P&T Committee Meeting Minutes
Commercial/Marketplace/GHP Kids
July 19, 2022

Present (via Teams):	**Absent:**
Bret Yarczower, MD, MBA – Chair	Holly Bones, Pharm.D.
Megan Ammon, Pharm.D.	Alyssa Cilia, RPh
Emily Antosh, Pharm.D.	Michael Evans, RPh
Kristen Bender, Pharm.D.	Tricia Heitzman, Pharm.D.
Jeremy Bennett, MD	Jason Howay, Pharm.D.
Kim Castelnovo	Keith Hunsicker, Pharm.D.
Kimberly Clark, Pharm.D.	Kelli Hunsicker, Pharm.D.
Rajneel Farley, Pharm.D.	Jonas Pearson, RPh
Kelly Faust Pharm.D.	William Seavey, Pharm.D.
Nichole Hossler, MD	Michael Shepherd, MD
Emily Hughes, Pharm.D.	Leslie Shumlas, Pharm.D.
Derek Hunt, Pharm.D.	Richard Silbert, MD
Kerry Ann Kilkenny, MD	Robert Strony, MD MBA
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.	
Aubrielle Smith Pharm.D.	
Kirsten Smith, Pharm.D.	
Michael Spishock, RPh	
Todd Sponenberg, Pharm.D.	
Jill Stone, Pharm.D.	
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)	
Brianna Price, Pharm.D. (Pharmacy Resident)	
Megan Sokol, Pharm.D. (Pharmacy Resident)	
Sarah Tucker, Pharm.D. (Pharmacy Resident)	
Rachelle Papcena (Pharmacy Student)	

Call to Order:
Dr. Bret Yarczower called the meeting to order at 1:02 p.m., Tuesday, July 19, 2022.

Review and Approval of Minutes:

Dr. Bret Yarczower asked for a motion or approval to accept the May 15, 2022 and June 2022 e-vote minutes as written. Minutes approved unanimously. None were opposed.

DRUG REVIEWS

CAMCEVI (leuprolide)

Review: Camcevi is a gonadotropin-releasing hormone (GnRH) agonist indicated for the treatment of adult patients with advanced prostate cancer. Camcevi contains leuprolide which inhibits gonadotropin secretion. Single subcutaneous doses of leuprolide result in an initial increase in circulating levels of LH and FSH, leading to a transient increase in gonadal steroid levels (testosterone and dihydrotestosterone in males). Chronic administration results in decreased levels of LH and FSH and leads to ovarian and testicular steroidogenesis suppression. In males, testosterone is reduced to below castration levels about 2 to 4 weeks after initiation of treatment and maintenance of these levels have been demonstrated for periods of up to 5 years in prostatic cancer patients.

Camcevi is a pre-mixed emulsion depot formulation of leuprolide mesylate. Other leuprolide formulations available on the market (e.g., Lupron Depot, Eligard) contain leuprolide acetate and require reconstitution and/or mixing prior to administration. Camcevi must be administered by a healthcare provider and has a recommended dosage of 42 mg subcutaneously once every 6 months which is equivalent to the other marketed leuprolide formulations when calculated on free base basis. It is supplied as a single-dose prefilled syringe containing 42 mg leuprolide for subcutaneous injection.

Efficacy findings of Camcevi are based on an open-label, single arm, multinational study FP01C-13¬ 001 in 137 patients with advanced prostate carcinoma who had baseline morning serum testosterone level >150 ng/dL and ECOG performance status scores of ≤ 2. Camcevi was administered at the recommended dose on Day 0 and again at Week 24. The major efficacy outcome evaluating medical castration rate (achieving and maintaining serum testosterone suppression to ≤ 50 ng/dL by week 4 through Week 48 of treatment) showed that serum testosterone levels were suppressed by Week 4 in 98.5% of patients and maintained from Week 4 through Week 48 in 97% of patients. PSA levels were also monitored and were lowered on average by 51% after 4 weeks and 83% after three months and remained suppressed through 48 weeks of treatment. Due to the heterogeneity of the patient population studied, these results should be interpreted with caution and the rapidity of PSA decline does not necessarily correlate with clinical benefit.

Safety data for Camcevi is based on previous findings for other leuprolide products and the labeling matches the Lupron Depot labeling. Overall findings were consistent with that expected in men in the demographic group and disease stated and were comparable to toxicities reported in previous clinical trials and post-marketing reports of leuprolide. During the FP01C-13¬ 001 clinical trial, the most common adverse reactions were hot flush, hypertension, injection site reactions, upper respiratory tract infections, musculoskeletal pain, fatigue, and pain in extremity. The safety and efficacy of Camcevi in pediatric patients has not been established. In study FP01C-13¬ 001, 74% of patients were 65 years of age or older and 37% were 75 years or older. No overall differences in safety or efficacy were observed between older and younger patients.

NCCN recommendations for Camcevi match previous leuprolide products and they do not appear to give preference for one salt form over another.

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

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

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

Outcome: Camcevi is a medical benefit and will be added to the medical benefit cost share list. If processed at a specialty pharmacy, Camcevi will process at the Specialty tier or Brand Non-Preferred tier for members with a three tier benefit. No prior authorization or limitations will apply.

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

ENJAYMO (sutimlimab-jome)

Review: Enjaymo is a classical complement inhibitor indicated to decrease the need for red blood cell transfusion due to hemolysis in adults with cold agglutinin disease (CAD). CAD is a rare form of autoimmune hemolytic anemia characterized by the premature destruction of red blood cells (hemolysis) attributable to cold agglutinins (autoantibodies with an optimum temperature of 3–4 °C or 37–39 °F). Cold agglutinins trigger hemolysis when they are exposed to temperatures below normal core body temperature. Once a red blood cell is recognized by the cold-induced antibody, it will cause agglutination, or clumping. The red blood cells then become bound to complement. Once the red blood cells are bound to complement, they can be attacked and destroyed by other immune cells. This results in a hemolytic anemia. Most cases of CAD are due to immunoglobulin M (IgM) antibodies. CAD can be primary (meaning the cause is unknown) or secondary (due to another condition, most commonly an infectious disease [especially M. pneumoniae and Epstein-Barr virus infection] or immunoproliferative disease [e.g., non-Hodgkin's lymphoma, chronic lymphocytic leukemia]).

The symptoms associated with CAD are generally triggered by exposure to cold temperatures and can be classified into hemolytic and circulatory symptoms. Hemolytic symptoms are characterized by paleness of the skin, fatigue, shortness of breath, dizziness, and palpitations. Severe hemolysis may lead to chest pain, deregulation of heart rate and blood pressure, jaundice, and dark-pigmented urine. Circulatory (or cold-induced) symptoms are characterized by coldness of the fingers and/or toes and painful bluish or reddish discoloration of the skin of the digits, ankles, and wrists (acrocyanosis or Raynaud's phenomenon). In severe cases, ulcers may develop on the extremities of digits. CAD can be diagnosed by laboratory tests. The following are required for diagnosis: Evidence of chronic hemolysis (examples: high reticulocyte count, High LDL, high indirect bilirubin, low haptoglobin), positive polyspecific direct antiglobulin test (DAT), positive monospecific DAT specific for C3d, and cold agglutinin titer ≥ 64 at 4 degrees Celsius.

Enjaymo is an immunoglobulin G, subclass 4 (IgG4) monoclonal antibody that inhibits the classical complement pathway and specifically binds to complement protein component 1, s subcomponent (C1s), a serine protease which cleaves C4. Inhibition of the classical complement pathway at the level of C1s prevents deposition of complement opsonins on the surface of red blood cells, resulting in inhibition of hemolysis in patients with CAD. Enjaymo is the first and only approved treatment for people with CAD. Patients should be vaccinated against encapsulated bacteria (e.g., Streptococcus pneumoniae, Neisseria meningitidis, and Haemophilus influenzae subgroup B) at least 2 weeks prior to treatment, according to the most current recommendations for patients with persistent complement deficiencies. Enjaymo is administered weekly for the first 2 weeks, then every 2 weeks thereafter. The recommended dosage of Enjaymo is based on body weight. Patients weighing 39 kg to <75 kg receive a dose of 6500 mg by intravenous infusion. Patients weighing ≥75 kg receive a dose of 7500 mg by intravenous infusion.

The treatment of CAD depends on the severity of the clinical manifestations. Avoidance of cold exposure, particularly to the head, face, and extremities, is necessary to decrease hemolysis and circulatory symptoms. If symptoms are mild or the destruction of red blood cells slows down, no additional treatment is warranted. About 25% of individuals will use supportive measures alone to manage their disease. However, if the rate of red blood cell destruction increases, additional management may be required.

Symptomatic primary CAD (anemia, circulatory symptoms, and requirement for transfusion) is usually treated with off-label rituximab as first-line therapy. Rituximab depletes antibody-producing B cells and therefore can reduce the agglutination or clumping of red blood cells. As monotherapy, rituximab is usually administered as a 375 mg/m2 once weekly via intravenous infusion for 4 doses. Single-agent rituximab has been shown to have an overall response rate of approximately 50% (complete responses are rare), with a median duration of response of around 6 to 11 months. While well tolerated, rituximab can take 1 to 2 months to show effects. Patients who respond to rituximab can repeat treatment once they progress.

Rituximab can also be used in combination with chemotherapy agents, such as bendamustine or fludarabine, for patients who can tolerate chemotherapy. Rituximab + bendamustine therapy is the most used combination due to its lower relative toxicity. When administered rituximab 375 mg/m2 on Day 1 and bendamustine 90 mg/m2 on Days 1 and 2 as four 28-day cycles, this combination has shown a 71% overall response rate with 40% of patients achieving a complete response. The median response duration in one study was over 7 years.

Plasmapheresis is another option and can remove cold agglutinins by removing IgM antibodies. This however does nothing to decrease IgM production. To date, no large trials have assessed its efficacy in CAD, so plasmapheresis is largely reserved as a temporary or emergency treatment. Transfusions are used when indicated, with use being more common in winter months due to cold temperatures and infection.

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

Clinical Discussion: Any comparison to other treatments for cold agglutinin? Question is if episodic vs. ongoing treatment is superior? No head to head comparisons. Should we reach out to hematology for input? Review was sent to specialists, but no feedback has been received to date. No additional comments or questions. The committee unanimously voted to accept the recommendations as presented. None were opposed.

Financial Discussion: Believe this will be most used in the Medicare population. Do we have any idea of how many members we currently have with CAD? Since the beginning of 2022 we have had 15 members receive Enjaymo; 10 of the 15 were Medicare members. No additional comments or questions. The committee unanimously voted to accept the recommendations as presented. None were opposed.

Outcome: Enjaymo will be a medical benefit and will be added to the medical benefit cost share list. If processed at a specialty pharmacy, Enjaymo should 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:

- Documentation of age greater than or equal to 18 years **AND**
- Medical record documentation that Enjaymo is prescribed by or in consultation with hematologist **AND**
- Medical record documentation of a diagnosis of primary cold agglutinin disease (CAD) based on:
    - Evidence of chronic hemolysis (examples: high reticulocyte count, High LDL, high

indirect bilirubin, low haptoglobin) **AND**
    - Positive polyspecific direct antiglobulin test (DAT) **AND**
    - Positive monospecific DAT specific for C3d **AND**
    - Cold agglutinin titer ≥ 64 at 4 degrees Celsius **AND**
- Hemoglobin ≤ 10.0 g/dL for new starts **AND**
- History of at least one blood transfusion within 6 months of starting Enjaymo **AND**
- Medical record documentation that secondary causes of CAD have been ruled out **AND**
- Medical record documentation of a prescribed dose that is consistent with FDA-approved package labeling, nationally recognized compendia, or peer-reviewed medical literature **AND**
- Medical record documentation that Enjaymo will not be used in combination with rituximab ± bendamustine or fludarabine **AND**
- Medical record documentation that patient is vaccinated against encapsulated bacteria (e.g., *Streptococcus pneumoniae*, *Neisseria meningitidis*, and *Haemophilus influenzae* subgroup B) at least 2 weeks prior to treatment
- Medical record documentation of a therapeutic failure on, intolerance to, or contraindication to rituximab ± bendamustine or fludarabine

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

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

IGALMI (dexmedetomidine)

Review: Igalmi is indicated in adults for the acute treatment of agitation associated with schizophrenia or bipolar I or II disorder. The safety and effectiveness of Igalmi has not been established beyond 24 hours from the first dose. There may be a risk for tolerance and tachyphylaxis if used in a manner other than indicated.

Igalmi should be administered under the supervision of a healthcare provider. A healthcare provider should monitor vital signs and alertness after Igalmi administration to prevent falls and syncope. Igalmi is administered sublingually or buccally and should not be chewed or swallowed. Igalmi dissolves in 6–8 minutes and 18 minutes following sublingual and buccal administration, respectively. Igalmi is supplied as 120 mcg and 180 mcg films. The films can be cut in half to obtain the 60 mcg and 90 mcg doses.

The management of acute agitation associated with schizophrenia and bipolar disorder includes non-pharmacological, behavioral, and psychological techniques alone or in combination with pharmacotherapy. According to Project BETA (Best Practices in Evaluation and Treatment of Agitation) 2012 guidelines, benzodiazepines are primarily used if the initial dose of the antipsychotic does not adequately control the patient's agitation. The most common used medications to treat acute agitation include haloperidol, loxapine, olanzapine, ziprasidone, risperidone, asenapine, lorazepam. Igalmi will likely be used as an alternative to benzodiazepines when additional therapy is required after administration of an antipsychotic.

Igalmi causes dose-dependent hypotension, orthostatic hypotension, and bradycardia. Igalmi should be avoided in patients with hypotension, orthostatic hypotension, advanced heart block, severe ventricular dysfunction, or history of syncope. After administration, patients should stay hydrated and should sit or lie down until vital signs are within normal range. Igalmi prolongs the QT interval. It should be avoided in patients at risk for torsades de pointes or sudden death. Patients should not operate a motor vehicle or hazardous machinery for at least 8 hours after taking Igalmi. The most common adverse reactions (incidence ≥ 5% and at least twice the rate of placebo) are somnolence, paresthesia or oral hypoesthesia, dizziness, dry mouth, hypotension, and orthostatic hypotension. The safety and effectiveness of Igalmi have not been established in pediatric patients. Dose adjustments are recommended in geriatric patients, as hypotension and/or bradycardia may be more pronounced in this population.

Dr. Bennett mentioned it is standard practice for providers to use a faster acting antipsychotic and a benzodiazepine at the same time for acute agitation in the inpatient setting. The traditional choices being either an IM (haloperidol, ziprasidone, olanzapine) or ODT (olanzapine, risperidone) antipsychotic given at the same time as a benzodiazepine (lorazepam IM or PO). This is ordered whether the member has standing orders for another daily antipsychotic or not. He believes it would be reasonable to require therapeutic failure or contraindication to the combination of an antipsychotic and benzodiazepine. In practice, patients with acute agitation often have symptoms that endure past 24 hours (average duration of agitation delirium is 5 days, average duration of agitation related to schizophrenia or bipolar mania after appropriate treatment is initiated is 3-4 days). He is not sure if limiting the authorization to 1 day would meet the member's needs, however he is not sure if we have an alternative if 1 day is all the safety data can support.

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

Clinical Discussion: Is a patient getting a prescription and taking this at home? This is only administered under the supervision of a healthcare provider. Anticipate most utilization will be bought and billed and used inpatient. May be used in long term care facilities. Does it always work? It was only compared to placebo in clinical trials and did decrease agitation scores. This is likely to be used last line. Do we need to include a measure of efficacy if repeat dosing is required? In Dr. Taylor's experience she feels the utilization will likely be low due to the route of administration and the difficulty administering an oral agent to an agitated patient. Are there concerns about applying a prior authorization for use in an outpatient setting when it's needed for an acutely agitated patient? Dr. Bennett confirmed that patients typically would not be treated in an outpatient setting but would likely be escorted to the emergency department if acutely agitated. 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: Igalmi is a medical benefit. The following prior authorization criteria will apply:

- Medical record documentation of age greater than or equal to 18 years **AND**
- Medical record documentation of a diagnosis of schizophrenia or bipolar I or II disorder **AND**
- Medical record documentation that Igalmi will be used to for the acute treatment of agitation **AND**
- Medical record documentation of a therapeutic failure on, intolerance to, or contraindication to the acute use of an antipsychotic and a benzodiazepine for the management of agitation **AND**
- Medical record documentation that Igalmi will be administered under the supervision of a healthcare provider

QUANTITY LIMIT: 2 films per fill

AUTHORIZATION DURATION: 7 days

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

QUVIVIQ (daridorexant)

Review: The International Classification of Sleep Disorders defines insomnia disorder as a complaint of trouble initiating or maintaining sleep, which is associated with daytime consequences and is not attributable to environmental circumstances or inadequate opportunity to sleep. Insomnia is considered chronic when it has persisted for at least 3 months for at least 3 times per week. Symptoms persisting for less than 3 months are considered short-term insomnia. Insomnia is a common condition: approximately 30% to 50% of the U.S. population experiences occasional, short-term insomnia. Prevalence of chronic insomnia disorder in industrialized nations is estimated to be at least 5% to 10%. Prevalence is higher in medically and psychiatrically ill populations, as well as in older adults.

Quviviq is indicated for the treatment of adult patients with insomnia characterized by difficulties with sleep onset and/or sleep maintenance. Quviviq is a dual orexin receptor antagonist (DORA), a newer class of medication for insomnia that blocks the binding of the wake-promoting neuropeptides orexins, which is thought to suppress wake drive. DORAs have proven effective for both sleep onset and sleep maintenance. They offer a unique mechanism of action that does not impact gamma aminobutyric acid (GABA) and could offer improved tolerability. However, additional head-to-head data are needed to further characterize Quviviq safety and efficacy profile compared to generic medications for insomnia. As more experience with their use is garnered, the position of DORAS in insomnia therapy is expected to evolve. Quviviq is now the third FDA-approved DORA after Belsomra (suvorexant), Eiasi's Dayvigo (lemborexant) of both brand and generic insomnia treatments. The recommended dosage is 25 mg to 50 mg once per night, taken orally within 30 minutes before going to bed, with at least 7 hours remaining prior to planned awakening.

Below are the AASM recommendations:
Recommended for sleep onset: eszopiclone, ramelteon, temazepam, triazolam, zaleplon, and zolpidem
Recommended for sleep maintenance: doxepin, eszopiclone, temazepam, Belsomra (suvorexant), and zolpidem

To ensure appropriate use, IPD recommends the following management approaches:
Trial of 2 or 3 generic medications for insomnia (zolpidem, eszopiclone, zaleplon, ramelteon, doxepin, temazepam, or triazolam) unless contraindicated or adverse effects are experienced. A requirement of 2 failures indicates a moderate level of management. Three failures indicate a higher degree of management.

Many payers have implemented step therapy on generic products before use of Dayvigo and Belsomra. It would be appropriate to mirror Quviviq utilization management to these existing policies.

Zolpidem, eszopiclone, zaleplon, temazepam, and triazolam are on the Beers List Criteria and should be avoided in elderly patients. Ramelteon and doxepin (generic silenor) are not on the Beers List Criteria and are preferred in the elderly.

Quviviq was well tolerated in clinical studies; the most common adverse reactions (in at least 5% of patients and greater than placebo) were headache and somnolence or fatigue. Labeled warnings and precautions include central nervous system (CNS)–depressant effects and daytime impairment, worsening depression/suicidal ideation, sleep paralysis, hypnagogic/hypnopompic hallucinations, and

cataplexy-like symptoms, complex sleep behaviors, compromised respiratory function, and the need to evaluate for comorbid diagnoses. Chance of somnolence and fatigue increased with age.

The prescribing information notes that because it can increase somnolence and drowsiness, geriatric patients are at higher risk of falls. In addition, no dose adjustments are necessary in patients > 65 yo. Safety and effectiveness are not established in pediatric patients. No hepatic or renal adjustments are necessary. Quviviq contains daridorexant, a Schedule IV controlled substance. Clinically important drug interactions include strong or moderate CYP3A4 inducers and inhibitors, alcohol, and other CNS depressants.

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 broader discussion of orexin receptors in other conditions? Individuals with a history of abuse and addiction are at higher risk of being addicted, but it does not cause a physician dependence. 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: Quviviq is a pharmacy benefit that will not be added to the Commercial, Exchange, or CHIP formularies. The following prior authorization criteria will apply:

- Medical record documentation of age greater than or equal to 18 years **AND**
- Medical record documentation of a diagnosis of insomnia **AND**
- Medical record documentation of therapeutic failure on, intolerance to, or contraindication to three (3) formulary alternatives.

GPI LEVEL: GPI-12

FORMULARY ALTERNATIVES: zolpidem immediate release, zolpidem extended release, zaleplon, eszopiclone, quazepam, estazolam, flurazepam, temazepam, triazolam, zolpidem sublingual, ramelteon

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

- QL FOR LETTER ONLY: 1 tablet per day, Max 30 day supply per fill

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

GAMASTAN (intramuscular immune globulin (human))

Review: Gamastan is a human immune globulin intramuscular solution indicated:

- For prophylaxis following exposure to hepatitis A. The prophylactic value of Gamastan is greatest when given before or soon after exposure to hepatitis A. Gamastan is not indicated in persons with clinical manifestations of hepatitis A or in those exposed more than 2 weeks previously.
- To prevent or modify measles in a susceptible person exposed fewer than 6 days previously. A susceptible person is one who has not been vaccinated and has not had measles previously. If a susceptible child who is immunocompromised is exposed to measles it is recommended to give Gamastan immediately.

- To modify varicella. Passive immunization against varicella in immunosuppressed patients is best accomplished by use of Varicella Zoster Immune Globulin (Human), however if unavailable Gamastan given promptly may also modify varicella.
- To modify rubella in exposed women who will not consider a therapeutic abortion.

Limitation of use:

- Gamastan is not standardized with respect to antibody titers against hepatitis B surface antigen (HBsAg) and must not be used for prophylaxis of viral hepatitis type B. Prophylactic treatment to prevent hepatitis B can best be accomplished with use of Hepatitis B Immune Globulin (Human), often in combination with Hepatitis B Vaccine.
- Gamastan is not indicated for routine prophylaxis or treatment of rubella, poliomyelitis, mumps, or varicella.

Gamastan is a polyclonal antibody that acts as a passive immunizing agent to neutralize viruses to prevent or improve disease. Gamastan is prepared from the plasma of healthy human donors.

Gamastan is the only immune globulin product approved for immediate protection against hepatitis A virus (HAV) and measles. However, vaccination is superior to immune globulin for protection against hepatitis A in regard to achievable antibody concentrations and durability of immune response. Groups that are indicated for immune globulin in combination with HAV vaccine are adult travelers >40 years at risk for relatively severe manifestations of HAV, with diminished ability to mount an adequate immune response, or with increased risk for HAV transmission following exposure. Other groups include persons with chronic liver disease and immunocompromised persons incapable of mounting an adequate immune response to HAV vaccine. Groups that are indicated for immune globulin in the absence of HAV vaccine are infant travelers less than 6 months of age and travelers when HAV vaccine is contraindicated. Widespread use of immune globulin for HepA prophylaxis is limited by expense, injection site discomfort, need for repeat injections and risk of bloodborne pathogen transmission.
Immune globulin should not be used for outbreak control for measles, mumps or rubella. Vaccination is preferable to immune globulin for postexposure prophylaxis to measles for susceptible individuals since vaccination provides active, life-long immunity. Immune globulin can prevent or diminish the severity of measles. Immune globulin is appropriate for persons with increased risk of complications or contraindications to vaccine, which includes pregnant women without evidence of immunity, immunocompromised persons and infants less than 12 months of age. Immune globulin is not appropriate for persons who have received one dose of measles-containing vaccine at 12 months of age or older, without immunosuppression.

Passive immunity against varicella-zoster virus (VZV) in the post exposure setting is typically accomplished with varicella-zoster immune globulin, or Varizig. Passive immunization is indicated after persons have a significant exposure and they are at high risk for severe infection/complications, are ineligible for vaccine, and can receive the immunotherapy within 10 days of exposure. High risk for severe infection/complications and ineligible for vaccine groups are immunocompromised patients who lack and evidence of immunity, pregnant women who lack evidence of immunity, newborns or mother who develop varicella 5 days before to 2 days after delivery, hospitalized premature infants born ≥28 weeks whose mothers do not have evidence of immunity, hospitalized premature infants born <28 weeks or who weight ≤1000 grams at birth, regardless of maternal evidence of immunity, and healthy term infants exposed to VZV within the first 2 weeks of life if the mother does not have evidence of immunity.

Vaccination for Rubella prior to pregnancy is the primary method to prevent Rubella during pregnancy. Efforts to control and prevent rubella are seen in routine childhood vaccination and vaccination of susceptible, nonpregnant adolescents and adults. Pregnancy termination is not recommended for individuals who are vaccinated during pregnancy or become pregnant soon after vaccination. Persons

are advised to avoid pregnancy for 28 days following vaccination, as rubella vaccine may cross the placenta and infect the fetus. Immunoglobulin is not routinely recommended for postexposure prophylaxis, and it has not been demonstrated to prevent asymptomatic infection, viremia or congenital rubella syndrome. Additionally, immunoglobulin administration makes a subsequent diagnosis of rubella more challenging in that the diagnosis relies on virus-specific IgM testing which can be associated with false-positives.

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

Clinical Discussion: Is there a time frame for when we need to have Part D recommendations? No stipulations for when the review must be completed. 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: Gamastan is a medical benefit. Gamastan will be added to the medical benefit cost share list when processed on the medical benefit. If processed at a specialty pharmacy, Gamastan will process at the Specialty tier or the Brand Non-preferred tier for members with a three tier benefit. No prior authorization criteria will apply.
Additional evidence of the criteria used to make this decision can be found in the drug review presented to the committee.

IBSRELA (tenapanor)

Review: Ibsrela (tenapanor) is a sodium/hydrogen exchanger 3 (NHE3) inhibitor indicated for treatment of irritable bowel syndrome with constipation (IBS-C) in adults. Ibsrela joins a crowded market for IBS-C that includes Linzess, lubiprostone, Trulance, and Zelnorm. Ibsrela introduces a fourth MOA to IBS-C therapies. The resulting softer and more frequent stools are the rationale for the development of Ibsrela as a novel, first-in-class NHE3 inhibitor to treat irritable bowel syndrome with constipation.

The approval of Ibsrela was based on two double-blind, placebo-controlled, randomized, multicenter trials in adult patients. In both trials, the primary endpoint was the proportion of responders, where a responder was defined as a patient achieving both the stool frequency and abdominal pain intensity responder criteria in the same week for at least 6 of the first 12 weeks of treatment. In Trials 1 and 2, the proportion of responders was greater in IBSRELA-treated patients compared to placebo-treated patients. In both trials, improvements from baseline in average weekly CSBMs and abdominal pain were observed by Week 1, with improvement maintained through the end of treatment.

Ibsrela does have a Black Box Warning for risk of serious dehydration in pediatric patients and is contraindicated in patients less than 6 years of age. The safety and effectiveness of Ibsrela have not been established in patients less than 18 years of age therefore use in patients less than 18 years of age should be avoided. In Trial 1 and Trial 2, diarrhea was the most common adverse reaction reported and the most common adverse reaction leading to discontinuation. In addition to diarrhea, hyperkalemia was reported in a patient population with chronic kidney disease and Type 2 diabetes mellitus. Less common but notable side effects included abdominal distension, flatulence, dizziness, rectal bleeding, and abdominal gastrointestinal sounds.

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: Ibsrela 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 age ≥ 18 years **AND**
- Medical record documentation of a diagnosis of irritable bowel syndrome with constipation (IBS-C) **AND**
- Medical record documentation of therapeutic failure on, contraindication to, or intolerance to Linzess

GPI LEVEL: GPI-12

FORMULARY ALTERNATIVES: Linzess

QUANTITY LIMIT: 60 tablets in 30 days

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

FLEQSUVY (baclofen oral suspension)

Review: Fleqsuvy is FDA approved for treatment of spasticity, relief of flexor spasms and pain, clonus, and muscular rigidity caused by multiple sclerosis. FDA also reports that there may be benefit with spinal cord injuries and diseases. It is not indicated for treatment of skeletal muscle spasm due to rheumatic disorders.

Fleqsuvy is a concentrated grape-flavored, oral yellow suspension, which is supplied as 25 mg/5 mL (5 mg/mL). Suspension must be shaken before administering. Remaining suspension should be discarded after 2 months of opening. Fleqsuvy should be initiated at low, divided doses, and increased based on response and tolerability. Recommended maximum dose is 80 mg daily. When discontinuing Fleqsuvy, reduce dose slowly to prevent withdrawal symptoms of hallucinations, seizures, high fever, altered mental status, exaggerated rebound spasticity, and muscle rigidity. In rare cases, abrupt discontinuation caused rhabdomyolysis, multiple organ failure, and death. Recommended titration (to initiate or discontinue therapy is:

- 1 mL (5 mg) three times daily for 3 days
- 2 mL (10 mg) three times daily for 3 days
- 3 mL (15 mg) three times daily for 3 days
- 4 mL (20 mg) three times daily for 3 days
- May increase 4 mL (20 mg) four times daily, 80mg maximum daily dose if necessary

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

Only a bioavailability study has been conducted to show its' equal comparative effectiveness compared to oral tablet baclofen. In the pharmacokinetic study, healthy adult males and females under fasting conditions at 20mg doses showed similar bioavailability for the oral suspension and tablets. 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: Are we not requiring failure of the solution because it's expensive or not on formulary? The baclofen solution has not yet been reviewed by P&T. No additional comments or questions. The committee unanimously voted to accept the recommendations as presented. None were opposed.

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

- 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

GPI LEVEL: GPI-14

FORMULARY ALTERNATIVES: baclofen tablets, tizanidine tablets

QUANTITY LIMIT: 80 mg (16 mL) daily

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

SEGLENTIS (celecoxib/tramadol)

Review: Seglentis (Celecoxib/tramadol hydrochloride) is Food and Drug Administration (FDA) approved for the management of acute pain in adults that is severe enough to require an opioid analgesic and for which alternative treatments are inadequate. Acute pain is defined by the CDC as pain lasting 4 weeks or less due to a variety of conditions, including post-surgical pain. Seglentis is a unique co-crystal formulation that improves the physicochemical properties (i.e., dissolution and solubility) and stability of both ingredients which allows for less opioid administration in conjunction with a faster onset of action for celecoxib.

A Randomized, Double-blind, Active- (Tramadol and Celecoxib) and Placebo-controlled, Parallel Groups, Phase 3 Clinical Trial was conducted to compare pain improvement (using Numerical Pain Rating Scale) over time (48 hours) between Seglentis vs Tramadol, Seglentis vs. Celecoxib and Seglentis vs. Placebo after bunionectomy with osteotomy. Data was recorded comparing baseline NPRS data prior to first dose, to NPRS data at each assessment period over 48 hours. Data was compared by subtracting NPRS scores from baseline and then summing the differences. The more negative the total, the better pain relief achieved. Per this endpoint, Seglentis proved superior to the Celecoxib 100 mg twice daily, Tramadol 50mg every 6 hours and Placebo over the 48-hour study period. The participants were followed for up to an additional 8 days post-trial, but no pain data was recorded or published for this time frame. A limitation of the trial consisted of not having a comparative arm that compared tramadol and celecoxib together vs. Seglentis. Additional studies would have to be conductive to prove superiority.

Seglentis' FDA approved dose is 2 tablets every 12 hours with dosages per tablet of 56mg of celecoxib and 44 mg or tramadol. Safety data consist of the same precautions associated with each drug individually. Those include addiction and abuse, CV thromboembolic events, gastrointestinal bleeding with complications, CYP P450 drug interactions, and others.

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

- Medical documentation of age 18 years or older **AND**
- Medical documentation of acute pain caused by medical condition **AND**
- Medical record documentation of therapeutic failure on, intolerance to, or contraindication to three (3) preferred formulary non-steroidal anti-inflammatory agents used in combination with tramadol, one of which must be celecoxib used in combination with tramadol

GPI LEVEL: GPI-14

FORMULARY ALTERNATIVES: tramadol, celecoxib, ibuprofen, naproxen, meloxicam

QUANTITY LIMIT: 224mg of celecoxib and 176 mg of tramadol per day (max 4 tablets daily)

AUTHORIZATION DURATION: 28 days

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

PYRUKYND (mitapivat)

Review: Pyrukynd is an oral pyruvate kinase activator indicated for the treatment of hemolytic anemia in adult patients with pyruvate kinase deficiency (PKD). PKD is a rare, inherited genetic disorder characterized by a mutation in the pyruvate kinase liver and red blood cell (RBC) PKLR gene, resulting in reduced adenosine triphosphate (ATP), shortened RBC lifespan from their normal lifespan of 120 days to only a few days to weeks, and chronic hemolysis. PKD ranges in disease severity and presents with a range of symptoms, including fatigue, pale skin, jaundice, shortness of breath, and tachycardia. Patients can develop additional complications, including splenomegaly, iron overload secondary to blood transfusions, osteoporosis, and gallstones that can lead to a cholecystectomy.

The disease prevalence is estimated at 1 per 20,000 in the Caucasian population. PKD can be diagnosed at birth or go undiagnosed into adulthood. Diagnosis of PKD is done through two diagnostic tests that are only available at specialized laboratories. The first test measures pyruvate kinase activity in RBCs (low activity indicative of PKD), while the second test detects mutations in the PKLR gene to help confirm the diagnosis.

Pyrukynd is the first FDA-approved therapy for hemolytic anemia in patients with PKD. Pyrukynd allosterically binds to the pyruvate kinase enzyme, causing an increase in activity of pyruvate kinase. There are no alternative treatments approved for PKD. Supportive therapies have been used to manage PKD prior to Pyrukynd, including blood transfusions, folic acid supplementation, splenectomy, and iron chelation therapy. Pyrukynd is supplied as an oral tablet (5 mg, 20 mg, and 50 mg). The starting dose is 5 mg by mouth twice daily, titrated in 4-week increments to 20 mg twice daily then 50 mg twice daily, if needed. Patients may achieve and maintain normal hemoglobin at any dose; therefore, hemoglobin and transfusion requirements should be assessed before increasing the dose level.

Pyrukynd was evaluated in two phase 3 clinical trials, the ACTIVATE trial and the ACTIVATE-T trial. The ACTIVATE trial was a multinational, randomized, double-blind, placebo-controlled trial in 80 adult patients with PKD not being regularly transfused. The ACTIVATE-T trial was a multinational, single-arm, open-label trial in 27 adult patients with PKD that required regular transfusions. In both trials, patients required at least 2 mutant alleles in the PKLR gene, at least 1 of those being a missense

mutation. Patients were excluded from the trial if they were homozygous for the R479H mutation or had 2 non-missense mutations. All patients required a hemoglobin concentration less than 10.0 g/dL.

Pyrukynd has a warning to avoid abrupt interruption or discontinuation of therapy to decrease the risk for acute hemolysis. The most common adverse reactions (> 10%) in the ACTIVATE trial were decreased estrone and estradiol in men, increased urate, back pain, and arthralgia. Serious adverse reactions (> 10%) that occurred in 1 patient each are atrial fibrillation, gastroenteritis, rib fracture, and musculoskeletal pain. Pyrukynd is a substrate of CYP3A and may require dose adjustments when co-administered with moderate inhibitors and inducers. Co-administration of Pyrukynd with strong inhibitors, strong inducers, and substrates with narrow therapeutic indexes should be avoided. Pyrukynd use should be avoided in patients with moderate or severe hepatic impairment. Safety and efficacy have not been established in pediatrics, but there are phase 3 clinical trials planned in pediatric patients aged 1 years and older with PKD. Clinical studies did not include enough patients over 65 to determine response in geriatric patients.

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

Clinical Discussion: When they compare the 60% of non-responders to the 40% who did respond, was there any analysis of the functioning enzyme or other characteristics that predicted success? Nothing in the trial that stood out but will consider reaching out to the manufacturer with the question. This is seen in infants but is currently only approved for treatment of adults. Consider adding language to policy so the reviewer knows that this requires taper and should not be abruptly discontinued. Package insert recommends 6 months of therapy before discontinuing for non-response. Will update authorization duration to reflect. No additional comments or questions. The committee unanimously voted to accept the recommendations as presented. None were opposed.

Financial Discussion: Should we share the policy with pediatric hematology for their reference? We will hold off until approved for pediatrics. No additional comments or questions. The committee unanimously voted to accept the recommendations as presented. None were opposed.

Outcome: Pyrukynd is a pharmacy benefit and will be added to the Commercial, Marketplace, and GHP Kids pharmacy formularies at the Specialty Tier or Brand Non-Preferred tier for members with a three-tier benefit. The following prior authorization criteria will apply:

- Medical record documentation of age 18 years or older **AND**
- Medical record documentation of diagnosis of pyruvate kinase deficiency (PKD) **AND**
- Medical record documentation of at least 2 mutant alleles in the PKLR gene, with at least 1 being a missense mutation **AND**
- Medical record documentation that the member is not homozygous for the R479H mutation **AND**
- Medical record documentation that Pyrukynd is being prescribed by or in consultation with a hematologist **AND**
- Medical record documentation that the member required red blood cell (RBC) transfusions for hemolytic anemia due to PKD within the last 12 months **AND**
- Medical record documentation of hemoglobin level less than or equal to 10 g/dL

GPI LEVEL: GPI-12

FORMULARY ALTERNATIVES: none

QUANTITY LIMIT: 2 tablets per day

AUTHORIZATION DURATION: 6 months. Subsequent approvals will be for an additional 6 months. Reauthorization requires medical documentation of an increase in hemoglobin of 1.5 g/dL from baseline **OR** reduction in transfusion burden.

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

ZIMHI (naloxone)

Review: Zimhi is an opioid antagonist indicated in adult and pediatric patients for the emergency treatment of known or suspected opioid overdose, as manifested by respiratory and/or central nervous system depression. Zimhi is intended for immediate administration as emergency therapy in settings where opioids may be present and is not a substitute for emergency care.

Zimhi is a single-dose prefilled syringe of 5mg naloxone hydrochloride for intramuscular and subcutaneous use only. It is administered into the anterolateral aspect of the thigh, through clothing if necessary. In pediatric patients under 1 year of age, the caregiver should pinch the thigh muscle while administering Zimhi. Zimhi is intended to be administered by individuals 12 years of age and older as younger patients and those with limited hand strength may find it difficult to administer. Zimhi may need to be repeated depending on the amount, type, and route of administration of the opioid ingested. If the desired response is not obtained after 2 to 3 minutes, an additional dose of Zimhi may be administered. If there is still no response and additional doses are available, additional doses may be administered every 2 to 3 minutes until emergency medical assistance arrives.

No clinical studies were conducted for the approval of Zimhi. Approval is based on results of pharmacokinetic studies in 14 healthy adults who received a single intramuscular injection of 5 mg Zimhi, which demonstrated a significantly higher C_{max} and AUC compared to single intramuscular injection of 2 mg naloxone hydrochloride. No pediatric studies were conducted for Zimhi. Use of Zimhi in pediatric patients is supported by adult bioequivalence studies and evidence from the safe and effective use of another naloxone hydrochloride injectable product.

Warnings, precautions, and adverse reactions are based on previous findings from naloxone intramuscular injection. During the pharmacokinetic study, the following adverse reactions were observed in Zimhi clinical studies in healthy volunteers without opioid dependence: nausea, dizziness, lightheadedness, and elevated bilirubin.

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

Clinical Discussion: The most common route of administration is nasal. Was this compared to intranasal formulation? It was not. It was only compared to intramuscular routes. Did they look at this with specific opioids? No, this was only a pharmacokinetic study with healthy individuals with no history of dependence. 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: Zimhi is a pharmacy benefit and will be added to the Brand Preferred tier of the Commercial, Marketplace, and GHP Kids formularies. It will not require a prior authorization.

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

CIBINQO (abrocitinib)

Review: Atopic dermatitis (AD) occurs due to immune dysregulation, which leads to skin barrier dysfunction such as dry skin, inflammation, discoloration, itching and rash. This inflammatory skin condition is a chronic or chronic relapsing disease depending on disease severity.

Cibinqo (abrocitinib) is one of the first oral Janus kinase 1 (JAK1) inhibitors that is FDA approved for AD, and is taken once daily to treat refractory, moderate to severe AD in patients ≥18 years old. Cibinqo has three approved dosages, 50 mg, 100 mg and 200 mg, but the 200 mg dose should only be used if no improvement is seen in the patient after 12 weeks of taking 100 mg. Cibinqo is considered for patients who have contraindications with other systemic drugs, including biologics, or have not had adequate control with these drugs. The patient must fail at least 1 biologic before Cibinqo can be considered for use due to its second-line indication and safety risks.

Cibinqo has Boxed Warnings consistent with other JAK inhibitors, which include mortality, malignancies, serious infection, thromboses, and major adverse cardiovascular events. During the first three months of treatment, Cibinqo is contraindicated with antiplatelet therapies, excluding aspirin ≤81 mg. In the Jade Mono-1, Jade Mono-2 and Jade Compare trials, ≥5% of patients taking Cibinqo reported nausea, nasopharyngitis, and headache. Other common adverse events (≥1%) reported in the clinical trials were herpes simplex, herpes zoster, increased blood creatinine phosphokinase, dizziness, fatigue, vomiting, oropharyngeal pain, acne, influenza, contact dermatitis, gastroenteritis impetigo, upper abdominal pain, abdominal discomfort, urinary tract infection, hypertension, and thrombocytopenia. Live vaccines should not be given to the patient before, during, or immediately after treatment of Cibinqo. Any necessary age-appropriate vaccines should be given before Cibinqo is initiated. Cibinqo is not recommended to be used in combination with other JAK inhibitors and immunosuppressants, biologic or otherwise.

Cibinqo's safety and efficacy in pediatric and geriatric patients have not been established. Dose modifications should be considered for renally or hepatically impaired patients, poor CYP2C19 metabolizers, and patients on strong CYP2C19 inhibitors.

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: Are there any contracting opportunities? Not at this point in time. No comments or questions. The committee unanimously voted to accept the recommendations as presented. None were opposed.

Outcome: Cibinqo is a pharmacy benefit and will be added to the Commercial, Marketplace, and GHP Kids formularies at the Specialty tier or Brand Non-Preferred tier for members with a three-tier benefit. The following prior authorization criteria will apply:

- Medical record documentation that Cibinqo is prescribed by or in consultation with an allergist, dermatologist, or immunologist **AND**
- Medical record documentation of age greater than or equal to 18 years **AND**
- Medical record documentation of a diagnosis of moderate to severe atopic dermatitis **AND**

- Medical record documentation of contraindication to, intolerance to, or therapeutic failure on an adequate trial of phototherapy (UVA/UVB treatment) **AND**
- Medical record documentation of one of the following:
    - Therapeutic failure on an adequate trial of at least one medium (or higher) potency topical corticosteroid **OR**
    - For members with an intolerance or contraindication to topical corticosteroids or for members in whom topical corticosteroids are inadvisable, therapeutic failure on, intolerance to, or contraindication to a topical calcineurin inhibitor **AND**
- Medical record documentation of contraindication to, intolerance to, or therapeutic failure to Dupixent

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

- QL FOR LETTER ONLY: 1 tablet per day, 30 day supply per fill

AUTHORIZATION DURATION: Initial approval will be for 6 months if the reviewing provider feels it is medically appropriate. Subsequent approval will be for 12 months and will require medical record documentation of lack of disease progression or continued disease improvement.

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

RELEUKO (filgrastim-ayow) and NYVEPRIA (pegfilgrastim-apgf)

Review: Releuko (filgrastim-ayow) is a 175 amino acid human granulocyte colony-stimulating factor (G-CSF) which is similar to the US-licensed referenced product, Neupogen. Releuko maintains the same indications as Neupogen, thus is indicated to 1) Decrease the incidence of infection, as manifested by febrile neutropenia, in patients with nonmyeloid malignancies receiving myelosuppressive anti-cancer drugs associated with significant incidence of severe neutropenia with fever 2) Reduce the time to neutrophil recovery and the duration of fever, following induction or consolidation chemotherapy treatment of patients with acute myeloid leukemia 3) Reduce the duration of neutropenia and neutropenia-related clinical sequelae, e.g. Febrile neutropenia, in patients with nonmyeloid malignancies undergoing myeloablative chemotherapy followed by bone marrow transplantation 4) Chronic administration to reduce the incidence and duration of sequelae of neutroprnia (e.g., fever, infections, oropharyngeal ulcers) in symptomatic patients with congenital neutropenia, cyclic neutropenia, or idiopathic neutropenia.

G-CSFs are glycoproteins which act on hematopoietic cells by binding to specific cell receptors by binding to specific cell surface receptors and stimulating proliferation, differentiation commitment, and some end-cell functional activation. Releuko is the third FDA approved filgrastim biosimilar, with the first being Zarxio (filgrastim-sndz) and second Nivestym (filgrastim-aafi). The dosing of Releuko (filgrastim-ayow) is consistent with the dosing of other Neulasta (filgrastim) products.

Nyvepria (pegfilgrastim-apgf) is also a 175 amino acid G-CSF which is similar to US-licensed referenced product, Neulasta. It has the same indications as Neulasta which is to decrease incidence of infection, as manifested by febrile neutropenia in patients with non-myeloid malignancies receiving myelosuppressive anti-cancer drugs associated with a clinically significant incidence of febrile neutropenia. Nyvepria (pegfilgrastim-apgf) is the fourth pegfilgrastim or Neulasta biosimilar on the market with the other three being Udenyca (pegfilgrastim-cbqv), Fulphila (pegfilgrastim-jmdb), and Ziextenzo (pegfilgrastim-bmez).

No clinically meaningful differences were found between the safety profiles of the Releuko and Nyvepria (pegfilgrastim-apgf)compared to their respective study drugs.

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: Releuko and Nyvepria are medical benefits. If processed at a specialty pharmacy, Releuko and Nyvepria will process on the Specialty tier or the Brand Non-preferred tier for members with a three-tier benefit. Because Releuko and Nyvepria have been proven to be highly similar to their reference product, it is recommended that the prior authorization and associated clinical criteria of their reference product, Neupogen and Neulasta, outlined by Commercial Policy 162.0 and MBP 59.0, apply:

NEUPOGEN, NEULASTA, FULPHILA, LEUKINE, UDENYCA, ZIEXTENZO, ZARXIO, GRANIX AND NIVESTYM, RELEUKO, and NYVEPRIA

- **Medical record documentation of a diagnosis of cancer, and when any of the following FDA labeled indications or uses supported by clinical guidelines are present:**

  Primary Prophylaxis – For the prevention of febrile neutropenia (FN) when the risk of FN due to the myelosuppressive chemotherapy regimen is 20% or greater. Those regimens include but are not limited to:
  - TC (paclitaxel/cisplatin, or cyclophosphamide/docetaxel or docetaxel/cisplatin or paclitaxel/carboplatin)
  - MVAC (methotrexate, vinblastine, doxorubicin, cisplatin)
  - AC (doxorubicin, cyclophosphamide, docetaxel)
  - AT (doxorubicin, paclitaxel)
  - TIC (paclitaxel, ifosfamide, mesna, cisplatin)
  - VAPEC-B (vincristine, doxorubicin, prednisolone, etoposide, cyclophosphamide, bleomycin)
  - DHAP (dexamethasone, cisplatin, cytarabine)

  AND
  - For requests for Neulasta/Neulasta Onpro, medical record documentation of a therapeutic failure on, intolerance to, or contraindication to Ziextenzo, Udenyca, Nyvepria **AND** Fulphila

  NOTE: Regimens not specified in this document must be listed on a nationally recognized guideline stating risk of FN of greater than 20%.

  OR

  For the prevention of FN when the risk of developing FN is less than 20%, but **any** other risk factor listed below is present:
  - Age 65 years or greater
  - Poor performance status
  - Previous history of FN
  - Extensive prior radiation or chemotherapy treatment
  - Poor nutritional status
  - Recent surgery or open wounds or active infection
  - Advanced cancer
  - Persistent neutropenia
  - Bone marrow involvement by tumor
  - Liver dysfunction (bilirubin greater than 2.0)

- Renal dysfunction (CrCl less than 50)

AND

- For requests for Neulasta/Neulasta Onpro, medical record documentation of a therapeutic failure on, intolerance to, or contraindication to Ziextenzo, Udenyca, Nyvepria **AND** Fulphila

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NEUPOGEN, NEULASTA, FULPHILA, LEUKINE, UDENYCA, ZIEXTENZO, ZARXIO, NIVESTYM, RELEUKO, and NYVEPRIA

- **Medical record documentation of any of the following FDA labeled indications or uses supported by clinical guidelines:**

Secondary Prophylaxis – prevention of FN when a previous cycle of chemotherapy resulted in a neutropenic complication and for which primary prophylaxis was not received, and a dose reduction will compromise disease-free or overall survival or treatment outcome

AND

- For requests for Neulasta/Neulasta Onpro, medical record documentation of a therapeutic failure on, intolerance to, or contraindication to Ziextenzo, Udenyca, Nyvepria **AND** Fulphila

Treatment of Febrile Neutropenia – as an adjunct to antibiotics in high-risk individuals with FN who are at high risk for infection related complications or when **any** of the following prognostic factors are documented:

- Age 65 years or greater
- Anticipated prolonged and profound neutropenia
- Uncontrolled primary disease
- Pneumonia
- Invasive fungal infection
- Hypotension
- Multi-organ dysfunction
- Hospitalized at the time of development of the fever

AND

- For requests for Neulasta/Neulasta Onpro, medical record documentation of a therapeutic failure on, intolerance to, or contraindication to Ziextenzo, Udenyca, Nyvepria **AND** Fulphila

Dose Dense Therapy – specifically in the treatment of node positive breast cancer, small cell lung cancer, and diffuse aggressive non-Hodgkin's lymphoma

AND

- For requests for Neulasta/Neulasta Onpro, medical record documentation of a therapeutic failure on, intolerance to, or contraindication to Ziextenzo, Udenyca, Nyvepria **AND** Fulphila

Stem Cell Transplantation – when one of the following is met:

- Bone marrow transplant (BMT) –
    - Documentation of a non-myeloid malignancy undergoing myeloablative chemotherapy followed by autologous or allogenic bone marrow transplant (G-CSF is given after BMT)

OR

- Peripheral Blood Progenitor Cell (Mobilization)Transplant (PBPC)
    - Used for mobilization of autologous hematopoietic progenitor cells into the peripheral blood for collection by leukapheresis. (G-CSF is given prior to and throughout leukapheresis)

AND

- For requests for Neulasta/Neulasta Onpro, medical record documentation of a therapeutic failure on, intolerance to, or contraindication to Ziextenzo, Udenyca, Nyvepria **AND** Fulphila

NOTE: Neulasta, Udenyca, Ziextenzo, Nyvepria and Fulphila are considered off-label for PBPC mobilization.

Leukemia or Myelodysplastic Syndromes – insured individuals with:

- Acute myeloid leukemia (AML) receiving induction or consolidation chemotherapy

- Acute lymphoblastic leukemia (ALL) after completion of the first few days of chemotherapy of the initial induction or the first post-remission course
- Myelodysplastic syndrome with less than 15% blasts in the bone marrow, or recurrent neutropenic infections are experienced

AND

- For requests for Neulasta/Neulasta Onpro, medical record documentation of a therapeutic failure on, intolerance to, or contraindication to Ziextenzo, Udenyca, Nyvepira **AND** Fulphila

Lymphoma – Age 65 years or greater treated with curative chemotherapy, e.g., CHOP (cyclophosphamide, doxorubicin, vincristine, prednisone)

AND

- For requests for Neulasta/Neulasta Onpro, medical record documentation of a therapeutic failure on, intolerance to, or contraindication to Ziextenzo, Udenyca, Nyvepira **AND** Fulphila

Radiation therapy –

- If prolonged delays secondary to neutropenia are anticipated
- As treatment for radiation injury secondary to doses of 3-10 Grays (Gy) or greater

AND

- For requests for Neulasta/Neulasta Onpro, medical record documentation of a therapeutic failure on, intolerance to, or contraindication to Ziextenzo, Udenyca, Nyvepria **AND** Fulphila

NOTE: Fulphila, Ziextenzo, Nyvepria and Udenyca are considered off-label for radiation injury syndrome; however, the biosimilars are considered medically accepted for this use by the NCCN guidelines.

NEUPOGEN, ZARXIO, NIVESTYM, RELEUKO

- **Medical record documentation of any of the following FDA labeled indications or uses supported by clinical guidelines:**

Severe Chronic Neutropenia – when the following criteria are met:

- Diagnosis of congenital, cyclic, or idiopathic neutropenia **AND**
- Documentation of an absolute neutrophil count (ANC) <500 cells/mm3 on three separate occasions during a 6 month period (for congenital or idiopathic neutropenia) **OR** five consecutive days of ANC <500 cells/mm3 per cycle (for cyclic neutropenia) **AND**
- Documentation that the member experienced a clinically significant infection, fever, or oropharyngeal ulcer during the past 12 months
- prolonged delays secondary to neutropenia are anticipated.

LEUKINE

- **Medical record documentation of any of the following FDA labeled indications or uses supported by clinical guidelines:**

Delayed Neutrophil Recovery or Graft Failure

- Medical record documentation that the member has had an allogeneic or autologous bone marrow transplant and neutrophil recovery* has not occurred.

*Note to reviewer: Neutrophil engraftment is defined as the first day of three consecutive days where the neutrophil count (ANC) is 500 cells/mm^3 or greater.

MEDISPAN AUTHORIZATION LEVEL: GPI-10

AUTHORIZATION DURATION: 6 months

NEULASTA/FULPHILA/ZIEXTENZO/UDENYCA/NYVEPRIA QUANTITY LIMIT: *No QLs need to be entered within the authorization unless the requested quantity exceeds the QL.*

- QL FOR LETTER ONLY: 1 syringe per 14 days (0.043 mL per day)

If an exception is made, Neupogen, Neulasta, Fulphila, Leukine, Udenyca, Ziextenzo, Zarxio, Granix, Releuko, and Nyvepria will be paid for under the member's prescription drug benefit.

EXCLUSIONS:
There is insufficient evidence in the published, peer reviewed medical literature to clearly establish that the use of colony stimulating factors (CSF) improves the health outcomes in any of the following indications. The use of CSF's for the following indications is considered not medically necessary and are **NOT COVERED:**

- Routine use as prophylaxis on most chemotherapy regimens; or
- Use as prophylaxis during chemotherapy regimens with a febrile neutropenia risk of less than 20% and no high risk for complications; or
- Use in insured members who are neutropenic but afebrile and not meeting any of the above criteria; or
- Use as an adjunct to antibiotics in uncomplicated febrile neutropenia; or use in relapsed or refractory myeloid leukemia; or
- Use in chemo-sensitization of myeloid leukemias; or
- Use prior to or concurrent with chemotherapy for acute myeloid leukemia; or
- Use prior to or concurrently with chemotherapy for "priming" effect; or
- Use to allow an increase in the dose-intensity of cytotoxic chemotherapy beyond the established dose ranges for these regimens; or
- Use during concomitant chemotherapy and radiation therapy; or
- Continued use if no response is seen within 45 days.

Medical Benefit Policy (MBP) Policy 59.0: White Blood Cell Stimulating Factors

Neupogen, Neulasta, Nivestym, Fulphila, Udenyca, Ziextenzo, Zarxio, Leukine, Granix, Releuko, and Nyvepria:
The use of white blood cell stimulating factor [Neupogen (filgrastim), Neulasta (pegfilgrastim), Nivestym (filgrastim-aafi), Fulphila (pegfilgrastim-jmdb), Udenyca (pegfilgrastim-cbqv), Granix (tbo-filgrastim), Ziextenzo (pegfilgrastim-bmez), Zarxio (filgrastim-sndz), or Leukine (sargramostim), Releuko (filgrastim-ayow) or Nyvepria (pegfilgrastim-apgf)] is considered medically necessary in insured individuals with a diagnosis of cancer, and when any of the following FDA labeled indications or uses supported by clinical guidelines are present:

1. Primary Prophylaxis - the prevention of febrile neutropenia (FN) when the risk of FN due to the myelosuppressive chemotherapy regimen is 20% or greater. Those regimens include but are not limited to:

- TC (paclitaxel/cisplatin, or cyclophosphamide/docetaxel or docetaxel/cisplatin or paclitaxel/carboplatin)
- MVAC (methotrexate, vinblastine, doxorubicin, cisplatin)
- AC (doxorubicin, cyclophosphamide, docetaxel)
- AT (doxorubicin, paclitaxel)
- TIC (paclitaxel, ifosfamide, mesna, cisplatin)
- VAPEC-B (vincristine, doxorubicin, prednisolone, etoposide, cyclophosphamide, bleomycin)
- DHAP (dexamethasone, cisplatin, cytarabine)

NOTE: *Regimens not specified in this document must be listed on a nationally recognized guideline stating risk of FN of greater than 20%.*

AND

- For requests for Neulasta/Neulasta Onpro, medical record documentation of a therapeutic failure on, intolerance to, or contraindication to Ziextenzo, Udenyca, Nyvepria **AND** Fulphila.

OR

For the prevention of FN when the risk of developing FN is less than 20%, but any other risk factor listed below is present:

- Age 65 years or greater
- Poor performance status
- Previous history of FN
- Extensive prior radiation or chemotherapy treatment
- Poor nutritional status
- Recent surgery or Open wounds or active infection
- Advanced cancer
- Persistent neutropenia
- Bone marrow involvement by tumor
- Liver dysfunction (bilirubin >2.0)
- Renal dysfunction (CrCl <50)

AND

- For requests for Neulasta/Neulasta Onpro, medical record documentation of a therapeutic failure on, intolerance to, or contraindication to Ziextenzo, Udenyca, Nyvepria **AND** Fulphila.

Neupogen, Neulasta, Nivestym, Fulphila, Udenyca, Ziextenzo, Zarxio, or Leukine, Releuko and Nyvepria:
May also be considered medically necessary for any of the following:

2. Secondary Prophylaxis – prevention of FN when a previous cycle of chemotherapy resulted in a neutropenic complication and for which primary prophylaxis was not received, and a dose reduction will compromise disease-free or overall survival or treatment outcome.

AND

- For requests for Neulasta/Neulasta Onpro, medical record documentation of a therapeutic failure on, intolerance to, or contraindication to Ziextenzo, Udenyca, Nyvepria **AND** Fulphila.

3. Treatment of Febrile Neutropenia - as an adjunct to antibiotics in high-risk individuals with FN who are at high risk for infection related complications or when **any** of the following prognostic factors are documented:

- Age 65 years or greater
- Anticipated prolonged and profound neutropenia
- Uncontrolled primary disease
- Pneumonia
- Invasive fungal infection
- Hypotension
- Multi-organ dysfunction
- Hospitalized at the time of development of the fever

AND

- For requests for Neulasta/Neulasta Onpro, medical record documentation of a therapeutic failure on, intolerance to, or contraindication to Ziextenzo, Udenyca, Nyvepria **AND** Fulphila.

4. Dose Dense Therapy – specifically in the treatment of node positive breast cancer, small cell lung cancer, and diffuse aggressive non-Hodgkin's lymphoma.

AND

- For requests for Neulasta/Neulasta Onpro, medical record documentation of a therapeutic failure on, intolerance to, or contraindication to Ziextenzo, Udenyca, Nyvepria **AND** Fulphila.

5. Stem Cell Transplantation- when one of the following is met:

- Bone Marrow Transplant (BMT)
  - Documentation of a non-myeloid malignancy undergoing myeloablative chemotherapy followed by autologous or allogenic bone marrow transplant (G-CSF is given after BMT)

OR

- Peripheral Blood Progenitor Cell (Mobilization)Transplant (PBPC)

- Used for mobilization of autologous hematopoietic progenitor cells into the peripheral blood for collection by leukapheresis. (G-CSF is given prior to and throughout leukapheresis)

AND

- For requests for Neulasta/Neulasta Onpro, medical record documentation of a therapeutic failure on, intolerance to, or contraindication to Ziextenzo, Udenyca, Nyvepria **AND** Fulphila.

Note: Neulasta, Udenyca, Ziextenzo, Nyvepria and Fulphila are considered off-label for PBPC mobilization

6. Leukemia or Myelodysplastic Syndromes – insured individuals with any of the following conditions:

- Acute myeloid leukemia (AML) receiving induction or consolidation chemotherapy
- Acute lymphoblastic leukemia (ALL) after completion of the first few days of chemotherapy of the initial induction or the first post-remission course
- Myelodysplastic syndrome with less than 15% blasts in the bone marrow, or recurrent neutropenic infections are experienced.

AND

- For requests for Neulasta/Neulasta Onpro, medical record documentation of a therapeutic failure on, intolerance to, or contraindication to Ziextenzo, Udenyca, Nyvepria **AND** Fulphila.

7. Lymphoma – Age 65 years or greater treated with curative chemotherapy, e.g., CHOP (cyclophosphamide, doxorubicin, vincristine, prednisone)

AND

- For requests for Neulasta/Neulasta Onpro, medical record documentation of a therapeutic failure on, intolerance to, or contraindication to Ziextenzo, Udenyca, Nyvepria **AND** Fulphila.

8. Radiation therapy – with any of the following conditions

- If prolonged delays secondary to neutropenia are anticipated.
- As treatment for radiation injury secondary to doses of 3-10 Grays (Gy) or greater

AND

- For requests for Neulasta/Neulasta Onpro, medical record documentation of a therapeutic failure on, intolerance to, or contraindication to Ziextenzo, Udenyca, Nyvepria **AND** Fulphila.

Note: Fulphila, Ziextenzo, Nyvepria and Udenyca are not indicated for radiation injury syndrome; however, the biosimilars are considered medically accepted for this indication by the NCCN guidelines.

Neupogen, Nivestym, Zarxio, Releuko: May also be considered medically necessary for the following:

9. Severe Chronic Neutropenia – when the following criteria are met

- Diagnosis of Congenital, Cyclic, or Idiopathic Neutropenia AND
- Documentation of an Absolute Neutrophil Count (ANC) <500 cells/mm^3 on three separate occasions during a 6 month period (for Congenital or Idiopathic Neutropenia) OR five consecutive days of ANC <500 cells/mm^3 per cycle (for Cyclic Neutropenia) AND
- Documentation that the member experienced a clinically significant infection, fever, or oropharyngeal ulcer during the past 12 months.

Leukine: May also be considered medically necessary for the following:

10. Delayed Neutrophil Recovery or Graft Failure

- Medical record documentation that the member has had an allogeneic or autologous bone marrow transplant and neutrophil recovery* has not occurred.

*Note to reviewer: Neutrophil engraftment is defined as the first day of three consecutive days where the neutrophil count (ANC) is 500 cells/mm^3 or greater.

AUTHORIZATION: When approved, the duration of the authorization will be for 6 months.

QUANTITY LIMITS:

- **Ziextenzo**: Facets RX Count: 144 (Q5120 Units), Darwin QL: 0.043mL per day (1 syringe per 14 days)
- **Udenyca**: Facets RX Count: 144 (Q5111 Units), Darwin QL: 0.043mL per day (1 syringe per 14 days)
- **Fulphila**: Facets RX Count: 144 (Q5108 Units), Darwin QL: 0.043mL per day (1 syringe per 14 days)
- **Neulasta/Neulasta Onpro**: Facets RX Count: 144 (J2506 Units), Darwin QL: 0.043mL per day (1 syringe per 14 days)
- **Nyvepria**: Facets RX Count: 144 (Q5122 Units), Darwin QL: 0.043 ML per day (1 syringe per 14 days)

EXCLUSIONS: There is insufficient evidence in the published, peer reviewed medical literature to clearly establish that the use of colony stimulating factors (CSF) improves the health outcomes in any of the following indications. The use of CSF's for the following indications is considered not medically necessary and are **NOT COVERED:**

- Routine use as prophylaxis on most chemotherapy regimens; or
- Use as prophylaxis during chemotherapy regimens with a febrile neutropenia risk of less than 20% and no high risk for complications; or
- Use in insured members who are neutropenic but afebrile and not meeting any of the above criteria; or
- Use as an adjunct to antibiotics in uncomplicated febrile neutropenia; or use in relapsed or refractory myeloid leukemia; or
- Use in chemo-sensitization of myeloid leukemias; or
- Use prior to or concurrent with chemotherapy for acute myeloid leukemia; or
- Use prior to or concurrently with chemotherapy for "priming" effect; or
- Use to allow an increase in the dose-intensity of cytotoxic chemotherapy beyond the established dose ranges for these regimens; or
- Use during concomitant chemotherapy and radiation therapy; or
- Continued use if no response is seen within 45 days.

FORMULARY ALTERNATIVES:

None

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

ZTALMY (ganaxolone)

Review: Ztalmy is a neuroactive steroid gamma-aminobutyric acid (GABA) A receptor positive modulator indicated for the treatment of seizures associated with cyclin-dependent kinase-like 5 (CDKL5) deficiency disorder (CDD) in patients 2 years of age and older. The precise mechanism by which ganaxolone exerts its therapeutic effects in the treatment of seizures associated with CDD is unknown, but its anticonvulsant effects are thought to result from positive allosteric modulation of the gamma-aminobutyric acid type A (GABAA) receptor in the CNS.

Ztalmy is supplied as an oral 50mg/ml suspension that is administered three times a day with food. Dosing recommendations are based on the patient's weight and should be titrated slowly (every 7 days minimum) to the maximum tolerated effective dose without exceeding the maximum daily weight-based dosing limits. Patients weighing 28kg or less should start at 6mg/kg three times daily to a maximum dose of 21mg/kg three times daily. Patients weighing more than 28kg should start at 150mg three times daily up to a maximum dose of 600mg three times daily.

The primary efficacy endpoint was the percentage change in the 28-day frequency of major motor seizures (defined similarly as in the 2-month period prior to screening) from a 6-week prospective baseline phase during the 17-week double-blind phase. Patients treated with Ztalmy had a significantly greater reduction in the 28-day frequency of major motor seizures compared to patients receiving

placebo (31% median reduction (ganaxolone group) vs 7% median reduction (placebo group)).

There are no black box warnings for Ztalmy. Warnings and precautions include the risk of Somnolence and Sedation, and Suicidal Behavior and Ideation. As with all antiepileptic drugs if Ztalmy is discontinued it should be withdrawn gradually to minimize the risk of increased seizure frequency and status epilepticus. The most common adverse reactions are somnolence, pyrexia, salivary hypersecretion, and seasonal allergy.

Cyclin-dependent kinase-like 5 (CDKL5) deficiency disorder (CDD) is a rare disorder, estimated to occur in approximately 1 in 40,000–60,000 live births, and the mutations are four times more prevalent in females compared to males. The manufacturer of Ztalmy estimated that there are ~2000 patients who are eligible for treatment with Ztalmy. A multidisciplinary approach to CDD that includes early interventional therapies, such as physical therapy, occupational therapy, and speech and augmentative communication therapy, is considered effective in facilitating an individual's development. For CDD-associated seizures, no single anticonvulsant is uniformly effective, and often, multiple anticonvulsants are needed.

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: Ztalmy is a pharmacy benefit and will be added to the Commercial, Exchange, and CHIP formularies at the Specialty Tier or BrandNP tier for members with a 3 Tier benefit. The following prior authorization criteria will apply:

- Medical record documentation that Ztalmy is prescribed by a neurologist **AND**
- Medical record documentation of age greater than or equal to 2 years old **AND**
- Medical record documentation of a diagnosis of CDKL5 Deficiency Disorder (CDD) **AND**
- Medical record documentation of genetic testing that confirms a cyclin-dependent kinase-like 5 (CDKL5) deficiency **AND**
- Medical record documentation that the patient is experiencing baseline seizures and documentation of the baseline frequency of seizures **AND**
- Medical record documentation of a therapeutic failure, intolerance, or contraindication to at least two previous antiepileptic therapies **AND**
- Medical record documentation that the requested daily dose does not exceed the following:
    - Weight < 28 kg: 63mg/kg/day **OR**
    - Weight > 28kg: 1800mg/day

GPI LEVEL: GPI-12

FORMULARY ALTERNATIVES: For patients aged ≥ 2 years: topiramate immediate release tablets, topiramate immediate release sprinkle capsules, lamotrigine immediate release springle capsules, carbamazepine, clobazam, levetiracetam IR, phenobarbital, phenytoin, pregabalin, topiramate extended release*, vigabatrin*, valproic acid
Additional Formulary Alternatives: gabapentin (3+), oxcarbazepine (4+), divalproex (10+), levetiracetam ER (12+), tiagabine (12+), lamotrigine ER (13+), felbamate (14+), and zonisamide (16+)
*prior authorization required

QUANTITY LIMIT: 36.7ml/day (1100ml/30 days)

AUTHORIZATION DURATION: Initial approval will be for 6 months. Subsequent approvals will be for an additional 12 months and will require medical record documentation of the following:

- Medical record documentation of a sustained reduction in monthly seizure frequency compared to baseline **AND**
- Medical record documentation that the requested daily dose does not exceed the following:
  - Weight < 28 kg: 63mg/kg/day **OR**
  - Weight > 28kg: 1800mg/day

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

CLASS REVIEWS

DIABETES MELLITUS

Agents for Type 2 Diabetes Mellitus (T2DM)			
Brand Name	**Generic**	**Generic Available?**	**Manufacturer**
Sodium-Glucose Cotransporter 2 Inhibitors (SGLT-2i)			
Farxiga Xigduo XR	dapagliflozin dapagliflozin/metformin	No No	AstraZeneca
Invokana Invokamet/Invokamet XR	canagliflozin canagliflozin/metformin	No No	Janssen
Jardiance Synjardy/Synjardy XR	empagliflozin empagliflozin/metformin	No No	Boehringer Ingelheim
Steglatro Segluromet	ertugliflozin ertugliflozin/metformin	No No	Merck Sharp & Dohme
Glucagon-Like Peptide 1 Receptor Agonists (GLP-1RA)			
Adlyxin	lixisenatide	No	Sanofi Pharmaceuticals
Bydureon	exenatide extended-release	No	AstraZeneca
Byetta	exenatide	No	AstraZeneca
Ozempic	semaglutide injection	No	Novo Nordisk
Rybelsus	semaglutide oral	No	Novo Nordisk
Trulicity	dulaglutide	No	Lilly
Victoza	liraglutide	No	Novo Nordisk
Dipeptidyl Peptidase-4 Inhibitors (DPP-4i)			
Januvia Janumet/Janumet XR	sitagliptin sitagliptin/metformin	No No	Merck Sharp & Dohme
Nesina Kazano	alogliptin alogliptin/metformin	Yes Yes	Takeda Pharmaceuticals
Tradjenta Jentadueto/Jentadueto XR	linagliptin linagliptin/metformin	No No	Boehringer Ingelheim
Onglyza Kombiglyze XR	saxagliptin saxagliptin/metformin	No	AstraZeneca

Background of Disease State: More than 37 million Americans have been diagnosed with diabetes. Of this group, 90-95% of them have type 2 diabetes. Type 2 diabetes occurs when cells in the body do not respond normally to insulin. Insulin is the key to moving sugar from the blood into the cells so that the body can use as energy. The pancreas tries to compensate by producing more insulin over time. Eventually, the pancreas can no longer keep up and blood sugars continue to rise leading to type 2 diabetes. Uncontrolled blood sugar for long periods of time can lead to microvascular complications such as retinopathy, nephropathy, and neuropathy as well as macrovascular complications such as ischemic heart disease, cerebrovascular disease, and peripheral artery disease.

Pharmacology/Place in Therapy: American Diabetes Association
First line therapy: usually Metformin unless patients have increased risk of atherosclerotic cardiovascular disease (ASCVD), heart failure (HF), and/or chronic kidney disease (CKD)

- **Clinical ASCVD or high risk**: GLP-1RA with proven cardiovascular disease (CVD) benefit or SGLT2i with proven CVD benefit
- **HF:** SGLT2i with proven benefit
- **CKD:**
  - With albuminuria: preferably SGLT2i with proven benefit or GLP-1RA with proven benefit
  - Without albuminuria: SGLT2i with proven benefit or GLP-1RA with proven benefit
- **Minimize hypoglycemia:** DPP-4i, GLP-1RA, SGLT2i, Thiazolidinedione (TZD)
- **Minimize weight gain/promote weight loss:** preferably GLP-1RA or SLGT2i
  - If GLP-1RA not tolerated or indicated, consider DPP-4i (weight neutral)
- **Cost and access limitations:** insulin, Sulfonylureas (SU), TZD

Drug Class	ASCVD Benefits	HF Benefits	Diabetic Kidney Disease Benefits
GLP-1RA	Trulicity, Victoza, Ozempic		Trulicity, Victoza, Ozempic
SGLT2i	Jardiance, Invokana	Jardiance, Invokana, Farxiga, Steglatro	Jardiance, Invokana, Farxiga

Recommendations:

Commercial (Traditional)/ Exchange (Marketplace)/ CHIP (Kids)		
Medication	**Current Policy**	**Recommendations**
Farxiga (dapagliflozin) **Xigduo XR (dapagliflozin/metformin)**	**Farxiga Policy 328.0** - Medical record documentation of a diagnosis of type II diabetes mellitus **AND** - Medical record documentation of age greater than or equal to 18 years **AND** - Medical record documentation of therapeutic failure on, intolerance to, or contraindication to Invokana **AND** Jardiance. **Xigduo XR Policy 359.0** - Medical record documentation of a diagnosis of type II diabetes mellitus **AND** - Medical record documentation of age greater than or equal to 18 years **AND** - Medical record documentation of therapeutic failure on, intolerance to, or contraindication to Jardiance in combination with metformin, Synjardy, or Synjardy XR **AND** - Medical record documentation of therapeutic failure on, intolerance to, or	**Recommend moving Farxiga and Xigduo XR to formulary with no prior authorization required.**

	contraindication to Invokana in combination with metformin, Invokamet, or Invokamet XR	
Invokana (canagliflozin) **Invokamet and Invokamet XR (canagliflozin/metformin)**	No prior authorization required.	**Recommend moving Invokana and Invokamet/Invokamet XR to non-formulary with the following criteria:** **Invokana Policy** - Medical record documentation of a diagnosis of type II diabetes mellitus **AND** - Medical record documentation of age greater than or equal to 18 years **AND** - Medical record documentation of therapeutic failure on, intolerance to, or contraindication to Farxiga **AND** Jardiance. **Invokamet/Invokamet XR Policy:** - Medical record documentation of a diagnosis of type II diabetes mellitus **AND** - Medical record documentation of age greater than or equal to 18 years **AND** - Medical record documentation of therapeutic failure on, intolerance to, or contraindication to Jardiance in combination with metformin, Synjardy, or Synjardy XR **AND** - Medical record documentation of therapeutic failure on, intolerance to, or contraindication to Farxiga in combination with metformin or Xigduo XR
Jardiance (empagliflozin) **Synjardy and Synjardy XR (empagliflozin/metformin)**	No prior authorization required.	**No changes recommended.**
Steglatro (ertugliflozin) **Segluromet (ertugliflozin/metformin)**	**Steglatro Policy 502.0** - Medical record documentation of a diagnosis of type II diabetes mellitus **AND** - Medical record documentation of age greater than or equal to 18 years **AND** - Medical record documentation of therapeutic failure on, intolerance to, or contraindication to Invokana **AND** Jardiance. **Segluromet Policy 504.0**	**Steglatro Policy 502.0** - Medical record documentation of a diagnosis of type II diabetes mellitus **AND** - Medical record documentation of age greater than or equal to 18 years **AND** - Medical record documentation of therapeutic failure on, intolerance to, or contraindication to Farxiga **AND** Jardiance. **Segluromet Policy 504.0** - Medical record documentation of a diagnosis of type II diabetes mellitus **AND** - Medical record documentation of age greater than or equal to 18 years **AND**

	- Medical record documentation of a diagnosis of type II diabetes mellitus **AND** - Medical record documentation of age greater than or equal to 18 years **AND** - Medical record documentation of therapeutic failure on, intolerance to, or contraindication to Jardiance in combination with metformin, Synjardy, or Synjardy XR **AND** - Medical record documentation of therapeutic failure on, intolerance to, or contraindication to Invokana in combination with metformin, Invokamet, or Invokamet XR	- Medical record documentation of therapeutic failure on, intolerance to, or contraindication to Jardiance in combination with metformin, Synjardy, or Synjardy XR **AND** - Medical record documentation of therapeutic failure on, intolerance to, or contraindication to Farxiga in combination with metformin or Xigduo XR
Adlyxin (lixisenatide)	**Adlyxin Policy 451.0** - Medical record documentation of a diagnosis of type 2 diabetes **AND** - Medical record documentation of therapeutic failure on, intolerance to, or contraindication to metformin, Victoza **AND** either Ozempic or Rybelsus	**No changes recommended.**
Bydureon **(exenatide extended-release)**	**Bydureon Policy 350.0** - Electronic step therapy of on-line prescription drug claims history showing 15 days use of Victoza **AND** Ozempic or Rybelsus, within the previous 180 days. If this electronic step is met, the claim will automatically adjudicate **OR** - If electronic step therapy criteria are not met, prescribing provider should request an exception for coverage indicating one of the following: o For members 18 years of age and older: medical record documentation of therapeutic failure on, intolerance to, or contraindication to Victoza **AND** either Ozempic or Rybelsus **OR** o For members between 10 and 18 years of age: medical record documentation of therapeutic failure on, intolerance to or contraindication to Victoza	**No changes recommended.**
Byetta (exenatide)	**Byetta Policy 131.0** - Medical record documentation of a diagnosis of type 2 diabetes **AND** - Medical record documentation of therapeutic failure on, intolerance to, or	**No changes recommended.**

	contraindication to metformin, Victoza **AND** either Ozempic or Rybelsus	
Ozempic (semaglutide)	No prior authorization required.	**No changes recommended.**
Rybelsus (semaglutide)	No prior authorization required.	**No changes recommended.**
Trulicity (dulaglutide)	No prior authorization required.	**No changes recommended.**
Victoza (liraglutide)	No prior authorization required.	**No changes recommended.**
Januvia (sitagliptin) **Janumet and Janumet XR (sitagliptin/metformin)**	**Januvia Policy 141.0** - Medical record documentation of therapeutic failure on, intolerance to, or contraindication to Tradjenta.	**No changes recommended.**
Nesina (alogliptin) **Kazano (alogliptin/metformin)**	**Alogliptin and Nesina Policy 196.0** - Medical record documentation of therapeutic failure on, intolerance to, or contraindication to Tradjenta. **Alogliptin/Metformin and Kombiglyze XR 225.0** - Medical record documentation of therapeutic failure on, intolerance to, or contraindication to Tradjenta in combination with metformin, Jentadueto, OR Jentadueto XR	**No changes recommended.**
Tradjenta (linagliptin) **Jentadueto and Jentadueto XR (linagliptin/metformin)**	No prior authorization required.	**No changes recommended.**
Onglyza (saxagliptin) **Kombiglyze XR (saxagliptin/metformin)**	**Alogliptin and Nesina Policy 196.0** - Medical record documentation of therapeutic failure on, intolerance to, or contraindication to Tradjenta. **Alogliptin/Metformin and Kombiglyze XR 225.0** - Medical record documentation of therapeutic failure on, intolerance to, or contraindication to Tradjenta in combination with metformin, Jentadueto, OR Jentadueto XR	**No changes recommended.**

Recommend adding Farxiga and Xigduo XR to formulary at the brand preferred tier with a quantity limit of 1 tablet per day.

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.

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

MULTIPLE SCLEROSIS

Agents for Multiple Sclerosis			
Brand Name	**Generic**	**Generic Available?**	**Manufacturer**
Immunomodulators			
Copaxone	glatiramer acetate	Yes	Teva
Glatopa	glatiramer acetate	Yes	Sandoz
Interferons			
Avonex	interferon beta-1a	No	Biogen
Rebif	interferon beta-1a	No	Serono
Extavia	interferon beta-1b	No	Novartis
Betaseron	interferon beta-1b	No	Bayer
Plegridy	peginterferon beta-1a	No	Biogen
Fumaric Acid Derivatives			
Tecfidera	dimethyl fumarate	Yes	Biogen
Vumerity	diroximel fumarate	No	Biogen
Bafiertam	monomethyl fumarate	No	Banner Life Sciences
Sphingosine 1-Phosphate (S1P) Receptor Modulators			
Gilenya	fingolimod	No	Novartis
Zeposia	ozanimod	No	Bristol Myers Squibb
Ponvory	ponesimod	No	Janssen
Mayzent	siponimod	No	Novartis
Monoclonal Antibodies			
Truxima	rituximab	No	Teva
Rituxan	rituximab	No	Biogen
Ruxience	rituximab	No	Pfizer
Tysabri	natalizumab	No	Biogen
Lemtrada	alemtuzumab	No	Genzyme
Kesimpta	ofatumumab	No	Novartis
Ocrevus	ocrelizumab	No	Genentech
Pyrimidine Synthesis Inhibitor			
Aubagio	teriflunomide	No	Genzyme
Antimetabolites			
Mavenclad	cladribine	No	Serono
Potassium Channel Blockers			
Ampyra	dalfampridine	Yes	Acorda Therapeutics

Background of Disease State: Multiple Sclerosis (MS): A complex neurodegenerative disease affecting the central nervous system (CNS)

- Etiology
  - Origin: Unknown entirely, but most widely accepted theory is that MS begins as an inflammatory immune-mediated disorder characterized by autoreactive lymphocytes
    - Predisposing factors: genetics, environment, immune abnormalities, and infection history
- Pathology:
  - 3 Pathways to Tissue Injury: inflammation, demyelination, axonal degradation
  - Multifocal Lesions: MS plaques (appear grey in white matter)
    - MRI is the gold standard for assessment
    - Affect the following:
      - Optic nerves leading to visual loss
      - Spinal cord leading to paralysis and sensory loss
      - Cerebral cortex impairing awareness, thought and memory
      - Deep nuclei of the cerebellum affecting movement and brainstem
- Phenotypes
  - Clinically Isolated Syndrome
    - First episode of neurological symptoms that lasts for 24 hours
  - Radiographic Isolated Syndrome
    - Treatment may be started if patient has high risk features (spinal cord lesions, enhancing lesions, male sex, <35 years of age, and/or oligoclonal bands in CSF)

- Relapsing and remitting
  - Most common (85%)
  - Periods of active inflammatory symptoms and plaques with periods of remission
- Progressive
  - Secondary Progressive MS (50% patients within 10-15 years)
    - Initially relapsing and remitting, then develops into secondary progressive Characterized by worsening neurologic function
- Primary Progressive MS
  - Onset of symptoms is severe without remissions

Pharmacology/Place in Therapy: American Academy of Neurologists

- *Recommendations for Starting DMT:*
  - Ascertain and incorporate/review preferences of safety, route of administration, lifestyle, cost, efficacy, common AEs, and tolerability in the choice of DMT
  - People presenting with a first demyelinating event and who do not meet the 2010 International Criteria for MS are commonly encountered in clinical practice.
  - Decisions concerning the selection of DMTs for people presenting with a first demyelinating event should abide by prescribing principles espoused in other recommendations.
  - After discussing the risks and benefits, clinicians should prescribe DMT to people with a single clinical demyelinating event and 2 or more brain lesions characteristic of MS who decide they want this therapy.
  - Clinicians should prescribe alemtuzumab, fingolimod, or natalizumab for people with MS with highly active MS.
  - DMTs should be available to all people with relapsing forms of MS.
  - People with MS with a positive JCV antibody test have a higher risk of developing PML while using natalizumab, particularly people with MS who have been treated for more than 2 years or have had prior immunosuppressive treatment.
  - Clinicians may initiate natalizumab treatment in people with MS with positive anti-JCV antibody indexes above 0.9 only when there is a reasonable chance of benefit compared with the low but serious risk of PML.
  - Ocrelizumab is the only DMT shown to alter disease progression in individuals with PPMS who are ambulatory.
- *Recommendations for Switching DMT:*
  - Clinicians should monitor MRI disease activity from the clinical onset of disease to detect the accumulation of new lesions in order to inform treatment decisions in people with MS using DMTs.
  - Clinicians should discuss switching from one DMT to another in people with MS who have been using a DMT long enough for the treatment to take full effect and are adherent to their therapy when they experience 1 or more relapses, 2 or more unequivocally new MRI-detected lesions, or increased disability on examination over a 1-year period.
  - Current evidence supports higher efficacy of alemtuzumab, natalizumab, fingolimod, and ocrelizumab compared with previously approved self-injectable DMTs.
  - Clinicians should evaluate the degree of disease activity, adherence, AE profiles, and mechanism of action when switching DMTs in people with MS with breakthrough disease activity during DMT use.
  - Clinicians should discuss a change to noninjectable or less frequently injectable DMTs in people with MS who report intolerable discomfort with the injections or in those who report “injection fatigue”.
  - Clinicians should discuss switching DMT or reducing dosage or frequency (where there are data on different doses when there are persistent laboratory abnormalities.
  - Clinicians should discuss switching to a DMT with a lower PML risk with people with MS taking natalizumab who are or become JCV antibody positive, especially with an index of above 0.9.
  - If a patient with MS develops a malignancy while using a DMT, clinicians should promptly discuss switching to an alternate DMT, especially for people with MS using azathioprine, methotrexate, mycophenolate, cyclophosphamide, fingolimod, teriflunomide, alemtuzumab, or dimethyl fumarate.
  - People with MS with serious infections potentially linked to their DMT should switch DMTs (does not pertain to PML management in people with MS using DMT).
  - Clinicians should switch DMTs in people with MS who have persistent natalizumab antibodies.

Recommendations:

Commercial (Traditional)/ Exchange (Marketplace)/ CHIP (Kids)

Medication	Current Policy	Recommendations
Copaxone (glatiramer acetate) **Glatopa (glatiramer acetate)**	**Copaxone Policy 559.0** - Medical record documentation of therapeutic failure on, intolerance to, or contraindication to glatiramer acetate. **Glatopa Policy 394.0** - Medical record documentation of a diagnosis of relapsing forms of multiple sclerosis **AND** - Medical record documentation of a therapeutic failure on, intolerance to, or contraindication to glatiramer acetate 20 mg/mL	No change
Avonex (interferon beta-1a)	No prior authorization required.	No change
Rebif (interferon beta-1a)	No prior authorization required.	No change
Extavia (interferon beta-1b)	No prior authorization required.	No change
Betaseron (interferon beta-1b)	No prior authorization required.	No change
Plegridy (peginterferon beta-1a)	No prior authorization required.	No change
Tecfidera (dimethyl fumarate)	No prior authorization required.	No change
Vumerity (diroximel fumarate)	**Vumerity Policy 649.0** - Electronic step therapy of on-line prescription drug claims history showing 15 days use of dimethyl fumarate within the previous 180 days. If this electronic step is met, the claim will automatically adjudicate **OR** - If the electronic step therapy criteria are not met, prescribing provider should request an exception for coverage indicating therapeutic failure on, intolerance to, or contraindication to dimethyl fumarate	No change
Bafiertam (monomethyl fumarate)	**Bafiertam Policy 648.0** - Electronic step therapy of on-line prescription drug claims history showing 15 days use of dimethyl fumarate within the previous 180 days. If this electronic step is met, the claim with automatically adjudicate **OR** - If the electronic step therapy criteria are not met, prescribing provider should request an exception for coverage indicating therapeutic failure on, intolerance to, or contraindication to dimethyl fumarate	No change
Gilenya (fingolimod)	No prior authorization required.	No change

Zeposia (ozanimod)	**Zeposia Policy 678.0** Note: Prior authorization is not required for diagnosis code G35. In the event a requestor would like a medical necessity review completed the following criteria would apply: - Medical record documentation of a diagnosis of Multiple Sclerosis	No change
Ponvory (ponesimod)	No prior authorization required.	No change
Mayzent (siponimod)	No prior authorization required.	No change
Tysabri (natalizumab)	**Tysabri Medical Benefit Policy (MBP) 57.0** - Medical record documentation of member being established on and responding to Tysabri **OR** - Medical record documentation of a diagnosis of a relapsing form of multiple sclerosis, including clinically isolated syndrome, relapsing-remitting disease, and active secondary progressive disease **AND** - Medical record documentation that the patient is 18 years or older **AND** - Medical record documentation that Tysabri is being prescribed by a neurologist **AND** - Patient is enrolled in a risk-minimization program, called the TOUCH™ Prescribing Program **AND** - Physician documentation that Tysabri is being used as monotherapy is provided **AND** - Medical record documentation that the member has been tested for anti-JCV antibody prior to start of Tysabri therapy - If patient is anti-JCV antibody positive, medical record documentation that benefits of drug outweigh the risks of progressive multifocal leukoencephalopathy (PML) and patient is aware of increased PML risk **AND** - Medical record documentation of therapeutic failure on, contraindication to, or intolerance to two formulary alternatives *NOTE: According to the American Academy of Neurology recommendation, Tysabri may be considered as a first line therapy in individuals with relapsing remitting multiple sclerosis who exhibit particularly aggressive initial course of disease and in whom the potential benefit is felt to outweigh the risk. Patients with a poor prognosis/aggressive disease include those with a heavy T2 lesion load, lesions in brain stem, cerebellum, and spinal cord.*	**Tysabri Medical Benefit Policy (MBP) 57.0** - Medical record documentation of member being established on and responding to Tysabri **OR** - Medical record documentation of a diagnosis of a relapsing form of multiple sclerosis, including clinically isolated syndrome, relapsing-remitting disease, and active secondary progressive disease **AND** - Medical record documentation that the patient is 18 years or older **AND** - Medical record documentation that Tysabri is being prescribed by a neurologist **AND** ~~- Patient is enrolled in a risk-minimization program, called the TOUCH™ Prescribing Program **AND**~~ - Physician documentation that Tysabri is being used as monotherapy is provided **AND** - Medical record documentation that the member has been tested for anti-JCV antibody prior to start of Tysabri therapy ○ If patient is anti-JCV antibody positive, medical record documentation that benefits of drug outweigh the risks of progressive multifocal leukoencephalopathy (PML) and patient is aware of increased PML risk **AND** - Medical record documentation of therapeutic failure on, contraindication to, or intolerance to two formulary alternatives **OR** medical record

		documentation of highly active disease course requiring aggressive treatment *NOTE: According to the American Academy of Neurology recommendation, Tysabri may be considered as a first line therapy in individuals with relapsing remitting multiple sclerosis who exhibit particularly aggressive initial course of disease and in whom the potential benefit is felt to outweigh the risk. Patients with a poor prognosis/aggressive disease include those with a heavy T2 lesion load, lesions in brain stem, cerebellum, and spinal cord.*
Lemtrada (alemtuzumab)	No prior authorization required.	No change
Kesimpta (ofatumumab)	No prior authorization required.	No change
Ocrevus (ocrelizumab)	**Ocrevus Medical Benefit Policy (MBP) 155.0** - Medical record documentation of age > 18 years **AND** - Medical record documentation Ocrevus is prescribed by a neurologist **AND** - Medical record documentation of a diagnosis of primary progressive MS (PPMS) **OR** - Medical record documentation of a diagnosis of a relapsing form of multiple sclerosis, including clinically isolated syndrome, relapsing-remitting disease, and active secondary progressive disease **AND** - For members with a diagnosis of a relapsing form of multiple sclerosis, medical record documentation of therapeutic failure on, intolerance to, or contraindication to two formulary alternatives.	**Ocrevus Medical Benefit Policy (MBP) 155.0** - Medical record documentation of age > 18 years **AND** - Medical record documentation Ocrevus is prescribed by a neurologist AND - Medical record documentation of hepatitis B screening **AND** - Medical record documentation of a diagnosis of primary progressive MS (PPMS) **OR** - Medical record documentation of a diagnosis of a relapsing form of MS, including clinically isolated syndrome, relapsing-remitting disease, and active secondary progressive disease **AND** - For members with a diagnosis of a relapsing form of multiple sclerosis, medical record documentation of therapeutic failure on, intolerance to, or contraindication to one formulary alternative.
Aubagio (teriflunomide)	**Aubagio 7mg Policy 275.0** - Medical record documentation of why patient is unable to utilize Aubagio 14 mg tablet once daily	No change
Mavenclad (cladribine)	**Mavenclad Policy 579.0** - Medical record documentation that Mavenclad is prescribed by a neurologist **AND**	No change

	- Medical record documentation of age greater than or equal to 18 years **AND** - Medical record documentation of a diagnosis of relapsing form of multiple sclerosis including relapsing-remitting disease and active secondary progressive disease **AND** *Note: Mavenclad is not indicated for the clinically isolated syndrome subtype of multiple sclerosis.* - Medical record documentation that Mavenclad will be used as monotherapy **AND** - Medical record documentation that the prescribed dose is appropriate for member's weight **AND** - Medical record documentation that member has not been treated with more than three (3) previous treatment cycles of Mavenclad for relapsing forms of multiple sclerosis **AND** - Medical record documentation of therapeutic failure on, intolerance to, or contraindication to two (2) formulary alternatives for the treatment of multiple sclerosis	
Ampyra (dalfampridine)	No prior authorization required.	No change

No changes recommended at this time based on cost.

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.

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

FAST FACTS

ENHERTU (fam-trastuzumab deruxtecan-nxki)

Clinical Summary: Enhertu is now indicated for the treatment of adult patients with unresectable or metastatic HER2-
positive breast cancer who have received a prior anti-HER2 based regimen in the metastatic setting or in the neoadjuvant or adjuvant setting and have developed disease recurrence during or within 6 months of completing therapy. Previously Enhertu had an accelerated approval for treatment of patients who had been treated with two or more prior anti-HER2-based regimens in the metastatic setting.

There is no change to the recommended dosage of Enhertu for the new indication. The recommended dosage for breast cancer, regardless of setting of the previous therapy (metastatic vs. neoadjuvant/adjuvant) is 5.4 mg/kg given as an intravenous infusion once every three weeks until disease progression or unacceptable toxicity.

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

Recommendation: There are no changes recommended to the formulary placement or auth duration for Enhertu. The following changes are recommended to the prior authorization criteria in Medical Benefit Policy 208.0 to incorporate the changes to the breast cancer indication:

- Prescription written by a hematologist or oncologist **AND**
- Medical record documentation of patient age greater than or equal to 18 years **AND**
- Medical record documentation of unresectable or metastatic HER2-positive breast cancer **AND**
- Medical record documentation of ~~two or more prior anti-HER2 based therapies in the metastatic setting~~ one of the following
    - Documentation of a prior anti-HER2 based therapy in the metastatic setting **OR**
    - Documentation of a prior anti-HER2 based therapy in the neoadjuvant or adjuvant setting **AND** documentation of disease recurrence during or within 6 months of completing therapy

Discussion: No comments or questions.

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

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

OPDIVO (nivolumab) & YERVOY (ipilimumab)

Clinical Summary: Opdivo and Yervoy, used in combination, are now indicated for the first-line treatment of adult patients with unresectable advanced or metastatic esophageal squamous cell carcinoma (ESCC). Opdivo, in combination with fluoropyrimidine- and platinum- containing chemotherapy, is now also indicated as first-line treatment of adult patients with unresectable advanced or metastatic ESCC. Previously, Opdivo was indicated for the adjuvant treatment of completely resected esophageal or gastroesophageal junction cancer with residual pathologic disease in adult patients who have received neoadjuvant chemoradiotherapy (CRT). It was also indicated for the treatment of adult patients with unresectable advanced, recurrent, or metastatic ESCC after prior fluoropyrimidine- and platinum-based chemotherapy. Previously, Yervoy was not indicated for the treatment of esophageal cancer.

Dosing for updated Indication is as follows: Opdivo 3 mg/kg every 2 weeks or 360 mg every 3 weeks with Yervoy 1 mg/kg every 6 weeks (30-minute intravenous infusion); continue until disease progression or unacceptable toxicity, or up to 2 years

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

Recommendation: No changes are recommended to the formulary placement of Opdivo or Yervoy. It is recommended to edit esophageal squamous cell carcinoma criteria for Medical Benefit Policy 126.0 for Opdivo. It is also recommended to add a section of esophageal squamous cell carcinoma to Medical Benefit Policy 91.0 for Yervoy to incorporate the new indication.

Medical Benefit Policy 126.0 (Opdivo)

9. Esophageal Squamous Cell Carcinoma
    - Prescription written by a hematologist/oncologist **AND**
    - Medical record documentation that patient is 18 years of age or older **AND**
    - One of the following:
        - Medical record documentation of unresectable advanced, recurrent, or metastatic esophageal squamous cell carcinoma (ESCC) **AND**
        - Medical record documentation of previous trial of fluoropyrimidine- and platinum-containing chemotherapy

        OR
        - Medical record documentation of unresectable advanced or metastatic esophageal squamous cell carcinoma (ESCC) **AND**
        - Medical record documentation that Opdivo will be given in combination with fluoropyrimidine- and platinum-containing chemotherapy **OR** in combination with ipilimumab (Yervoy) **AND**
        - Medical record documentation that the regimen is being given as first-line treatment

Medical Benefit Policy 91.0 (Yervoy)

7. Esophageal Squamous Cell Carcinoma
    - Prescription written by a hematologist/oncologist **AND**
    - Medical record documentation that patient is 18 years of age or older **AND**
    - Medical record documentation of unresectable advanced or metastatic esophageal squamous cell carcinoma (ESCC) **AND**
    - Medical record documentation that Yervoy is being given in combination with nivolumab (Opdivo)

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

RUBRACA (rucaparib)

Background: Clovis Oncology Inc. has voluntarily withdrawn the indication for Rubraca for the treatment of BRCA-mutated ovarian cancer after 2 or more chemotherapies. This withdrawal is based on overall survival data from the ARIEL4 trial which demonstrated an increased risk of death in participants with BRCA-mutated ovarian cancer treated with Rubraca after 2 or more chemotherapies.

There are no changes to the other indications of Rubraca. It will continue to be available for maintenance treatment of recurrent epithelial ovarian, fallopian tube, or primary peritoneal cancer in patients who are in complete or partial response to platinum-based chemotherapy and for patients with deleterious BRCA-associated metastatic castration-resistant prostate cancer who have been treated with androgen-receptor-directed therapy and a taxane-based chemotherapy.

Recommendation: There are no changes recommended to the formulary placement, auth duration, or quantity limits. The following changes are recommended for Commercial Policy 442.0 to remove the withdrawn indication:

Ovarian Cancer

- Medical record documentation that Rubraca is prescribed by an oncologist or hematologist **AND**
- Medical record documentation of age greater than or equal to 18 years **AND**
- Medical record documentation of a diagnosis of recurrent epithelial ovarian, fallopian tube, or primary peritoneal cancer **AND** medical record documentation of Rubraca being used as maintenance treatment after a complete or partial response to platinum-based chemotherapy **OR**
- ~~Medical record documentation of deleterious BRCA mutation (germline and/or somatic)-associated epithelial ovarian, fallopian tube, or primary peritoneal cancer (as verified by a Food and Drug Administration-approved test) who have been treated with two or more chemotherapies~~

Discussion: Was this included in the policy due to FDA approval. Yes, likely included as part of an accelerated approval and after confirmatory trials were completed, there was no benefit. No additional comments or questions.

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

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

VIJOICE QUANTITY LIMIT UPDATE

BACKGROUND: In addition to 50 mg and 125 mg tablets, Vijoice is available as a therapy pack containing a 200 mg tablet and a 50 mg tablet to make up a daily dose of 250 mg.

Recommendation: It is recommended that the following quantity limit be added to Commercial, Exchange, and CHIP:

- 250 mg Therapy Pack (200 mg and 50 mg tablets): 2 tablets per day, 28 day supply per fill

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.

EYLEA UPDATE

Background: It is recommended to update the prior authorization criteria for Eylea (MBP 94.0) to define baseline visual acuity more specifically as a result of discussion with Dr. Benjamin Hale M.D. and Dr. Herbert Ingraham M.D.

Recommendation:
MBP 94.0 Eylea (aflibercept)

- Medical record documentation of a diagnosis of diabetic retinopathy with or without macular edema **AND**
- Medical record documentation of therapeutic failure on, intolerance to, or contraindication to intravitreal bevacizumab (Avastin) **OR** medical record documentation of baseline best-corrected visual acuity 20/50 or worse.

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.

AMELUZ UPDATE

Background: Upon annual review and PARP approval, it was found that updated Ameluz labeling requires use of Ameluz in combination with photodynamic therapy (PDT) using a BF-RhodoLED or RhodoLED® XL lamp. Previously, the only FDA approved lamp was the BF-RhodoLED lamp. To obtain DHS approval of MBP 149.0 Ameluz (aminolevulinic acid), GHP updated the Ameluz policy to include the new XL lamp.

Recommendation: No changes are recommended to the formulary placement of Ameluz at this time. It is recommended that MBP 149.0 be updated to account for the additional approved lamp as follows:

- Medical record documentation that Ameluz will be used in conjunction with the BF-RhodoLED lamp **OR** BF-RhodoLED XL lamp

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.

QUANTITY LIMIT AND BENLYSTA UPDATE

Background: In 2021, a list of drugs for the Medicaid line of business was brought to P&T. This list was a list of drugs that GHP had a quantity limit for that DHS did not have. For these drugs, the following criterion was added to the respective drug policies to accompany the quantity limit: “Medical

record documentation that (drug) is prescribed with a dose and duration of therapy that is consistent with FDA-approved package labeling, nationally recognized compendia, or peer-reviewed medical literature." DHS requires that drugs with both a medical and pharmacy policy have consistent criteria across policies (assuming shared indications).

Recommendation (Quantity Limit): It is recommended that the committee give a blanket approval to allow for the following verbiage to be added to the appropriate drug policies in the event that GHP proposes a quantity limit when DHS does not have a coded quantity limit. These changes will also apply to medical policies for shared indications to ensure consistency between medical and pharmacy policies.

- Medical record documentation that (drug) is prescribed with a dose and duration of therapy that is consistent with FDA-approved package labeling, nationally recognized compendia, or peer-reviewed medical literature.

Recommendation (Benlysta): On annual review, the following was added to MBP 90.0 (initial and reauthorization criteria) to ensure consistency with Pharmacy Policy 1409.0F which was updated in 2021 as part of the quantity limit process.

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

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.

INFLIXIMAB & RITUXIMAB UPDATE

Background: It is recommended to modify reauthorization verbiage of Remicade, Inflectra, Renflexis, and Avsola's policy (MBP 5.0) and Rituxan, Riabni, Truxima, and Ruxience's policy (MBP 48.0) to align with current strategy of having all members, regardless of diagnosis and if established on a non-preferred product, transition to a preferred biosimilar product for applicable lines of business.

Recommendation:
For Infliximab:
MBP 5.0 Remicade (infliximab), Inflectra (infliximab-dyyb), Renflexis (infliximab-abda), Avsola (infliximab-axxq)

AUTHORIZATION DURATION: ~~Approval will be given for an initial duration of six (6) months. For continuation of coverage, medical record documentation of clinical improvement or lack of progression in the signs and symptoms of the treated indication at six (6) months of infliximab therapy is required.~~

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

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 all requests will require:

- Medical record documentation of continued or sustained improvement in the signs and symptoms of the treated indication while on infliximab therapy **AND**
- One of the following:
  - For infliximab biosimilar requests other than Avsola (e.g. Renflexis, Inflectra), medical record documentation of a therapeutic failure on, intolerance to, or contraindication to infliximab-axxq (Avsola) **OR**
  - For infliximab reference product requests (i.e. Remicade), medical record documentation of a therapeutic failure on, intolerance to, or contraindication to infliximab-axxq (Avsola) AND infliximab-abda (Renflexis), AND infliximab-dyyb (Inflectra).

For Rituximab:
MBP 48.0 Rituxan (rituximab), Truxima (rituximab-abbs), Ruxience (rituximab-pvvr), and Riabni (rituximab-arrx)

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

- Medical record documentation of continued disease improvement or lack of disease progression. The medication will no longer be covered if patient experiences toxicity or worsening of disease. **AND**
- For rituximab reference product requests (i.e. Rituxan), medical record documentation of a therapeutic failure on, intolerance to, or contraindication to rituximab-pvvr (Ruxience) AND rituximab-arrx (Riabni) AND rituximab-abbs (Truxima).

For all other indications: Initial approval will be for **6 months** or less if the reviewing provider feels it is medically appropriate (*except for the diagnosis for ITP). Subsequent approvals will be for an additional **12 months** or less if the reviewing provider feels it is medically appropriate and will require:

- Medical record documentation of continued disease improvement or lack of disease progression. The medication will no longer be covered if patient experiences toxicity or worsening of disease. **AND**
- For rituximab reference product requests (i.e. Rituxan), medical record documentation of a therapeutic failure on, intolerance to, or contraindication to rituximab-pvvr (Ruxience) AND rituximab-arrx (Riabni) AND rituximab-abbs (Truxima).

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.

SITE OF CARE POLICY UPDATE

Background: On October 1st, 2019 Geisinger Health Plan (GHP) implemented a new site of care program for infliximab products and intravenous/subcutaneous immune globulin products, which direct members to the most cost-effective, yet clinically appropriate location to receive drug infusions under the medical benefit. The site of care program is administered as part of the existing prior authorization

program which requires clinical approval of the medication as well as approval at hospital based outpatient facilities via the following prior authorization criteria. Since that time, additional drugs have been added to the site of care program in phases.

On September 15th, 2022 GHP will implement Phase 12 drugs (Adakveo, Crysvita, Evenity, Evkeeza, Tepezza) to the site of care program. The current Site of Care Policy (MBP 181.0) will apply in addition to the drugs' respective existing clinical prior authorization program.

Recommendation: It is recommended that the following changes (highlighted in green) be made to MBP 181.0 so that this policy may apply to the Phase 12 drugs (Adakveo, Crysvita, Evenity, Evkeeza, Tepezza). No changes are recommended to the criteria for self-injected drugs.

1. Abatacept (Orencia IV)
2. Agalsidase Beta (Fabrazyme)
3. Alglucosidase Alfa (Lumizyme)
4. Alpha$_1$-Proteinase Inhibitor [Human] products
5. Belimumab (Benlysta IV)
6. Benralizumab (Fasenra)
7. Burosumab (Crysvita)
8. C1 esterase Inhibitor [Human] (Cinryze)
9. Casimersen (Amondys 45)
10. Canakinumab (Ilaris)
11. Certolizumab (Cimzia)
12. Crizanlizumab (Adakveo)
13. Denosumab (Prolia, Xgeva)
14. Eculizumab (Soliris)
15. Edaravone (Radicava)
16. Elapegademase-lvlr (Revcovi)
17. Elosulfase alfa (Vimizim)
18. Eptinezumab (Vyepti)
19. Eteplirsen (Exondys 51)
20. Evinacumab (Evkeeza)
21. Galsulfase (Naglazyme)
22. Golodirsen (Vyondys 53)
23. Golimumab (Simponi Aria)
24. Idursulfase (Elaprase)
25. Immune Globulin (IVIG)
26. Imiglucerase (Cerezyme)
27. Inebilizumab (Uplizna)
28. Infliximab & infliximab biosimilar products
29. Laronidase (Aldurazyme)
30. Mepolizumab (Nucala)
31. Omalizumab (Xolair)
32. Patisiran (Onpattro)
33. Ravulizumab (Ultomiris)
34. Romosozumab (Evenity)
35. Sebelipase alfa (Kanuma)
36. Taliglucerase alfa (Elelyso)
37. Teprotumumab (Tepezza)
38. Tildrakizumab (Ilumya)
39. Tocilizumab (Actemra IV)
40. Ustekinumab (Stelara)
41. Vedolizumab (Entyvio)
42. Velaglucerase alfa (Vpriv)
43. Vestronidase alfa-vjbk (Mepsevii)
44. Viltolarsen (Viltepso)

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.

NON-PREFERRED TOPICAL CORTICOSTEROIDS

Background: To aid in reviewing prior authorization cases more efficiently it has been decided to create a policy for non-preferred topical corticosteroids.

The preferred corticosteroid formulary alternatives have also been updated. This update will affect the following policies:

- 41.0 Enbrel
- 67.0 Pimecrolimus

- 84.0 Humira
- 151.0 Verdeso (only low potency alternatives)
- 317.0 Valchlor
- 318.0 Stelara
- 379.0 Cosentyx
- 431.0 Taltz
- 456.0 Eucrisa
- 457.0 Dupixent
- 583.0 Duobrii
- 609.0 Enstilar

Recommendation:
Prior authorization criteria for policy:

- Medical record documentation of therapeutic failure on, intolerance to, or contraindication to three (3) formulary alternatives [one (1) of which must be of a similar potency]

Formulary Alternatives:

- 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 (Florone/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)

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.

2023 MARKETPLACE FORMULARY UPDATES

Recommendation: The following changes are recommended for the 2023 Marketplace Formulary. Unless otherwise specified, members will not be grandfathered.

Formulary Removals:

Drug Name	Recommendation	Rationale
Absorica Oral Capsule 10 MG, 20 MG, 30 MG, 40 MG	Move to Non-Formulary 1/1/2023	Multi-source brand, generic on formulary
Bydureon BCise Subcutaneous Auto-injector 2 MG/0.85ML	Move to Non-Formulary 1/1/2023	Improved rebate opportunity for formulary GLP-1 agonists if moved to NF. No current utilization.
Bydureon Subcutaneous Pen-injector 2 MG	Move to Non-Formulary 1/1/2023	Product Discontinued
Carbaglu Oral Tablet Soluble 200 MG	Move to Non-Formulary 1/1/2023	Multi-source brand, generic will be added formulary
Clindagel External Gel 1 %	Move to Non-Formulary 1/1/2023	Multi-source brand, generic on formulary
Eurax External Lotion 10 %	Move to Non-Formulary Immediately	Product Discontinued
Ferriprox Oral Tablet 1000 MG	Move to Non-Formulary 1/1/2023	Multi-source brand, generic on formulary
Ferriprox Oral Tablet 1000 MG	Move to Non-Formulary 1/1/2023	Multi-source brand, generic on formulary
Ferriprox Twice-A-Day Oral Tablet 1000 MG	Move to Non-Formulary 1/1/2023	Multi-source brand, generic on formulary
Ilumya Subcutaneous Solution Prefilled Syringe 100 MG/ML	Move to Non-Formulary 1/1/2023	Improved rebate opportunity for formulary agents if moved to NF. No current utilization.
Ilumya Subcutaneous Solution Prefilled Syringe 100 MG/ML	Move to Non-Formulary 1/1/2023	Improved rebate opportunity for formulary agents if moved to NF. No current utilization.
Jynarque Oral Tablet 15 MG	Move to Non-Formulary 1/1/2023	Multi-source brand, generic on formulary

Jynarque Oral Tablet 30 MG	Move to Non-Formulary 1/1/2023	Multi-source brand, generic on formulary
Jynarque Oral Tablet Therapy Pack 15 MG	Move to Non-Formulary 1/1/2023	Multi-source brand, generic on formulary
Jynarque Oral Tablet Therapy Pack 15 MG	Move to Non-Formulary 1/1/2023	Multi-source brand, generic on formulary
Pradaxa Oral Capsule 110 MG	Move to Non-Formulary 1/1/2023	Improved rebate opportunity for formulary agents if moved to NF. No current utilization.
Pradaxa Oral Capsule 150 MG	Move to Non-Formulary 1/1/2023	Improved rebate opportunity for formulary agents if moved to NF. 4 active members currently utilizing will be grandfathered.
Pradaxa Oral Capsule 75 MG	Move to Non-Formulary 1/1/2023	Improved rebate opportunity for formulary agents if moved to NF. No current utilization.
Revlimid Oral Capsule 10 MG	Move to Non-Formulary 1/1/2023	Multi-source brand, generic on formulary
Revlimid Oral Capsule 15 MG	Move to Non-Formulary 1/1/2023	Multi-source brand, generic on formulary
Revlimid Oral Capsule 25 MG	Move to Non-Formulary 1/1/2023	Multi-source brand, generic on formulary
Revlimid Oral Capsule 5 MG	Move to Non-Formulary 1/1/2023	Multi-source brand, generic on formulary
Samsca Oral Tablet 15 MG	Move to Non-Formulary 1/1/2023	Multi-source brand, generic on formulary
Slow Fe Oral Tablet Extended Release 142 (45 Fe) MG	Move to Excluded 1/1/2023	Currently on Tier 7 (Medical Benefit)
Taltz Subcutaneous Solution Auto-injector 80 MG/ML	Move to Non-Formulary 1/1/2023	Improved rebate opportunity for formulary agents if moved to NF. 4 active members currently utilizing will be grandfathered.

Taltz Subcutaneous Solution Prefilled Syringe 80 MG/ML	Move to Non-Formulary 1/1/2023	Improved rebate opportunity for formulary agents if moved to NF. No current utilization.
Vimpat Oral Tablet 100 MG, 150 MG, 200 MG, 50 MG	Move to Non-Formulary 1/1/2023	Multi-source brand, generic on formulary
Zytiga Oral Tablet 250 MG, 500 MG	Move to Non-Formulary 1/1/2023	Multi-source brand, generic on formulary

Formulary Additions/PA Changes

Drug Name	Recommendation	Rationale
Carglumic Acid Oral Tablet Soluble 200 MG	Add to Tier 5, PA. No change to existing PA criteria.	Multi-source brand removed.
Celontin Oral Capsule 300 MG	Remove PA	PA removal required to meet the unrestricted drug count threshold set by the benchmark plan.
Hydrocodone Bitartrate ER Capsule Extended Release 12 Hours 10 MG, 15 MG, 20 MG, 30 MG, 40 MG, 50 MG	Add to Tier 2, PA. No change to existing PA criteria.	Addition to formulary required to meet the threshold for formulary long acting opioids set by the benchmark plan.
Hydromorphone HCl ER Oral Tablets Extended Release 24 Hours 8 MG, 12 MG, 16 MG, 32 MG	Add to Tier 2, PA. No change to existing PA criteria.	Addition to formulary required to meet the threshold for formulary long acting opioids set by the benchmark plan.

Discussion: No comments or questions.

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

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

QUARTERLY CASE AUDIT

Background: The Quarterly Case Audit for 1st quarter 2022 was held on June 2, 2022. There were no formulary changes proposed at this meeting. We will continue to look for opportunities to create more drug specific policies at future quarterly case audit meetings.

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

Meeting adjourned at 4:11 pm

Future Scheduled Meetings

The next bi-monthly scheduled meeting will be held on September 20th, 2022 at 1:00 p.m.

Meeting will be held virtually via phone/Microsoft Teams.