorization criteria of applicable policies are updated to account for the updated indication as outlined below.

For Pemphigus Vulgaris (PV)

- Prescription written by a dermatologist **AND**
- Member is 18 years of age or older **AND**
- Medical record documentation of a diagnosis of moderate to severe pemphigus vulgaris **AND**
- Medical record documentation of a contraindication to, intolerance to, or therapeutic failure on corticosteroids AND a 12-week trial of at least one (1) nonsteroidal immunomodulatory medication (e.g. azathioprine, cyclophosphamide, or mycophenolate).

Other Recommendations:
If being billed through medical, Rituxan does not currently require prior authorization for the diagnosis of non-Hodgkin Lymphoma (Diagnosis Codes: C82.00 through C85.99 and C86.0 through C88.9). It is recommended that a note be added to the NHL section clarifying that prior authorization is not needed for a diagnosis of NHL to be consistent with the coding of the product.

MBP 48.0
For Non-Hodgkin Lymphoma
Note: Prior authorization is not required for diagnosis codes C82.00 through C85.99 and C86.0 through C88.9.
OR

- Medical record documentation of a diagnosis of Non-Hodgkin Lymphoma

For Multiple Sclerosis
Currently, if approved to treat multiple sclerosis, the authorization duration for Rituxan is limited to 6 months by MBP 48.0. After discussion with Geisinger Neurology, clinical improvement often is not seen until after two complete treatment cycles of Rituxan. An authorization duration of 6 months does not allow for the second cycle of Rituxan to be given without reauthorization.

It is recommended that the authorization duration of Rituxan be increased to 12 months when approved for the treatment of multiple sclerosis to allow for an adequate number of infusions to be provided prior to assessing clinical efficacy of treatment.

Discussion: No questions or comments.

Outcome: Kevin Szczecina 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.

UPDATES

IVIG Update

Review: Recent approval of the Soliris MBP policy (54.0) includes the criterion of medical record documentation of failure on intolerance to, or contraindication to IVIG in the treatment of generalized Myasthenia Gravis.

Recommendation: It is recommended that the criteria below be added to MBP 4.0:

Refractory Chronic Debilitating Myasthenia Gravis

1. Medical record documentation of refractory Chronic Debilitating Myasthenia Gravis AND
2. Prescribed by or in consultation with a neuromuscular specialist AND
3. Medical record documentation of therapeutic failure on, intolerance to, or contraindication to at least one corticosteroid AND
4. Medical record documentation of therapeutic failure on, intolerance to, or contraindication to at least one cholinesterase inhibitor AND
5. Medical record documentation of therapeutic failure on, intolerance to, or contraindication to at least one non-steroidal immunosuppressive therapy

Discussion: No comments or questions.

Outcome: Keith Hunsicker made a motion to accept the presented recommendations. Jamie Miller 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.

Kanuma Drug Review Update

Kanuma (sebelipase alfa), is a hydrolytic lysosomal cholesteryl ester and triacylglycerol-specific enzyme indicated for the treatment of patients with a diagnosis of Lysosomal Acid Lipase deficiency. Kanuma was originally presented during our May 17, 2016 P&T committee meeting, at which time the following formulary recommendation was to consider it a medical benefit requiring prior authorization. A recommendation was made by Dr. Bret Yarczower to table the proposed policy criteria recommendations until he could review our proposed criteria with a Clinical Specialist, and better understand the exact role in therapy. Recently Dr. Yarczower reviewed our proposed criteria with Dr. Can Ficicioglu, MD, PhD, who is the Director of the Newborn Metabolic Screening Program and the Lysosomal Storage Diseases program at Children's Hospital of Philadelphia. Dr. Ficicioglu agreed with our proposed policy criteria recommendations and had no further suggestions.

Recommendation: Requests for Kanuma should require a 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

QUANTITY LIMITS:
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.

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.

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.

Discussion: No questions or comments

Outcome: Kim Clark made a motion to accept the presented recommendations. Jamie Miller 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.

Rituxan Policy Update

Review: Recent approval of the Soliris policy includes the criterion of medical record documentation of failure on intolerance to, or contraindication to Rituxan in the treatment of generalized Myasthenia Gravis. Currently the Rituxan policy does not encapsulate the indication of refractory chronic debilitating Myasthenia Gravis.

Recommendations: It is recommended that the criteria noted below be added to the policy:
Refractory Chronic Debilitating Myasthenia Gravis
1. Medical record documentation of refractory Chronic Debilitating Myasthenia Gravis AND
2. Prescribed by or in consultation with a neuromuscular specialist AND
3. Medical record documentation of therapeutic failure on, intolerance to, or contraindication to at least one corticosteroid AND
4. Medical record documentation of therapeutic failure on, intolerance to, or contraindication to at least one cholinesterase inhibitor AND
5. Medical record documentation of therapeutic failure on, intolerance to, or contraindication to at least one non-steroidal immunosuppressive therapy

AUTHORIZATION DURATION: Initial approval will be for 6 months or less if the reviewing provider feels it is medically appropriate (except for the diagnosis for ITP). Subsequent approvals will be for an additional 6 months or

less if the reviewing provider feels it is medically appropriate and will require medical record documentation of continued disease improvement or lack of disease progression. The medication will no longer be covered if patient experiences toxicity or worsening of disease.

Note: Corticosteroids: betamethasone, dexamethasone, methylprednisolone, prednisone
Cholinesterase inhibitors: pyridostigmine, neostigmine
Immunosuppressants: azathioprine, mycophenolate, cyclosporine, Rituxan

Discussion: No questions or comments.

Outcome: Keith Hunsicker made a motion to accept the presented recommendations. Phil Krebs 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.

Fasenra Policy Update

Review: During our June submission of our proposed policy criteria for Fasenra which included requiring a blood eosinophil count greater than or equal to 300 cells/microL, DHS questioned our rationale for this requirement noting the following:

"In trials 1 and 2 while patients with a baseline blood eosinophil count ≥300 cells/μL showed a numerically greater response than those with counts < 300 cells/μL reductions in exacerbation rates were observed irrespective of baseline peripheral eosinophil counts. Additionally, patients in trial 3 were required to have blood eosinophil counts ≥ 150 cells/mcL."

Recommendation: It is recommended that our criteria be updated to be in alignment with DHS and clinical trial inclusion criteria to the lower level of 150 cells/microL

Discussion: No questions or comments.

Outcome: Todd Sponenberg made a motion to accept the presented recommendations. Jamie Miller 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.

Prostaglandin Analog Eye Drop Formulary Status and Policy Updates

Review: A recent analysis of the prostaglandin analog eye drop class has revealed an opportunity to configure the current formulary placement to improve access and decrease costs to the plan and members by expanding our formulary agents.

Recommendation: Zioptan will be added to the brand tier requiring step therapy:

- On-line prescription drug claim history showing 15 days use of Latanoprost within previous 180 days. If step therapy criteria are not met, prescribing provider should request an exception for coverage

Additionally, Policy 1090.0 F now encompasses both Lumigan and Zioptan but will be updated to include Lumigan, Travatan Z, Vyzulta and Rescula (retire policy 1211.0F) (Travatan Z will remain non-formulary but will now have a drug policy) with the following criterion:

- Medical record documentation of an intolerance to, contraindication to, or therapeutic failure on Latanoprost (generic Xalatan) and Zioptan.

Discussion: No questions or comments.

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

Probuphine Policy Update

Review: As part of the Medication Assisted Treatment (MAT) updates brought to the May 2018 P&T meeting, criteria requiring the review of Pennsylvania's Prescription Drug Monitoring Program (PDMP) were added to the non-preferred MAT policies (Suboxone, Bunavail, Zubsolv and Sublocade). Currently, the Probuphine policy does not contain the PDMP language.

Recommendation: It is recommended that the PDMP language below be added to MBP 146.0 to be consistent with the other non-preferred MAT policies:

Add to initial and re-authorization criteria:

- There is confirmation that the prescriber or the prescriber's delegate has conducted a review of Pennsylvania's Prescription Drug Monitoring Program (PDMP) prior to prescribing Probuphine

Discussion: No questions or comments.

Outcome: Jamie Miller made a motion to accept the presented recommendations. 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.

Erleada Policy Update

Review: A recent analysis of the Erleada policy has shown that an update to the current criteria is needed.

Recommendation: Below reflects the proposed addition to the current criteria (*italicized* and **bolded**).

- Medical record documentation that Erleada is prescribed by an oncologist or urologist **AND**
- Medical record documentation of a diagnosis of prostate cancer with evidence of non-metastatic disease **AND**
- Medical record documentation that the member is no longer responding to castration or is hormone resistant **AND**

- Medical record documentation that a gonadotropin-releasing hormone (GnRH) analog will be used concurrently ***OR member has had bilateral orchiectomy***

Discussion: No questions or comments.

Outcome: Kevin Szczecina made a motion to accept the presented recommendations. Jamie Miller 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 Policy Update

Review: During the ongoing annual review of the GHP Family Policies by DHS, numerous changes were requested. It is recommended the Committee approve the changes noted below:

Recommendation: It is recommended that the following changes requested by DHS be approved:

Policy 1163.0F Dificid – removed "Therapeutic failure on, intolerance to, or contraindication to Metronidazole, unless the patient has documented severe Clostridium difficile" due to updated clinical practice guidelines from the Infectious Disease Society of America, which now favor a 10-day course of vancomycin or fidaxomycin rather than metronidazole for first-line therapy of mild/moderate CDI in adults.

Policy 1172.0F Pertzye, Viokace – added standard grandfathering language due to variability between products.

Policy 1173.0F Brand Coverage – request was made to address medications considered to have a narrow therapeutic index, so the policy was updated to (added criterion is underlined):

- medical record documentation of a therapeutic failure on, or intolerance to the generic formulary agent(s) **OR**
- an intolerance to or contraindication to the inactive ingredients of the generic formulary agent(s) **AND**
- medical record documentation of a therapeutic failure on, or intolerance to or contraindication to up to three formulary alternatives if available

OR

- The medication is considered to have a narrow therapeutic index and the patient is currently stable on the requested narrow therapeutic index medication.

Policy 1195.0F Acthar – currently, GHP Family considers the use of Acthar for Multiple Sclerosis Exacerbations to be not medically necessary because it has not been proven to be more effective than corticosteroids. However, it is an FDA-approved indication and DHS has advised us per our HealthChoices contract we must perform a clinical review when a request is made for its use for the treatment of an MS exacerbation. As a result, the following criteria was adopted:
For acute exacerbations of MS:

A) Prescribed by a neurologist AND
B) Documentation of non-response to steroids or clearly identifiable reason a steroid cannot be used. Must try three different steroids (i.e. Medrol, prednisone, and Decadron) or two courses of two different steroids

Policy 1204.0F Iclusig - the current GHP Family policy criteria is as follows:

1. Medical record documentation of a diagnosis of one of the following:
   - Medical record documentation of an adult with chronic phase, accelerated phase or blast phase chronic myeloid leukemia (CML) **OR** Philadelphia chromosome positive acute lymphoblastic leukemia (Ph+ALL) **AND**
   - Medical record documentation of resistance or intolerance to one prior tyrosine kinase inhibitor therapy **OR** medical record documentation of CML cell mutation T315I

AND:

2. Prescription must be written by a Hematologist or Oncologist.

However, Iclusig's indication is:

- Treatment of adult patients with chronic phase, accelerated phase, or blast phase chronic myeloid leukemia (CML) or Ph+ ALL for whom no other tyrosine kinase inhibitor (TKI) therapy is indicated
- Treatment of adult patients with T315I-positive CML (chronic phase, accelerated phase, or blast phase) or T315I-positive Philadelphia chromosome positive acute lymphoblastic leukemia (Ph+ ALL)

As a result, the "CML" underlined in the second bullet point above was removed.

Policy 1341.0F Quantity Limit – remove the Authorization Duration

Discussion: No questions or comments.

Outcome: Jamie Miller made a motion to accept the presented recommendations. Rajneel Chohan seconded the motion. Bret Yarczower opposed the change to the Acthar policy but approved all other changes. No others members 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 4:22 pm.

Future Scheduled Meetings
Tuesday, September 18, 2018 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.