

**P&T Committee Meeting Minutes
Commercial/Marketplace/GHP Kids
September 21, 2021**

Present (via Teams): Bret Yarczower, MD, MBA – Chair Megan Ammon, Pharm.D. Kristen Bender, Pharm.D. Jeremy Bennett, MD Dean Christian, MD Alyssa Cilia, RPh Kimberly Clark, Pharm.D. Rajneel Farley, Pharm.D. Kelly Faust Pharm.D. Tricia Heitzman, Pharm.D. Jason Howay, Pharm.D. Keith Hunsicker, Pharm.D. Kelli Hunsicker, Pharm.D. Derek Hunt, Pharm.D. Jamie Miller, RPh Kimberly Reichard, Pharm.D. Melissa Renn, Pharm.D. Kristen Scheib, Pharm.D. William Seavey, Pharm.D. Michael Shepherd, MD Leslie Shumlas, Pharm.D. Aubrielle Smith Pharm.D. Michael Spishock, RPh Todd Sponenberg, Pharm.D. Jill Stone, Pharm.D. Robert Strony, MD MBA Kevin Szczecina, RPh Amanda Taylor, MD Brandon Whiteash, Pharm.D. Adam Root (non-voting participant)	Absent: Holly Bones, Pharm.D. Kim Castelnovo Michael Evans, RPh Nichole Hossler, MD Phillip Krebs, R.EEG T Perry Meadows, MD Austin Paisley, Pharm.D. Jonas Pearson, RPh Angela Scarantino Richard Silbert, MD
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Call to Order:

Dr. Bret Yarczower called the meeting to order at 1:03 p.m., Tuesday, September 21, 2021.

Review and Approval of Minutes:

Dr. Bret Yarczower asked for a motion or approval to accept the July 20, 2021 and August 28, 2021 minutes as written. Minutes approved unanimously. None were opposed.

DRUG REVIEWS

ARTESUNATE (artesunate)

Review: Artesunate for Injection is an antimalarial indicated for the initial treatment of severe malaria in adult and pediatric patients. Treatment of severe malaria with Artesunate for Injection should always be followed by a complete treatment course of an appropriate oral antimalarial regimen. Artesunate, and its active metabolite DHA, inhibit protein and nucleic acid synthesis and lead to ultrastructural changes as well as decrease in parasite growth and survival. Both artesunate and DHA are active against the different asexual forms of Plasmodium parasites, including the chloroquine resistant strains, and clear parasitemia within 48 to 72 hours. Artesunate and DHA are not active against the hypnozoite liver stage forms of *P. vivax* or *P. ovale* so concomitant therapy with an antimalarial agent such as an 8-aminoquinoline drug is necessary to prevent relapses of malaria.

The CDC and WHO recommend that all patients with severe malaria, regardless of infecting species be treated with intravenous artesunate as soon as possible. Treatment with intravenous artesunate should continue for at least 24 hours after initiation of treatment before switching to an oral follow-up treatment once the patient is able to tolerate oral therapy. Artesunate has been available in the U.S. since 2007 through the FDA's Expanded Access program from the CDC under an investigational new drug (IND) protocol for treatment of severe malaria. Artesunate will continue to be available through the CDC IND protocol while Artesunate for Injection™ is launched and distributed.

The efficacy of intravenous artesunate for the treatment of severe malaria was evaluated in a randomized, active-controlled trial in Asia (Trial 1) and a supportive published randomized active-controlled trial in Africa (Trial 2).

Trial 1 was an international randomized, open-label, multicenter trial conducted in Bangladesh, India, Indonesia, and Myanmar in 1,461 hospitalized patients with severe malaria. Patients were randomized to intravenous treatment with either intravenous artesunate or intravenous quinine. Efficacy was based on in-hospital mortality rates which were significantly lower in the artesunate group (13%) compared to the quinine group (21%).

Trial 2 was a randomized, open-label, multicenter trial comparing parenteral artesunate to parenteral quinine in pediatric patients (<15 years of age) with severe malaria in nine African countries. Dosing was similar to trial 1, except both artesunate and quinine could be administered either intravenously or intramuscularly (not an approved route of administration). Treatment with artesunate showed an improvement of in-hospital mortality rates over quinine with rates comparable to Trial 1

There are no black box warnings for Artesunate. Warnings and precautions include hypersensitivity, including anaphylaxis, and post-treatment hemolysis. Post-artesunate delayed hemolysis is characterized by decreased hemoglobin and laboratory evidence of hemolysis (decreased haptoglobin, increased lactate dehydrogenase) occurring at least 7 days after initiating artesunate treatment. Some reported cases were severe enough to require transfusion. Patients need to be monitored for 4 weeks following treatment for evidence of hemolytic anemia.

During Trial 1, the most common adverse reactions were acute renal failure requiring dialysis, hemoglobinuria, and jaundice. During Trial 2, the safety profile was generally similar to that of Trial 1, but a greater incidence of neurological impairment at hospital discharge was observed in the artesunate group compared to the quinine arm.

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. The committee unanimously voted to accept the recommendations as presented. None were opposed.

Financial Discussion: No comments or questions. The committee unanimously voted to accept the recommendations as presented. None were opposed.

Outcome: Artesunate will be covered as a medical benefit and will not be added to the Commercial, Marketplace, or GHP Kids Pharmacy formularies. When processed at a specialty pharmacy, Artesunate will process at the Specialty tier or the Brand Non-preferred tier for members with a three tier benefit. No prior authorization will be required.

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

PONVORY (ponesimod)

Review: Ponvory is a sphingosine 1-phosphate (S1P) receptor 1 modulator that binds with high affinity to S1P receptor 1. It blocks the capacity of lymphocytes to egress from lymph nodes and reduces the number of circulating lymphocytes in the peripheral blood. The exact mechanism of Ponvory in multiple sclerosis is unknown but may involve the reduction of lymphocyte migration into the central nervous system.

The efficacy of Ponvory was evaluated in the OPTIMUM trial, a randomized, double blind, parallel group, active-controlled superiority study in patients with relapsing forms of MS. The study included patients with an Expanded Disability Status (EDSS) score of 0 to 5.5 at baseline, had experienced at least one relapse within the prior year, two relapses within the prior 2 years, or had at least one gadolinium-enhancing lesion on a brain MRI within the prior 6-months or at baseline. Patients were randomized 1:1 to receive Ponvory (20 mg once daily beginning with the 14-day dose titration)(n=567) or teriflunomide 14 mg (n=566).

The primary endpoint, annualized relapse rate, was statistically significantly lower in patients treated with Ponvory compared to patients receiving teriflunomide (Table 2). The number of Gd-enhancing lesions and the number of new or enlarging T2 lesions were statistically significantly lower in patients treated with Ponvory compared to Placebo. There was no statistically significant difference in 3-month and 6-month confirmed disability progression outcomes for Ponvory compared to teriflunomide treated patients. The effects of Ponvory on the ARR and secondary MRI outcomes were consistent between exploratory subgroups, including age, gender, prior non-steroid therapy for MS, and baseline disease activity.

Overall, Ponvory has a safety profile consistent with other S1P receptor modulators with the second best monitoring requirements. Ponvory is contraindicated in patients who, in the previous 6 months, have had a myocardial infarction, unstable angina, stroke, transient ischemic attack, decompensated heart failure requiring hospitalization, or Class III or IV heart failure. It is also contraindicated in patients who have Mobitz type II second-degree, third-degree atrioventricular block, or sick sinus syndrome, or sino-atrial block, unless patient has a functioning pacemaker. Warnings include risk of infection due to reduction in peripheral lymphocyte count of 30-40%, respiratory effects, including reduction in forced expiratory volume over 1 second and diffusion lung capacity for carbon monoxide, liver injury, including elevations in transaminases, increased blood pressure, increased risk of cutaneous malignancies, macular edema,

posterior reversible encephalopathy syndrome (PRES), and severe increase in disability and immune system effects after stopping Ponvory. During clinical trials, the most common adverse reactions occurring in at least 10% of patients were upper respiratory tract infection, hepatic transaminase elevation, and hypertension.

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. The committee unanimously voted to accept the recommendations as presented. None were opposed.

Financial Discussion: No comments or questions. The committee unanimously voted to accept the recommendations as presented. None were opposed.

Outcome: Ponvory is a pharmacy benefit and will be added to the formulary on the Specialty Tier or the Brand Non-Preferred Tier for members with a three-tier benefit. Ponvory will not require prior authorization. The following quantity limit will apply:

QUANTITY LIMIT:

Starter Pack: 14 tablets per 180 days

20 mg tablets (maintenance dose): 1 tablet per day

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

QELBREE (viloxazine)

Review: Qelbree is a norepinephrine reuptake inhibitor indicated for the treatment of ADHD in pediatric patients ages 6-17 years of age. It will compete with atomoxetine which shares a similar mechanism; however, Qelbree has added beneficial effects on serotonin modulation. There are currently no studies comparing the two medications, so the clinical implications of these slightly varied mechanisms are unknown.

Qelbree is available in 100 mg, 150 mg, and 200 mg extended-release capsules. Children ages 6 to 11 should start at a dose of 100 mg once daily. They may titrate up 100 mg on a weekly basis up to a maximum dose of 400 mg. The recommended starting dose in children 12 to 17 years of age is 200 mg. This may be titrated up 200 mg weekly to a maximum dose of 400 mg. The medication does have specific dosing for renal impairment. The initial dosage is 100 mg one daily. This can be titrated up 50-100 mg at weekly increments until a max dose of 200 mg once daily is reached. Capsules may be swallowed whole or sprinkled over applesauce for children that may have issues swallowing capsules.

Qelbree was evaluated in three clinical trials consisting of 1118 patients with ADHD. The primary endpoint used in each study was the change from baseline to the end of the study (EOS) on the cumulative score of Attention Deficit Hyperactivity Disorder Rating Scale-5 (ADHD-RS-5). Secondary endpoints of the studies included the change from baseline at EOS for both the Clinical Global Impression-Improvement (CGI-I) score and Weiss Functional Impairment Rating Scale-Parent (WFIRS-P). Study 1 consisted of 477 patients with ADHD ages 6 to 11. There was a 1-week titration period starting at 100 mg once daily and a 5-week maintenance phase. Participants were randomized 1:1:1 to receive Qelbree 100 mg, Qelbree 200 mg, or placebo once daily as a single dose. Study 2 had 313 participants between 6 and 11 years of age with ADHD. These participants underwent a 3-week titration

period starting at 100 mg once daily and a 5-week maintenance phase. They were randomized 1:1:1 to receive Qelbree 200 mg, Qelbree 400 mg, or placebo given as a single daily dose. Study 3 looked at a total of 310 children ages 12 to 17 with ADHD. These patients underwent a 1-week titration starting at 200 mg once daily and a 5-week maintenance phase. They were randomized 1:1:1 to receive Qelbree 200 mg, Qelbree 400 mg, or placebo given daily as a single dose. Each of the studies demonstrated a statistically significant greater reduction from baseline in the ADHD-RS-5 total score in groups receiving Qelbree 200 mg or 400 mg when compared to those on placebo. A statistically significant improvement was also seen in the CGI-I score for the groups receiving treatment with Qelbree 200 mg and 400 mg.

Qelbree has a black box warning for suicidal thoughts and behaviors. The medication is contraindicated in patients receiving treatment with a monoamine oxidase inhibitor (MAOI) currently or within the past 14 days and patients being treated with sensitive CYP1A2 substrates or CYP1A2 substrates with known narrow therapeutic ranges. Warnings for the medication include a potential increase in heart rate and blood pressure, mania or hypomania, and somnolence and fatigue. The safety profile for Qelbree was very similar among each of the studies. The most common side effects observed among the treatment population included somnolence, decreased appetite, fatigue, nausea, vomiting, insomnia, and irritability.

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

Clinical Discussion: There was discussion regarding the inclusions of specific limitations of coverage within the policy. It was discussed whether a blanket statement should be utilized or if these statements should be drug specific. There are concerns about policy maintenance if specific limitations are included. There was additional discussion regarding whether the inclusion of this statement is necessary at all given this warning exists with several other medications that inhibitor CYP enzymes. Ultimately it was decided to remove the limitations of coverage recommendation and consider it as something that we will add to all policies at a future date. The committee unanimously voted to accept the recommendations as presented. None were opposed.

Financial Discussion: There was discussion regarding whether it's appropriate to also consider failure of stimulant options prior to allowing a non-stimulant option. Behavioral Health Specialist, Dr. Bennett, felt it was reasonable to require failure of a stimulant prior to approval of Qelbree. No comments or questions. The committee unanimously voted to accept the recommendations as amended. None were opposed.

Outcome: Qelbree is a pharmacy benefit and will be added to the formulary on the Brand Non-Preferred Tier. Qelbree will require prior authorization with the following criteria:

- Medical record documentation of a diagnosis of attention deficit disorder (ADD) or attention deficit hyperactivity disorder (ADHD) **AND**
- Medical record documentation of therapeutic failure on, intolerance to, or contraindication to atomoxetine **OR** documentation that member has difficulty swallowing **AND**
- Medical record documentation of therapeutic failure on, intolerance to, or contraindication to amphetamine-dextroamphetamine ER **AND** methylphenidate ER unless precluded by a valid pre-existing medical condition (e.g. personal or family history of substance use disorder, substance misuse, etc.)

QUANTITY LIMIT:

Qelbree 100mg: 1 tablet per day

Qelbree 150 mg: 2 tablets per day

Qelbree 200 mg: 2 tablets per day

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

EVEKEO ODT (amphetamine sulfate)

Review: Evekeo ODT is a CNS stimulant indicated for the treatment of ADHD in pediatric patients 3 to 17 years of age. Evekeo ODT is supplied as 2.5 mg, 5 mg, 10 mg, 15 mg, and 20 mg oral disintegrating tablets in blister packs. For patients 3 to 5 years of age, the recommended starting dose is 2.5 mg daily. An additional dose may be administered 4 to 6 hours after. The dose should be titrated at increments of 2.5 mg at weekly intervals depending on response and tolerability. For patients 6 to 17 years of age, the recommended starting dose is 5 mg once or twice daily. If necessary, an additional dose can be administered after 4 to 6 hours. The dose may be titrated in increments of 2.5 mg or 5 mg at weekly intervals until optimal response is obtained. Only in rare cases will it be necessary to exceed a total of 40 mg daily.

The safety and effectiveness of Evekeo ODT for the treatment of ADHD has been established based on an adequate and well-controlled study of immediate-release amphetamine sulfate (Evekeo). Following a single dose oral administration of Evekeo ODT in healthy subjects, exposures were comparable to that after administration of immediate release amphetamine sulfate tablets (Evekeo).

Evekeo is contraindicated in patients with known hypersensitivity to amphetamine products or other ingredients in Evekeo ODT. Evekeo is also contraindicated in patients receiving concomitant treatment with monoamine oxidase inhibitors (MAOIs) or within 14 days following discontinuation of treatment with an MOAI due to an increased risk of hypertensive crisis. There are warnings for potential for abuse and dependence, serious cardiovascular reactions, blood pressure and heart rate increases, psychiatric adverse reactions, long-term suppression of growth, seizures, peripheral vasculopathy including Raynaud's phenomenon, and serotonin syndrome. The most common adverse reactions (incidence \geq 4% and at a rate at least twice placebo) in pediatric patients are: decreased appetite and insomnia.

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

Clinical Discussion: Do we need to incorporate language to allow prior to failure of alternatives if they have difficulty swallowing? Will bring back as an e-vote if it's determined an updated to criteria is recommended. No comments or questions. The committee unanimously voted to accept the recommendations as presented. None were opposed.

Financial Discussion: No comments or questions. The committee unanimously voted to accept the recommendations as presented. None were opposed.

Outcome: Evekeo ODT is a pharmacy benefit and will not be added to the formulary. The following quantity limit will be added to Evekeo and Evekeo ODT. Evekeo ODT will require prior authorization with the following criteria:

Attention Deficit Hyperactivity Disorder (ADHD) (Evekeo and Evekeo ODT)

- Medical record documentation of a diagnosis of attention deficit hyperactivity disorder (ADHD) **AND**
- Medical record documentation of age greater than or equal to 3 years **AND**
- **For members greater than or equal to 6 years of age:** Medical record documentation of a therapeutic failure on, intolerance to, or contraindication to three of the following formulary

alternatives: dexamethylphenidate immediate release, dextroamphetamine immediate release, dextroamphetamine/amphetamine immediate release, or methylphenidate immediate release

- **For members greater than or equal to 3 years of age:** Medical record documentation of a therapeutic failure on, intolerance to, or contraindication to dextroamphetamine immediate release **AND** dextroamphetamine/amphetamine immediate release

MEDISPAN LEVEL: GPI-12

QUANTITY LIMIT:

- Evekeo ODT 2.5 mg tablet: 2 tablets per day (when available)
- Evekeo ODT 5 mg tablet: 2 tablets per day
- Evekeo ODT 10 mg tablet: 2 tablets per day
- Evekeo ODT 15 mg tablet: 2 tablets per day
- Evekeo ODT 20 mg tablet: 2 tablets per day
- Evekeo 5 mg tablet: 3 tablets per day
- Evekeo 10 mg tablet: 6 tablets per day

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

ROSZET (rosuvastatin/ezetimibe)

Review: Roszet is a combination of rosuvastatin, an HMG CoA-reductase inhibitor (statin), and ezetimibe, a dietary cholesterol absorption inhibitor, indicated in adults:

- As an adjunct to diet in patients with primary non-familial hyperlipidemia to reduce low-density lipoprotein cholesterol (LDL-C)
- Alone or as an adjunct to other LDL-C lowering therapies in patients with homozygous familial hypercholesterolemia (HoFH) to reduce LDL-C.

There were no clinical studies performed for Roszet. Approval of Roszet is based on previous clinical trials of rosuvastatin as monotherapy and ezetimibe added to ongoing statin therapy which showed that the combination of medications reduces total cholesterol, LDL-C, Apo-B, and non-HDL-C in adults with primary hyperlipidemia. Approval for Roszet in the treatment of HoFH is based on previous clinical trials of rosuvastatin monotherapy and ezetimibe added to existing statin therapy showing efficacy in reduction LDL-C in the treatment of patients with HoFH. The safety profile of Roszet is based on adverse events reported in previous clinical trials of rosuvastatin and ezetimibe as monotherapy and in combination with statins.

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. The committee unanimously voted to accept the recommendations as presented. None were opposed.

Financial Discussion: No comments or questions. The committee unanimously voted to accept the recommendations as presented. None were opposed.

Outcome: Roszet is a pharmacy benefit and will not be added to the formulary. Roszet will require prior authorization with the following criteria:

- Medical record documentation of a diagnosis of primary non-familial hyperlipidemia or homozygous familial hypercholesterolemia AND
- Medical record documentation of age greater than or equal to 18 years AND
- Medical record documentation of therapeutic failure on or intolerance to rosuvastatin AND ezetimibe used in combination

QUANTITY LIMIT: 1 tablet per day

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

DURYSTA (bimatoprost implant)

Review: Durysta is a prostaglandin analog indicated for the reduction of intraocular pressure (IOP) in patients with open angle glaucoma (OAG) or ocular hypertension (OHT). Durysta is a single administration implant formulation of bimatoprost, used for reduction of intraocular pressure. Durysta is the first-in-class sustained release, biodegradable implant designed to lower IOP. Bimatoprost is a prostaglandin analog believed to lower IOP by increasing outflow of aqueous humor through the trabecular meshwork and uveoscleral routes.

Treatment options for lowering IOP include pharmacologic therapy, laser therapy and/or surgery. Generally, pharmacologic therapy or laser therapy are considered first line treatment due to increased risk of complications with surgical intervention. The choice between pharmacologic or laser therapy should be an individualized decision made between the patient and doctor. Prostaglandin analogs are considered first line treatment among pharmacologic treatment options. Other treatment options include beta-blockers, carbonic anhydrase inhibitors, alpha blockers and rho kinase (ROCK) inhibitors.

The American Academy of Ophthalmology (AAO) guidelines do not recommend one prostaglandin analog over another. A study to compare agents in the class demonstrated latanoprost, bimatoprost and travoprost were comparable in their ability to reduce IOP. Durysta provides an alternate treatment option for patients who cannot tolerate topical drops, have difficulty instilling drops, or are noncompliant with topical drop therapy.

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

Clinical Discussion: Based on prior discussion, the contraindications section that was initially recommended will be omitted from the final policy. The committee unanimously voted to accept the recommendations as presented. None were opposed.

Financial Discussion: No comments or questions. The committee unanimously voted to accept the recommendations as presented. None were opposed.

Outcome: Durysta is a medical benefit. When Durysta is processed at a specialty pharmacy, it will be processed on the Specialty tier or the Brand Non-preferred tier for members with a three tier benefit.

Durysta will require prior authorization with the following criteria:

- Prescription written by or in consultation with an ophthalmologist **AND**
- Medical Record documentation of a diagnosis of open-angle glaucoma (OAG) or ocular hypertension (OHT) **AND**
- Medical record documentation that patient has not received a previous administration of Durysta to the requested eye **AND**
- Medical record documentation of intolerance to, contraindication to, or therapeutic failure on latanoprost **AND** travoprost **AND** bimatoprost

AUTHORIZATION DURATION: One implant per eye per lifetime (Facets RX count 10 per eye per lifetime, Darwin RX count 1 per eye per lifetime).

CONTRAINDICATIONS:

- Active or suspected ocular or periocular infections
- Corneal endothelial cell dystrophy (e.g. Fuchs' Dystrophy)
- Prior corneal transplantation, or endothelial cell transplants (e.g. Descemet's Stripping Automated Endothelial Keratoplasty (DSAEK))
- Absent or ruptured posterior lens capsule (laser posterior capsulotomy in pseudophakic patients is not a contraindication if the intraocular lens fully covers the opening in the posterior capsule)
- Hypersensitivity to bimatoprost or any other component of the product

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

RYLAZE (asparaginase erwinia chrysanthemi (recombinant)-rywn)

Review: Rylaze is an asparagine specific bacterial enzyme (L-asparaginase) produced by fermentation of genetically engineered *Pseudomonas fluorescens* bacterium containing the DNA which encodes for asparaginase *Erwinia chrysanthemi*. It catalyzes the conversion of L-asparagine to aspartic acid and ammonia, which leads to the killing of leukemic cells with the depletion of plasma asparagine. Leukemic cells with low expression of asparagine synthetase have a reduced ability to synthesize asparagine, and therefore depend on an exogenous source of asparagine for survival. Rylaze is a short-acting asparaginase product which offers an alternative to asparaginase products derived from *Escherichia coli* (*E. coli*), to which up to 30% of patients develop a hypersensitivity or allergy.

Study JZP458-201 is a single-arm, open-label, multi-cohort trial which evaluated the efficacy of Rylaze for the treatment of 102 patients with ALL or LBL who have developed hypersensitivity to *E.coli*-derived asparaginase as a component of a multi-agent chemotherapeutic regimen. A treatment course consisted of Rylaze at various doses administered intramuscularly every Monday, Wednesday, and Friday for a total of 6 doses to replace each dose of pegaspargase. Efficacy was based on demonstration of the achievement and maintenance of nadir serum asparaginase activity (NSAA) above the level of 0.1 U/mL. Results of modeling and simulations showed that for the recommended dosage of Rylaze 25 mg/m² IM every 48 hours, 93.6% of patients maintained NSAA \geq 0.1 U/mL at 48 hours after a dose.

There is no black box warning for Rylaze but there are warnings and precautions for hypersensitivity, pancreatitis, thrombosis, hemorrhage and hepatotoxicity. During clinical trials, there was one fatal adverse

reaction (infection), and serious adverse reactions were reported in 55% of patients treated with the recommended dosage of Rylaze. All patients treated with Rylaze developed neutropenia, anemia, or thrombocytopenia. The most common non-hematological adverse reactions in patients were abnormal liver test, nausea, musculoskeletal pain, fatigue, infection, headache, pyrexia, drug hypersensitivity, febrile neutropenia, decreased appetite, stomatitis, bleeding, and hyperglycemia.

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. The committee unanimously voted to accept the recommendations as presented. None were opposed.

Financial Discussion: No comments or questions. The committee unanimously voted to accept the recommendations as presented. None were opposed.

Outcome: Rylaze is a medical benefit. When Rylaze is processed at a specialty pharmacy, it will be processed on the Specialty tier or the Brand Non-preferred tier for members with a three tier benefit. Rylaze will require prior authorization with the following criteria:

- Medical record documentation that Rylaze is prescribed by a hematologist or oncologist **AND**
- Medical record documentation of age greater than or equal to 1 month **AND**
- Medical record documentation that Rylaze will be given as a component of a multi-agent chemotherapeutic regimen in patients with a diagnosis of acute lymphoblastic leukemia (ALL) and lymphoblastic lymphoma (LBL) **AND**
- Medical record documentation of a hypersensitivity to *E. coli*-derived asparaginase

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

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

ZEGALOGUE (dasiglucagon)

Review: Zegalogue is an antihypoglycemic agent indicated for the treatment of severe hypoglycemia in pediatric and adult patients with diabetes aged 6 years and above. In 2019, Gvoke and Baqsimi glucagon products available in more patient-friendly preparations (syringe/autoinjector/nasal powder) were FDA-approved. Zegalogue is now the second product that comes in easy-to-use prefilled syringe and autoinjector options. At room temperature, the shelf life of Gvoke is 24 months, 18 months for Baqsimi, and 12 months for Zegalogue. However, Zegalogue can be kept in refrigeration until expiration on package. Gvoke is approved for 2 years and up, Baqsimi is approved for 4 years and older, and Zegalogue is approved for 6 years and older. Glucagon emergency kit is weight-based.

Zegalogue is available as an 0.6 mg/0.6mL autoinjector and prefilled syringe for subcutaneous use only. The recommended dose is 0.6 mg administered by subcutaneous injection into the lower abdomen, buttocks, thigh, or outer upper arm. If there is no response after 15 minutes, an additional dose of 0.6 mg from a new device may be administered.

There were three randomized, double-blind, placebo-controlled, multicenter trials conducted in patients with type 1 diabetes. Trial A and Trial B were conducted in adult patients. Trial C was conducted in pediatric patients aged 6 years to 17 years. In all trials, patients were randomized to Zegalogue 0.6 mg, placebo, or (in Trial A and C) glucagon for injection. The primary endpoint for all 3 trials was time to plasma glucose recovery. In trial A, the median time to plasma glucose recovery was statistically significantly shorter for Zegalogue (10 minutes) versus placebo (40 minutes). The median time to plasma glucose recovery was similar between Zegalogue (10 minutes) and glucagon (12 minutes). In Trial B, the median time to plasma glucose recovery was statistically significantly shorter for Zegalogue (10 minutes) versus placebo (35 minutes). In Trial C, The median time to plasma glucose recovery was statistically significantly shorter for Zegalogue (10 minutes) versus placebo (30 minutes). The mean time to plasma glucose recovery was numerically similar between Zegalogue (10 minutes) and glucagon (10 minutes).

Zegalogue is contraindicated in patients with pheochromocytoma because of the risk of substantial increase in blood pressure and insulinoma because of the risk of hypoglycemia. The most common adverse reactions ($\geq 2\%$) in adult patients are: nausea, vomiting, headache, diarrhea, and injection site pain. The most common adverse reactions ($\geq 2\%$) in pediatric patients are: nausea, vomiting, headache, and injection site pain. The safety and effectiveness have not been established in pediatric patients younger than 6 years of age.

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. The committee unanimously voted to accept the recommendations as presented. None were opposed.

Financial Discussion: No comments or questions. The committee unanimously voted to accept the recommendations as presented. None were opposed.

Outcome: Zegalogue is a pharmacy benefit and will be added to the formulary on the brand non-preferred tier. Zegalogue will require step therapy with the following criteria:

- Medical record documentation of therapeutic failure on, intolerance to, or contraindication to Glucagon emergency kit/injection **AND** Gvoke **AND** Baqsimi

QUANTITY LIMIT: 2 units per fill (1.2 mL per fill)

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

FAST FACTS

KEYTRUDA (pembrolizumab)

Updated Indication: Keytruda is a programmed death receptor-1 (PD-1)-blocking antibody now indicated:

- In combination with lenvatinib for the first-line treatment of adult patients with advanced renal cell carcinoma
- For the treatment of patients with high-risk early-stage triple-negative breast cancer (TNBC) in combination with chemotherapy as neoadjuvant treatment, and then continued as a single agent as adjuvant treatment after surgery AND
- for the treatment of patients with locally advanced or metastatic urothelial carcinoma who:
 - are not eligible for any platinum-containing chemotherapy, or
 - who have disease progression during or following platinum-containing chemotherapy or within 12 months of neoadjuvant or adjuvant treatment with platinum-containing chemotherapy.

This is a removal of part of the previous indication for patients who are not eligible for cisplatin-containing chemotherapy and whose tumors express PD-L1 [Combined Positive Score (CPS) ≥ 10] as determined by an FDA-approved test.

Current formulary status: Medical Benefit, requires prior authorization; When processed at a specialty pharmacy: Specialty tier or Brand NP tier.

Recommendation: There are no changes to the formulary placement of Keytruda. The following changes are recommended to the criteria in the Medical Benefit Policy 119.0 for Keytruda to incorporate the new indications. The following changes are recommended to the authorization duration of Keytruda to incorporate the new TNBC indication which is indicated for a total of up to 24 weeks as neoadjuvant treatment followed by up to 27 weeks of adjuvant treatment. A previous change to the authorization duration for adjuvant treatment of metastatic melanoma (completely resected melanoma) was approved in May 2019 but was not updated in MBP 119.0. The following changes to the authorization duration in MBP 119.0 are recommended to reflect that change along with the new indication for TNBC:

12. Renal Cell Carcinoma (RCC)

- Prescription written by a hematologist/oncologist AND
- Medical record documentation that patient is ≥ 18 years of age AND
- Medical record documentation of a diagnosis of advanced renal cell carcinoma AND
- Medical record documentation that Keytruda is being used in combination with axitinib (Inlyta) OR lenvatinib (Lenvima) AND
- Medical record documentation that Keytruda in combination with axitinib (Inlyta) OR lenvatinib (Lenvima) are being used as first-line treatment for advanced disease

17. Triple Negative Breast Cancer

- Prescription written by a hematologist/oncologist AND
- Medical record documentation of age greater than or equal to 18 years AND
- Medical record documentation of one of the following:
 - Medical record documentation of locally recurrent unresectable or metastatic triple-negative breast cancer (TNBC) AND both of the following:
 - Medical record documentation that tumors express PD-L1 [Combined Positive Score (CPS) greater than or equal to 10] as determined by an FDA approved test AND

- Medical record documentation that Keytruda will be given in combination with chemotherapy (paclitaxel, paclitaxel protein-bound, or gemcitabine and carboplatin).

OR

- Medical record documentation of high-risk, early-stage triple-negative breast cancer (TNBC) **AND**
- Medical record documentation that Keytruda will be given in combination with chemotherapy as neoadjuvant treatment, and then continued as a single agent as adjuvant treatment after surgery

6. Urothelial Carcinoma

- Prescription written by a hematologist/oncologist **AND**
- Medical record documentation that patient is ≥ 18 years of age **AND**
- Medical record documentation of locally advanced or metastatic urothelial carcinoma **AND**
- Medical record documentation of one of the following:
 - Disease progression during or following platinum-containing chemotherapy

OR

- Disease progression within 12 months of neoadjuvant or adjuvant treatment with platinum-containing chemotherapy

OR

- Patient is not eligible cisplatin-containing chemotherapy* **AND**
- Tumors express PD-L1 (combined positive score [CPS] greater than or equal to 10) as determined by an FDA-approved test

OR

- Patient is not eligible for any platinum-containing chemotherapy (regardless of PD-L1 status)

OR

- Patient has high-risk, non-muscle invasive bladder cancer (NMIBC)** **AND**
- Patient's disease is unresponsive to an adequate trial of Bacillus Calmette-Guerin (BCG) therapy** **AND**
- Patient is ineligible for or has elected not to undergo cystectomy

*Note:

- In clinical trials, patients who were not considered cisplatin-eligible had the following characteristics: baseline creatinine clearance of <60 mL/min, ECOG performance status of 2, ECOG 2 and baseline creatinine clearance of <60 mL/min, other reasons (Class III heart failure, Grade 2 or greater peripheral neuropathy, and Grade 2 or greater hearing loss).

AUTHORIZATION DURATION: Initial approval will be for **6 months** or less if the reviewing provider feels it is medically appropriate. Subsequent approvals will be for an additional **12 months** or less if the reviewing provider feels it is medically appropriate and will require medical record documentation of continued disease improvement or lack of disease progression. The medication will no longer be covered if patient experiences toxicity or worsening of disease.

Recommended Authorization duration:

For adjuvant treatment of metastatic melanoma (completely resected melanoma) and neoadjuvant/adjuvant treatment of early-stage triple negative breast cancer:

Initial approval will be for 6 months. One subsequent approval will be for an additional 6 months and will require medical record documentation of continued disease improvement or lack of disease progression. The medication will no longer be covered if patient experiences toxicity or worsening of disease.

Authorization of Keytruda for the adjuvant treatment of metastatic melanoma should not exceed the FDA-approved treatment duration of 1 year (12 months). Authorization of Keytruda for the treatment of early-stage triple negative breast cancer should not exceed the approved treatment duration of 24 weeks for neoadjuvant therapy and 27 weeks for adjuvant therapy. 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

For all other indications:

Initial approval will be for 6 months. Subsequent approvals will be for 12 months and will require medical record documentation of continued disease improvement or lack of disease progression. The medication will no longer be covered if patient experiences toxicity or worsening of disease.

Discussion: No comments or questions.

Outcome: The committee unanimously voted to accept the recommendations as presented. None were opposed.

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

LENVIMA (lenvatinib)

Updated Indication: Lenvima is now indicated in combination with pembrolizumab, for the first line treatment of adult patients with advanced renal cell carcinoma (RCC).

Lenvima has another previously approved indication in renal cell carcinoma: in combination with everolimus, for the treatment of adult patients with advanced renal cell carcinoma (RCC) following one prior anti-angiogenic therapy

Current formulary status: Oral Oncology Brand NP (\$0 copay); requires PA

Recommendation: There are no changes needed to the formulary placement, quantity limits, or authorization duration for Lenvima. The following changes are recommended for Commercial Policy 373.0:

Renal Cell Carcinoma

- Medical record documentation that Lenvima is prescribed by an oncologist **AND**
- Medical record documentation of one of the following:
 - Medical record documentation of use in combination with Afinitor (everolimus) for surgically unresectable advanced or metastatic renal cell carcinoma with predominant clear-cell histology **AND**
 - Medical record documentation of a therapeutic failure on or intolerance to one prior anti-angiogenic therapy, including, but not limited to, Sutent (sunitinib), Votrient (pazopanib), Inlyta (axitinib), Nexavar (sorafenib), Avastin (bevacizumab), Afinitor (everolimus), or Torisel (temsirolimus)

OR

- Medical record documentation in combination with pembrolizumab for the treatment of advanced renal cell carcinoma (RCC) **AND**

- o Medical record documentation the Lenvima in combination with pembrolizumab (Ketyruda) are being used as first-line treatment for advanced disease

Discussion: No comments or questions.

Outcome: The committee unanimously voted to accept the recommendations as presented. 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 FASPRO (daratumumab and hyaluronidsae-fihj)

Updated Indication: Darzalex Faspro is now indicated for the treatment of adult patients with multiple myeloma in combination with pomalidomide and dexamethasone in patients who have received at least one prior line of therapy including lenalidomide and a proteasome inhibitor (PI).

Darzalex Faspro was previously indicated for the treatment of adult patients with multiple myeloma:

- in combination with bortezomib, melphalan and prednisone in newly diagnosed patients who are ineligible for autologous stem cell transplant (ASCT)
- in combination with lenalidomide and dexamethasone in newly diagnosed patients who are ineligible for autologous stem cell transplant and in patients with relapsed or refractory multiple myeloma who have received at least one prior therapy
- in combination with bortezomib, thalidomide, and dexamethasone in newly diagnosed patients who are eligible for autologous stem cell transplant
- in combination with bortezomib and dexamethasone in patients who have received at least one prior therapy
- as monotherapy, in patients who have received at least three prior lines of therapy including a proteasome inhibitor (PI) and an immunomodulatory agent or who are double-refractory to a PI and an immunomodulatory agent

Darzalex Faspro was also previously indicated in combination with bortezomib, cyclophosphamide and dexamethasone for the treatment of adult patients with newly diagnosed light chain (AL) amyloidosis.

Note: Darzalex is indicated for adult patients with multiple myeloma in combination with pomalidomide and dexamethasone in patients who have received at least two prior therapies including lenalidomide and a proteasome inhibitor.

Current formulary status: Darzalex Faspro is a medical benefit and requires a prior authorization. If Darzalex Faspro processes through a specialty pharmacy, it will process at the Specialty tier or the Brand Non-Preferred tier for members with a three tier benefit.

Recommendation: There will be no changes to formulary status, authorization duration, or quantity limits at this time. However, it is recommended to make the following updates to the current criteria:

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

If newly diagnosed multiple myeloma (transplant ineligible):

- Medical record documentation that the member is not 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 one of the following options:
 - Bortezomib (Velcade), melphalan, AND prednisone [VMP] **OR**
 - Lenalidomide (Revlimid) **AND** dexamethasone

OR

If newly diagnosed multiple myeloma (transplant eligible):

- Medical record documentation that the member is eligible for stem-cell transplantation **AND**
- Medical record documentation that Darzalex will be given in combination with bortezomib (Velcade), thalidomide, and dexamethasone (DVTd)

OR

If relapsed/refractory multiple myeloma:

- 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 one prior line of therapy including lenalidomide and a proteasome inhibitor (including but not limited to Velcade*, Kyprolis*, or Ninlaro*) **AND** Darzalex will be prescribed in combination with pomalidomide and dexamethasone **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 **OR**
 - ~~Medical record documentation that Darzalex will be prescribed in combination with carfilzomib (Kyprolis) and dexamethasone~~

OR

If light-chain (AL) amyloidosis:

- Prescription written by or in consultation with and hematologist/oncologist **AND**
- Medical record documentation of a diagnosis of light-chain (AL) amyloidosis **AND**
- Medical Record documentation that the patient does NOT have New York Heart Association (NYHA) Class IIIB (as defined by slight limitation during daily living activity and comfortable at rest) or Class IV heart failure, or mayo cardiac stage IIIB* **AND**
- Medical record documentation that Darzalex Faspro will be used in combination with bortezomib, cyclophosphamide and dexamethasone

ADDITIONAL RECOMMENDATIONS: Darzalex received approval for adult patients with multiple myeloma in combination with pomalidomide and dexamethasone in patients who received at least two prior therapies including lenalidomide and a proteasome inhibitor. This indication was approved June 16,

2017, however it was never presented for approval at P&T. It is recommended to update the current policies to include all of the FDA approved indications.

Recommendation (for Darzalex): There are no changes to formulary status or authorization duration at this time. However, it is recommended to update the criteria to include all the FDA-approved indications:

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

If newly diagnosed multiple myeloma (transplant ineligible):

- Medical record documentation that the member is not 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 one of the following options:
 - Bortezomib (Velcade), melphalan, **AND** prednisone [VMP] **OR**
 - Lenalidomide (Revlimid) **AND** dexamethasone

OR

If newly diagnosed multiple myeloma (transplant eligible):

- Medical record documentation that the member is eligible for stem-cell transplantation **AND**
- Medical record documentation that Darzalex will be given in combination with bortezomib (Velcade), thalidomide, and dexamethasone (DVTd)

OR

If relapsed/refractory multiple myeloma:

- 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 two prior lines of therapy including lenalidomide and a proteasome inhibitor (including but not limited to Velcade*, Kyprolis*, or Ninlaro*) **AND** Darzalex will be prescribed in combination with pomalidomide and dexamethasone **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 **OR**
 - Medical record documentation that Darzalex will be prescribed in combination with carfilzomib (Kyprolis) and dexamethasone

AUTHORIZATION DURATION: Initial approval will be for 12 months or less if the reviewing provider feels it is medically appropriate. Subsequent approvals will be for an additional 12 months or

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

Discussion: There was discussion regarding a difference in the number of prior line failures between Darzelex and Darzalex FasPro. Darzalex FasPro only requires 1, Darzalex requires 2. This matches the FDA labeling. No additional comments or questions.

Outcome: The committee unanimously voted to accept the recommendations as presented. None were opposed.

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

JEMPERLI (dostarlimab-gxly)

Updated Indication: Jemperli is now indicated for treatment of adult patients with mismatch repair deficient (dMMR) recurrent or advanced solid tumors, as determined by an FDA-approved test, that have progressed on or following prior treatment and who have no satisfactory alternative treatment options.

Previously Jemperli was only indicated for dMMR recurrent or advanced endometrial cancer.

Current formulary status: Medical Benefit, requires prior authorization; When processed at a specialty pharmacy: Specialty tier or Brand NP tier.

Recommendation: There are no changes recommended to the formulary placement or the authorization duration of Jemperli. It is recommended that the following prior authorization criteria be added to the Medical Benefit Policy for Jemperli:

Solid Tumors

- Medical record documentation that Jemperli is prescribed by a hematologist or oncologist **AND**
- Medical record documentation of age greater than or equal to 18 years **AND**
- Medical record documentation of a diagnosis of recurrent or advanced solid tumors **AND**
- Medical record documentation of mismatch repair deficient (dMMR) as determined by an FDA approved test **AND**
- Medical record documentation of disease progression on or following at least one prior treatment **AND**
- Medical record documentation of no satisfactory alternative treatment options

Discussion: No comments or questions.

Outcome: The committee unanimously voted to accept the recommendations as presented. None were opposed.

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

PADCEV (enfortumab vedotin-ejfv)

Updated Indication: Padcev is now indicated for the treatment of adult patients with locally advanced or metastatic urothelial cancer who are ineligible for cisplatin-containing chemotherapy and have previously received one or more prior lines of therapy.

The other indication for Padcev is for adult patients with locally advanced or metastatic urothelial cancer who have previously received a programmed death receptor-1 (PD-1) or programmed death-ligand 1 (PD-L1) inhibitor and platinum-containing chemotherapy.

Current formulary status: Medical Benefit, requires prior authorization; When processed at a specialty pharmacy: Specialty tier or Brand NP tier.

Recommendation: There are no changes recommended to the formulary placement or authorization duration of Padcev. The following changes are recommended for Medical Benefit Policy 209.0 to incorporate the new indication for Padcev:

- Medical record documentation that prescription is written by a hematologist or oncologist AND
- Medical record documentation of age greater than or equal to 18 years AND
- Medical record documentation of locally advanced or metastatic urothelial cancer AND
- **Medical record documentation of one of the following:**
 - Medical record documentation that member has received a programmed death receptor-1 (PD-1) or programmed death-ligand 1 (PD-L1) inhibitor, and a platinum-containing chemotherapy in the neoadjuvant/adjuvant, locally advanced or metastatic setting OR
 - **Medical record documentation that member has received at least one prior line of therapy and is ineligible for cisplatin-containing chemotherapy***

***Note to reviewer:** In clinical trials, patients who were not considered cisplatin-eligible had one or more of the following characteristics: baseline creatinine clearance of 30 – 59 mL/min, ECOG performance status of 2, or Grade 2 or greater hearing loss.

Discussion: No comments or questions

Outcome: The committee unanimously voted to accept the recommendations as presented. None were opposed.

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

MYRBETRIQ (mirabegron)

Updated Indication: Myrbetriq is a beta-3 adrenergic agonist indicated for neurogenic detrusor overactivity (NDO) in pediatric patients aged 3 years and older weighing 35 kg or more.

Previously only indicated for overactive bladder (OAB) in adult patients with symptoms of urge urinary incontinence, urgency, and urinary frequency, either alone or in combination with the muscarinic antagonist solifenacin succinate.

Myrbetriq Granules is a beta-3 adrenergic agonist indicated for the treatment of NDO in pediatric patients aged 3 years and older

Current formulary status: Brand preferred (tablets only)

Recommendation:

- **Myrbetriq Tablets:** No changes are needed for formulary placement or quantity limit
- **Myrbetriq Oral Suspension:** Myrbetriq is a pharmacy benefit and should be added to the Brand Preferred tier of the Geisinger Gold formulary. It will be limited to use for those 3 to 18 years of age (requiring prior authorization for indication and age)
 - **Age Limit:** 3 to 18 years of age
 - **Quantity Limit:** 10 mL (80 mg) per day

Discussion: No comments or questions.

Outcome: The committee unanimously voted to accept the recommendations as presented. None were opposed.

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

TYVASO (treprostinil)

Updated Indication: Tyvaso is now indicated for pulmonary hypertension associated with interstitial lung disease (PH-ILD; WHO Group 3) to improve exercise ability. The study establishing effectiveness predominately included patients with etiologies of idiopathic interstitial pneumonia (IIP) (45%) inclusive of idiopathic pulmonary fibrosis (IPF), combined pulmonary fibrosis and emphysema (CPFE) (25%), and WHO Group 3 connective tissue disease (22%).

Previously, Tyvaso was only indicated for the treatment of pulmonary arterial hypertension (PAH; WHO Group 1) to improve exercise ability.

Current formulary status: Tyvaso is a pharmacy benefit available at the Specialty tier or Brand Non-Preferred tier for members with a three tier benefit. Tyvaso requires a prior authorization.

Recommendation: There will be no changes to formulary status or quantity limits at this time. However, it is recommended to add the following criteria to the current policy to reflect the new indication:

Pulmonary Hypertension

- Medical record documentation that Tyvaso is prescribed by a cardiologist or pulmonologist AND
- Medical record documentation of a diagnosis of pulmonary hypertension associated with interstitial lung disease (World Health Organization Group 3 Pulmonary Hypertension)

Discussion: No comments or questions.

Outcome: The committee unanimously voted to accept the recommendations as presented. None were opposed.

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

DRIZALMA SPRINKLE (duloxetine delayed-release capsules)

Updated Indication: Drizalma Sprinkle capsules are now indicated for the treatment of fibromyalgia in adult patients.

Although duloxetine (generic Cymbalta) is indicated for fibromyalgia in adults and pediatric patients 13 years and older, due to Eli Lilly and Company Inc.'s marketing exclusivity rights, this drug product is not labeled with that pediatric information.

Other indications for Drizalma Sprinkle are major depressive disorder, diabetic peripheral neuropathic pain, and chronic musculoskeletal pain in adult patients and generalized anxiety disorder in adults and pediatric patients ages 7 years and older.

Current formulary status: NF, requires a prior authorization, QL: 2 capsules per day

Recommendation: There are no changes to the formulary placement or the quantity limits for Drizalma Sprinkle for the new indication. The following changes are recommended to Commercial Policy 597.0 to incorporate the new indication:

- Medical record documentation of one of the following:
 - Medical record documentation major depressive disorder, diabetic peripheral neuropathic pain, chronic musculoskeletal pain, or fibromyalgia in members age greater than or equal to 18 years **OR**
 - Medical record documentation of generalized anxiety disorder in members age greater than or equal to 7 years

AND

- Medical record documentation of difficulty swallowing **OR**
- Medical record documentation of administration through a nasogastric tube **OR**
- Medical record documentation of therapeutic failure on, intolerance to, or contraindication to three (3) formulary alternatives, one of which must be duloxetine capsules

Discussion: No comments or questions.

Outcome: The committee unanimously voted to accept the recommendations as presented. None were opposed.

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

ZEPOSIA (ozanimod)

Updated Indication: Zeposia is now indicated for the treatment of moderately to severely active ulcerative colitis in adults.

Previously, Zeposia was indicated for the treatment of multiple sclerosis.

Current formulary status: Specialty tier or brand non-preferred tier for members with a 3-tier benefit. Zeposia does not require prior authorization but does have a quantity limit.

Recommendation: No changes are needed for the formulary placement of Zeposia. For a multiple sclerosis diagnosis, Zeposia will continue to be available without a prior authorization. For the new

indication of ulcerative colitis, a prior authorization will be required with the following criteria and authorization duration. There is no change needed to the current quantity limits of Zeposia.

For Ulcerative Colitis

- Medical record documentation that Zeposia is prescribed by a gastroenterologist **AND**
- Medical record documentation of a diagnosis of moderate to severe ulcerative colitis **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 Humira **AND** Entyvio **AND** Infliximab **AND**
- Medical record documentation that Zeposia is not being used concurrently with a TNF blocker or other biologic agent

For Multiple Sclerosis (MS)

Note: *Prior authorization is not required for diagnosis code G35. In the event a requestor would like a medical necessity review completed the following criteria would apply:*

- Medical record documentation of a diagnosis of Multiple Sclerosis

QUANTITY LIMITS:

- 7 Day Starter Pack: 7 capsules per 180 days
- Starter Kit (7 Day Starter Pack and 0.92 mg 30 count bottle): 37 capsules per 180 days
- 0.92 mg capsules: 1 capsule per day

AUTHORIZATION DURATION:

For Multiple Sclerosis: Approval will be entered as an open-ended authorization.

For Ulcerative Colitis: Approval will be given for an initial duration of six (6) months. For continuation of coverage, medical record documentation of clinical improvement or lack of progression in the signs and symptoms of ulcerative colitis at six (6) months of Zeposia therapy is required.

After the initial six (6) month approval, subsequent approvals for coverage will be for a duration of one (1) year requiring medical record documentation of continued or sustained improvement in the signs and symptoms of ulcerative colitis while on Zeposia therapy.

Discussion: No comments or questions.

Outcome: The committee unanimously voted to accept the recommendations as presented. 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

ISTODAX (romidepsin)

Previous Indications: Istodax is a histone deacetylase (HDAC) inhibitor indicated for:

- Treatment of cutaneous T-cell lymphoma (CTCL) in adult patients who have received at least one prior systemic therapy.
- Treatment of peripheral T-cell lymphoma (PTCL) in adult patients who have received at least one prior therapy. This indication is approved under accelerated approval based on response rate. Continued approval for this indication may be contingent upon verification and description of clinical benefit in confirmatory trials

Celgene Corporation, a wholly owned subsidiary of Bristol-Myers Squibb has voluntarily withdrawn the indication of Istodax for treatment of peripheral T-cell lymphoma (PTCL). Previously, Istodax had received accelerated approval for PTCL based on response rate in two prior clinical studies. A confirmatory Phase 3 study evaluating Istodax plus CHOP (Ro-CHOP) versus CHOP in first-line PTCL patients did not meet its primary efficacy endpoint of progression free survival. Istodax remains on the market for the treatment of patients with cutaneous T-cell lymphoma who have received at least one prior systemic therapy.

Recommendations: It is recommended that Medical Benefit Policy 78.0 be updated to reflect the removal of the PTCL indication as follows:

1. Cutaneous T-cell lymphoma:
 - Physician provided documentation of a diagnosis of cutaneous T-cell lymphoma **AND**
 - Physician provided documentation of disease progression while on at least one prior systemic therapy
2. Peripheral T-cell lymphoma:
 - Physician provided documentation of a diagnosis of peripheral T-cell lymphoma **AND**
 - Physician provided documentation of disease progression while on at least one prior therapy

Discussion: No comments or questions.

Outcome: The committee unanimously voted to accept the recommendations as presented. None were opposed.

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

XIAFLEX (collagenase clostridium histolyticum)

Geisinger Health plan was asked to review medical necessity criteria for Xiaflex.

Current Formulary Status/Prior Authorization Criteria: Currently, Medical Benefit Policy 80.0 Xiaflex for the indication of Peyronie's disease (PD) requires that Xiaflex be used in combination with, or have documented therapeutic failure on, intolerance to, or contraindication to pentoxifylline.

Recommendations: There are no changes recommended to the formulary placement or quantity limit for Xiaflex. It is recommended to make the following changes to MBP 80.0:

MBP 80.0

Xiaflex (collagenase clostridium histolyticum) will be considered medically necessary when all of the following criteria are met:

1. For treatment of Dupuytren contracture:

- Medical record documentation of Dupuytren's contracture with a palpable cord AND
- Prescribed by a provider experienced in injection procedures of the hand and treating Dupuytren's contracture

LIMITATIONS:

Xiaflex® will be limited to a maximum of three (3) injections per cord

1. For treatment of Peyronie's disease:

- Medical record documentation of a diagnosis of moderate to severe Peyronie's Disease with a palpable plaque and curvature deformity of at least 30 degrees at the start of therapy AND
- ~~Medical record documentation that Xiaflex will be used in combination with (or therapeutic failure on, intolerance to, or contraindication to) pentoxifylline~~

LIMITATIONS:

Xiaflex® will be limited to a maximum of 8 total injection procedures (4 treatment cycles) per plaque.

Discussion: No comments or questions.

Outcome: The committee unanimously voted to accept the recommendations as presented. None were opposed.

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

MENOPUR

Background: At the 2Q2021 quarterly case audit review, it was brought to our attention that we have approved 100% of the Menopur requests we received (17 requests). For 1Q2021, we had a 96.77% approval percentage for Menopur (31 requests). We discussed removing the prior authorization from Menopur due to the high approval percentage. Removal of the prior authorization from Menopur does not impact any of our existing rebates for fertility agents.

Recommendation: There are no changes to formulary status at this time. However, it is recommended to remove the prior authorization from Menopur.

Discussion: No comments or questions.

Outcome: The committee unanimously voted to accept the recommendations as presented. None were opposed.

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

DESVENLAFAXINE ER TABLETS

Background: Based on discussion at the Quarterly Case Audit for 2nd quarter 2021, it was recommended that it be determined if desvenlafaxine ER (generic Khedezla) be added to formulary to the Commercial line of business or a policy be created to ensure consistency among reviewers.

Recommendation: After review of MAC pricing and the significant cost differences, it is recommended that the desvenlafaxine ER remain nonformulary and the following prior authorization criteria and quantity limits apply:

- For desvenlafaxine ER (generic Khedezla), do not see medical record documentation of therapeutic failure on, intolerance to, or contraindication to desvenlafaxine succinate ER (generic Pristiq).

QUANTITY LIMIT: 1 tablet per day

Discussion: No comments or questions.

Outcome: The committee unanimously voted to accept the recommendations as presented. None were opposed.

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

IVERMECTIN ORAL

Background: The Centers for Disease Control and Prevention (CDC) recently released a health advisory notice alerting clinicians that there is insufficient evidence for the National Institutes of Health (NIH) COVID-19 Treatment Guidelines Panel to recommend the use of ivermectin for prevention or treatment of COVID-19. Geisinger Health Plan has experienced increased utilization of ivermectin from 2020 to 2021. Due to increased utilization as well as the information outlined above, changes are recommended to ivermectin oral to ensure safe and appropriate utilization of ivermectin tablets.

Recommendation: No changes are recommended to the tiering of ivermectin tablets at this time. Prior authorization should be added to ivermectin tablets. If able to be operationalized by the pharmacy claims processing system, requests should process at point-of-sale if a FDA-approved or medically accepted (as defined by GHP P&T committee) diagnosis code is submitted to GHP by the pharmacy as part of the drug claim. Requests requiring prior authorization will be reviewed for medical necessity on a case-by-case basis utilizing Administrative Policy 3.0 Formulary Exception as a guide. If the above strategy is not able to be operationalized, prior authorization will apply to all claims reviewing for medical necessity on a case-by-case basis utilizing Administrative Policy 3.0 Formulary Exception as a guide. Currently, in addition to FDA-approved diagnoses, a medically accepted diagnosis of scabies will be added to the exemption list.

QUANTITY LIMIT: 1 tablet per day

Discussion: There was discussion regarding the need to update ivermectin to a PA across the board rather than only when used for COVID due to other off label use for lyme disease, babesiosis, etc. It was decided that the edit should be added to approve only when an FDA approved indication or scabies (CDC

recommendation) is submitted as the diagnosis. We may updated in the future to include other medically acceptable indications. No additional comments or questions.

Outcome: The committee unanimously voted to accept the recommendations as presented. None were opposed.

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

DESCOVY ACA TIERING EXCEPTION UPDATE

Background: The United States Preventive Services Task Force (USPSTF) currently recommends that clinicians offer preexposure prophylaxis (PrEP) with effective antiretroviral therapy to persons who are at high risk of HIV acquisition. Presently, emtricitabine/tenofovir as well as Descovy are Food and Drug Administration (FDA) approved for this indication. Geisinger operationalizes this requirement by covering emtricitabine/tenofovir as well as it's component parts for \$0 at point-of-sale when the pharmacy enters an appropriate submission clarification code (SCC).

Recommendation: The current ACA Tiering Exception Policy allows for coverage of brand name Truvada when deemed appropriate, but the current policy does not address \$0 coverage of Descovy if it's determined a member is unable to take brand or generic emtricitabine/tenofovir. It is recommended that the following language is added to Commercial policy 17.0 OT ACA Tiering Exception to allow for these exceptions if approved:

- Medical record documentation that Descovy is prescribed as preexposure prophylaxis (PrEP) for a member at high risk of HIV acquisition **AND**
- Medical record documentation of therapeutic failure on, intolerance to, or contraindication to emtricitabine/tenofovir

If an exception is made, the multiple source brand medication **or Descovy** will be covered for \$0 cost share under the member's prescription drug benefit

Discussion: No comments or questions.

Outcome: The committee unanimously voted to accept the recommendations as presented. None were opposed.

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

QUARTERLY CASE AUDIT

The Quarterly Case Audit for 2nd quarter 2021 was held on September 2, 2021. Updates for Menopur, desvenlafaxine ER, and tranexamic acid were brought to this P&T meeting for various lines of business. The policies created for desvenlafaxine ER and tranexamic acid will help to ensure consistency among reviewers. We will continue to look for opportunities to create more drug specific policies at future quarterly case audit meetings.

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

IMMUNOMODULATOR AND ORAL ONCOLOGY RENEWAL CRITERIA REMOVAL

Background: After review of prior authorization data from September 1, 2020 through August 31, 2021 it was identified that immunomodulator products and oral oncology products both have a high renewal approval rate.

Recommendation: In order to reduce PA burden for low value authorizations, it is recommended that the prior authorization (PA) on the following medications is converted from a standard PA to a PA for new starts only. A one-time authorization will be placed to allow the initial fill to process. This will allow members currently on therapy to continue uninterrupted but will also prompt re-review for members with a disruption in therapy. A lookback period of 90 days will be utilized.

ORAL ONCOLOGY

Abiraterone (Zytiga)	Copiktra	Iressa
Everolimus (Afinitor)	Cotellic	Kisqali
Afinitor Disperz	Daurismo	Koselugo
Alecensa	Erivedge	Lapatinib (Tykerb)
Alunbrig	Erleada	Lenvima
Ayvakit	Erlotinib (Tarceva)	Lonsurf
Balversa	Fotivda	Lorbrena
Bosulif	Gavreto	Lumakras
Braftovi	Gilotrif	Lynparza
Brukinsa	Ibrance	Mektovi
Cabometyx	Iclusig	Nexavar
Calquence	Idhifa	Ninlaro
Caprelsa	Imbruvica	Nubeqa
Odomzo	Tabrecta	Vitrakvi
Onureg	Tagrisso	Vizimpro
Pemazyre	Talzenna	Votrient
Piqray	Tasigna	Xalkori
Pomalyst	Tazverik	Xospata
Qinlock	Tepmetko	Xpovio
Retevmo	Tibsovo	Xtandi
Revlimid	Truseltiq	Yonsa
Rozlytrek	Tukysa	Zejula
Rubraca	Turalio	Zelboraf
Rydapt	Ukoniq	Zolinza
Sprycel	Venclexta	Zydelig
Stivarga	Verzenio	Zykadia
Sutent	Inlyta	
Cometriq	Inqovi	

IMMUNOMODULATORS

Actemra Self-Injectable	Kineret	Simponi
Cimzia	Olumiant	Skyrizi

Cosentyx	Orencia SC	Stelara
Enbrel	Otezla	Taltz
Humira	Rinvoq	Tremfya
Kevzara	Siliq	Xeljanz/Xeljanz XR

In order to ensure that members are receiving ongoing care from their prescribing specialist a report will be developed to identify members who are no receiving appropriate follow-up care from their prescriber. The following language will be added to the drug policies:

- The medication will no longer be covered if it is identified that the member is not receiving appropriate follow-up care from the prescribing specialist.

Discussion: No comments or questions.

Outcome: The committee unanimously voted to accept the recommendations as presented. None were opposed.

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

DESCOVY ACA TIERING EXCEPTION UPDATE

Recommendation: It is recommended that the following multi-source brand and non-FDA approved drugs are removed from the Commercial formulary effective 1/1/2022:

Brand Name	GPI
Afinitor Oral Tablet 2.5 MG	21532530000310
Afinitor Oral Tablet 5 MG	21532530000320
Afinitor Oral Tablet 7.5 MG	21532530000325
Bleph-10 Ophthalmic Solution 10%	86102010102010
Cafergot Oral Tablet 1-100 MG	67991002100310
Carafate Oral Suspension 1 GM/10ML	49300010001820
Cordran External Lotion 0.05 %	90550065004105
Coumadin Oral Tablet 1 MG	83200030200303
Coumadin Oral Tablet 10 MG	83200030200325
Coumadin Oral Tablet 2 MG	83200030200305
Coumadin Oral Tablet 2.5 MG	83200030200310
Coumadin Oral Tablet 3 MG	83200030200311
Coumadin Oral Tablet 4 MG	83200030200313
Coumadin Oral Tablet 5 MG	83200030200315
Coumadin Oral Tablet 6 MG	83200030200317
Coumadin Oral Tablet 7.5 MG	83200030200320
Delestrogen Intramuscular Oil 20 MG/ML	24000035201710
Delestrogen Intramuscular Oil 40 MG/ML	24000035201715
E.E.S. Granules Oral Suspension Reconstituted 200 MG/5ML	03100030301910
EryPed 200 Oral Suspension Reconstituted 200 MG/5ML	03100030301910

EryPed 400 Oral Suspension Reconstituted 400 MG/5ML	03100030301915
Exjade Oral Tablet Soluble 125 MG	93100025007320
Exjade Oral Tablet Soluble 250 MG	93100025007330
Exjade Oral Tablet Soluble 500 MG	93100025007340
Ferriprox Oral Tablet 500 MG	93100028000320
Icar-C Plus Oral Tablet 100-250-0.025-1 MG	82992004300330
Kaletra Oral Solution 400-100 MG/5ML	12109902552020
Kuvan Oral Packet 100 MG	30908565103020
Kuvan Oral Packet 500 MG	30908565103040
Kuvan Oral Tablet 100 MG	30908565100320
Makena Intramuscular Oil 250 MG/ML	26000010101710
Mar-Cof CG Expectorant Oral Liquid 225-7.5 MG/5ML	43997002280947
MoviPrep Oral Solution Reconstituted 100 GM	46992006302120
Naftin External Gel 1 %	90150078004010
Naftin External Cream 2 %	90150078003720
Nexium Oral Packet 10 MG	49270025103010
Nexium Oral Packet 20 MG	49270025103020
Nexium Oral Packet 40 MG	49270025103040
Nitrostat Sublingual Tablet Sublingual 0.3 MG	32100030000710
Nitrostat Sublingual Tablet Sublingual 0.4 MG	32100030000715
Nitrostat Sublingual Tablet Sublingual 0.6 MG	32100030000720
Plaquenil Oral Tablet 200 MG	13000020100305
ProAir HFA Inhalation Aerosol Solution 108 (90 Base) MCG/ACT	44201010103410
Proventil HFA Inhalation Aerosol Solution 108 (90 Base) MCG/ACT	44201010103410
Roxicodone Oral Tablet 5 MG	65100075100310
Salvax External Foam 6 %	90750030003940
Saphris Sublingual Tablet Sublingual 10 MG	59155015100730
Saphris Sublingual Tablet Sublingual 2.5 MG	59155015100710
Saphris Sublingual Tablet Sublingual 5 MG	59155015100720
Sklice External Lotion 0.5 %	90900017004120
Suboxone Sublingual Film 12-3 MG	65200010208250
Suboxone Sublingual Film 2-0.5 MG	65200010208220
Suboxone Sublingual Film 4-1 MG	65200010208230
Suboxone Sublingual Film 8-2 MG	65200010208240
Tamiflu Oral Capsule 30 MG	12504060200110
Tamiflu Oral Capsule 45 MG	12504060200115
Tamiflu Oral Capsule 75 MG	12504060200120
Tamiflu Oral Suspension Reconstituted 6 MG/ML	12504060201910
Tarceva Oral Tablet 100 MG	21360025100330
Tarceva Oral Tablet 150 MG	21360025100360
Tarceva Oral Tablet 25 MG	21360025100320
Tepadina Injection Solution Reconstituted 100 MG	21100040002150
Tepadina Injection Solution Reconstituted 15 MG	21100040002105
Transderm Scop (1.5 MG) Transdermal Patch 72 Hour 1 MG/3DAYS	50200060008610

Tridesilon External Cream 0.05 %	90550035003705
Tykerb Oral Tablet 250 MG	21533026100320
Urogesic-Blue Oral Tablet 81.6 MG	1251290
Veletri Intravenous Solution Reconstituted 0.5 MG	40170040102110
Veletri Intravenous Solution Reconstituted 1.5 MG	40170040102130
Veripred 20 Oral Solution 20 MG/5ML	22100040202060
Zytiga Oral Tablet 250 MG	21406010200320
Zytiga Oral Tablet 500 MG	21406010200330
Adapalene-Benzoyl Peroxide External Pad 0.1-2.5 %	90059902034320
AgonEaze External Kit 2.5-2.5 %	90859902906410
Aprizio Pak External Kit 2.5-2.5 %	90859903796420
Belladonna Alkaloids-Opium Rectal Suppository 16.2-30 MG	49109902155210
Belladonna Alkaloids-Opium Rectal Suppository 16.2-60 MG	49109902155220
BP 10-1 External Emulsion 10-1 %	90059903201615
BP Cleansing Wash External Emulsion 10-4 %	90059903211618
BPO External Gel 4 %	90050010004012
BPO External Gel 8 %	90050010004014
CadiraMD External Kit 2.5-2.5 %	90859903786420
Calcium-Folic Acid Plus D Oral Wafer 1342-1 MG	79109907203125
DermacinRx Empricaine External Kit 2.5-2.5 %	90859902906410
DermacinRx Prizopak External Kit 2.5-2.5 %	90859902906410
Dermazene External Cream 1-1 %	90159902153710
Dritho-Creme HP External Cream 1 %	90250020003725
Econasil External Kit 1 %	90159903246420
Ed-Spaz Oral Tablet Disintegrating 0.125 MG	49101030107220
Escavite D Oral Tablet Chewable 0.25-6 MG	78450000000505
Escavite LQ Oral Liquid 0.25-6 MG/ML	78450000000910
Escavite Oral Tablet Chewable 0.25-7.5 MG	78450000000507
Floriva Oral Liquid 0.25-400 MG-UNIT/ML	79309902750920
Floriva Oral Tablet Chewable 0.25 MG	78460000000510
Floriva Oral Tablet Chewable 0.5 MG	78460000000515
Floriva Oral Tablet Chewable 1 MG	78460000000520
Fluorabon Oral Solution 0.55 (0.25 F) MG/0.6ML	79300020002039
Fluoritab Oral Solution 0.275 (0.125 F) MG/DROP	79300020002030
Fluoritab Oral Tablet Chewable 1.1 (0.5 F) MG	79300020000510
Fluoritab Oral Tablet Chewable 2.2 (1 F) MG	79300020000515
Flura-Drops Oral Solution 0.55 (0.25 F) MG/DROP	79300020002035
Homatropaire Ophthalmic Solution 5 %	86350030102010
Homatropine HBr Ophthalmic Solution 5 %	86350030102010
Hydrocortisone-Iodoquinol External Cream 1-1 %	90159902153710
Hyophen Oral Tablet 81.6 MG	16992005150325
Iodine Strong Oral Solution 5 %	79350032002020
Isoxsuprine HCl Oral Tablet 20 MG	40100030100310
Ketoconazole-Hydrocortisone External Cream 2-2.5 %	90159902783720
Lido BDK External Kit 2.5-2.5 %	90859902906410

Lidocaine HCl External Cream 3 %	90850060103730
Lidocaine HCl External Cream 3.88 %	90850060103775
Lidocaine HCl External Lotion 3 %	90850060104140
Lidocort External Cream 3-0.5 %	89991002263720
Lido-K External Lotion 3 %	90850060104140
LidoPure Patch External Kit 5 %	90859902096420
Lido-Sorb External Lotion 3 %	90850060104140
Lidozion External Lotion 3 %	90850060104140
Livixil Pak External Kit 2.5-2.5 %	90859902906410
Nuvakaan External Kit 2.5-2.5 %	90859902906410
Oracit Oral Solution 490-640 MG/5ML	56202020002020
Oscimin Oral Tablet 0.125 MG	49101030100310
Oscimin Oral Tablet Disintegrating 0.125 MG	49101030107220
Oscimin SR Oral Tablet Extended Release 12 Hour 0.375 MG	49101030107420
Oscimin Sublingual Tablet Sublingual 0.125 MG	49101030100710
Paregoric Oral Tincture 2 MG/5ML	47100040001510
PB-Hyoscy-Atropine-Scopolamine Oral Elixir 16.2 MG/5ML	49109904051030
PB-Hyoscy-Atropine-Scopolamine Oral Tablet 16.2 MG	49109904050320
Phenazopyridine HCl Oral Tablet 100 MG	56300010100305
Phenazopyridine HCl Oral Tablet 200 MG	56300010100310
Phenylephrine HCl Ophthalmic Solution 2.5 %	86350037102010
Phosphasal Oral Tablet 81.6 MG	16992005200322
PR Benzoyl Peroxide Wash External Liquid 7 %	90050010000907
Prilovix External Kit 2.5-2.5 %	90859902906410
Prilovix Lite External Kit 2.5-2.5 %	90859902906410
Prilovix Lite Plus External Kit 2.5-2.5 %	90859902906410
Prilovix Plus External Kit 2.5-2.5 %	90859902906410
Prilovix Ultralite External Kit 2.5-2.5 %	90859902906410
Prilovix Ultralite Plus External Kit 2.5-2.5 %	90859902906410
Prilovixil External Kit 2.5-2.5 %	90859903796420
Quflora FE Pediatric Oral Liquid 0.25-9.5 MG/ML	78450000000915
Quflora Pediatric Oral Solution 0.25 MG/ML	78441000002005
Quflora Pediatric Oral Solution 0.5 MG/ML	78441000002010
Quflora Pediatric Oral Tablet Chewable 0.25 MG	78441000000505
Quflora Pediatric Oral Tablet Chewable 0.5 MG	78441000000510
Quflora Pediatric Oral Tablet Chewable 1 MG	78441000000520
Salicylic Acid External Cream 6 %	90750030003712
Salicylic Acid External Foam 6 %	90750030003940
Salicylic Acid External Gel 6 %	90750030004005
Salicylic Acid External Liquid 27.5 %	90750030000948
Salicylic Acid External Lotion 6 %	90750030004140
Salicylic Acid External Shampoo 6 %	90750030004530
Salicylic Acid External Solution 26 %	90750030002010
Salicylic Acid Wart Remover External Liquid 27.5 %	90750030000948
Salicylic Acid-Cleanser External Kit 6 % (Cream)	90750030406420

Salvax External Foam 6 %	90750030003940
Selenium Sulfide External Shampoo 2.25 %	90300050004525
Sila III External Therapy Pack 0.1 %	9055990268B185
SSKI Oral Solution 1 GM/ML	43202010002060
SSS 10-5 External Cream 10-5 %	90059903203720
SSS 10-5 External Foam 10-5 %	90059903203920
Sulfacetamide-Sulfur-Sunscreen External Kit 9-4.5 %	90059903236420
Urea External Cream 39 %	90660080003724
Urea External Cream 40 %	90660080003725
Urea External Cream 45 %	90660080003730
Urea External Cream 47 %	90660080003732
Urea External Lotion 40 %	90660080004140
Urea Hydrating External Foam 35 %	90669902823935
Urea Nail External Gel 45 %	90660080004045
Ure-K External Cream 50 %	90660080003735
Urimar-T Oral Tablet 120 MG	16992005200330
Urin DS Oral Tablet 81.6 MG	16992005200322
Uro-458 Oral Tablet 81 MG	16992005200320
Urogesic-Blue Oral Tablet 81.6 MG	16992004200325
Uro-MP Oral Capsule 118 MG	16992005200128
Ustell Oral Capsule 120 MG	16992005200130
Vilamit MB Oral Capsule 118 MG	16992005200128
Vilevex MB Oral Tablet 81 MG	16992005200320
Xurea External Cream 39 %	90660080003724
Zilacaine Patch External Therapy Pack 5 %	9085990211B130

Discussion: No comments or questions.

Outcome: The committee unanimously voted to accept the recommendations as presented. None were opposed.

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

DUR/ADHERENCE UPDATE

Drug Use Evaluations (DUEs)

- Statin Use in Persons with Diabetes DUE
 - This is our 2021 2nd quarter Geisinger Health Plan DUE for all LOBs
 - From this report, we identified **1,564 members** age 40 to 75 with at least 2 distinct fills of any diabetic medication(s) without a statin claim. We sent an educational letter to providers to encourage prescribing of a statin to members, if medically appropriate.
 - The Print Shop completed the mail merge and sent out letters to the member's providers on 8/2/2021.
 - We will re-run this data in about 3 months to analyze the impact of the letter.

- See below for the number of letters sent:
 - For COMM: **613**
 - For D6: **372**
 - For TP23: **4**
 - For TP33: **2**
 - For TP41: **2**
 - For TP45: **34**
 - For TP46: **11**
 - For TP49: **2**
 - For TP50: **11**
 - For TP56: **2**
 - For TP64: **3**
 - For TPA6: **2**
 - For TPA7: **3**
 - For TPB3: **1**
 - For TPD2: **1**
 - For TPE0: **4**
 - For TPF0: **1**
 - For TPF2: **2**
 - For TPH2: **0**
 - For TPI0: **4**
 - For TPI2: **4**
 - For TPL0: **0**
 - For TPM2: **2**
 - For TPN1: **1**
 - For TPU1: **2**
 - For TPW1: **2**
 - For WF89: **11**
 - For EMYD: **0**
 - For SASE: **6**
 - For SAI1: **1**
 - For SASF: **1**
 - For SASN: **55**
 - For SASX: **5**
 - For PM70: **2**
 - For PM71: **1**
 - For TG48/TG51: **397**

- Asthma DUE

- This is our 2021 1st quarter Geisinger Health Plan DUE for all LOBs
- From this report, we identified **209 members** who received 4 or more prescriptions for an asthma medication within the past 6 months but did not receive an asthma controller medication in that same 6-month period. We sent letters to providers which included fill history for rescue medications.
- The Print Shop completed the mail merge and sent out letters to the members' providers on 6/18/2021.
- We will re-run this data in about 3 months to analyze the impact of the letter.
- See below for the number of letters sent:
 - For COMM: **79**
 - For D6: **61**
 - For TP23: **1**
 - For TP33: **0**
 - For TP41: **0**
 - For TP45: **3**
 - For TP46: **1**
 - For TP49: **0**
 - For TP50: **1**
 - For TP56: **0**
 - For TP64: **0**
 - For TPA6: **1**
 - For TPA7: **0**
 - For TPB3: **0**
 - For TPD2: **0**
 - For TPE0: **2**
 - For TPF0: **0**
 - For TPI0: **0**
 - For TPI2: **0**
 - For TPL0: **1**
 - For TPM2: **2**
 - For TPN1: **0**
 - For TPU1: **0**
 - For TPW1: **0**
 - For WF89: **5**
 - For EMYD: **17**
 - For SASE: **1**
 - For SAI1: **1**
 - For SASF: **0**
 - For SASN: **6**
 - For SASX: **0**
 - For PM70: **0**
 - For PM71: **0**
 - For TG48/TG51: **26**

- For TPF2: **0**
 - For TPH2: **1**
- Statin Use in Persons with Diabetes DUE
 - This is the 2020 4th quarter MedImpact DUE for Commercial/Exchange and GHP Family
 - From this report, we identified members whose medication history was suggestive of the presence of diabetes and who were not receiving a statin drug during the previous three-month period.
 - The Print Shop completed the mail merge and sent out letters to the member's providers on 12/3/2020.
 - Adam K. re-ran this data on 4/6/2021 to analyze the effectiveness of the letter. Of the original 618 members that we sent letters; 419 are still active. Of those 419 members, 88 now have a claim for a statin medication. This equates to about 21% of the targeted members.
 - See below for letters sent:

▪ For GHS01: 98	▪ For GHS05: 87
▪ For GHS25: 9	▪ For GHS90: 95
▪ For GT045: 33	▪ For GT046: 26
▪ For GT062: 26	▪ For GT095: 87
▪ For GT400: 99	▪ For GT900: 60
- Asthma DUE
 - This is the 2020 3rd quarter MedImpact DUE for all LOBs
 - From this report, we identified members who received 4 or more prescriptions for an asthma medication over a 12-month period but did not receive an asthma controller medication in that same 12-month period.
 - The Print Shop completed the mail merge and sent out letters to the member's providers on 8/26/2020.
 - Adam K. re-ran this data on 12/11/2020 to analyze the effectiveness of the letter. Of the original 412 members that we sent letters, 372 are still active. Of those 372 members, 30 now have a claim for a controller medication. This equates to about 8.1% of the targeted members.
 - See below for letters sent:

▪ For GHS01: 98	▪ For GHS05: 62
▪ For GHS25: 4	▪ For GHS90: 99
▪ For GT023: 2	▪ For GT036: 1
▪ For GT045: 5	▪ For GT046: 6
▪ For GT056: 3	▪ For GT062: 1
▪ For GT070: 1	▪ For GT089: 2
▪ For GT095: 22	▪ For GT106: 1
▪ For GT140: 2	▪ For GT210: 1
▪ For GT291: 1	▪ For GT310: 3
▪ For GT400: 96	▪ For GT902: 2

In Progress

- Working internally to create new quarterly DUEs
- Working on collaboration with PNM to improve statin use (HEDIS measures)
- Working on collaboration with CM to improve medication adherence (HEDIS measures)

Ongoing

- Duplicate Anticoagulant Report
 - We get this report **weekly** for **all LOBs** flagging members filling duplicate anticoagulant medications. We personally reach out to the providers/members of the flagged members to confirm proper medication therapy.
 - For 2021:
 - For COMM (Commercial): **6 members** reviewed and **0 interventions** made
 - For D6 (Exchange): **4 members** reviewed and **0 interventions** made
 - For TG48/GH51: **4 members** reviewed and **1 intervention** made
 - For TP45: **0 members** reviewed and **0 interventions** made
 - For TP56: **0 members** reviewed and **0 interventions** made
 - For EMYD: **2 members** reviewed and **0 interventions** made
 - For MT38: **0 members** reviewed and **0 interventions** made
 - For TP74: **0 members** reviewed and **0 interventions** made
- Duplicate Specialty Therapy
 - We run an in-house retrospective report **quarterly** for **all LOBs** with help from Adam Kelchner and Aubrielle Smith. These members are identified and written up and sent to a medical director if follow up is needed.
 - For Commercial/Exchange/TPA in 2021, we reviewed Q2 2021 data and **0 members** were referred to Dr. Yarczower for additional follow-up.
- Suboxone with an Opioid Report
 - We get this report **weekly** for **all LOBs** from Adam Kelchner and we are writing up each member that flags on the report. These members are being discussed at our weekly meeting with Dr. Meadows. He looks into whether it is appropriate to end the opioid authorizations still in place or if further intervention is required.
 - For Commercial/Exchange/TPA in 2021, see below for the new members reviewed and those referred to Dr. Meadows:
 - For COMM: we have reviewed **7 new members** and **3 members** were referred to Dr. Meadows
 - For D6: we have reviewed **6 new members** and **2 members** were referred to Dr. Meadows
 - For EMYD: we have reviewed **4 new members** and **2 members** were referred to Dr. Meadows
 - For TG48: we have reviewed **3 new members** and **1 member** was referred to Dr. Meadows
- Ending Opioid Authorizations
 - We are working on identifying members who have active opioid authorizations in place but have since started Buprenorphine therapy. The letter is sent to the members notifying them the opioid authorization has been ended due to the start of buprenorphine therapy.
 - For Commercial/Exchange/TPA in 2021, see below for the number of letters we have sent to members notifying them that we are ending their opioid authorization(s):
 - For D6: **1**
 - For COMM: **1**
 - For EMYD: **0**
 - For TG48/TG51: **1**

- Opioid Overutilization Report
 - We get this report **monthly** from PerformRx and we write up each member that flags on the report. We have been monitoring the members that are continuously showing up on the report by any change in their MED. For those members we deem appropriate we will send a letter to their PCP.
 - For Commercial/Exchange/TPA in 2021, see below for the number of reviewed cases.
 - For COMM: we have reviewed **1 patient** and sent **1 case** to Dr. Meadows for review
 - For EMYD: we have reviewed **3 patients** and sent **0 cases** to Dr. Meadows for review
 - For TG48: we have reviewed **2 patients** and sent **0 cases** to Dr. Meadows for review
- FWA Reports
 - We get this report **weekly** for **all LOBs** from Jeremy Baker. We prepare this report by determining which claims need to be verified, and our GHP technician makes calls to pharmacies to correct/verify claims.
 - We review claims for anti-hypertensives, statins, 1-day supply, and inhalers
 - For COMM in 2021, we have reviewed cases and corrected claims, resulting in a **cost savings/avoidance of \$1,307.42**
 - For D6 in 2021, we have reviewed cases and corrected claims, resulting in a **cost savings/avoidance of \$107.18**
 - For TG48, TG51 in 2021, we reviewed cases and corrected claims, resulting in a **cost savings/avoidance of \$239.99**
 - For SASN in 2021, we reviewed cases and corrected claims, resulting in a **cost savings/avoidance of \$583.3**
- Severity Report
 - We get this report **monthly** for **all LOBs** on members who have filled a medication that has a level one interaction with another medication they have a claim for
 - For Commercial/Exchange/TPA in 2021:
 - *We are working with PerformRx on a revision to this report*
- Tobacco Cessation Program
 - We get this report **monthly** to identify members on prolonged tobacco cessation treatment. We send a letter and resource pamphlet to provide additional behavioral health support through Geisinger Health and Wellness.
 - For Commercial/Exchange/TPA in 2021, we have sent letters to the below number of members:
 - For COMM: **11**
 - For D6: **7**
 - For EMYD: **21**
 - For SASN: **0**
 - For SASE: **2**
 - For TG48, TG51: **4**
 - For TPB3: **1**
 - For TP23: **0**
 - For TP45: **0**
 - For TP46: **0**
 - For TP56: **0**
 - For TP88: **0**

- For TPA6: **0**
 - For WF89: **0**
- STENT Adherence Report
 - We get this report **monthly** to identify members on an antiplatelet medication and then flag for betablocker and statin medication claims.
 - In 2021, we have sent letters encouraging adherence to the below number of members:
 - **Members for Antiplatelet:**
 - COMM: **60**
 - D6: **51**
 - EMYD: **4**
 - SASN: **5**
 - TG48, TG51: **11**
 - TP23: **0**
 - TP45: **2**
 - TP46: **1**
 - TP56: **1**
 - TP88: **2**
 - TPA6: **0**
 - WF89: **4**
 - TPD2: **1**
 - SASE: **1**
 - SASF: **1**
 - TPB3: **0**
 - TPF2: **1**
 - TPIO: **1**
 - TPL0: **1**
 - TPM2: **1**
 - **Members for Beta-Blocker:**
 - COMM: **82**
 - D6: **58**
 - EMYD: **4**
 - SASN: **4**
 - TG48, TG51: **38**
 - TP23: **1**
 - TP45: **1**
 - TP46: **0**
 - TP56: **0**
 - TP88: **0**
 - TPA6: **0**
 - WF89: **1**
 - TPIO: **1**
 - SASE: **1**
 - **Members for Statin:**
 - COMM: **98**
 - D6: **61**
 - EMYD: **14**
 - SASN: **3**
 - TG48, TG51: **25**
 - TP23: **2**
 - TP45: **3**
 - TP46: **2**
 - TP56: **0**
 - TP88: **1**
 - TPA6: **2**
 - WF89: **1**
 - SASE: **4**
 - TPB3: **1**
 - TP41: **1**

- *member may flag for more than one measure and are included in the count for each measure
 - We are also attempting telephonic outreach to members who are non-adherent in all 3 measures to encourage adherence.
- **HEDIS Initiatives: *We are awaiting first round of proactive data for 2021***
- **Asthma Medication Ratio (AMR)**
 - Jesse Barsh runs this report **monthly**, and we send letters to the flagged members who have a ratio of controller to total asthma medications of < 0.5.
 - For Commercial/Exchange in 2021, see below for the number of letters sent to members:
 - COMM: **7**
 - D6: **9**
 - EMYD: **0**
 - TG48/TG50: **0**
- **Antidepressant Medication Management (AMM)**
 - Jesse Barsh runs this report **monthly**, and we send letters to the flagged members who appear non-adherent to their antidepressant medications.
 - For Commercial/Exchange in 2021, see below for the number of letters sent to members:
 - Effective Acute Phase:
 - COMM: **0**
 - D6: **0**
 - EMYD: **0**
 - TG48/TG50: **0**
 - Effective Continuation Phase:
 - COMM: **69**
 - D6: **46**
 - EMYD: **0**
 - TG48/TG50: **0**
- **Adherence to Antipsychotics for Individuals with Schizophrenia (SAA)**
 - Jesse Barsh runs this report **monthly**, and we send letters to the flagged members who appear non-adherent to their antipsychotic medications.
 - HEDIS Specifications: The percentage of members 19-64 years of age during the measurement year with schizophrenia or schizoaffective disorder who were dispensed and remained on an antipsychotic medication for at least 80% of their treatment period.
 - For Commercial/Exchange in 2021, see below for the number of letters sent to members:
 - COMM: **0**
 - D6: **1**
 - EMYD: **0**
 - TG48/TG50: **0**
- **Statin Therapy for Patients with Cardiovascular Disease (SPC)**
 - We get this report **monthly** to identify members with cardiovascular disease and who have not received a statin medication or who are non-adherent to statin therapy
 - For Commercial/Exchange in 2021, see below for the number of letters sent to **providers** to encourage statin therapy initiation:
 - COMM: **21**
 - D6: **17**
 - EMYD: **0**

- TG48/TG50: **0**
 - For Commercial/Exchange in 2021, see below for the number of letters sent to **members** to promote statin adherence:
 - COMM: **17**
 - D6: **5**
 - EMYD: **0**
 - TG48/TG50: **0**
- Statin Therapy for Patients with Diabetes (SPD)
 - We get this report **monthly** to identify members with cardiovascular disease and who have not received a statin medication or who are non-adherent to statin therapy
 - For Commercial/Exchange in 2021, see below for the number of letters sent to **providers** to encourage statin therapy initiation:
 - COMM: **196**
 - D6: **105**
 - EMYD: **0**
 - TG48/TG50: **0**
 - For Commercial/Exchange in 2021, see below for the number of letters sent to **members** to promote statin adherence:
 - COMM: **20**
 - D6: **9**
 - EMYD: **0**
 - TG48/TG50: **0**
- Persistence of Beta-Blocker Treatment After a Heart Attack (PBH)
 - We get this report **monthly** to identify members with a diagnosis of AMI who received beta-blocker treatment for 6 months after discharge and who are non-adherent to beta-blocker therapy
 - For Commercial/Exchange in 2021, see below for the number of letters sent to **members**:
 - COMM: **0**
 - D6: **0**
 - EMYD: **0**
 - TG48/TG50: **0**

Completed

- Commercial/Exchange DUR/FWA Program Fliers
 - Last updated 08/2021 next update 02/2022
- Current Provider Letters
 - Congestive Heart Failure DUE
 - Coronary Artery Disease DUE
 - Statin Use in Persons with Diabetes DUE
 - Asthma Med Ratio DUE
 - Opioid Overutilization
 - Severity Report
 - Duplicate Anticoagulant Report
 - Statin Therapy for Patients with Cardiovascular Disease (SPC)
 - Statin Therapy for Patients with Diabetes (SPD)
- Current Member Letters
 - Ending Opioid Authorizations
 - Adherence to Antipsychotics (SAA)
 - Antidepressant Medication Management (AMM)

- Asthma Medication Ratio (AMR)
- Statin Therapy for Patients with Cardiovascular Disease (SPC)
- Statin Therapy for Patients with Diabetes (SPD)
- Persistence of Beta-Blocker Treatment After a Heart Attack (PBH)
- STENT Adherence Report

Discussion: No comments or questions.

Outcome: The committee unanimously voted to accept the recommendations as presented. None were opposed.

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

Meeting adjourned at 3:49 pm

Future Scheduled Meetings

The next bi-monthly scheduled meeting will be held on November 16th, 2021 at 1:00 p.m.

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 or will be held virtually.