P&T Committee Meeting Minutes
Commercial/Marketplace/GHP Kids
November 15, 2022

Present (via Teams):	**Absent:**
Bret Yarczower, MD, MBA – Chair	Kristen Bender, Pharm.D.
Amir Antonius, Pharm.D.	Holly Bones, Pharm.D.
Emily Antosh, Pharm.D.	Alyssa Cilia, RPh
Jeremy Bennett, MD	Michael Evans, RPh
Kim Castelnovo	Nichole Hossler, MD
Kimberly Clark, Pharm.D.	Jason Howay, Pharm.D.
Rajneel Farley, Pharm.D.	Jonas Pearson, RPh
Kelly Faust Pharm.D.	Michael Shepherd, MD
Tricia Heitzman, Pharm.D.	Richard Silbert, MD
Emily Hughes, Pharm.D.	
Keith Hunsicker, Pharm.D.	
Kelli Hunsicker, Pharm.D.	
Derek Hunt, Pharm.D.	
Kerry Ann Kilkenny, MD	
Philip Krebs, R.EEG T	
Briana LeBeau, Pharm.D.	
Ted Marines, Pharm.D.	
Lisa Mazonkey, RPh	
Tyreese McCrea, Pharm.D.	
Perry Meadows, MD	
Jamie Miller, RPh	
Mark Mowery, Pharm.D.	
Austin Paisley, Pharm.D.	
Kimberly Reichard, Pharm.D.	
Melissa Renn, Pharm.D.	
Melissa Sartori, Pharm.D.	
Angela Scarantino	
Kristen Scheib, Pharm.D.	
William Seavey, Pharm.D.	
Leslie Shumlas, Pharm.D.	
Aubrielle Smith Pharm.D.	
Kirsten Smith, Pharm.D.	
Michael Spishock, RPh	
Todd Sponenberg, Pharm.D.	
Jill Stone, Pharm.D.	
Robert Strony, MD MBA	
Luke Sullivan, DO	
Kevin Szczecina, RPh	
Amanda Taylor, MD	
Ariana Wendoloski, Pharm.D.	
Brandon Whiteash, Pharm.D.	
Margaret Whiteash, Pharm.D.	
Jeremy Garris (non-voting participant)	
Mallory Ellis, Pharm.D. (Pharmacy Resident)	
Rachelle Moore (Pharmacy Student)	
Prachi Trivedi (Pharmacy Student)	

Call to Order:
Dr. Bret Yarczower called the meeting to order at 1:01 p.m., Tuesday, November 15, 2022.

Review and Approval of Minutes:
Dr. Bret Yarczower asked for a motion or approval to accept the September 20, 2022 minutes as written. Minutes approved unanimously. None were opposed.

DRUG REVIEWS

RASUVO (methotrexate injection)

Review: Rasuvo is a single dose, manually triggered autoinjector containing methotrexate 50mg/ml indicated for the treatment of adult patients with severe, active rheumatoid arthritis, adult patients with severe, recalcitrant, disabling psoriasis, and patients with polyarticular juvenile idiopathic arthritis. Rasuvo is not indicated for treatment of neoplastic disease and is dosed subcutaneously once weekly at a dose of 7.5mg to 30mg, depending on indication and disease severity. Efficacy of Rasuvo was extrapolated from studies with other formulations of methotrexate, which demonstrated effectiveness of Rasuvo in RA and pJIA. Safety evidence shows no unexpected adverse effects with Rasuvo versus other formulations of methotrexate (injectable and oral).

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

Clinical Discussion: Kim Clark asked if the intention is to only allow a 28 day supply or if members would be allowed to receive a 90 day supply? Allow up to an 84 day supply as no other methotrexate products are limited. No additional 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: Rasuvo is a pharmacy benefit and will not be added to the Commercial, Exchange, or CHIP formularies. The following prior authorization criteria will apply:

- For Rheumatoid Arthritis:
    - Medical record documentation of treatment of severe, active rheumatoid arthritis **AND**
    - Medical record documentation of age 18 years and older **AND**
    - Medical record documentation of therapeutic failure on, intolerance to, or contraindication to at least one prior first line therapy (including NSAIDs) **AND**
    - Medical record documentation of therapeutic failure on, intolerance to, or contraindication to methotrexate vials
- For Polyarticular Juvenile Idiopathic Arthritis:
    - Medical record documentation of treatment of active polyarticular juvenile idiopathic arthritis **AND**
    - Medical record documentation of therapeutic failure on, intolerance to, or contraindication to at least one prior first line therapy (including NSAIDs) **AND**
    - Medical record documentation of therapeutic failure on, intolerance to, or contraindication to methotrexate vials

- For Psoriasis:
    - Medical record documentation of treatment of severe, recalcitrant, disabling psoriasis **AND**
    - Medical record documentation of age 18 years and older **AND**
    - Medical record documentation of therapeutic failure on, intolerance to, or contraindication to at least one prior therapy **AND**
    - Medical record documentation of therapeutic failure on, intolerance to, or contraindication to methotrexate vials

GPI Level: GPI-12

QUANTITY LIMIT: 4 syringes per 28 days

FORMULARY ALTERNATIVES: methotrexate vials, methotrexate tablets

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

MOUNJARO (tirzepatide)

Review: Mounjaro is indicated for adults with type 2 diabetes mellitus to improve glycemic control as an adjunct to diet and exercise. Mounjaro is the first dual agonist of glucose-dependent insulin (GIP) receptor and glucagon-like peptide-1 (GLP-1) receptor. Mounjaro should be considered for use when a patient without ASCVD is concerned about weight loss and needs additional glycemic control. Mounjaro may provide kidney protection.

Mounjaro is available as a single-dose injector pen in various strengths. The initial dosing recommendation is 2.5mg injected subcutaneously once and can be increased to 5mg after 4 weeks and continually increased in 2.5mg increments every 4 weeks up to a maximum of 15 mg once weekly.

A total of 5 clinical trials (SURPASS-1, -2, -3, -4, and -5) evaluated the efficacy of Mounjaro whether as monotherapy or compared to other therapies. Mounjaro produced a statistically significant reduction in HbA1c compared to placebo, semaglutide 1 mg, insulin degludec 100 units/mL, and insulin glargine 100 units/mL.
Mounjaro is contraindicated in patients who have a personal or family history of medullary thyroid carcinoma or who have Multiple Endocrine Neoplasia Syndrome (MEN2). Mounjaro carries warnings/precautions for pancreatitis, hypersensitivity reactions, and hypoglycemia when used concomitantly with insulin or insulin secretagogues. Mounjaro may alter the absorption of oral medications due to delayed gastric emptying. The most common adverse reactions associated with Mounjaro (≥5% of patients and greater than placebo) are nausea, vomiting, diarrhea, constipation, decreased appetite, dyspepsia, and abdominal pain.

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

Clinical Discussion: Was there a detection of any reduction in CV risk? Nothing included in the package insert. We don't believe CV outcomes have been analyzed yet.

Weight loss as the primary indication is not a reason to include this, but it is a beneficial side effect of the medication.

Was there any increased risk of hypoglycemia? There is a risk if this is used in combination with insulin or a sulfonylurea. There were cases of severe hypoglycemia in the group of patients where Mounjaro was added onto basal insulin. When used as monotherapy there were no severe hypoglycemic events in clinical trials.

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 amended. None were opposed.

Outcome: Mounjaro will be a pharmacy benefit and will be added to formulary at the Brand Preferred tier. Mounjaro will require a prior authorization with the following criteria:

- Medical record documentation of a diagnosis of Type 2 diabetes mellitus

GPI Level: GPI-12

QUANTITY LIMIT: 2 mL every 28 days for all strengths

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

ADLARITY (donepezil transdermal system)

Review: Adlarity is an acetylcholinesterase inhibitor indicated for the treatment of mild, moderate, and severe dementia of Alzheimer's type.

Alzheimer disease (AD) is the most common cause of dementia and one of the leading sources of morbidity and mortality in the aging population. The hallmark neuropathic changes of AD are diffuse and neuritic plaques and neurofibrillary tangles. A definitive diagnosis of AD requires histopathologic examination, which is rarely done in life, but most studies of AD rely on clinical criteria to define cases. Clinical presentations of AD include but are not limited to deterioration in cognition, functional ability, behavior, and non-cognitive symptoms including depression, delusions, and hallucinations.

Multiple clinical studies were conducted comparing donepezil tablets versus placebo in mild to moderate AD and moderate to severe AD. These studies found donepezil treatment was statistically significantly superior to placebo when assessing daily function, cognitive performance, and overall clinical effect. There is no evidence that donepezil alters the course of the underlying dementing process.

The efficacy of Adlarity is based on a relative bioavailability study in healthy subjects comparing Adlarity transdermal system to Aricept tablets. In a relative bioavailability study following administration of multiple doses in 60 healthy volunteers, donepezil exposure (i.e., AUC_{tau} and C_{max} at steady state) from once weekly Adlarity 10 mg/day was comparable with that from daily donepezil tablets 10 mg/day. Donepezil exposure was 21-24% higher when applied to the back.

Adhesion of Adlarity was assessed for both 5mg/day and 10mg/day doses over a period of 168-hours. In subjects wearing 5mg/day patch and 10mg/day patch on the back, 94% and 91% of the patches exhibited 80% or greater surface area adhesion at all timepoints evaluated (every 12 hours) respectively. In a separate study, which assessed wear at different application sites (back, thigh, and buttock), at least 85% of the transdermal systems applied at every site exhibited 80% or greater surface area adhesion for the duration of wear.

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

Clinical Discussion: Was there any observable difference in outcomes between those on pills vs. those on patches? Nothing that we were able to identify.

No additional 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: Adlarity is a pharmacy benefit and will not be added to the Commercial, Exchange, or CHIP formularies. The following prior authorization criteria will apply:

- Prescription written by or in consultation with a neurologist **AND**
- Medical record documentation of a diagnosis of ALS (amyotrophic lateral sclerosis) **AND**
- Medical record documentation of baseline functional status (as evidenced by a scoring system such as ALSFRS-R, or by physician documentation of subjective reports on speech, motor function, pulmonary function, etc.) **AND**
- Medical record documentation that Radicava is being given in combination with riluzole OR intolerance or contraindication to riluzole
- Medical record documentation of a diagnosis of mild to moderate dementia of Alzheimer's type **AND**
- Medical record documentation of therapeutic failure on, intolerance to, or contraindication to three (3) formulary alternatives, one of which must be oral donepezil

OR

- Medical record documentation of a diagnosis of severe dementia of Alzheimer's type **AND**
- Medical record documentation of therapeutic failure on, or contraindication to donepezil tablets

QUANTITY LIMIT: 4 transdermal patches per 28 days

MEDISPAN AUTHORIZATION LEVEL: GPI-12

RPH SIGNOFF REQUIRED: No

FORMULARY ALTERNATIVES: donepezil tablets, donepezil ODT, galantamine tablets, galantamine ER capsules, rivastigmine capsules

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

VOQUENZA (vonoprazan)

Review: Voquezna Triple Pak and Voquezna Dual Pak are indicated for the treatment of Helicobacter pylori (H. pylori) infection in adults. H. pylori is a common bacterial infection worldwide, with an overall prevalence in the United States of 35%. Voquezna Triple Pak contains vonoprazan tablets, amoxicillin capsules, and clarithromycin tablets while Voquezna Dual Pak contains vonoprazan tablets and amoxicillin capsules. Vonoprazan suppressed basal and stimulated gastric acid secretion at the secretory surface of the gastric parietal cell through inhibition of the H+, K+-ATPase enzyme system in a potassium competitive manner. Vonoprazan has been characterized as a type of gastric proton pump inhibitor since it blocks the final step of acid production. Amoxicillin is a beta-lactam antibacterial drug. Clarithromycin is a macrolide antimicrobial drug. Acid suppression enhances the replication of H. pylori bacteria and the stability and effectiveness of antimicrobials in the treatment of H. pylori infection. The standard of care for H. pylori treatment includes an acid suppressive agent used in combination with antibiotic therapy. Resistance to several of the antibiotics used in these regimens has risen in the United States which has led to declining eradication rates. The choice of initial antibiotic regimen to treat H. pylori should be guided by previous exposure to macrolides, high levels of macrolide resistance where the patient lives or has lived, and presence of a penicillin allergy.

The safety and effectiveness of Voquezna were evaluated in the Phase 3, randomized, controlled, double-blind, triple therapy/open-label dual therapy pHalcon-HP trial. 992 adults with H. pylori infection confirmed by urea breath test were randomized 1:1:1 to receive Voquezna Triple Pak, Voquezna Dual Pak, or lansoprazole triple-therapy. Both Voquezna products were shown to be non-inferior to lansoprazole triple therapy in patients who did not have a clarithromycin- or amoxicillin-resistant strain of H. pylori at baseline. Both Voquezna regimens were shown to be superior to lansoprazole triple-therapy in patients who had a clarithromycin-resistant strain of H. pylori at baseline and in the overall population.

Voquezna is contraindicated in patients with known hypersensitivity to vonoprazan, amoxicillin, or any other beta-lactams for both products and clarithromycin, or any other antimicrobial for the Voquezna Triple Pak. Voquezna is also contraindicated with rilpivirine-containing products. Voquezna has warnings and precautions for hypersensitivity reactions, severe cutaneous adverse reactions (SCAR), and Clostridioides difficile-associated diarrhea (CDAD). Voquezna Triple Pak has additional contraindications due to the clarithromycin component that include: pimozide; lomitapide, lovastatin, and simvastatin; ergot alkaloids (ergotamine or dihydroergotamine); colchicine in renal or hepatic impairment; and history of cholestatic jaundice/hepatic dysfunction with use of clarithromycin. Voquezna Triple Pak has additional warnings and precautions due to the clarithromycin component that include: QT prolongation; hepatotoxicity; serious adverse reactions due to concomitant use with other drugs (colchicine, some lipid-lowering agents, some calcium channel blockers, and other drugs); embryo-fetal toxicity; and myasthenia gravis.

Safety and effectiveness of Voquezna in pediatric patients have not been established. In geriatric patients, Voquezna triple Pak increased the risk of torsades de pointes due to the clarithromycin component. Especially in elderly patients, there have been reports of colchicine toxicity with concomitant use of clarithromycin and colchicine, some of which occurred in patients with renal insufficiency; deaths have been reported in some patients. The most common adverse reactions (≥2%) for Voquezna Dual Pak were diarrhea, abdominal pain, vulvovaginal candidiasis, and nasopharyngitis. The most common adverse reactions (≥2%) for

Voquezna Triple Pak were dysgeusia, diarrhea, vulvovaginal candidiasis, headache, abdominal pain, and hypertension.

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

Clinical Discussion: Does clarithromycin needs to be avoided due to increased risk of torsades de pointes or increased risk of myocardial infarction? There is an increased risk of QT prolongation. Torsades de pointes was increased in geriatric patients due to the clarithromycin component.

No additional 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: Voquezna is a pharmacy benefit and will not be added to the Commercial, Marketplace, or GHP Kids formularies. The following prior authorization criteria will apply:

- Medical record documentation of a diagnosis of *Helicobacter pylori (H. pylori)* infection **AND**
- Medical record documentation that member is 18 years of age and older **AND**
- Medical record documentation of therapeutic failure on, intolerance to, or contraindication to two prior therapies for *H. pylori* infection

GPI LEVEL: GPI-12

QUANTITY LIMIT:

- **Voquezna Triple Pak:** 112 tablets/capsules per 14 days
- **Voquezna Dual Pak:** 112 tablets/capsules per 14 days

AUTHORIZATION DURATION: 14 days, RX count 1

FORMULARY ALTERNATIVES: amoxicillin, clarithromycin, levofloxacin, metronidazole, rifabutin, tetracycline, esomeprazole, lansoprazole, omeprazole, pantoprazole, rabeprazole

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

AMVUTTRA (vutrisiran)

Review: Amvuttra is indicated for the treatment of polyneuropathy of hereditary transthyretin-mediated amyloidosis (hATTR) in adults. Amvuttra is the third approved agent for the treatment of the polyneuropathy of hATTR, a rare, genetic, and progressive multi-organ disorder. Treatment options for hATTR have historically been limited to organ transplantation (liver, heart) or investigational agents. Vutrisiran is a double-stranded siRNA-GalNAc conjugate that causes degradation of mutant and wild-type transthyretin (TTR) mRNA through RNA interference, which results in a reduction of serum TTR protein and TTR protein deposits in tissues. Amvuttra joins

Onpattro (patisiran), another small interfering ribonucleic acid (siRNA) treatment produced by the same manufacturer given as an IV infusion every 3 weeks as well as Tegsedi (inotersen), an antisense oligonucleotide (ASO) agent, self-administered as a weekly subcutaneous injection, as the third agent FDA approved for patients with polyneuropathy of hATTR. Both siRNA and ASO have similar mechanisms of action by targeting the mRNA of TTR, but differ by drug delivery, administration, efficacy, and safety. Currently there are two other agents in Phase 3 clinical trials being evaluated for the same indication. Amvuttra is a 25mg/0.5ml single-dose prefilled syringe administered by subcutaneous injection at a fixed dose of 25mg once every 3 months. Amvuttra should be administered by a healthcare professional.

The FDA approval of Amvuttra is based on positive 9-month results from the Phase 3 HELIOS-A study (NCT03759379), a randomized, open-label, multicenter study of patients with polyneuropathy caused by hATTR amyloidosis. The trial included patients age 18-85 with a diagnosis of hATTR with a Neuropathy Impairment Score (NIS) of 5-130, and Polyneuropathy Disability (PND) score of <IIIb. Patients who received prior TTR-lowering treatment (Onpattro, Tegsedi) were excluded from the trial, however prior TTR stabilizer (Vyndamax, Vyndaqel) use was permitted, but therapy had to be discontinued prior to enrollment in the trial. The efficacy of Amvuttra was assessed by comparing the Amvuttra group in the HELIOS-A study with the placebo group from the Phase 3 APOLLO study (NCT01960348) of Onpattro. The primary endpoint was change from baseline to Month 9 in the modified neurologic impairment score + 7 (mNIS+7) and resulted in statistically significant improvements with the Amvuttra group having a 2.2 decrease in score from baseline compared to placebo group having a 14.8 increase in score from baseline (higher scores indicate severity of disease). The NIS objectively measures deficits in cranial nerve function, muscle strength, and reflexes, and the +7 assesses postural blood pressure, quantitative sensory testing, and peripheral nerve electrophysiology. Secondary endpoints evaluated in the trial included Change from baseline to Month 9 in the Norfolk quality of life-diabetic neuropathy (Norfolk QoL-DN) score, 10-meter walk test (10-MWT), and modified body mass index (mBMI), with statistically significant improvements seen in the Norfolk QoL-DN and 10-MWT scores for the Amvuttra group and the mBMI score nominally favoring the Amvuttra group.

The most commonly reported adverse events in Amvuttra-treated patients included arthralgia (11%), dyspnea (7%), and vitamin A decrease (7%). A serious adverse reaction of atrioventricular (AV) block (heart block) occurred in 2 patients (1.6%) treated with Amvuttra, including one case of complete AV block. Injection site reactions were reported in 5 patients (4%) and were mild and transient. Because of the decrease in serum vitamin A levels, supplementation at the recommended daily allowance of vitamin A is advised for patients taking Amvuttra. Amvuttra has no black box warnings.

Amvuttra has the convenience of a quarterly SC administration without the safety concerns and monitoring requirements of Tegsedi (REMS program for thrombocytopenia and glomerulonephritis) and given less frequently than the IV infused Onpattro. While Tegsedi is self-administered, both Amvuttra and Onpattro have potential to be administered through Site of Care programs in the home by a healthcare professional. Thus, IPD Analytics anticipates Amvuttra will become a preferred product for the treatment of hATTR-PN. Amvuttra is also currently undergoing Phase 3 trials in the HELIOS-B study to evaluate it's effectiveness for treatment of patients with cardiomyopathy of transthyretin-mediated amyloidosis (ATTR-CM), including both hATTR and wild-type ATTR (ATTRwt). Topline results are expected in early 2024.

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

Clinical Discussion: Can we modify the first criterion to state Medical Geneticist? Yes, it will be updated.

Did any of the studies specify whether this is a single gene variant or is there a host of variants that could be mediating this disease? We are unsure. Phil will investigate to ensure we are aligned if we get requests for the genetic testing. We will also look at the other medications indicated for this.

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

Financial Discussion: No comments or questions. Austin voiced that he is in agreement with adding Amvuttra to the site-of-care list. The committee unanimously voted to accept the recommendations as presented. None were opposed.

Outcome: Amvuttra will be covered as a medical benefit for Commercial, Exchange, and CHIP members. Amvuttra will be added to the medical benefit cost share list when processed on the medical benefit. If processed at a specialty pharmacy, Amvuttra will process at the Specialty tier or the Brand Non-preferred tier for members with a three-tier benefit. The following prior authorization criteria will apply:

- Prescription written by or in consultation with a neurologist, specialist at a hereditary transthyretin-mediated amyloidosis (hATTR) treatment center, or geneticist **AND**
- Medical record documentation of age greater than or equal to 18 years **AND**
- Medical record documentation of diagnosis of hereditary transthyretin-mediated amyloidosis as confirmed by all of the following:
    - Biopsy of tissue/organ to confirm amyloid presence **AND**
    - Immunohistochemistry or mass spectroscopy to differentiate ATTR amyloidosis from amyloid light-chain amyloidosis **AND**
    - Genetic testing to differentiate between hereditary and wild-type ATTR amyloidosis **AND**
- Medical record documentation of Amvuttra being used to treat polyneuropathy **AND**
- Medical record documentation of familial amyloid polyneuropathy (FAP) stage 1-2 and/or polyneuropathy disability score of I, II, IIIA, or IIIB **AND**
- Medical record documentation of a dose and duration of therapy that is consistent with FDA-approved package labeling, nationally recognized compendia, or peer-reviewed medical literature **AND**
- Medical record documentation that Amvuttra will not be used in combination with other RNA interference treatment **AND**
- Medical record documentation that the member has been evaluated and treated by a contracted Center of Excellence in amyloidosis management

NOTES: Center of Excellence (COE) requirements do not apply to strategic partner TPA plans (i.e., Northern Light Health).

<u>FAP stage:</u>

1-unimpairmend ambulation
2- assistance with ambulation

3- wheelchair-bound or bedridden

Polyneuropathy disability score:

I- preserved walking, sensory disturbances
II- impaired walking without need for stick/crutches
IIIa- walking with 1 stick/crutch
IIIb- walking with 2 sticks/crutches
IV-wheelchair-bound or bedridden

GPI Level: GPI-10

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. The medication will no longer be covered if the member progresses to FAP stage 3 and/or polyneuropathy disability score IV (wheelchair-bound or bedridden).

QUANTITY LIMIT: 0.5 mL per 84 days to be coded in Darwin for claims processed through specialty vendor. Currently Amvuttra does not have a unique HCPCS code assigned to it and is billed with a miscellaneous Jcode when billed through medical. Alnylam Pharmaceuticals submitted an application to CMS in the 3rd quarter 2022 for a unique HCPCS code, these codes are expected to be released in January 2023. At that time a Facets RX count quantity limit should be added respective of the updated HCPCS code units to reflect a limitation of one 25mg (0.5ml) syringe every 3 months to policy quantity limit language.

RPH SIGNOFF REQUIRED: Yes

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

EPSOLAY (benzoyl peroxide 5%)

Review: Epsolay is a recently approved topical cream for the treatment of inflammatory lesions of rosacea in adults. Epsolay is the only FDA-approved benzoyl peroxide product that is indicated for the treatment of inflammatory lesions of rosacea in adults. It is the first and only microencapsulated benzoyl peroxide product. The benzoyl peroxide is encapsulated within silica-based microcapsules which create a barrier between the skin and the medication. These microcapsules are designed to slowly release benzoyl peroxide over time which makes the product more tolerable and effective. It comes as a 5% cream in a 30-gram pump. Each gram of Epsolay contains 50 mg of benzoyl peroxide. Patients should prime the pump before use. It is recommended to apply a pea-sized amount once daily to each area of the face on clean and dry skin. Patients should avoid the eyes, lips, and mouth. Patients should wash hands after use and only use Epsolay for topical use.

Epsolay was evaluated in two multicenter, randomized, double-blind, vehicle-controlled trials in subjects with moderate-to-severe papulopustular rosacea. These trials were conducted with 733 subjects who were all 18 years old or older. Patients were treated with either Epsolay or a vehicle cream for 12 weeks. Patients in the trial had to have a minimum of 15 to 70 inflammatory lesions and no more than 2 nodules. A nodule was defined as a papule or pustule greater than 5 mm in diameter. Patients also must have had an Investigator Global Assessment

(IGA) score of 3 (moderate) or 4 (severe). IGA is a tool used to assess the severity of a patient's rosacea.

There were two primary efficacy endpoints that were looked at in these trials. The first endpoint was based on the patient's IGA scores. A "treatment success" was defined as an IGA score of 0 (clear) or 1 (almost clear). The second endpoint was an absolute change in the amount of inflammatory lesions when compared to baseline.

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: Epsolay is a pharmacy benefit and will not be added to the Commercial, Marketplace, or CHIP formulary. Epsolay will be added to existing policy 112.0 (azelaic acid/Finacea). Policy 112.0 will be updated to the following:

- Medical record documentation of a diagnosis of rosacea with inflammatory lesions **AND**
- Medical record documentation of therapeutic failure on, intolerance to, or contraindication to three (3) formulary alternatives

GPI LEVEL: GPI-12 for Finacea Foam, GPI-14 for Epsolay

RPH SIGNOFF REQUIRED: No

FORMULARY ALTERNATIVES: metronidazole (gel/cream/lotion), ivermectin 1% cream, azelaic acid gel

Additional Recommendations:

- Remove the PA from Azelaic Acid Gel for Commercial/Exchange and CHIP
- Update Commercial/Exchange policy 112.0 to both Finacea Foam and Epsolay
    - The policy will now read:
    - Medical record documentation of a diagnosis of **rosacea with inflammatory lesions** AND
    - Medical record documentation of therapeutic failure on, intolerance to, or contraindication to **three (3)** formulary alternatives

    GPI LEVEL: GPI-12 for Finacea Foam, **GPI-14 for Epsolay**

    FORMULARY ALTERNATIVES: metronidazole (gel/cream/lotion), **ivermectin 1% cream, azelaic acid gel**

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

EYSUVIS (loteprednol etabonate ophthalmic suspension)

Review: Eysuvis is a corticosteroid indicated for the short-term (up to two weeks) treatment of the signs and symptoms of dry eye disease.

Eysuvis 0.25% is supplied as sterile ophthalmic suspension. It is available in a 10 mL bottle. It contains 2.5 mg/mL of loteprednol etabonate. One to two drops of Eysuvis should be administered into each eye four times daily for up to two weeks. This should only be renewed after examination under magnification such as a slit lamp and evaluation of the intraocular pressure.

Approximately 16 million people in the United States have dry eye disease and approximately 75-90% experience dry eye flares. Kala estimates these patients may experience as many as 6 flares per year. Dry eye disease flares are a rapid-onset, inflammation-driven response to a variety of triggers that typically cannot be managed with a patient's ongoing maintenance therapy (e.g. artificial tears, chronic prescription therapies). Because inflammation can play a key role in dry eye disease, topical corticosteroids are an effective treatment option for dry eye flares and have been used off-label for many years. Options include loteprednol 0.5% suspension and 0.1% fluorometholone suspension. There were two case studies showing relief of symptoms and improvement in objective measures with nonpreserved methylprednisolone drops.

The first line treatment for patients that have dry eye disease are tear supplementation, environmental coping strategies, amelioration of eyelid abnormalities, application of warm compress, and discontinuation of any medications that contribute to dryness. Treatment involves topical cyclosporine, topical lifitegrast, and intranasal varenicline. Low-dose glucocorticoid eye drops can help relieve the symptoms and signs of dry eye disease and are useful on a short term basis. These drops can have significant side effects with continued use, including cataracts and glaucoma. As topical steroids have potential risk, they should be administered under the direction and continued supervision of an eye care professional.

A prospective multicenter randomized, double-blind study by Sheppard et al showed that loteprednol etabonate 0.5% induction prior to initiation of long-term topical cyclosporine accelerated improvement of dry eye signs and symptoms and significantly reduced cyclosporine stinging compared to artificial tears.

Eysuvis is the only FDA approved short term prescription eye drop that quickly treats at the source of dry eye symptom flare-ups. Eysuvis is a novel formulation that utilizes mucus-penetrating particle drug delivery technology to enhance penetration of loteprednol, a corticosteroid, into target tissue of the eye. Eysuvis is intended to be used intermittently for the treatment of dry eye flares; however, it may also be used as induction therapy for the first few weeks to provide relief while waiting for chronic therapies, such as Xiidra and Restasis to start working. Although, this is the first FDA-approved corticosteroid indicated for the treatment of dry eye disease, ophthalmic corticosteroids have been prescribed off-label for this condition for many years. There are no studies comparing Eysuvis to other topical steroids for the treatment of dry eye disease.

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

Clinical Discussion: Kim Clark recommended approving by GPI-14 since the GPI-12 will capture all other loteprednol ophthalmic products. 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: Eysuvis is a pharmacy benefit that will not be added to the Commercial, Exchange, or CHIP formularies. Eysuvis will require a prior authorization with the following criteria:

- Prescription written by an optometrist or ophthalmologist **AND**
- Medical record documentation that Eysuvis is being used for the short-term (up to two weeks) treatment of the signs and symptoms of dry eye disease **AND**
- Medical record documentation that Eysuvis will be prescribed according to the Food and Drug Administration (FDA) approved dose* **AND**
- Medical record documentation of therapeutic failure on, intolerance to, or contraindication to loteprednol 0.5% suspension **OR** fluorometholone 0.1% suspension

***NOTE:** The FDA approved dose is one to two drops into each eye four times daily for up to two weeks.

GPI LEVEL: GPI-14

FORMULARY ALTERNATIVES: hydrocortisone, cortisone, dexamethasone, fludrocortisone, methylprednisolone, prednisone, prednisolone

QUANTITY LIMIT: 8.3 mL (1 bottle) per 14 days, min and max day supply 14

AUTHORIZATION DURATION: 14 days, Rx count 1

Additional Recommendations: Policy 567.0 for loteprednol suspension, it is recommended to update the loteprednol suspension section of the policy to include criteria for dry eye disease. It is recommended to update the criteria to the following:

For loteprednol suspension

- Medical record documentation for treatment of steroid-responsive inflammatory conditions of the palpebral and bulbar conjunctiva, cornea, and anterior segment of the globe **OR**
- Medical record documentation of use for post-operative inflammation and pain following ocular surgery **AND**
- Medical record documentation of therapeutic failure on, intolerance to, or contraindication to three (3) formulary alternatives

OR

- Medical record documentation for use of a medically accepted indication for the short-term treatment of the signs and symptoms of dry eye disease

Discussion/Outcome: No comments or questions. 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.

PRIORIX (Measles, Mumps, Rubella Vaccine, Live)

Review: Priorix is a vaccine indicated for active immunization for the prevention of measles, mumps, and rubella in individuals 12 months of age and older. Priorix is a suspension for injection supplied as a single-dose vial of lyophilized antigen component to be reconstituted with the accompanying prefilled syringe of sterile water diluent component. A single dose after reconstitution is approximately 0.5 mL. The first dose is administered at 12 through 15 months of age, and the second dose is administered at 4 through 6 years of age.

In clinical trials, Priorix has similar effects to M-M-R II. Allergic vaccine reactions, febrile seizures, thrombocytopenia, syncope, latex, risk of vaccine virus transmission, and limitation of vaccine effectiveness are listed on the label under warnings and precautions. Adverse reactions include pain, redness, swelling, irritability, loss of appetite, drowsiness, and fever.

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: Dr. Hossler asked why we put vaccines on a formulary. To allow members to receive them by a pharmacist. She questioned if the cost sharing was the same regardless of administration site which it is.

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

Outcome: Priorix will be covered as a medical or pharmacy benefit and will not require prior authorization. Priorix will be covered as a preventive vaccine for a $0 copay.

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

JYNNEOS (Smallpox and Monkeypox Vaccine, Live, Non-replicating)

Review: Jynneos (Smallpox and Monkeypox Vaccine) was FDA approved in 2019 and is indicated for the prevention of smallpox and monkeypox infection in patients aged 18 years or older that are determined to be at high risk of contracting monkeypox or smallpox infection. Jynneos is currently not approved by the FDA for use in patients less than 18 years old, however, it is available for use, under an Emergency Use Authorization, which allows for its use in adolescent and pediatric patients less than 18 years old. Under the EUA, it is recommended that children at risk or post-exposure prophylaxis (PEP) be considered for vaccination as young as 6 months. For a child younger than 6 months, the CDC recommends consulting with public health authorities for Jynneos use.

As of Oct 21,2022, the CDC does not recommend routine vaccination or pre-exposure prophylaxis for the general public as data suggest the specific populations for the 2022 outbreak are more impacted. Those groups include, gay, bisexual, MSM and non-binary people with a new diagnosis of an STD within 6 months and those who have more than one sex partner. Also included are people who have sex at a commercial sex venue within the past 6 months and sex in association with a large public event in a geographic area when monkeypox transmission is occurring. Sexual partners of people with the previous risks and those who anticipate experiencing the above risks.

After monkeypox exposure, patients will typically develop a rash that is similar in appearance to smallpox. The rash can appear on or near the genitals, hands, feet, chest, face, or mouth. Other symptoms of infection can include fever, chills, swollen lymph nodes, exhaustion, body aches, headache, and respiratory symptoms. The incubation period of monkeypox is 3-17 days with illness lasting from 2-4 weeks. For known exposure to disease, it is recommended, to administer Jynneos within 4 days to prevent or decrease severity of disease.
Jynneos' mechanism of action is defined by eliciting both a humoral and cellular immune mediated responses to ortho-poxviruses. Smallpox and monkeypox vaccine are a live, third-generation smallpox vaccine containing Modified Vaccinia Ankara, which is replication deficient and cannot cause disease in humans or reproduce in human cells. (1)

Jynneos vaccine is given by administering two doses of 0.5 ml subcutaneously 4-weeks apart. Jynneos is supplied as a frozen single-dose vial. Once thawed, it should be used immediately or refrigerated according to package instructions and used within 12 hours. On Aug 9, 2022, an EUA was approved to increase vaccine supply for the current 2022 outbreak by allowing two doses of 0.1 ml to be administered intradermally 4 weeks apart. The EUA also allowed for administration subcutaneously only of 0.5ml in patients aged 18 years or less. Booster doses in the community setting are still being determined, while in the occupational setting (those that work with and encounter orthopoxviruses) should be vaccinated every 2 to 10 years. Currently, there is no human data available for the efficacy of Jynneos vaccine. Data was inferred from animal studies and immunogenicity studies which analyzed the number of neutralizing antibodies produced in comparison to smallpox vaccine, ACAM2000. ACAM2000 was previously approved for prevention of smallpox infection and has an off-label indication for prevention of monkeypox. The primary immunogenicity endpoint was geometric mean titer (GMT) of vaccinia neutralizing antibodies assessed by PRNT at "peak visits" defined as two weeks after the second dose of JYNNEOS and four weeks after the single dose of ACAM2000. Analyses of antibody responses were performed in the per-protocol immunogenicity (PPI) population, consisting of individuals who received all vaccinations and completed all visits up until the peak visit without major protocol violations pertaining to immunogenicity assessments. Table 2 presents the pre-vaccination and "peak visit" PRNT GMTs from Study 7. Per results,

Jynneos produced more neutralizing antibodies in comparison to ACAM2000, which indicates that this Jynneos, maybe as, if not, more effective in building immunity against both smallpox and monkeypox viruses.

Adverse events of Jynneos include both local and systemic reactions such as pain (84.9%) redness (60.8%), swelling (51.6%), itching (43.1%) muscle pain (42.8%), headache (34.8%), fatigue (30.4%), nausea (1.5%), chills (10.4%) and fever (1.7%). Serious adverse events include cardiovascular side effects such as Cardiac disorder (SUBQ: 1% to 2%; including ECG abnormality [abnormal T waves on ECG, increased ST segment on ECG, inversion T wave on ECG], palpitations, tachycardia, troponin increased in blood specimen)

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: Jynneos will be both a medical and pharmacy benefit for subcutaneous administration for members 18 years and older and a medical benefit only for intradermal administration and for members 18 years or younger. It will be added to the vaccine tier when commercially available. It will be covered as a preventative vaccine for $0 copay.

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

CAROSPIR (spironolactone)

Review: CaroSpir is available as a 25 mg/5 mL suspension (5 mg/mL). It is indicated for the treatment of Class III or IV heart failure and reduced ejection fraction, as add-on therapy for the treatment of hypertension, and for the management of edema in adult cirrhotic patients when edema is not responsive to fluid and sodium restriction.

To note CaroSpir oral suspension is not therapeutically equivalent to tablet forms of Spironolactone and should not be used in patients requiring a dose greater than 100 mg, as dosages over 100 mg may cause higher than expected Spironolactone concentrations compared to the tablet formulation. I will discuss dosing specific to CaroSpir next.

Dosing for the treatment of heart failure is as following: patients with a serum potassium of <5 mEq/L and an eGFR > 50 mL/min/1.73m^2 should initiate therapy at 10 mg (2 mLs) to 20 mg (4 mLs) once daily and titrate their dose up to 37.5 mg (7.5 mLs) once daily as tolerated. Potassium and eGFR should be closely monitored and the dose adjusted if necessary.

Dosing for the treatment of hypertension is as follows: initiate a dose of 20 mg (4 mLs) daily in 1 or 2 divided doses and titrate up to 75 mg (15 mLs) in 1 or 2 divided doses.

Dosing for the treatment of Edema associated with Hepatic Cirrhosis is as follows: initiate 75 mg (15 mLs) daily in 1 or 2 divided doses. Therapy is typically initiated in a hospital setting and titrated slowly.

CaroSpir is contraindicated and should not be used in patients who have a diagnosis of hyperkalemia, Addison's disease or in conjunction with Eplerenone. With regards to warnings and precautions, CaroSpir is a potassium sparing aldosterone antagonist and for this reason may cause fluid and electrolyte imbalances especially in patients with heart failure, renal disease, or cirrhosis. Monitor and correct electrolyte imbalances if they occur (hyponatremia, hypomagnesemia, hypocalcemia, and hyperkalemia) throughout therapy with CaroSpir. With CaroSpir patients will increase fluid output which can lead to hypotension and worsening renal function, monitoring for drug interactions and renal function is important to ensure proper dosing and prevent adverse side effects. As seen with Spironolactone tablets, CaroSpir has the potential to cause gynecomastia (increase in breast gland tissue in boys or men). This is also the most prevalent adverse reaction associate with CaroSpir.

Adverse reactions include: renal dysfunction, GI side effects like diarrhea, cramping, nausea and vomiting, gynecomastia. As mentioned above it is important to identify drug interactions including medications that can increase potassium like ACE inhibiters, ARBs, aldosterone blockers, NSAIDs, heparin and low molecular weight heparin, and trimethoprim. CaroSpir will work to reduce renal clearance of medications like Lithium which can lead to lithium toxicity and increase levels of Digoxin if administered together.

The use of mineralocorticoid receptor antagonists for the treatment of hypertension in pregnancy is generally not recommended as spironolactone can cause feminization of a male fetus and high dosages can be associated with intrauterine growth restriction. Use of alternative agents is recommended.

Safety and effectiveness in pediatric patients has not been established. Monitoring is required for the geriatric population in the presence of decreased renal function as CaroSpir is excreted by the kidneys and may lead to a higher risk of hyperkalemia. For any patient age 65 and older with a CrCl of less than 30 mL/min CaroSpir should be avoided due to the risk of hyperkalemia. If CaroSpir is being used for the treatment of heart failure in patients with an eGFR between 30 and 50 mL/min/1.73m2 the initial dose should be 10 mg once daily and if the eGFR falls below 30 mLs/minute then CaroSpir should be avoided.

No new clinical trials were conducted for the approval of CaroSpir but the previously completed RALES (Randomized Aldactone Evaluation Study) trial was utilized for the approval of CaroSpir.

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

Clinical Discussion: If you see that members are on other tablets or capsules would we consider that if they state members have difficulty swallowing? Yes, we could. In our experience we haven't really seen this issue. No comments or questions. The committee unanimously voted to accept the recommendations as presented. None were opposed.

Financial Discussion: If you see that members are on other tablets or capsules would we consider that if they state members have difficulty swallowing? Yes, we could. In our experience we haven't really seen this issue. No additional comments or questions. The

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

Outcome: CaroSpir is a pharmacy benefit and will not be added to the Commercial, Marketplace, or CHIP formulary. The following prior authorization criteria will apply:

- Medical record documentation of an FDA approved indication **AND**
- Medical record documentation of therapeutic failure on, intolerance to, or contraindication to three (3) formulary diuretics, one of which must be spironolactone tablets **OR**
- If the member has trouble swallowing, medical record documentation of therapeutic failure on, intolerance to, or contraindication to furosemide oral liquid **OR**
- If the member has trouble swallowing, medical record documentation of a diagnosis of heart failure.

GPI LEVEL: GPI-12

RPH SIGNOFF REQUIRED: Yes

QUANTITY LIMIT: 20 mL per day

FORMULARY ALTERNATIVES:
Loop diuretics: Bumetanide, Furosemide (tablets, solution), Torsemide
Potassium sparing diuretics: Spironolactone tablets, Spironolactone-hydrochlorothiazide, Eplerenone, Amiloride, Amiloride-hydrochlorothiazide, Triamterene-hydrochlorothiazide
Thiazide diuretics: Hydrochlorothiazide, Indapamide, Metolazone, Chlorthalidone

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

DYANAVEL XR (amphetamine)

Review: Dyanavel XR extended-release tablet is a stimulant indicated for the treatment of ADHD in patients greater than 6 years old. Limited safety and efficacy data is available and guidelines have not been updated to include it. The recommended dosage of Dyanavel XR extended-release tablet is to start with 2.5 or 5 mg once daily in the morning in children 6 years of age or older. The dose may be increased by increments of 2.5mg to 10mg per day, every 4 to 7 days. The maximum dosage is 20mg per day. Dyanavel XR should be administered once daily in the morning, with or without food. It can be chewed or swallowed whole. The conversion of Dyanavel XR suspension to Dyanavel XR tablet is 1:1.

The approval of Dyanavel XR extended-release tablets, in pediatric patient greater then 6 years of age, was based on the clinical trial on the safety and efficacy of Dyanavel XR suspension by Childress et al as well as the bioavailability comparison study by Pardo et al. The dose-optimized, randomized, parallel-group, double-blind, placebo-controlled laboratory classroom study looked at Dyanavel XR suspension use vs placebo in patients 6 to 12 years of age with an active diagnosis of ADHD. It evaluated the SKAMP score and found statistically significant effects when comparing Dyanavel XR oral suspension to placebo. The bioavailability study by Pardo et al looked at the pharmacokinetics of Dyanavel XR suspension and Dyanavel XR

tablets (both chewed and swallowed) and found there to be no statistically significant difference in the pharmacokinetic profiles of the two formulations.

Dyanavel XR extended-release tablets are contraindicated to use if the patient has a known hypersensitivity to amphetamine products or has used MAOI's within 14 days. The safety profile is expected to be similar to the Dyanavel XR suspension and other amphetamine products. Marked common adverse effects includes dry mouth, anorexia, weight loss, abdominal pain, nausea, insomnia, restlessness, emotional lability, dizziness, and tachycardia.

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: Dyanavel XR tablets are a pharmacy benefit and will not be added to the Commercial, Exchange, or CHIP formularies. Dyanavel XR tablets will be added to the Commercial Policy 94.0 which includes other non-preferred ADHD stimulants:

- Medical record documentation of a diagnosis of attention deficit disorder (ADD) or attention deficit hyperactivity disorder (ADHD) **AND**
- Medical documentation of therapeutic failure on, intolerance to, or contraindication to methylphenidate CD (generic Metadate CD) **AND** amphetamine/dextroamphetamine SR combination

MEDISPAN AUTHORIZATION LEVEL: GPI-12

FORMULARY ALTERNTATIVES: dextroamphetamine, dextroamphetamine/amphetamine combination, dextroamphetamine/amphetamine SR combination, methylphenidate, methylphenidate sustained-release, methylphenidate extended-release, Metadate CD, guanfacine ER, atomoxetine

RPH SIGNOFF REQUIRED: no

Additional Recommendations: Adzenys XR-ODT tablets are a pharmacy benefit and will have its current policy (Commercial Policy 423.0-Adzenys-XR ODT) retired and be added to the Commercial Policy 94.0-Stimulants for ADHD which includes other non-preferred ADHD stimulants.

Current Commercial Policy 423.0- Adzenys-XR ODT Prior Authorization Criteria:
Current Policy Prior Authorization Criteria

- Medical record documentation of a diagnosis of ADHD **AND**
- Medical record documentation of age greater than or equal to 6 years **AND**
- Medical documentation of therapeutic failure on, intolerance to, or contraindication to methylphenidate CD (generic Metadate CD) AND amphetamine/dextroamphetamine SR combination

Updated Criteria under Commercial Policy 94.0- Stimulants for ADHD:

- Medical record documentation of a diagnosis of ADHD **AND**
- Medical documentation of therapeutic failure on, intolerance to, or contraindication to methylphenidate CD (generic Metadate CD) AND amphetamine/dextroamphetamine SR combination

Discussion/Outcome: No comments or questions. 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.

VTAMA (tapinarof)

Review: Plaque psoriasis is chronic autoimmune disease characterized by large areas of raised areas of erythematous oval plaques with adherent silvery scales. The disease is caused by a series of factors that lead to the over induction of the immune system. An outside stimulus induces keratinocyte hyperproliferation, while proinflammatory cytokines stimulate TNF-alpha to recruit myeloid dendritic cells. Myeloid dendritic cells and macrophages produce IL-23, thus leading to the activation of effector Tcell (T helper type 17 (Th17) and Tc17 cells. Th17 and Tc17) which stimulate keratinocytes to proliferate and recruit more proinflammatory cells. This creates a negative feedback group.

The topical agent Vtama has a novel approach to resolving the skin plaque caused by psoriasis. Prior to the introduction of Vtama, topical corticosteroids, Vitamin D analogs, retinoids, calcineurin inhibitors and emollients were typically considered as a main stay of treatment for mild psoriasis or as adjuvant therapy for moderate to severe psoriasis. Mild plaque psoriasis is defined by having under 3% of body surface covered, whereas between 3%-10% covered is known as moderate psoriasis. Severe plaque psoriasis is typically when more than 10% of the body is covered in plaques or when the plaques affect quality of life. Vtama is a first in class medication indicated for plaque psoriasis in adults that is applied once daily for any disease severity and does not have limitations for where on the body it can be applied, or for duration of treatment.

Vtama (Tapinarof) 1% cream is an aryl hydrocarbon receptor (AhR) agonist, however the specific mechanism of action for its therapeutic benefits is unknown. It is speculated that Vtama improves plaque psoriasis by modulating the T helper type 17 (Th17) cytokines such as interleukin (IL) 17A and IL-17F, thus regulating normal skin protein expression. Vtama selectively binds to AhR, a ligand-dependent transcription factor which is primarily responsible for gene expression in skin cells and plays an important role in skin homeostasis. AhR regulates the expression of IL-17, IL-22, and the terminal differentiation of CD4+ Th17 and Th22 cells. Vtama has the ability to induce skin barrier genes that are down regulated in psoriasis such as filaggrin and loricrin.

Vtama was proven to be effective and safe by PSOARING 1 and PSOARING 2 trials. The trials were multicenter, randomized, double-blind, vehicle-controlled trials. The primary endpoint of the trials was proportion of patients who achieved treatment success, defined as a Physician's Global Assessment (PGA) score of 0 (clear) or 1 (almost clear) and at least a 2-grade improvement from baseline at Week 12. Both trials showed a 36% and 40% success rate in the Vtama arms, and a 6% success rate for the placebo arms in both trials. In a safety study,

PSOARING 3, folliculitis (22.7%), contact dermatitis (5.5%), and upper respiratory tract infection (4.7%) were the most common side effects. Skin irritation and burning were common, occurring in 85% of patients.

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: Vtama will not be added to the Commercial, Exchange and GHP Kids pharmacy formularies. Vtama will require prior authorization. The following prior authorization criteria apply:

- Medical record documentation that patient is 18 years of age or older **AND**
- Medical record documentation of a diagnosis of plaque psoriasis **AND**
- Medical record documentation of therapeutic failure on, intolerance to, or contraindication to at least one (1) medication from all of the following:
    - Topical corticosteroid (at least medium or higher potency) OR topical calcineurin inhibitor **AND**
    - Topical retinoid **AND**
    - Topical vitamin D analog

GPI LEVEL: GPI-12

FORMULARY ALTERNTATIVES:

Topical Vitamin D Analogs: calcipotriene 0.005% solution/cream/ointment (Dovonex), calcitriol 3mcg/gm ointment (Vectical)
Topical Retinoids: tazarotene 0.1% cream/gel (Tazorac)
Low-potency topical corticosteroids: alclometasone dipropionate 0.5% cream and ointment (Aclovate); desonide 0.05% cream, ointment and lotion (Desowen); fluocinolone acetonide 0.01% cream, solution, body and scalp oil (Synalar/Derma-Smoothe); hydrocortisone 1% and 2.5% cream, ointment, and lotion (Hytone)
Medium-potency topical corticosteroids: betamethasone valerate 0.1% cream and lotion (Valisone); fluocinolone acetonide 0.025% cream and ointment (Synalar); flurandrenolide 0.05% cream, ointment, and lotion (Cordran); fluticasone propionate 0.05% cream and lotion (Cutivate); hydrocortisone butyrate 0.1% cream, ointment and solution (Locoid); hydrocortisone valerate 0.2% cream and ointment (Westcort); mometasone 0.1% cream (Elocon); prednicarbate 0.1% cream and ointment (DermAtop); triamcinolone acetonide 0.025% cream, ointment and lotion (Kenalog); triamcinolone 0.1% cream, ointment and lotion (Kenalog); triamcinolone acetonide 0.147 mg/g aerosol (Kenalog Spray)
High-potency topical corticosteroids: amcinonide 0.1% cream, ointment and lotion (Cyclocort); augmented betamethasone dipropionate 0.05% cream (Diprolene AF); betamethasone dipropionate 0.05% cream, ointment and lotion (Diprolene); betamethasone valerate 0.1% ointment (Valisone); betamethasone valerate 0.12% foam

(Luxiq); desoximetasone 0.25% cream, ointment and 0.05% cream, gel, ointment (Topicort/Topicort LP);); diflorasone 0.05% cream (FIorone/Psorcon); fluocinonide 0.05% cream, ointment, gel and solution (Lidex); fluticasone 0.005% ointment (Cutivate); mometasone 0.1% ointment (Elocon); triamcinolone 0.5% cream and ointment (Kenalog) Very high-potency topical corticosteroids: augmented betamethasone dipropionate 0.05% ointment, gel and lotion (Diprolene); clobetasol 0.05% cream, ointment, scalp lotion, shampoo, foam, spray (Temovate/Clobex/Olux) diflorasone diacetate 0.05% ointment (ApexiCon/Psorcon E), fluocinonide 0.1% cream (Vanos), halobetasol 0.05% cream and ointment (Ultravate)

RPH SIGNOFF REQUIRED: No

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

ELYXYB (celecoxib)

Review: Elyxyb is an oral solution NSAID indicated for the acute treatment of migraine with or without aura in adults. Elyxyb is not indicated for the preventative treatment of migraine.

NSAIDs are first line for acute treatment for mild to moderate migraines along with acetaminophen. NSAIDs plus triptans appear to be more effective than either class alone.

Oral migraine-specific agents are first-line for moderate to severe migraine including oral triptans plus NSAIDs. If these are not tolerated, calcitonin gene-related peptide (CGRP) antagonists are next. When vomiting or severe nausea is present, treatment moves to non-oral migraine-specific medications including subcutaneous formulations.

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: Elyxyb is a pharmacy benefit and will not be added to the Commercial, Marketplace, or GHP Kids formulary. The following prior authorization criteria will apply:

- Medical record documentation of diagnosis of migraine with or without aura **AND**
- Medical record documentation of age greater than or equal to 18 years of age **AND**
- Medical record documentation of celecoxib capsules AND 2 additional formulary alternatives **OR**
- If a barrier or difficulty with swallowing, medical record documentation of celecoxib capsules **AND** 2 additional formulary liquid NSAID alternatives

*Per celecoxib package insert: “For patients that have difficulty swallowing capsules, the contents of a CELEBREX capsule can be added to applesauce. The entire capsule contents are

carefully emptied onto a level teaspoon of cool or room temperature applesauce and ingested immediately with water. The sprinkled capsule contents on applesauce are stable for up to 6 hours under refrigerated conditions (2-8° C/ 35-45° F)

MEDISPAN AUTHORIZATION LEVEL: GPI-12

QUANTITY LIMIT: 144 mL per 30 days

FORMULARY ALTERNTATIVES: celecoxib, choline magnesium salicylate, diclofenac, diclofenac extended release, diflunisal, etodolac, etodolac extended release, fenoprofen, flurbiprofen, ibuprofen, indomethacin, indomethacin sustained-release, ketoprofen, ketorolac, meclofenamate, meloxicam, nabumetone, naproxen, naproxen sodium, naproxen ec, oxaprozin, piroxicam, salsalate, sulindac, tolmetin

RPH SIGNOFF REQUIRED: No

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

GLOPERBA (colchicine)

Review: Gloperba is indicated for prophylaxis of gout flares in adult patients. Gloperba has not been studied for acute treatment of gout flares during prophylaxis. Gout is a form of inflammatory arthritis that is caused by uric acid crystal deposits in joints, leading to painful swelling that can progress to chronic gouty arthritis if untreated.

Gloperba is available as a 0.6 mg/5 mL ready-to-use oral solution. The recommended dose is 0.6 mg (5 mL) administered by mouth once or twice daily, without regards to meals. The maximum daily dose is 1.2 mg (10 mL) per day.

The American College of Rheumatology Guideline for the Management of Gout provides evidence and guidance for the pharmacologic treatment of gout. When initiating urate lowering therapy (ULT) there is an increased risk of gout flares of unknown cause, potentially linked to the mobilization of crystals. Anti-inflammatory prophylaxis therapy with colchicine, non-steroidal anti-inflammatory drugs (NSAIDs), or prednisone/prednisolone is recommended when initiating ULT and continued concomitantly for at least 3 to 6 months. Shorter durations of prophylaxis were associated with increased gout flares. After stopping prophylaxis therapy, flare activity should be monitored and anti-inflammatory therapy continued as needed if flares continue.

Approval of Gloperba is based upon previous clinical trials of colchicine for prophylaxis of gout flares. No new clinical trials were completed for Gloperba.

Colchicine is a substrate of CYP3A4 and P-glycoprotein (P-gp). Toxicities have been reported when colchicine is administered with inhibitors of CYP3A4 or P-gp and fatalities have been reported when used with dual inhibitors of both CYP3A4 and P-gp. It is contraindicated to use Gloperba in conjunction with drugs that inhibit both CYP3A4 and P-gp in patients with renal or hepatic impairment. If possible, the concomitant use of Gloperba with CYP3A4 inhibitors or P-gp inhibitors should be avoided. If co-administration with a CYP3A4 inhibitor of P-gp inhibitor is necessary, the dose of Gloperba should be adjusted and the patient should be closely

monitored. Co-administration of Gloperba with HMG-CoA reductase inhibitors and fibrates may increase the risk of myopathy and requires monitoring of muscle pain or weakness. Gloperba is contraindicated in patients with both renal and hepatic impairment. Dose reduction or alternative treatments should be considered in patients with severe renal impairment or severe hepatic impairment

Gloperba has warnings for fatal overdoses, blood dyscrasias, toxicity, drug interactions with CYP3A4 and P-gp inhibitors, and neuromuscular toxicity. The most common adverse reactions are gastrointestinal symptoms, including diarrhea, nausea, vomiting, and abdominal pain. The safety and effectiveness has not been established in pediatric patients. Colchicine has been studied in pregnancy over decades and there has not been any drug associated risks for major birth defects, miscarriage, or adverse outcomes. When used in geriatric patients, consideration should be given to reducing the dose of Gloperba due to increased incidence of decreased renal function and higher medication use in this patient population.

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

Clinical Discussion: What should we be looking for on re-review after the initial 6 month approval? It's only recommended to continue if member is still experiencing flares. Would recommend reviewing with the initial criteria again.

No additional 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: Gloperba is a pharmacy benefit and will not be added to the Commercial, Marketplace, or GHP Kids formularies. The following prior authorization criteria will apply:

- Medical record documentation of age 18 years or older **AND**
- Medical record documentation that Gloperba is being used for prophylaxis of gout flares **AND**
- Medical record documentation that Gloperba will be used in combination with urate lowering therapy (ULT) **AND**
- Medical record documentation of difficulty swallowing **OR**
- Medical record documentation of therapeutic failure on, intolerance to, or contraindication to three (3) generic formulary anti-inflammatory gout prophylactic agents, one of which much be generic colchicine tablets **OR** generic colchicine capsules

NOTE: Medical record documentation that patient is not currently prescribed drugs that inhibit both CYP3A4 and P-gp if they have renal or hepatic impairment.

MEDISPAN AUTHORIZATION LEVEL: GPI-12

QUANTITY LIMIT: 300 mL per 30 days (10 mL/day)

FORMULARY ALTERNTATIVES: colchicine, celecoxib, diclofenac, etodolac, fenoprofen, flurbiprofen, ibuprofen, ketoprofen, meclofenamate, mefenamic acid, meloxicam, nabumetone, naproxen, oxaprozin, piroxicam, sulindac, tolmetin, cortisone, dexamethasone,

fludrocortisone, hydrocortisone, methylprednisolone, prednisolone, prednisone

RPH SIGNOFF REQUIRED: Yes

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

OZOBAX/BACLOFEN ORAL SOLUTION (baclofen oral solution)

Review: Ozobax is a GABA-ergic agonist that is FDA approved to treat multiple sclerosis related spasticity, including relief of flexor spasms and concomitant pain, clonus, and muscular rigidity. It is also shown to help in those with spinal cord injuries and/or diseases. It is not to be used in treatment of muscle spasms related to rheumatic disorders.

Ozobax is available as a 5mg/5mL concentration in a 473 mL bottle. It is an off-white, grape-flavored oral solution. It is to be kept refrigerated and is good until the date on the bottle. Recommended dosing for Ozobax is to initiate at a low dose, in divided doses, and to increase every 3 days until a clinical response is experienced. Maximum daily dose is 80mg daily. To stop the medication, medication should be reduced slowly. Dosing regimen is as follow:

5 mL (5 mg) three times daily for 3 days
10 mL (10 mg) three times daily for 3 days
15 mL (15 mg) three times daily for 3 days
20 mL (20 mg) three times daily for 3 days
May increase to 20 mL (20 mg) four times daily

Oral baclofen is first-line therapy for spasticity related to multiple sclerosis, followed by oral Tizanidine, oral dantrolene, intrathecal baclofen, and Botox injections. Ozobax would be a liquid alternative to first-line oral baclofen for those who cannot swallow or tolerate the oral generic tablets or suspension (Fleqsuvy).

Only a bioavailability study has been conducted to show its' equal comparative effectiveness compared to oral tablet baclofen. In the controlled pharmacokinetic study, 63% of 175 patients experienced transient drowsiness of those receiving baclofen compared to placebo. Due to clinical trials being conducted under different conditions, adverse reaction rates from trial cannot be directly compared to another drug that would be relevant for practice.

Safety Considerations are to be considered for use in those who are pregnant, as baclofen may increase risk of late-onset neonatal withdrawal symptoms. Baclofen is found in breastmilk, and should be avoided, if possible, for those lactating. Baclofen may increase risk of late-onset neonatal withdrawal symptoms. Per FDA, Baclofen's' safety and efficacy not established under the age of 12 years. For the geriatric population, start low in dose and slowly increase as needed due to side effect profile and excretion via the kidneys. Finally, for those with any renal impairment, baclofen should be given with caution and at low doses as it is primarily excreted by the kidneys.

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: RPh signoff is recommended. No additional comments or questions. The committee unanimously voted to accept the recommendations as presented. None were opposed.

Outcome: Ozobax is a pharmacy benefit and will not be added to the Commercial, Exchange, or CHIP formularies. It will be added to Commercial Policy 9.0 for Brand Medications.

- Medical record documentation of a therapeutic failure on, or intolerance to the generic formulary agent(s) **OR**
- Medical record documentation of a therapeutic failure on, intolerance to, or contraindication to the inactive ingredients of the generic formulary agent(s)

AND

- Medical record documentation of therapeutic failure on, intolerance to, or contraindication to up to three formulary alternatives, if available

Baclofen oral solution (NDA authorized generic) is a pharmacy benefit and will be added to the Commercial and CHIP formularies at the generic tier and the Exchange formulary at the non-preferred generic tier. The following prior authorization criterion will apply to baclofen oral solution:

- Medical record documentation of a diagnosis of spasticity from multiple sclerosis **OR** spinal cord injuries and/or diseases **AND**
- Medical record documentation of an age greater than or equal to 12 years **AND**
- Medical record documentation of inability to tolerate or swallow tablets **OR**
- Medical record documentation of therapeutic failure on, or contraindication to the preferred formulary alternatives, both baclofen tablets and tizanidine tablets

NOTE: Medical record documentation that patient is not currently prescribed drugs that inhibit both CYP3A4 and P-gp if they have renal or hepatic impairment.

MEDISPAN AUTHORIZATION LEVEL: GPI-14

QUANTITY LIMIT: 80 mg (16 mL) per day

FORMULARY ALTERNTATIVES: baclofen and tizanidine tablets

RPH SIGNOFF REQUIRED: Yes

Additional Recommendations: Based on the formulary addition of baclofen oral solution for Commercial/Exchange/CHIP, the following changes will be made to Policy 712.0 for Fleqsuvy:

Current Commercial Policy 423.0- Adzenys-XR ODT Prior Authorization Criteria:
Current Policy Prior Authorization Criteria

- Medical record documentation of a diagnosis of spasticity from multiple sclerosis **OR** spinal cord injuries and/or diseases **AND**
- Medical record documentation of age greater than or equal to 12 years **AND**
- Medical record documentation of one of the following:
    - Medical record documentation of inability to tolerate or swallow tablets **AND** therapeutic failure on, or contraindication to baclofen oral solution **OR**

- Medical record documentation of therapeutic failure on, or contraindication to three (3) preferred formulary alternatives, baclofen tablets, baclofen oral solution, **AND** tizanidine tablets

Discussion/Outcome: No comments or questions. 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.

ZTILDO (lidocaine 1.8% topical system)

Review: ZTlido is a local anesthetic, containing lidocaine. The FDA's preferred name for patch is now topical system. The ZTlido topical system (lidocaine 1.8%) was designed to be worn for 12 hours per day (maximum of 3 patches at one time), just like the lidocaine 5% patch. The new patch was designed differently—to be thinner and in a nonaqueous formulation, which resulted in improved biopharmaceutical efficiency and drug delivery. 36mg of lidocaine is used in the ZTlido 1.8% topical system versus 700mg in the lidocaine in the 5% patch. This thinner and lighter formulation has been proven to adhere better and can be worn through moderate exercise.

One of the biggest downfalls for patches, or topical systems, is adhesion. Technology is progressing to make these patches, thinner, and more adhesive to skin, even during moderate exercise. Bioequivalence was demonstrated to the lidocaine 5% patch, and studies support its use in PHN. It is inferred that both lidocaine topical system 1.8% and lidocaine 5% will have a similar efficacy in PHN.

The treatment for Post Herpetic Neuralgia (PHN) is usually multi-modal. Gabapentinoids are usually first line in the treatment of PHN. Lidocaine patches are usually further down the treatment algorithm due to small numbers in trials, and varying efficacy.

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: ZTlido is a pharmacy benefit and will not be added to the Commercial, Exchange, or CHIP formularies. The following prior authorization criteria will apply:

- Medical record documentation of a therapeutic failure on, or intolerance to the generic formulary agent(s) **OR**
- Medical record documentation of a Food and Drug Administration (FDA) approved indication (post-herpetic neuralgia) AND
- Medical record documentation of therapeutic failure, intolerance to, or contraindication to a gabapentinoid (gabapentin or pregabalin) AND lidocaine 5% patches

MEDISPAN AUTHORIZATION LEVEL: GPI-14

QUANTITY LIMIT: 3 patches per day

FORMULARY ALTERNTATIVES: lidocaine 5% patches* (*prior authorization required), gabapentin, pregabalin

RPH SIGNOFF REQUIRED: No

Additional Recommendations: It is recommended that the following additional criteria be added to Commercial policy 179.0 for generic lidocaine patches:

- Medical record documentation of a Food and Drug Administration (FDA) approved indication (postherpetic neuralgia) **AND**
- Medical record documentation of therapeutic failure, intolerance to, or contraindication to a gabapentinoid (gabapentin or pregabalin)

FORMULARY ALTERNATIVES: ~~**none**~~ **gabapentin, pregabalin**

Discussion/Outcome: No comments or questions. 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.

LINE EXTENSION REVIEWS

Clinical Review:

MEDICATION	INDICATION	DOSAGE/ HOW SUPPLIED	FORMULARY ALTERNATIVES	RECOMMENDATIONS
WYNZORA (calcipotriene/ betamethasone diproprionate)	Topical treatment of plaque psoriasis in patients 18 years of age and older	Apply to affected areas once daily for up to 8 weeks. Do not use more than 100 grams per week 0.005-0.064% topical cream in a 60 gram tube	Commercial/Exchange/CHIP: **Vitamin D Analogs:** calcipotriene 0.005% cream/ointment*, calcitriol 3 mcg/g ointment* Topical Corticosteroids Medicare: Vitamin D Analogs: Calcipotriene 0.005% cream/ointment/solution, calcitriol 3mcg/g ointment Topical corticosteroids	Commercial/Exchange/CHIP: Leave NF, Add to Enstilar Policy 609.0 With the following changes: • Medical record documentation of a diagnosis of plaque psoriasis **AND** • Medical record documentation of therapeutic failure, intolerance to, or contraindication to a combination of a topical vitamin D analog and a topical corticosteroid **AND** • For Enstilar: Medical record documentation of age greater than or equal to 12 years **AND** • For Wynzora: Medical record documentation of age greater than or equal to 18 years

				Medicare: MC2 Therapeutics, Inc. is non-participating with CMS and Wynzora is currently excluded from coverage.
ZILXI (minocycline topical foam)	Treatment of inflammatory lesions of rosacea in adults.	Apply a small amount of topical foam in a thin layer over all areas of the face. Each gram contains 15 mg of minocycline and is suppled in 30 gram of 1.5% foam in pressurized aluminum aerosol container	Commercial/Exchange/CHIP: metronidazole (gel/cream/lotion), ivermectin 1% cream, azelaic acid gel Medicare: metronidazole (gel/cream/lotion), azelaic acid 15% gel, ivermectin 1% cream Medicaid: metronidazole (gel/cream/lotion), ivermectin 1% cream, azelaic acid gel	Commercial/Exchange/CHIP: Leave NF, Add to Finacea Foam Policy 112.0 Medicare: Leave NF, Add to Finacea Foam Policy 28.0 D Medicaid: Leave NF, Add to Epsolay Policy, • Medical record documentation of a diagnosis of rosacea with inflammatory lesions AND • Medical record documentation of therapeutic failure on, intolerance to, or contraindication to three (3) formulary alternatives

IMPEKLO (clobetasol proprionate lotion)	Relief of inflammatory and pruritic manifestations of corticosteroid-responsive dermatosis in patients 18 years of age and older	Apply to affected areas twice daily. Total dosage should not exceed 50 grams per week. Do not use more than 10 pump actuations per application twice daily or 20 pump actuations per day for more than 7 days 0.15 mg of clobetasol per pump actuation, in a metered dose pump containing 68 grams of lotion which delivers no less than 138 actuations	Commercial/Exchange/CHIP: Aclometasone, Acinonide, Clobetasol, Desonide, Diflorasone, Fluocinolone, Fluocinonide, Halobetasol, mometasone, triamcinolone Medicare : Aclometasone, Acinonide, Clobetasol, Desonide, Diflorasone, Fluocinolone, Fluocinonide, Halobetasol, mometasone, triamcinolone	Commercial/Exchange/Chip: Leave NF, review with admin policy Medicare: Leave NF, review with admin policy
TWYNEO (tretinoin/benzoyl peroxide)	Treatment of acne vulgaris in adults and pediatric patients 9 years of age and older	Apply thin layer to affected areas once daily on clean dry skin 50 gram bottle with pump	Commercial/Exchange/CHIP: adapalene, benzoyl peroxide, topical clindamycin, clindamycin/benzoyl peroxide, oral doxycycline, topical erythromycin, erythromycin/benzoyl peroxide, isotretinoin, oral minocycline, sulfacetamide/sulfur, topical tretinoin Medicare : adapalene 0.1% gel/cream, adapalene 0.3% gel, tretinoin cream/gel*, tazarotene 0.1% cream, clindamycin, erythromycin, clindamycin and benzoyl peroxide, erythromycin and benzoyl peroxide gel	Commercial/Exchange/Chip: Leave NF, review with Commercial Policy 476.0 for non-preferred acne medications Medicare: Leave NF, review with admin policy

			(*Prior authorization required)	
MINOLIRA ER (minocycline ER)	Treat only inflammatory lesions of non-nodular moderate to severe acne vulgaris in patients 12 years of age and older	Approximately 1 mg/kg once daily for 12 weeks. 105 and 135 mg tablets can be split along score lines and dosed according to patient body weight 105 mg and 135 mg tablets in bottles of 30 tablets	Commercial/Exchange/CHIP: adapalene, benzoyl peroxide, topical clindamycin, clindamycin/benzoyl peroxide, oral doxycycline, topical erythromycin, erythromycin/benzoyl peroxide, isotretinoin, oral minocycline, sulfacetamide/sulfur, topical tretinoin Medicare: adapalene 0.1% gel/cream, adapalene 0.3% gel, tretinoin cream/gel*, tazarotene 0.1% cream, clindamycin, erythromycin, clindamycin and benzoyl peroxide, erythromycin and benzoyl peroxide gel (*Prior authorization required)	Commercial/Exchange/Chip: Leave NF, review with Commercial Policy 476.0 for non-preferred acne medications Medicare: Leave NF, review with admin policy
ACTICLATE (doxycycline hyclate)	• Rickettsial infections • Sexually transmitted infections • Respiratory tract infections • Specific bacterial infections • Ophthalmic infections • Anthrax, including inhalational	100 mg once or twice daily, specific dosing dependent on indication 75 and 150 mg scored tablets in bottles of 60	Commercial/Exchange/CHIP: doxycycline hyclate tablets, doxycycline hyclate capsules, doxycycline delayed release tablets Medicare: doxycycline hyclate tablets, doxycycline hyclate capsules, doxycycline delayed release tablets	Commercial/Exchange/Chip: Leave NF, review with Brand with generic policy Medicare: Leave NF, review with Brand with generic policy

	anthrax (post-exposure) • Alternative treatment for selected infections when penicillin is contraindicated • Adjunctive therapy for acute intestinal amebiasis and severe acne • Prophylaxis of malaria		Other generics dependent on indication	
LICART (diclofenac epolamine 24 hours external patch)	Topical treatment of acute pain due to minor strains, sprains and contusions.	Apply 1 patch per day to the most painful area 1.3 % 24 hour external patch, come in resealable envelopes containing 5 topical systems with 3 envelopes per box	Commercial/Exchange/CHIP: diclofenac epolamine patch*, celecoxib, choline magnesium salicylate, diclofenac, diclofenac extended release, diflunisal, etodolac, etodolac extended release, fenoprofen, flurbiprofen, ibuprofen, indomethacin, indomethacin sustained-release, ketoprofen, ketorolac, meclofenamate, meloxicam, nabumetone, naproxen, naproxen sodium, naproxen ec, oxaprozin, piroxicam, salsalate, sulindac, tolmetin Medicare: diclofenac epolamine patch*, Celecoxib, diclofenac, diflunisal, etodolac, etodolac extended release, fenoprofen, flurbiprofen,	Commercial/Exchange/Chip: Leave NF, review with admin policy, add QL: 30 patches per 30 days Medicare: Leave NF, review with admin policy, add QL: 30 patches per 30 days

			ibuprofen, ketoprofen, meclofenamate, meloxicam, nabumetone, naproxen, naproxen sodium, oxaprozin, piroxicam, sulindac, tolmetin	
ELEPSIA XR (levetiracetam)	Adjunctive therapy for the treatment of partial-onset seizures in patients 12 years and older	Initial dose 1000 mg once daily, increase by 1000 mg every 2 weeks to maximum recommended dose of 3000 mg once daily 1000 mg and 1500 mg ER tablets in bottles of 30, 100, and 500 tablets	Commercial/Exchange/CHIP: levetiracetam ER, levetiracetam IR, levetiracetam solution, carbamazepine, phenobarbital, phenytoin, pregabalin, lamotrigine IR, oxcarbazepine, topiramate IR, topiramate ER*, gabapentin, Aptiom*, divalproex, tiagabine, Fycompa* Medicare: levetiracetam, carbamazepine, divalproex, valproic acid, gabapentin, lamotrigine, oxcarbazepine, phenytoin, tiagabine, topiramate, Lyrica, Sabril*, Aptiom*, Vimpat	Commercial/Exchange/Chip: Leave NF, review with admin policy, add QL: 3 tablets per day Medicare: Tripoint Pharmaceuticals in non-participating with CMS and Elepsia XR is currently excluded from coverage.
PURIXAN (mercaptopurine suspension)	Treatment of patients with acute lymphoblastic leukemia (ALL) as part of a combination chemotherapy maintenance regimen	1.5 to 2.5 mg/kg (50 to 75 mg/m^2) orally once daily 2000 mg/100 mL (20 mg/mL) oral suspension	Commercial/Exchange/CHIP: mercaptopurine tablets Medicare: mercaptopurine tablets	Commercial/Exchange/Chip: Leave NF, review with admin policy Medicare: Leave on Brand NP tier, no PA required

XATMEP (methotrexate oral solution)	• Treatment of pediatric patients with acute lymphoblastic leukemia (ALL) as a component of a combination chemotherapy maintenance regimen • Management of pediatric patients with active polyarticular juvenile idiopathic arthritis (pJIA) who are intolerant of or had an inadequate response to first-line therapy	ALL Starting Dose: 20 mg/m^2 given one time weekly PIJA Starting Dose: 10 mg/m^2 given once weekly 2.5 mg/milliliter oral solution	Commercial/Exchange/CHIP: methotrexate tablets, NSAIDS (for JIA) Medicare: JIA: celecoxib, methotrexate oral tablets ALL: methotrexate oral tablets	Commercial/Exchange/CHIP: Add to Formulary, PA with the following Criteria, Juvenile Idiopathic Arthritis 1. Documentation of age 18 years or younger AND 2. Medical record documentation of Polyarticular Juvenile Idiopathic arthritis following an insufficient response or intolerance to a 3-month trial of a formulary NSAID or other first line therapy. **OR** Acute Lymphoblastic Leukemia 1. Documentation of age 18 years or younger AND 2. Medical record documentation of Acute Lymphoblastic leukemia used as part of a combination chemotherapy maintenance regimen Medicare: Leave on Brand NP tier, requires PA, Policy 609.0D

				Juvenile Idiopathic Arthritis 1. Documentation of age 18 years or younger AND 2. Medical record documentation of Polyarticular Juvenile Idiopathic arthritis following an insufficient response or intolerance to a 3-month trial of a formulary NSAID or other first line therapy. **OR** Acute Lymphoblastic Leukemia 1. Documentation of age 18 years or younger AND 2. Medical record documentation of Acute Lymphoblastic leukemia used as part of a combination chemotherapy maintenance regimen OR 3. Diagnosis of a medically acceptable indication
VESICARE LS	Treatment of neurogenic detrusor overactivity in pediatric patients aged 2 years and older	Starting doses of 2 mL to 5 mL based on body weight, administered once daily.	Commercial/Exchange/CHIP: oxybutynin tablets, oxybutynin solution (6 and older), botox (5 years and older)	Commercial/Exchange/CHIP: Leave NF, review with admin policy,add QL: 10 milliliters per day

(solifenacin suspension)		Maximum doses of 4 mL to 10 mL 5 mg/5mL oral suspension	Medicare: oxybutynin tablets, oxybutynin solution	Medicare: Leave NF, review with admin policy, QL: 10 milliliters per day
EGRIFTA (tesamorelin)	Reduction of excess abdominal fat in HIV-infected adult patients with lipodystrophy	1.4 mg, (0.35 mL) injected subcutaneously once daily SDV for injection 2 mg vial and 10 mL of sterile water diluent, available in packages containing 30 of each vial	Commercial/Exchange/CHIP: none Medicare: none	Commercial/Exchange/CHIP: Excluded except for certain TPAs that cover Medicare: Excluded
COARTEM (artemether/ Lumefantrine)	Treatment of Acute, uncomplicated malaria infections due to Plasmodium falciparum in patients 2 months of age and older with bodyweight of 5 kg and above Not approved for severe or complicated P.falciparum malaria or prevention	Adults 16 years and older weighing at least 35 kg: 3 day treatment schedule: 4 tablets as a single dose, 4 tablets 8 hours later, then 4 tablets twice daily for the next two days (total 24 tablets) Pediatric weight based dosing: Follows the same 3 day treatment schedule as adults with 1 to 4 tablets per dose.	Commercial/Exchange/CHIP: Atovaquone/proguanil, chloroquine, mefloquine, quinine* Medicare: Atovaquone/proguanil, chloroquine, mefloquine, quinine*	Commercial/CHIP: Leave NF, review with admin policy, QL: 24 tablets per fill Exchange: Leave on Brand NP tier, review with admin policy, QL: 24 tablets per fill Medicare: Leave on Brand NP tier, no PA required,

		20 mg/120 mg tablets in bottles of 24		
ONZETRA XSAIL (sumatriptan nasal powder)	Acute Treatment of Migraine with or without aura in adults Not indicated for prophylaxis or cluster headache	22 mg (11 mg administered in each nostril). If the migraine has not resolved in 2 hours, a second dose may be administered (Max: 2 doses per 24 hours (44mg/4 nosepieces). Safety of treatment more than 4 headaches in 30 day period has not been established. 11 mg capsules contained in a disposable nosepiece and a reusable breath-powered delivery device body. Available in Kits containing 8 doses	Commercial/Exchange/CHIP: dihydroergotamine nasal spray, diclofenac, ibuprofen, naproxen, butorphanol nasal spray, almotriptan*^, eletriptan*^, frovatriptan*^, naratriptan^, rizatriptan^, sumatriptan^, zolmitriptan^, sumatriptan/naproxen*^ Medicare: almotriptan**, naratriptan**, rizatriptan**, sumatriptan**, zolmitriptan**	Commercial/Exchange/CHIP: Leave NF, review with admin policy Medicare: Leave NF, review with admin policy
THIOLA EC (tiopronin delayed release)	Prevention of cystine stone formation in adults and pediatric patients 20 kg and greater with severe homozygous cystinuria, in combination with high fluid intake,	Adults: Initial dose 800 mg/day Pediatric Initial dose weighing ≥ 20 kg: 15 mg/kg per day (up to 50 mg/kg)	Commercial/Exchange/CHIP: none Medicare: none	Commercial/Exchange/CHIP: Leave NF, Review with admin policy Medicare: Leave NF, review with admin policy

	alkali, and diet modification.	Adminstered in 3 divided doses and adjusted every 3-6 months to maintain urinary cystine concentration < 250 mg/L 100 mg in bottles of 300 and 300 mg tablets in bottles of 90		
DUAKLIR PRESSAIR (aclindinium/ Formoterol)	Maintenance treatment of patients with chronic obstructive pulmonary disease (COPD)	400 mcg/12mcg oral inhalations twice daily (morning and evening) PRESSAIR inhalers which deliver 30 metered dose or 60 metered doses of 400 mcg/12 mcg	Commercial/Exchange/CHIP: fluticasone/salmeterol, Wixela Inhub, Anoro Ellipta, Arnuity Ellipta, Breo Ellipta, Incruse Ellipta, Spiriva Handihaler/Respimat, Stiolto Respimat, Striverdi Respimat, Trelegy Ellipta^, Tudorza Pressair# Medicare: fluticasone/salmeterol^, Wixela Inhub^, budesonide/formoterol^, Incruse Ellipta, Stiolto Respimat^, Trelegy Ellipta^, Tudorza Pressair#	Commercial/Exchange/CHIP: Leave NF, Review with admin policy Medicare: Leave NF, Review with admin policy
ACCRUFER (ferric maltol)	Treatment of iron deficiency in adults	30 mg twice daily, 1 hour before or 2 hours after a meal. Continue until ferritin levels are within the normal range. Treatment duration depends on iron deficiency, but generally requires at least 12 weeks of treatment.	Commercial/Exchange/CHIP: ferumoxytol, Injectafer, Auryxia*, Velphoro* Medicare: ferumoxytol, Injectafer, Auryxia*, Velphoro#	Commercial/Exchange/CHIP: Leave NF, review with admin policy, QL: 2 capsules per day Medicare: Leave NF, review with admin policy, QL: 2 capsules per day

		30 mg capsules in bottles of 60 capsules.		
THYQUIDITY (levothyroxine oral solution)	• Replacement therapy in primary (thyroidal), secondary (pituitary), and tertiary (hypothalamic) congenital or acquired hypothyroidism • Adjunct to surgery and radioiodine therapy in the management of thyrotropin-dependent well-differentiated thyroid cancer	Single daily oral dose on an empty stomach Adults: start at full replacement dose, approximately 1.6 mcg per kg per day and adjust by 12.5 to 25 mcg increments every 4-6 weeks based on serum TSH levels	Commercial/Exchange/CHIP: levothyroxine, Armour thyroid, Levo-T, Levoxyl, NP Thyroid, Synthroid, Unithroid Medicare: levothyroxine, Levo-T, Levoxyl, Synthroid, Unithroid	Commercial/Exchange/CHIP: Leave NF, review with admin policy Medicare: Leave NF, review with admin policy
LOREEV XR (lorazepam XR sprinkle capsule)	Treatment of anxiety disorders in adults who are receiving stable, evenly divided three times daily dosing with lorazepam tablets	Given once daily in the morning with a dose equivalent to the total daily dose of lorazepam tablets. The effectiveness of treatment for more than 4 months has not been assessed in clinical studies.	Commercial/Exchange/CHIP: alprazolam, alprazolam XR, alprazolam intensol, diazepam tablets, diazepam oral solution, lorazepam tablet, lorazepam intensol, oxazepam Medicare: alprazolam, alprazolam XR, alprazolam intensol, diazepam	Commercial/Exchange/CHIP: Leave NF, review with admin policy Medicare: Leave NF, review with admin policy

		1 mg, 1.5 mg, 2 mg, 3 mg capsules, in bottles of 30 and 100 capsules	tablets, diazepam oral solution, lorazepam tablet, lorazepam intensol,	
MYCAPSSA (octreotide delayed release capsules)	Long-term maintenance treatment in acromegaly patients who have responded to and tolerated treatment with octreotide or lanreotide.	Initial dose: 20 mg orally twice daily. Titrate based on IGF-1 levels and signs and symptoms in increments of 20 mg daily. Maximum dose 80 mg daily 20 mg capsules in a wallet of 28 capsules	Commercial/Exchange/CHIP: bromocriptine, lanreotide SQ, octreotide SQ, Sandostatin LAR Depot, Signifor, Signifor LAR, Somatuline Depot, Medicare: bromocriptine, lanreotide, octreotide, Signifor, Signifor LAR, Somatuline Depot	Commercial/Exchange/CHIP: Leave NF, review with admin policy, QL: 4 capsules per day Medicare: Leave NF, review with admin policy, QL: 4 capsules per day
UPNEEQ (oxymetazoline hydrochloride ophthalmic solution)	Treatment of acquired blepharoptosis in adults	Instill one drop into one or both ptotic eye(s) once daily 0.3 mL of 0.1% ophthalmic solution in 30 single use containers	Commercial/Exchange/CHIP: none Medicare: none	Commercial/Exchange/CHIP: Leave NF, review with admin policy, Medicare: RVL Pharmaceuticals is currently non-participating with CMS and Upneeq is excluded from coverage.
SOTYLIZE (sotalol oral solution)	• Treatment of life-threatening ventricular arrythmias • Maintenance of normal sinus rhythm in patients with highly	Initial dose: 80 mg (once or twice daily based on CrCl)	Commercial/Exchange/CHIP: sotalol tablets, amiodarone, disopyramide, flecainide	Commercial/Exchange/CHIP: Leave NF, review with admin policy Medicare: Leave NF, review with admin policy

	symptomatic atrial fibrillation/flutter (AFIB/AFL)	For Ventricular Arrhythmia, the dose can be increased by 80 mg per day every 3 days For AFIB/AFL, the dose can be increased to 160 mg once or twice daily 5 mg/mL oral solution in 250 and 480 mL bottles.	Medicare: sotalol tablets, amiodarone, disopyramide, flecainide	
QDOLO/Tramadol Oral Solution (NDA Authorized Generic) (tramadol oral solution)	For the management of adult patients with pain severe enough to require an opioid analgesic and for which alternative treatments are inadequate	Start at 25 mg/day and titrate in 25 mg increments as separate doses every 3 days to reach 100 mg daily (25 mg four times daily), Thereafter may be increased by 50 mg as tolerated to reach 200 mg/day (50 mg four times daily). After titration, 50 to 100 mg every 4 to 6 hours not to exceed 400 mg/day Qdolo: 5 mg/mL oral solution, supplied in 16 ounce bottles	Commercial/Exchange/CHIP: tramadol tablets, tramadol-acetaminophen, oxycodone, oxycodone oral solution, acetaminophen-codeine oral solution, morphine oral solution Medicare: tramadol tablets, tramadol-acetaminophen, oxycodone, oxycodone oral solution, acetaminophen-codeine oral solution, morphine oral solution	Commercial/Exchange/CHIP: Qdolo: Leave NF, review with Brand with Generic Policy, QL: 80 mL per day Tramadol Oral Solution: Leave NF, Review with Commercial Policy 488.0 for Opioid Use as non-preferred short acting-opioids Medicare: Qdolo: Athena Biosciences is currently non-participating with CMS and Qdolo is excluded from coverage.

		Tramadol Oral Solution: 1 unit dose cup (5 mL), 40 unit dose cups (200 mL)		Tramadol Oral Solution: Palmetto Pharmaceuticals is currently non-participating and Tramadol Oral solution is excluded from coverage
SITAVIG (acyclovir buccal tablet)	Treatment of recurrent herpes labialis (cold sores) in immunocompetent adults	One 50 mg buccal tablet applied as a single dose to the upper gum region (canine fossa). 50 mg buccal tablets, packaged in 1 blister, boxes of 2	Commercial/Exchange/CHIP: acyclovir capsule, acyclovir suspension, acyclovir tablet, acyclovir ointment, famciclovir, valacylovir Medicare: acyclovir capsule, acyclovir suspension, acyclovir tablet, acyclovir ointment, famciclovir, valacylovir	Commercial/Exchange/CHIP: Leave NF, review with admin policy QL: 1 tablet per fill Medicare: Leave NF, review with admin policy
CYSTADANE (betaine anhydrous for oral solution)	Treatment of homocystinuria to decrease elevated homocysteine blood concentrations (Includes • Cystathionine beta-synthase (CBS) deficiency • 5,10-methylenetetrahydrofolate reductase (MTHFR) deficiency • Cobalamin cofactor metabolism (cbl) defect	Adults and pediatric patients 3 year of age and older: 6 grams per day administered in divided dose of 3 grams twice daily Pediatric patients < 3 years: 100 mg/kg/day divided into twice daily doses, then increased weekly by 50 mg/kg increments. Powder for oral solution in bottles containing 180 grams	Commercial/Exchange/CHIP: folic acid Medicare: none	Commercial/Exchange/CHIP: Leave NF, review with admin policy Medicare: Leave NF, review with admin policy

		of betaine anhydrous. One level scoop is equivalent to 1 gram of betaine anhydrous powder. This is mixed in 4-6 ounces of liquid.		
VERSACLOZ (clozapine suspension)	• Treatment-resistant schizophrenia. Efficacy was established in an active controlled study • Reducing suicidal behavior in patients with schizophrenia or schizoaffective disorder. Efficacy was established in an active- controlled study	Starting dose is 12.5 mg once or twice daily, can be increased in increments of 25 mg to 50 mg per day, if well-tolerated to achieve a target dose of 300 mg to 450 mg per day (in divided doses) by the end of two weeks. Maximum dose is 900 mg / day 50 mg/mL in 100 mL bottle	Commercial/Exchange/CHIP:clozapine tablet, clozapine ODT, aripiprazole, haloperidol, Latuda*, olanzapine, olanzapine ODT, paliperidone ER, quetiapine, risperidone, Vraylar*, ziprasiodone Medicare: clozapine tablet, clozapine ODT, aripiprazole, haloperidol, Latuda*, olanzapine, olanzapine ODT, paliperidone ER*, quetiapine, risperidone, Vraylar*, ziprasiodone	Commercial/Exchange/CHIP: Leave NF, review with admin policy Medicare: Leave Brand NP tier, no PA required
TUZISTRA XR (codeine polistirex/ Chlorpheniramine polistirex)	Temporary relief of cough and upper respiratory symptoms associated with allergy or the common cold in patients 18 years of age and older.	10 milliliters every 12 hours as needed, not to exceed 2 doses (20 mL) in 24 hours Oral Suspension containing 14.7 mg codeine and 2.8 mg chlorpheniramine per 5 mL, in 16 oz bottles.	Commercial/Exchange/CHIP: benzonatate, coditussin ac, guaifenesin-codeine solution, hydrocodone/chlorpheniramine suspension, hydrocodone/homatropine tablet and solution, promethazine vc/codeine, promethazine-codeine Medicare:none	Commercial/Exchange/CHIP: Leave NF, review with admin policy Medicare: Excluded through Part D

CYSTADROPS (cysteamine ophthalmic)	Treatment of corneal cystine crystal deposits in adults and children with cystinosis.	One drop in each eye, four times daily during waking hours. Supplied as 5 mL sterile viscous solution in a 10 mL amber glass bottle	Commercial/Exchange/CHIP: none Medicare: Cystaran 0.44% Medicaid: none	Commercial/Exchange/CHIP: Leave NF, review with admin policy Medicare: Add to Formulary, no PA to match Cystaran Ophthalmic Solution Medicaid: Leave NF, review with admin policy
TOLSURA (itraconazole 65 mg capsule)	treatment of the following fungal infections in immunocompromised and non-immunocompromised adult patients: • Blastomycosis, pulmonary and extrapulmonary • Histoplasmosis, including chronic cavitary pulmonary disease and disseminated, non-meningeal histoplasmosis, and • Aspergillosis, pulmonary and extrapulmonary, in patients who are intolerant of or who are	Blastomycosis/Histoplasmosis 130 mg / day, can increased to max 260 mg/day if needed Aspergillosis 130 mg once daily or twice daily Life threatening Situations: loading dose of 130 mg three times daily for the first 3 days, followed by recommended dosing based on indication. Treat for a minimum of 3 months and until clinical and laboratory parameters	Commercial/Exchange/CHIP: itraconazole capsules & solution* Medicare:itraconazole capsule*	Commercial/Exchange/CHIP: Leave NF, review with admin policy Medicare: Leave NF, review with admin policy

	refractory to amphotericin B therapy.	indicate active fungal infection has subsided.		
BRONCHITOL (mannitol)	Add-on maintenance therapy to improve pulmonary function in adult patients 18 years of age and older with cystic fibrosis. Use BRONCHITOL only in adults who have passed the BRONCHITOL Tolerance Test.	400 mg (10 capsules) twice daily by oral inhalation in the morning and evening. Inhaler must be replaced after 7 days of use. 40 mg of mannitol per capsule, supplied in cartons of 10 (Bronchitol tolerance test), 140 (7 day-pack), and 560 (4-week pack) capsules and co-packaged with 1, 1, and 4 inhalers respectively.	Commercial/Exchange/CHIP: Pulmozyme*, HyperSal Nebulization Solution 7% Medicare: Pulmozyme*, HyperSal Nebulization Solution 7%	Commercial/Exchange/CHIP: Leave NF, review with admin policy, QL: 560 capsules per 28 days Medicare: Leave NF, review with admin policy, QL: 560 capsules per 28 days
GIMOTI (metoclopramide nasal spray)	Relief of symptoms in adults with acute and recurrent diabetic gastroparesis.	1 spray in one nostril 30 minutes before each meal and at bedtime (maximum of four times daily) for 2 to 8 weeks, depending on symptomatic response 15 mg/actuation, 10 mL amber glass bottle with metered spray pump attachment, sufficient for 4 weeks of 4 times a day use	Commercial/Exchange/CHIP: metoclopramide tablet, metoclopramide solution Medicare: metoclopramide tablet, metoclopramide solution	Commercial/Exchange/CHIP: Leave NF, review with admin policy Medicare: Leave NF, review with admin policy

PRESTALIA (perindopril argninine/ amlodipine)	Indicated for the treatment of hypertension to lower blood pressure: • In patients not adequately controlled with monotherapy • As initial therapy in patients likely to need multiple drugs to achieve their blood pressure goals	Recommended starting dose 3.5/2.5 mg once daily, adjust according to blood pressure goals, waiting 7 to 14 days between titration steps. The maximum recommended dose is 14/10 mg once daily 3.5/2.5 mg tablets, 7/5 mg tablets, and 14/10 mg tablets, each in bottles of 90 tablets	Commercial/Exchange/CHIP: perindopril, amlodipine, benazepril, captopril, enalapril, fosinopril, lisinopril, quinapril, ramipril, felodipine, isradipine, nicardipine, nifedipine, Olmesartan/amlodipine, valsartan/amlodipine, candesartan, irbesartan, olmesartan, valsartan Medicare: perindopril, amlodipine, benazepril, captopril, enalapril, fosinopril, lisinopril, quinapril, ramipril, felodipine, isradipine, nicardipine, nifedipine, Olmesartan/amlodipine, valsartan/amlodipine, candesartan, irbesartan, olmesartan, valsartan	Commercial/Exchange/CHIP: Leave NF, review with admin policy Medicare: Adhera Therapeutics, Inc is currently non-participating with CMS and Prestalia is excluded from coverage.
EXSERVAN (riluzole oral film)	Treatment of amyotrophic lateral sclerosis (ALS)	50 mg twice daily, taken at least 1 hour before or 2 hours after a meal 50 mg oral film, carton of 60 pouches	Commercial/Exchange/CHIP: riluzole tablets, Tiglutik Suspension Medicare:riluzole tablets, , Tiglutik Suspension Medicaid: riluzole tablets, Tiglutik Suspension	Commercial/Exchange/CHIP: Add to formulary, Add to Commercial Policy 556.0 Tiglutik, QL: 60 films/30 days Medical record documentation of age greater than or equal to 18 years **AND** • Medical record documentation that Tiglutik is prescribed by or in consultation with a neurologist **AND**

				• Medical record documentation of a diagnosis of amyotrophic lateral sclerosis (ALS) **AND** • Medical record documentation of therapeutic failure on, intolerance to, or contraindication to riluzole tablets **OR** • Medical record documentation that member has dysphagia or is unable to swallow tablets Medicare: Add to formulary, add to Part D Policy 736.0D Tiglutik, QL: 60 films/30 days 1. Prescription written by or in consultation with neurologist **AND** 2. Documentation of member age 18 year or older **AND** 3. Medical record documentation of diagnosis of ALS (amyotrophic lateral sclerosis) **AND** 4. Medical record documentation of therapeutic failure on, intolerance

				to, or contraindication to riluzole tablets OR documentation that the patient has dysphagia or is unable to swallow tablets. Medicaid: Add to formulary, QL: 60 films/30 days, Add to Policy 1491.0F for Tiglutik
ATELVIA (risedronate delayed release tablets)	Treatment of postmenopausal osteoporosis	35 mg orally once per week 35 mg delayed release tablets in dosepak of 4 tablets	Commercial/Exchange/CHIP: risderonate 150 mg, risedronate 35 mg (generic Actonel), risedronate 30 mg Medicare: risderonate 150 mg, risedronate 35 mg (generic Actonel), risedronate 30 mg, risedronate 35 mg delayed release (QL) (generic Atelvia)	Commercial/Exchange/CHIP:Leave NF, review with admin policy, QL: 4 tablets per 28 days Medicare:Leave NF, review with Brand with Generic Policy, QL: 4 tablets per 28 days
FARESTON/ TOREMIFENE (toremifene)	Treatment of metastatic breast cancer in postmenopausal women with estrogen-receptor positive or unknown tumors.	60 mg orally once daily until disease progression 60 mg tablets in bottles of 7 and 30	Commercial/Exchange/CHIP: anastrozole, letrozole, exemestane, tamoxifen Medicare: anastrozole, letrozole, exemestane, tamoxifen	Commercial/Exchange/CHIP: Fareston: Leave NF, review with Brand with Generic Policy Toremifene: Add to Formulary, no PA required

				Medicare: Fareston: Leave NF, review with Brand with Generic Policy Toremifene: Leave on Generic tier, no PA required
EGATEN (triclabendazole)	Treatment of fascioliasis in patients 6 years of age and older.	2 doses of 10 mg/kg given 12 hours apart in patients 6 years of age and older (if the dosage cannot be adjusted exactly, round the dose upwards) 250 mg functionally scored tablets in blister pack of 4 tablets	Commercial/Exchange/CHIP: none Medicare: none	Commercial/Exchange/CHIP: Leave NF, review with admin policy Novartis has been donating Egaten to the WHO since 2005, currently supplied by the WHO during epidemic outbreaks Medicare: Leave NF, review with admin policy Novartis has been donating Egaten to the WHO since 2005, currently supplied by the WHO during epidemic outbreaks
VISTOGARD	Emergency treatment of adult and pediatric patients: • following a fluorouracil or	Adults: 10 grams (1 packet) orally every 6 hours for 20 doses, without regard to meals.	Commercial/Exchange/CHIP: none Medicare: none	Commercial/Exchange/CHIP: Leave NF, review with admin policy

(uridine triacetate oral granules)	capecitabine overdose regardless of the presence of symptoms, or • who exhibit early-onset, severe or life-threatening toxicity affecting the cardiac or central nervous system, and/or early-onset, unusually severe adverse reactions (e.g., gastrointestinal toxicity and/or neutropenia) within 96 hours following the end of fluorouracil or capecitabine administration	Pediatric: 6.2 grams/m2 of body surface area (not to exceed 10 grams per dose) orally every 6 hours for 20 doses, without regard to meals. Orange-flavored oral granules in single dose packets containing 10 grams of uridine triacetate, in cartons of 4 packets and 20 packets		Medicare: Leave NF, review with admin policy

Cost Effectiveness:

DRUG	AWP/MAC per unit ($)	AWP/MAC per treatment course/30 day supply #	Notes
WYNZORA	$24 / gram	$1,440 /60 gram tube	Comparable to Enstilar cost, significantly more expensive than generic alternatives
ZILXI	$19.40 / gram	$582 / 30 grams	Comparable to Epsolay cost, significantly more expensive than generic alternatives
IMPEKLO	$8.80 / gram	$600.12 / 68 gram pump bottle	Significantly more expensive compared to generic alternatives
TWYNEO	$17.00 / gram	$510 / 30 gram pump bottle	Significantly more expensive compared to generic alternatives
MINOLIRA ER	$29.60 / tablet	$444 - $888	Significantly more expensive compared to generic alternatives
ACTICLATE	$44.10 / tablet	$882 - $1,764	Significantly more expensive compared to generic alternatives

LICART	$29.80 / patch	$894 / 30 patches	Significantly more expensive than generic diclofenac epolamine 1.3% (MAC price - $8.78 / patch)
ELEPSIA XR	$41.70 / tablet	$1,250 / 30 days	Price is comparable to other branded antiepileptics, significantly more expensive than generic alternatives
PURIXAN	$16.40 / milliliter	$4,428 / 30 days (based on body weight 70 kg)	Significantly more expensive than mercaptopurine tablets (MAC: 1.30 per tablets), NCCN does not recommend one product over the other
XATMEP	$20.11 / milliliter	$1,152 per month (based on BSA of 1.8m^2)	Significantly more expensive than methotrexate tablets (MAC: $0.48 per tablets)
VESICARE LS	$2.10 / milliliter	$630 / 30 days supply (based on max dose)	
EGRIFTA	$260 / vial	$7,790 / 30 vials	
COARTEM	$6.13 / tablet	$147 / 24 tablets	
ONZETRA XSAIL	$70.50 / unit	$1,130 / Kit (2 units/dose, 8 doses per kit)	Significantly more expensive compared to other formulary

			alternatives available generically
THIOLA EC	$34 -100 mg tablets $101 – 300 mg tablets	$8,100 / 30 days (800 mg dose as 2x100 mg tabs, 2 x 300 mg tabs)	
DUAKLIR PRESSAIR	$750 / inhaler	$750 / inhaler	More expensive than other 2 ingredient inhalers, price is comparable to Trelegy Ellipta (3 ingredients)
ACCRUFER	$10.30 / capsule	$610 / 30 day supply	
THYQUIDITY	$1.32 / milliliter (100 mcg/5mL)	$222 / 30 day supply (based on starting dose of 1.6 mcg/kg for 70 kg patient)	Significantly more expensive than generic levothyroxine tablets
LOREEV XR	$17.00 / sprinkle capsule	$510 / 30 day supply	Significantly more expensive compared to generic alternatives
MYCAPSSA	$126 / capsule	$7,560 - $15,120 / 30 day supply	
UPNEEQ	$8.33 / pouch	$250 - $500	
SOTYLIZE	$2.27 / milliliter	$1,089 – $2,179 / 30 days (for 80 mg – 160 mg daily dose)	Significantly more expensive than sotalol tablets (MAC 0.17 / 80 mg tablet)

QDOLO	$1.47 / milliliters	$117.60 / day $3,528 / 30 day (based on max of 400 mg/day)	Significantly more expensive than generic tramadol tablets (MAC: $0.07 / tablet)
Tramadol Oral Solution (NDA Authorized Generic)	$/ milliliters	$ / 200 mL	
SITAVIG	$572 / tablet	$572 / dose	Significantly more expensive than Acyclovir tablets and suspension ($0.06-$0.18 / tablet, $0.27 / milliliter)
CYSTADANE	$12.18 / gram	$2,191 / 180 grams	
VERSACLOZ	$10.12 / milliliter	$1,821 - $2,732 / 30 days of target dose 300 mg – 450 mg	
TUZISTRA XR	$1.50 / milliliter	$30 / day	Significantly more expensive compared to generic alternatives
CYSTADROPS	$476 / mL	$2,380 / 5 mL bottle	Price is comparable to one bottle of Cystaran ophthalmic solution, but is dosed every 4 hours compared to every waking hour for Cystaran)

TOLSURA	$47.26 / capsule	$2,840 - $5,670 / 30 day supply	Significantly more expensive than itraconazole capsule (MAC: $0.82 / 100 mg capsule)
BRONCHITOL	$7.46 per inhalation capsule	$4,178 / 28 days	Price is comparable to Pulmozyme, considered second line to Pulmozyme + HyperSal
GIMOTI	$214. 30 / milliliter	$2,100 per 9.8 mL spray bottle	Significantly more expensive than metoclopramide tablets (MAC: $0.02-$0.03 / tablet)
PRESTALIA	$6.81 / tablet	$204 / 30 days supply	Significantly more expensive than peridopril tablets (MAC: $0.49 - $0.57 / tablet) + amlodipine ($0.08 / tablet)
EXSERVAN	$62.86 / film	$1,885 / 30 films	Price is comparable to Tiglutik Oral Solution
ATELVIA	$80 / tablet	$320	Generics available
Risedronate 35 mg (ER)	$27.34 / tablet		Still considerably more expensive than risedronate 35 mg tablets (generic Actonel, MAC: $9.38 / tablet)
FARESTON	$51.99 / tablet	$1,560 / 30 days	Generics Available

TOREMIFENE	$18.56 / tablet	$556 / 30 days	
VISTOGARD	$4,815 / packet	$96,312 / 20 doses	

Formulary Recommendations Based on Cost Analysis

DRUG	COMMERCIAL RECOMMENDATIONS	MEDICARE RECOMMENDATIONS	MEDICAID RECOMMENDATIONS
XATMEP	Add to Oral Oncology Brand NP tier. See Clinical Recommendations for PA criteria (to match Medicare Policy)	-	-
CYSTADROPS	-	Add to Specialty tier without a PA to match Cystaran placement	-
EXSERVAN	Add to Specialty tier/ Brand NP tier for members with three tier benefit to match Tiglutik placement	Add to Specialty tier Tiglutik placement	Add to Brand tier Tiglutik placement
TOREMIFENE	Add to generic tier, no PA required	-	-

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

FAST FACTS

PEMAZYRE (pemigatinib)

Clinical Summary: Pemazyre is now indicated for the treatment of adults with relapsed or refractory myeloid/lymphoid neoplasms (MLNs) with fibroblast growth receptor 1 (FGFR1) rearrangement. Previously Pemazyre was indicated for the treatment of cholangiocarcinoma with a FGFR2 fusion or other rearrangement. At this time, there are no FDA approved tests available for the detection of FGFR1 rearrangement.

The recommended dosage of Pemazyre for the new indication is 13.5 mg once daily on a continuous basis continued until disease progression or unacceptable toxicity. For the cholangiocarcinoma indication, Pemazyre is given once daily for 14 days, followed by 7 days off therapy in 21 day cycles.

Approval for the new indication is based on results of the FIGHT-203 trial, an open-label, single-arm trial in 28 patients with MLNS with FGFR1 rearrangement. Patients included in the trial had documented myeloid/lymphoid neoplasms with 8p11 rearrangement shown to be an FGFR1 activating mutation based on cytogenic evaluation. Patents could have relapsed after allogeneic hematopoietic stem cell transplantation or after a disease modifying therapy or were not a candidate for allo-HSCT or other disease modifying therapies. Patients received Pemazyre 13.5 mg once daily in 21-day cycles as either a continuous or intermittent schedule. In patients with chronic phase in the marrow (n=18), efficacy was based on complete response (MDS/MPN Working Group response criteria for MDS/MPN neoplasms/CR in extramedullary disease (EMD) using Lugano criteria if applicable). Complete response was achieved in 78% (14/18) of patients, median time to CR was 104 days, and median duration of CR was not reached.

In patients with blast phase in the marrow (n=4), efficacy was based on CR (<5% blasts in the bone marrow, no evidence of disease, and full recovery of peripheral blood counts). Two out of 4 patients achieved a CR (duration 1+ and 94 days).

In patients with EMD only, efficacy was based on CR using Lugano criteria. One out of 3 patients with EMD only achieved a CR (duration 64+ days).

For all patients, complete cytogenic response rate was 79%.

No new safety signals were identified and the adverse reactions observed in the FIGHT-203 trial are consistent with the known safety profile of Pemazyre.

Current formulary status: Oral Oncology Brand NP tier ($0 copay), PA required QL: 14 tablets per 21 days

Recommendation: There are no changes recommended for the formulary placement and authorization for Pemazyre. The following changes to the prior authorization and quantity limit will be added to Commercial Policy 627.0 for Pemazyre:

- Medical record documentation that Pemazyre 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 one of the following:

- Medical record documentation of unresectable locally advanced or metastatic cholangiocarcinoma **AND**
- Medical record documentation of a fibroblast growth factor receptor 2 (FGFR2) fusions or other rearrangement as verified by a Food and Drug Administration (FDA) approved test **AND**
- Medical record documentation of one prior line of therapy

OR

- Medical record documentation of relapsed or refractory myeloid/lymphoid neoplasms (MLNS) **AND**
- Medical record documentation of a fibroblast growth factor receptor 1 (FGFR1) rearrangement

NOTE: The FDA approved test for cholangiocarcinoma is the FoundationOne CDx.

MEDISPAN AUTHORIZATION LEVEL: GPI-12, number of claims authorized = 1, enter for the remainder of the calendar year

QUANTITY LIMIT: *No QLs need to be entered within the authorization unless the requested quantity exceeds the QL.*

- QL FOR LETTER ONLY: ~~14 tablets per 21 days~~ 1 tablet per day

RE-AUTHORIZATION CRITERIA: Pemazyre is configured as a prior authorization for new starts only. Pemazyre will no longer be covered if it is identified that the member is not receiving appropriate follow-up care from the prescribing specialist or if the member has greater than or equal to a 90 day break in therapy.

- Medical record documentation that the member is receiving appropriate follow-up care from the prescribing specialist

Discussion: Kim asked if we could code quantity limits specific to indication. The 14 tablets per 21 days is still appropriate for the treatment of cholangiocarcinoma with a FGFR2 fusion or other rearrangement. Confirmed we can but we will need to update the policy to require entry of the quantity limit in both the letter and within the claims processing system.

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.

RETEVMO (selpercatinib)

Clinical Summary: Retevmo is now indicated for the treatment of adult patients with locally advanced or metastatic solid tumors with a RET gene fusion that have progressed on or following prior systemic treatment or who have no satisfactory alternative treatment options.

There are no changes to the recommended dosage of Retevmo and the recommended dose is based on body weight 120 mg for patients weighing less than 50 kg and 160 mg weighing 50 kg or greater twice daily (approximately every 12 hours) until disease progression or unacceptable toxicity.

Support for the new indication comes from another cohort of the LIBRETTO-001 clinical trial in 41 patients with locally advanced or metastatic RET fusion-positive solid tumors other than NSCLC and thyroid cancer with disease progression on or following prior systemic treatment or who had no satisfactory alternative treatment options. Efficacy results showed a overall response rate of 44% (4.9% complete, 39% partial) and a median duration of response of 24.5 months, with 67% of patients achieving a response lasting at least 6 months.

Current formulary status: Oral Oncology Brand NP tier, requires PA, QL: 40 mg capsules: 2 capsules per day, 80 mg capsules: 4 capsules per day

Recommendation: There are no changes recommended to the formulary placement, quantity limits, or authorization duration of Retevmo. The following prior authorization criteria will be added to Policy 632.0 for Retevmo to incorporate the new indication:

Solid Tumors

- Medical record documentation that Retevmo 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 locally advanced or metastatic solid tumors with a RET gene fusion **AND**
- Medical record documentation of progression on or following prior systemic therapy **OR**
- Medical record documentation that patient has 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.

UPDATES

ERYTHROPOIETIN, DARBEPOETIN, AND MIRCERA UPDATE

Background: It is recommended to update the units of measurement for erythropoietin levels and the general guidance criteria of the erythropoietin and darbepoetin therapy policy (MBP 49.0) and to update both initial and reauthorization criteria of the Mircera policies (MBP 130.0 Commercial policy 376.0 and Part D policy 471.0D). The update to the erythropoietin and darbepoetin policy is intended to clarify the requested time for a repeat hemoglobin to be submitted. The update to the Mircera policies is intended to align policies for all erythropoiesis-stimulating agents (ESA) to account for low ferritin and transferrin saturation levels for patients also on iron chelating agents.

Recommendation: MBP 49.0 Erythropoietin and Darbepoetin Therapy
2. Treatment of symptomatic anemia in zidovudine-treated HIV infected insured individuals when all of the following criteria are met:
- Endogenous erythropoietin levels of 500 ~~M~~mU/mL or less; AND
- Ferritin greater than or equal to 100 ng/mL or transferrin level saturation greater than or equal to 20% or a history of chelation therapy for iron; AND
- Zidovudine doses of 4200 mg or less per week; AND
- Hgb less than or equal to 10 g/dL for new starts OR Hgb less than 12 g/dL for continuation of therapy

4. Treatment of symptomatic anemia secondary to myelodysplastic syndrome (MDS) when all of the following criteria are met:
- Hgb less than or equal to 10 g/dL for new starts OR Hgb less than 12 g/dL for continuation of therapy AND
- Ferritin greater than or equal to 100ng/dL or transferrin level saturation greater than or equal to 20% OR a history of chelation therapy for iron; AND
- Baseline endogenous erythropoietin levels of 500 ~~M~~mU/mL or less (NCCN Clinical Practice Guidelines in Oncology – Myelodysplastic Syndromes v2.2010)

GENERAL GUIDEANCE:
- For continuation of therapy, a repeat hgb no greater than 3 months old should be submitted ~~after 3-12 months of therapy~~.
- In individuals whose Hgb is greater than or equal to 12gm/dL or rises by 1gm/dl in any two-week period, additional doses should be withheld or reduced. ~~(In insured individuals with Hgb of greater than or equal to 12 gm/dL Erythropoietin or Darbepoetin therapy will not be covered according to FDA recommendations,~~ Except when being used for reduction of allogeneic blood transfusion in anemic insured individuals undergoing surgery).
- For initiation or continuation of therapy, a ferritin level no greater than 3 months old and/or transferrin saturation level no greater than 6 months old should be submitted.
- The member should receive supplemental iron if serum ferritin is less than 100ng/ml and transferrin saturation is less than 20 percent.

MBP 130.0 Mircera (methoxy polyethylene glycol-epoetin beta)
For initial authorization in adult patients:

- Medical record documentation of age 18 years or greater **AND**
- Medical record documentation of use for the treatment of anemia associated with chronic kidney disease (CKD) in patients on dialysis and patients not on dialysis **AND**
- Hemoglobin (Hgb) less than 10 g/dL for new starts **AND**
- Ferritin greater than or equal to 100 ng/mL or transferrin level saturation greater than or equal to 20%, or a history of chelation therapy for iron

For initial authorization in pediatric patients:

- Medical record documentation of age 5 years or greater **AND**
- Medical record documentation of use for the treatment of anemia associated with chronic kidney disease in patients on dialysis **AND**
- Medical record documentation that patient's hemoglobin has stabilized on and patient is converting to Mircera from another erythropoiesis-stimulating agent **AND**
- Hemoglobin (Hgb) less than 11 g/dL for new starts **AND**
- Ferritin greater than or equal to 100 ng/mL or transferrin level saturation greater than or equal to 20%, or a history of chelation therapy for iron

For continuation of therapy, a repeat Hgb no greater than 3 months old should be submitted ~~after 12 months of therapy~~.

For continuation of therapy in adult patients:

- Medical record documentation of age 18 years or greater **AND**
- Medical record documentation of use for the treatment of anemia associated with chronic kidney disease (CKD) in patients on dialysis and patients not on dialysis **AND**
- Hemoglobin (Hgb) less than 11 g/dL for continuation of therapy **AND**
- Ferritin greater than or equal to 100 ng/mL or transferrin level saturation greater than or equal to 20%, or a history of chelation therapy for iron

For continuation of therapy in pediatric patients:

- Medical record documentation of age 5 years or greater **AND**
- Medical record documentation of use for the treatment of anemia associated with chronic kidney disease in patients on dialysis **AND**
- Hemoglobin (Hgb) less than 11 g/dL for continuation of therapy **AND**
- Ferritin greater than or equal to 100 ng/mL or transferrin level saturation greater than or equal to 20%, or a history of chelation therapy for iron

In individuals whose Hgb is greater than or equal to 12gm/dL or rises by 1gm/dl in any two-week period, additional doses should be withheld or reduced.

AUTHORIZATION DURATION: Each authorization period (initial and re-authorization) will be defined as a period of 12 months. Re-authorization will be considered based on continuation of therapy criteria listed above.

Commercial Policy 376.0 Mircera
For new starts:

- Medical record documentation of use for the treatment of anemia associated with chronic kidney disease (CKD) in adult patients on dialysis and patients not on dialysis AND
- Medical record documentation of hemoglobin (hgb) less than 10 g/dL for new starts AND

- Medical record documentation of ferritin greater than or equal to 100 ng/mL or transferrin level saturation greater than or equal to 20%, or a history of chelation therapy for iron

For continuation of therapy, a repeat hemoglobin (hgb) no greater than 3 months old should be submitted ~~after 3 months of therapy~~. The following criteria will apply to requests for continuation of therapy:

- Medical record documentation of use for the treatment of anemia associated with chronic kidney disease (CKD) in adult patients on dialysis and patients not on dialysis AND
- Medical record documentation of hemoglobin (hgb) less than 12 g/dL for continuation of therapy AND
- Medical record documentation of ferritin greater than or equal to 100 ng/mL or transferrin level saturation greater than or equal to 20%, or a history of chelation therapy for iron

NOTE: In individuals whose hemoglobin (hgb) is greater than or equal to 12 g/dL or rises by 1 g/dL in any two-week period, additional doses should be withheld or reduced.

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.

CRYSVITA UPDATE

BACKGROUND: It is recommended to update the prior authorization criteria and authorization duration for medical benefit policy (MBP) 182.0 Crysvita to correctly reflect FDA-approved dosing recommendations and contraindications.
Recommendation: MBP 182.0 Crysvita (burosumab-twza)
X-linked hypophosphatemia

- Medical record documentation that the patient is at least 6 months of age or older **AND**
- Medical record documentation that Crysvita is being prescribed by, or in consultation with, an endocrinologist, geneticist, or nephrologist **AND**
- Medical record documentation of a diagnosis of X-linked hypophosphatemia as evidenced by one of the following:
    - Reduced TmP/GFR ratio **AND** Reduced or normal plasma concentration of 1,25-dihydroxycholecalciferol (1,25-DHCC) or 25-hydroxyvitamin D [25(OH)D] **OR**
    - Genetic testing confirming a mutation in the PHEX (Phosphate regulating Endopeptidase on the X chromosome) gene

  AND
- Medical record documentation that the patient is not concurrently using active vitamin D analogs (e.g. calcitriol, paricalcitol, doxercalciferol, calcifediol) or phosphate supplements

FGF23-related hypophosphatemia in tumor-induced osteomalacia (TIO)

- Medical record documentation that the patient is at least 2 years of age or older **AND**

- Medical record documentation that Crysvita is being prescribed by, or in consultation with, an endocrinologist, nephrologist, geneticist, or oncologist **AND**
- Medical record documentation of a diagnosis of FGF23-related hypophosphatemia in tumor-induced osteomalacia (TIO) associated with phosphaturic mesenchymal tumors **AND**
- Medical record documentation of an elevated serum level of FGF23 **AND**
- Medical record documentation that tumors cannot be curatively resected or localized **AND**
- Medical record documentation that the patient is not concurrently using active vitamin D analogs (e.g. calcitriol, paricalcitol, doxercalciferol, calcifediol) or phosphate supplements.

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 the following criteria are met:

- Medical record documentation that patient is being followed regularly by and receiving medication from an endocrinologist, nephrologist, geneticist or oncologist **AND**
- Medical record documentation that Crysvita is improving patient's disease as evidenced by normalized or improved serum phosphorus levels **AND**
- Medical record documentation that the patient is not concurrently using active Vitamin D analogs (e.g. calcitriol, paricalcitol, doxercalciferol, calcifediol) or phosphate supplements

Note: Per FDA labeling, supplementation with cholecalciferol or ergocalciferol is recommended to maintain 25-hydroxy vitamin D levels in the normal range for age.

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 3:28 pm

Future Scheduled Meetings

The next bi-monthly scheduled meeting will be held on January November 17th, 2022 at 1:00 p.m.

Meeting will be held virtually via phone/Microsoft Teams.