P&T Committee Meeting Minutes
Commercial/Marketplace/CHIP
November 21, 2023

Present (via Teams):	**Absent:**
Bret Yarczower, MD, MBA – Chair	Jeremy Bennett, MD
Amir Antonius, Pharm.D.	Alyssa Cilia, RPh
Emily Antosh, Pharm.D.	Michael Dubartell, MD
Kristen Bender, Pharm.D.	Michael Evans, RPh
Kim Castelnovo, RPh	Nichole Hossler, MD
Kimberly Clark, Pharm.D.	Jason Howay, Pharm.D.
Bhargavi Degapudi, MD	Kelli Hunsicker, Pharm.D.
Kelly Faust, Pharm.D.	Perry Meadows, MD
Tricia Heitzman, Pharm.D.	Jonas Pearson, RPh
Keith Hunsicker, Pharm.D.	Angela Scarantino
Derek Hunt, Pharm.D.	William Seavey, Pharm.D.
Emily Jacobson, Pharm.D.	Michael Shepherd, MD
Kerry Ann Kilkenny, MD	
Philip Krebs, R.EEG T	
Briana LeBeau, Pharm.D.	
Ted Marines, Pharm.D.	
Lisa Mazonkey, RPh	
Tyreese McCrea, Pharm.D.	
Jamie Miller, RPh	
Mark Mowery, Pharm.D.	
Austin Paisley, Pharm.D.	
Kimberly Reichard, Pharm.D.	
Melissa Sartori, Pharm.D.	
Kristen Scheib, Pharm.D.	
Leslie Shumlas, Pharm.D.	
Aubrielle Smith-Masri, Pharm.D.	
Kirsten Smith, Pharm.D.	
Michael Spishock, RPh	
Todd Sponenberg, Pharm.D.	
Jill Stone, Pharm.D.	
Luke Sullivan, DO	
Kevin Szczecina, RPh	
Amanda Taylor, MD	
Ariana Wendoloski, Pharm.D.	
Brandon Whiteash, Pharm.D.	
Margaret Whiteash, Pharm.D.	
Joshua Buffington, Pharmacy Student	
Morgan Casciole, Pharmacy Resident	
Jennifer Lee, Pharmacy Student	
Taylor Warner, Pharmacy Resident	
Birju Bhatt, MD (non-voting participant)	
Keri Jon Donaldson (non-voting participant)	
Jeremy Garris, Pharm.D. (non-voting participant)	

Call to Order:
Dr. Bret Yarczower called the meeting to order at 1:02 p.m., Tuesday, November 21, 2023.

Review and Approval of Minutes:
Dr. Bret Yarczower asked for a motion or approval to accept the Sept 19, 2023 e-vote minutes as written. Minutes approved unanimously. None were opposed.

DRUG REVIEWS

BRIXADI (buprenorphine)

Review: Brixadi (buprenorphine) is an extended-release maintenance injection that is indicated for the treatment of moderate to severe opioid use disorder in patients who have initiated treatment with a single dose of a transmucosal buprenorphine or currently being treated with a transmucosal buprenorphine product. Brixadi can be administered to the patient on either a weekly or monthly dosing schedule, with a recommended weekly dose being 24 mg. Brixadi is only available through limited distribution REMS program due to significant risk of serious harm or death associated with inappropriate IV administration. In clinical trials, Brixadi was shown to be noninferior in response rate and the mean proportion of opioid-negative urine samples for 24 weeks when compared to sublingual combination of buprenorphine and naloxone. Brixadi, a partial opioid agonist analgesic, has interactions with CYP3A4 inhibitors and inducers and serotonergic drugs. Patients on Brixadi should be monitored for the risk of abuse and misuse, respiratory depression and withdrawal syndrome.

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 voted by majority to accept the recommendations as presented.

Financial Discussion: No comments or questions. The committee voted by majority to accept the recommendations as presented.

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

QUANTITY LIMIT:

- 4 syringes per 28 days of Brixadi weekly injection
- 1 syringe per 28 days of Brixadi monthly injection

Discussion: No comments or questions. The committee voted by majority to accept the recommendations as presented.

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

VYVGART HYTRULO (efgartigimod alfa and hyaluronidase injection)

Review: Vyvgart Hytrulo is a human IgG antibody fragment that binds and reduces IgG in the body to decrease effects of immunoglobulin in the system. The Hyaluronidase in this solution increases permeability of tissue for greater absorption of drug. Its FDA labeled indication is for adult patients with generalized Myasthenia Gravis with a positive diagnosis of Anti-acetylcholine receptor antibodies.

Vyvgart Hytrulo is given by a health care professional only, at a dose of 1,008/ 11,200 Units SubQ once weekly for 4 weeks over 30-90 seconds and can repeat, if needed, no sooner than 50 days from first dose of last treatment cycle.

A Phase 3, Randomized, Open-Label, Parallel-Group Study Vyvgart Hytrulo showed a statistically significant reduction in AChR-Ab levels and IgG levels compared to Vyvgart; 62.2% and 59.7% respectively. Vyvgart Hytrulo's place in therapy has not been confirmed by guidelines for MG, however expert consensus and analyzation of the drug places it after trial of other non-biologic medications, unless otherwise indicated.

The most common adverse events for this drug are infections, specifically upper respiratory infections and urinary tract infections, as well as some injection site reactions.

Vyvgart Hytrulo also has limited distribution through specialty pharmacies/distributors

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: Dr. Bret Yarczower asked if we reached out to neurology regarding this. Kristen Scheib, Pharm.D., responded that we are waiting for a class review to be completed before soliciting feedback. Keith Hunsicker, Pharm.D., stated that we do have providers utilizing the IV formulation so we will probably have uptick of SQ formulation due to easier dosing. Kristen Scheib, Pharm.D., agreed and stated we do have utilization of the IV formulation in about 25 members. The committee unanimously voted to accept the recommendations as presented. None were opposed.

Outcome: Vyvgart Hytrulo will be a medical benefit and will be added to the medical benefit cost share list. If processed at a specialty pharmacy, Vyvgart Hytrulo will process at the Specialty tier or Brand Non-Preferred tier for members with a three-tier benefit. Vyvgart Hytrulo will be added to existing policy MBP 260 for Vygart, where the following additional prior authorization criteria should apply (please note updates needed for formulary alternatives to remove products not orally available):

<u>For Initial Approval</u>

- Medical record documentation of age greater than or equal to 18 years **AND**
- Medical record documentation that Vyvgart Hytrulo is prescribed by or in consultation with a neurologist **AND**
- Medical record documentation of a diagnosis of generalized myasthenia gravis that is anti-acetylcholine receptor (AChR) antibody positive **AND**
- Medical record documentation of Myasthenia Gravis Foundation of America Clinical Classification (MFGA) II to IV **AND**
- Medical record documentation of Myasthenia Gravis Activities of Daily Living (MG-ADL) total score of 5 or more at baseline **AND**
- Medical record documentation of therapeutic failure on, intolerance to, or contraindication to corticosteroids **AND**
- Medical record documentation of therapeutic failure on, intolerance to, or contraindication to at least two (2) non-steroidal immunosuppressive therapies **OR** One (1) immunosuppressive therapy and required chronic plasmapheresis or plasma exchange (PE) **AND**
- Medical record documentation of failure on, intolerance to, or contraindication to intravenous immunoglobulin (IVIG)

GPI-LEVEL: GPI-12

QUANTITY LIMIT: 4 vials/50 days

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

- Medical record documentation of continued disease improvement or lack of disease progression **AND**
- Medical record documentation of positive response to therapy as evidenced by a 2-point reduction from baseline in Myasthenia Gravis-Activities of Daily Living (MG-ADL) total score

Medication will no longer be covered if patient experiences toxicity or worsening of disease.

RPH SIGNOFF REQUIRED: Yes

FORMULARY ALTERNATIVES:

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

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

RYSTIGGO (rozanolixizumab-noli)

Review: Rystiggo is a neonatal Fc receptor blocker indicated for the treatment of generalized myasthenia gravis (gMG) in adult patients who are anti-acetylcholine receptor (AChR) or anti-muscle-specific tyrosine kinase (MuSK) antibody positive. Myasthenia gravis is a primary disorder of neuromuscular transmission characterized by fluctuating motor weakness in ocular, bulbar, limb, and respiratory muscles. In myasthenia gravis, there is an antibody-mediated immunologic attack directed at proteins in the postsynaptic membrane of the neuromuscular junction. Severity of disease can vary between individuals; however, generally it improves with rest and worsens with activity. Pregnancy, infection, surgery, and stress can all be aggravating factors. Most patients (approximately two-thirds) initially present with only ocular muscle weakness, with 85% of patients eventually developing generalized myasthenia gravis (gMG).

There are approximately 71,000 individuals (20/100,000) with MG in the United States. It is typically diagnosed in young women 20-30 years of age or men over 50 years of age, with life expectancy remaining near normal. The majority of patients (approximately 85%) with gMG are anti-acetylcholine receptor (AChR) antibody positive. AChR antibody positive individuals have autoantibodies that attack and decrease the amount of AChRs at the postsynaptic neuromuscular junction over time, leading to decreased muscular contraction. The remaining serologic diagnoses in gMG are MuSK antibody positive, LRP4 antibody positive, or seronegative. The Myasthenia Gravis Foundation of America (MGFA) developed a clinical classification system dividing MG into five main classes that are used by providers to evaluate severity and by researchers for clinical trials.

Rystiggo is supplied as a 280 mg/2 ml (140 mg/ml) single-dose vial for subcutaneous (SC) infusion. The recommended dosage is administered as a SC infusion once weekly for 6 weeks. The subsequent treatment cycles should be administered based on clinical evaluation. The safety of initiating subsequent cycles sooner than 63 days from the start of the previous treatment cycle has not been established. The recommended dose is based on body weight of patient and is administered as a subcutaneous infusion using an infusion pump at a rate of up to 20 mL/hour.

Dosing Chart

Body Weight of Patient	Dose	Volume to be Infused
Less than 50 kg	420 mg	3 mL

50 kg to less than 100 kg	560 mg	4 mL
100 kg and above	840 mg	6 mL

The available treatments for gMG help to manage symptoms by decreasing disease activity and restoring muscle strength. Cholinesterase inhibitors (i.e. pyridostigmine, neostigmine) are the initial treatment for most patients, with many patients having positive response to therapy and some responding long-term. However, many patients with gMG will require additional therapy with immunosuppressants for symptom management. Glucocorticoids are used initially until patients have inadequate response or side effects and require switching to or adding on nonsteroidal immunosuppressive therapies (NSISTs) (i.e. azathioprine, mycophenolate). NSISTs take several months to show effects so bridging with intravenous immunoglobulin (IVIG) or plasma exchange (PE) is typically required. Rapid immunomodulating therapies (IVIG or PE) may be required in patients with severe disease or rapidly worsening disease. Additionally, some patients require a thymectomy but will usually continue medications.

Patients with refractory disease (10-20%) may require biologic therapies if nonresponsive to nonsteroidal immunosuppressive drugs. Anti-AChR-antibody-positive gMG patients may need chronic immunotherapy with Fc receptor (FcRn) antagonists or complement inhibitors, both classes indicated for anti-AChR antibody positive gMG. Rystiggo is a humanized immunoglobulin G4 monoclonal antibody that binds to FcRn and reduces circulating levels of IgG. The other FcRn antagonists in the same class as Rystiggo include Vyvgart (intravenous infusion) and Vyvgart Hytrulo (subcutaneous injection). Soliris and Ultomiris are the only FDA-approved complement inhibitors. Patients that are anti-MuSK antibody-positive typically have a poor response to cholinesterase inhibitors and require steroids and nonsteroidal immunosuppressive drugs, with limited data recommending rituximab. Rystiggo is the only FDA-approved therapy for patients with anti-MuSK antibody-positive gMG. The International Consensus Guidance for the Management of Myasthenia Gravis has not been updated since 2020, before the approval of any FcRn antagonists. Therefore, there are not specific guidelines for preference of therapies in refractory disease. However, FcRn antagonists are considered safer, less expensive, and more flexible in dosing than complement inhibitors.

Rystiggo was evaluated in a multicenter, randomized, double-blind, placebo-controlled phase 3 clinical trial called the MycarinG trial. Patients included 200 adult patients with gMG diagnosis and confirmed anti-AChR antibody-positive or anti-MuSK antibody-positive. There was a 4-week screening period, 6-week treatment period, and 8-week observation period. Patient were randomized 1:1:1 to be treated with weight-tiered doses of Rystiggo SC infusion (7 mg/kg or 10 mg/kg) or placebo once weekly for 6 weeks. To be included, patients needed presence of autoantibodies against AChR or MuSK, MGFA Clinical Classification Class II to IVa, Myasthenia Gravis-Activities of Daily Living (MG-ADL) score > 3 (with > 3 points non-ocular), be on a stable dose of MG therapy prior to screening (cholinesterase inhibitors, steroids, or NSISTs), and serum IgG levels > 5.5 g/L. Majority of patients (89.5%) were anti-AChR antibody-positive and 10.5% were anti-MuSK antibody-positive.

The primary efficacy endpoint was the comparison of change from baseline between treatment groups in MG-ADL total score at Day 43. The MG-ADL scale includes 8 signs/symptoms that are affected in gMG and provides scores to assess disease impact on daily functions. The MG-ADL scale ranges from 0 to 24 (higher score worse impairment) and each item is assessed on a 4-point scale from 0 (normal function) to 3 (full loss of function). The Rystiggo MG-ADL total score change from baseline (-3.4 points for both doses) was found to be statistically significant when compared to placebo (-0.8 points), with a p-value <0.001. The secondary endpoint was change between treatment groups from baseline to Day 43 in the Quantitative Myasthenia Gravis (QMG) total score. QMG is a 13-item categorial grading system assessing muscle weakness, with each item on a 4-point scale from 0 (no weakness) to 3 (severe weakness). The Rystiggo QMG total score change from baseline (-5.4 points and -6.7 points in 7 mg/dk and 10 mg/kg dose groups, respectively) was found to be statistically significant when compared to placebo (-1.9 points), with a p-value <0.001.

The most common adverse reactions (>10%) to Rystiggo were headache, infections, diarrhea, pyrexia, hypersensitivity reactions, and nausea. There are no contraindications or Black Box Warnings. Rystiggo may increase the risk of infection and administration should be delayed in patients with active infection. Monitor for signs/symptoms of infection in patients treated with Rystiggo. Evaluate the need to administer

age-appropriate vaccines before initiating a new treatment cycle. Rystiggo has a warning for causing aseptic meningitis and patients should be monitored for symptoms. Rystiggo also has a warning for hypersensitivity reactions including angioedema and rash and if a hypersensitivity reaction occurs the infusion should be discontinued and appropriate therapy initiated. Rystiggo may reduce effectiveness of medications that bind to the human neonatal FcRn and close monitoring should be conducted and consideration of discontinuing Rystiggo if concomitant long-term use of such medications is essential.

There is limited data on Rystiggo use in pregnant women, but animal data suggests it may cause fetal harm. The safety and effectiveness of Rystiggo has not been established in pediatric patients. There was not an adequate number of patients aged 65 and over to determine response compared to younger adults.

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

Clinical Discussion: Dr. Bret Yarczower asked if we think providers are using the MG-ADL score. Keith Hunsicker, Pharm.D., stated when initially reaching out to neurology it wasn't common but they felt it could be easily implemented and we now see it submitted with requests. The committee unanimously voted to accept the recommendations as presented. None were opposed.

Financial Discussion: Keith Hunsicker, Pharm.D., stated rituximab and cholinesterase inhibitors were removed due to a review of Ultomiris and recognizing there may not be clinically meaningful outcomes for patients taking these drugs. The committee unanimously voted to accept the recommendations as presented. None were opposed.

Outcome: Rystiggo is a medical benefit and will be added to the medical benefit cost share list. The following prior authorization criteria will apply:

- Medical record documentation of age 18 years or older **AND**
- Medical record documentation that Rystiggo is prescribed by or in consultation with a neurologist **AND**
- Medical record documentation of a diagnosis of generalized myasthenia gravis (gMG) that is anti-acetylcholine receptor (AChR) positive **OR** anti-muscle-specific tyrosine kinase (MuSK) antibody positive **AND**
- Medical record documentation of a prescribed dose and administration that is consistent with FDA-approved package labeling, nationally recognized compendia, or peer-reviewed medical literature **AND**
- Medical record documentation of Myasthenia Gravis Foundation of America Clinical Classification (MGFA) Class II to IVa **AND**
- Medical record documentation of a baseline Myasthenia Gravis-Activities of Daily Living (MG-ADL) score greater than or equal to 3 (with at least 3 points being non-ocular) **AND**
- Medical record documentation of therapeutic failure on, intolerance to, or contraindication to corticosteroids **AND**
- Medical record documentation of therapeutic failure on intolerance to, or contraindication to at least two (2) non-steroidal immunosuppressive therapies **OR** has failed at least one (1) immunosuppressive therapy and required chronic plasmapheresis or plasma exchange (PE) **AND**
- Medical record documentation of failure on, intolerance to, or contraindication to intravenous immunoglobulin (IVIG)

FORMULARY ALTERNATIVES:
Corticosteroids: dexamethasone, methylprednisolone, prednisone
Cholinesterase inhibitors: pyridostigmine
Immunosuppressants: azathioprine, mycophenolate, cyclosporine, Rituxan

AUTHORIZATION DURATION: 6 months

REAUTHORIZATION CRITERIA: Subsequent approvals will be for an additional 6 months and will require:

- Medical record documentation of continued disease improvement or lack of disease progression **AND**
- Medical record documentation that the member is responding positively to therapy as evidenced by an improvement of Myasthenia Gravis-Activities of Daily Living (MG-ADL) total score from baseline

RPH SIGNOFF REQUIRED: Yes

GPI LEVEL: GPI-12

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

VANFLYTA (quizartinib)

Review: Vanflyta is a kinase inhibitor indicated in combination with standard cytarabine and anthracycline induction and cytarabine consolidation, and as maintenance monotherapy following consolidation chemotherapy, for the treatment of adult patients with newly diagnosed acute myeloid leukemia (AML) that is FLT3 internal tandem duplication (ITD)-positive as detected by an FDA-approved test. Vanflyta is not indicated as maintenance monotherapy following allogeneic hematopoietic stem cell transplantation (HSCT), improvement in overall survival with Vanflyta in this setting has not been demonstrated. Vanflyta is a small molecule inhibitor of the receptor tyrosine kinase FLT3. Vanflyta and its major active metabolite (AC886) inhibit FLT3 kinase activity, inhibit downstream FLT3 receptor signaling, and blocking FLT3-ITD-depenedent cell proliferation. Vanflyta showed antitumor activity in a mouse model of FLT3-ITD-dependent leukemia.

A treatment course consists of up to 2 cycles of Vanflyta in combination with induction cytarabine and anthracycline, up to 4 cycles of Vanflyta in combination with high-dose cytarabine consolidation and up to 36 cycles of Vanflyta as maintenance monotherapy or until disease progression or unacceptable toxicity. Vanflyta maintenance therapy should be initiated following consolidation chemotherapy upon blood count recovery of absolute neutrophil count >500/mm^3 and platelet count >50,000/mm^3. The recommended dosages of Vanflyta during the different phases of therapy are shown in Table 3.

Table 3. Vanflyta Dosage Regimen

VANFLYTA Initiation	Induction*	Consolidation†	Maintenance
	Starting on Day 8 (for 7 + 3 regimen)‡	**Starting on Day 6**	**Starting on Day 1**
Dose	35.4 mg orally once daily	35.4 mg orally once daily	• Administer 26.5 mg orally once daily Days 1 through 14 of the first cycle if QTcF is less than or equal to 450 ms. • Increase the dose to 53 mg once daily on Day 15 of the first cycle if QTcF is less than or equal to 450 ms. Maintain the 26.5 mg once daily dose if QTcF greater than 500 ms was observed during induction or consolidation.
Duration (28-day cycles)	Two weeks in each cycle (Days 8 to 21)‡	Two weeks in each cycle (Days 6 to 19)	• Once daily with no break between cycles for up to 36 cycles

* Patients can receive up to 2 cycles of induction.
† Patients can receive up to 4 cycles of consolidation.
‡ For 5 + 2 regimen as the second induction cycle, VANFLYTA will be given on Days 6 to 19.

Vanflyta should only be administered if QTcF is less than or equal to 450 ms. During induction and consolidation, ECGs should be performed prior to initiation and then once weekly during treatment or more frequently if clinically indicated. During maintenance, ECGs should be performed prior to initiation, once weekly for at least the first month following dose initiation and escalation and thereafter as clinically indicated. The dosage should only be escalated if the QTcF is less than or equal to 450 ms. Recommended dosage adjustments for adverse reactions for Vanflyta are shown in Table 4.

Table 4. Recommended dosage adjustments for adverse reactions for Vanflyta

Current Dosage	Modified Dosage
53 mg once daily	35.4 mg once daily
35.4 mg once daily	26.5 mg once daily
26.5 mg once daily	Interrupt
17.7 mg once daily	Interrupt

The dosage of Vanflyta should be reduced when administered with strong CYP3A inhibitors as shown in Table 5. If the current dosage of Vanflyts is 17.7 mg once daily, Vanflyta treatment should be interrupted for the duration of strong CYP3A inhibitor use. After discontinuation of a strong CYP3A inhibitor for 5 half-lives, Vanflyta can be resumed at the dose that was taken before initiating the strong inhibitor.

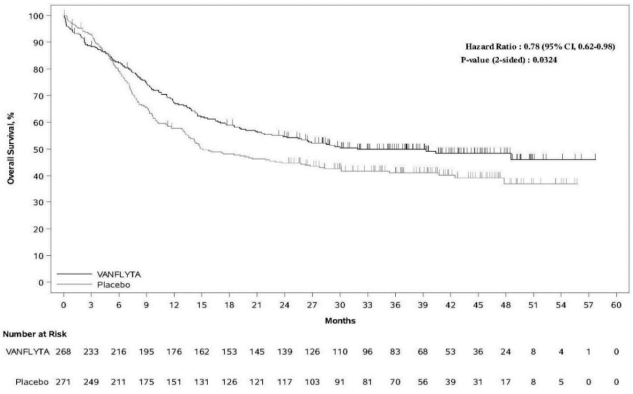
Table 5. Dosage Adjustments for Concomitant Use with Strong CYP3A Inhibitors

Current Dosage	Modified Dosage
53 mg once daily	26.5 mg once daily
35.4 mg once daily	17.7 mg once daily
26.5 mg once daily	17.7 mg once daily

Vanflyta is supplied as 17.7 mg tablets and 26.5 mg tablets.

The efficacy of Vanflyta in combination with chemotherapy was evaluated in QuANTUM-First, a randomized, double-blind, placebo-controlled study of 539 patients with newly diagnosed FLT3-ITD positive AML. Patients were randomized 1:1 to receive Vanflyta (n=268) or placebo (n=271) in combination with induction and consolidation therapy and as maintenance monotherapy. Patients who proceeded to hematopoietic stem cell transplantation (HSCT) initiated maintenance therapy after recovery from the HSCT. Efficacy was based on overall survival (OS), measured from the date of randomization until death by any cause. The primary analysis was conducted after a minimum follow-up of 24 months after the randomization of the last patient. The study demonstrated a statistically significant improvement in OS for the Vanflyta arm (Figure 1).

Figure 1. Kaplan-Meier Curve for Overall Survival in QuANTUM-First



The complete remission (CR) rate in the Vanflyta arm was 55% with a median duration of CR of 38.6 months and the CR in the placebo arm was 55% with a median duration of CR of 12. 4 months.

Vanflyta has a black box warning for QT prolongation, Torsades De Pointes, and cardiac arrest. Vanflyta prolongs the QT interval in a dose- and concentration-related manner. Prior to Vanflyta administration, patients should be monitored for hypokalemia and hypomagnesemia, in addition to ECG monitoring. Of the 1,081 patients with AML treated with Vanflyta in clinical trials, torsades de pointes occurred in approximately 0.2% of patients, cardiac arrest occurred in 0.6%, including 0.4% with a fatal outcome, and 0.1% of patients experienced ventricular fibrillation. These severe cardiac arrhythmias occurred predominantly during the induction phase. Vanflyta is available through the VANFLYTA REMS due to serious risk of QT prolongation, torsades de pointes, and cardiac arrest.

Vanflyta also has a warning for embryo-fetal toxicity based on the mechanism of action and the results of animal reproduction studies. During clinical trials, serious adverse reactions in ≥ 5% of patients who received Vanflyta plus chemotherapy were febrile neutropenia (11%). Fatal adverse reactions occurred in 10% of patients who received Vanflyta plus chemotherapy, including sepsis, fungal infections, brain edema, and one case each of febrile neutropenia, pneumonia, cerebral infarction, acute respiratory distress syndrome, pulmonary embolism, ventricular dysfunction, and cardiac arrest. Permanent discontinuation due to adverse reactions occurred in 20% of patients, most frequently sepsis. Dose interruptions and dosage reductions occurred in 34% and 19% of patients, respectively. The most common (>20%) adverse reactions, including laboratory abnormalities, are lymphocytes decreased, potassium decreased, albumin decreased, phosphorus decreased, alkaline phosphatase increased, magnesium decreased, febrile neutropenia, diarrhea, mucositis, nausea, calcium decreased, abdominal pain, sepsis, neutropenia, headache, creatine phosphokinase increased, vomiting, and upper respiratory tract 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: No comments or questions. The committee unanimously voted to accept the recommendations as presented. None were opposed.

Financial Discussion: Dr. Bret Yarczower asked if we will still see use in Rydapt. Kim Reichard, Pharm.D., stated Vanflyta is a little more specific in indication and limited in the mutations to be treated so they will need Rydapt still. The committee unanimously voted to accept the recommendations as presented. None were opposed.

Outcome: Vanflyta is a pharmacy benefit and will be added to the Oral Oncology Brand Non-Preferred tier ($0 copay) for Commercial, Marketplace, and GHP Kids formulary. The following prior authorization criteria will apply:

- Medical record documentation of age greater than or equal to 18 years **AND**
- Medical record documentation that Vanflyta is prescribed by a hematologist or oncologist **AND**
- Medical record documentation of newly diagnosed acute myeloid leukemia (AML) **AND**
- Medical record documentation that member is FLT3 internal tandem duplication (ITD)-positive as detected by an FDA-approved test* **AND**
- Medical record documentation that Vanflyta will be used in combination with standard cytarabine and anthracycline induction, in combination with cytarabine consolidation, and as maintenance monotherapy following consolidation chemotherapy (excludes maintenance monotherapy following allogeneic hematopoietic stem cell transplantation)

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

Authorization of Vanflyta for the treatment of FLT3-ITD positive acute myeloid leukemia (AML) should not exceed the FDA-approved treatment duration of 2 cycles of induction, up to 4 cycles of consolidation, and up to 36 cycles as maintenance. For requests exceeding the above limit, medical record documentation of the following is required:

- Peer-reviewed literature citing well-designed clinical trials to indicate that the member's healthcare outcome will be improved by dosing beyond the FDA-approved treatment duration

RPH SIGNOFF REQUIRED: Yes

QUANTITY LIMIT: 56 tablets per 28 days

GPI LEVEL: GPI-12

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

ZAVZPRET (zavegepant)

Review: Zavzpret (zavegepant) is a nasal spray calcitonin gene-related peptide (CGRP) inhibitor approved for the for the acute treatment of migraines with or without aura in adults. Zavzpret is not currently indicated for the prevention of migraine.

Approximately 40 million Americans over the age of 12 suffer from migraines. They are most common in patients between the ages of 18 and 44. Women are affected more often than men. The three-fold increase in the female population is likely hormonally driven. Migraines are often hereditary; nearly 90% of those with migraines have a family history. Migraines are characterized by headaches of moderate to severe intensity lasting 4 to 72 hours in duration. The debilitating headaches are often accompanied by additional symptoms such as visual disturbances, nausea, vomiting, dizziness, extreme sensitivity to sound, light, touch, and smell, or tingling/numbness in the extremities or face. Migraines are classified as episodic or chronic. Migraines are considered episodic when the individual has 0 to 14 headache days per month, which makes up the majority of migraine sufferers. Chronic migraines are classified as 15 or more headache days per month. The American Headache Society publishes guidelines for the treatment of migraines. They recommend mild to moderate headaches be treated with NSAIDs, nonopioid analgesics, acetaminophen, or caffeinated analgesics. For moderate to severe migraines, agents such as triptans, dihydroergotamine, or CGRP receptor antagonists may be used for treatment. These options may also be used in mild to moderate attacks that do not respond well to nonspecific therapy.

Zavzpret is the first nasally administered calcitonin gene-related peptide inhibitor approved for the acute treatment of migraines. Nasal administration may provide benefit for patients that experience nausea and vomiting during migraine episodes. Though the nasal option may be appealing to such patients, it is likely going to be an expensive alternative to other non-oral treatment options for abortive therapy.
The recommended dose is 10 mg intranasally as needed. No more than one spray (10 mg) should be used in a 24-hour period. Safety has not been established for the treatment of more than 8 migraines in a 30-day period. Zavzpret use should be avoided in patients taking drugs that inhibit or induce OATP1B3 or NTCP. Zavzpret should also be avoided in combination with nasal decongestants or separate administration by at least 1 hour.

Two phase 3 randomized, double-blind, placebo-controlled trials were conducted to demonstrate efficacy of Zavzpret for the acute treatment of migraine. In the first study, participants were randomized to receive a single dose of zavegepant 10 mg or placebo. Efficacy was based on endpoints of pain freedom, defined as reduction of headache pain from moderate or severe to no pain, and most bothersome symptom freedom, defined as absence of self-defined most bothersome symptoms. The second study compared Zavegepant 5 mg, 10 mg, 20 mg, and placebo in patients with 2-8 moderate or severe migraine headaches per month, for efficacy based on the endpoints of pain and most bothersome symptom freedom. In both studies, zavegepant 10 mg demonstrated statistically significant superiority in both co-

primary endpoints. Zavegepant 20 mg showed statistical significance in both endpoints when compared to placebo, but there was no difference between the zavegepant 5 mg group and placebo. Zavegepant also demonstrated significance in multiple secondary outcomes including pain relief at 15 and 30 minutes, return to normal function in 30 minutes, and several measures of sustained pain relief.
No head-to-head trials have been conducted to compare Zavzpret to Nurtec ODT, Ubrelvy, or other abortive medications. Based on efficacy at the co-primary endpoints compared to placebo, zavegepant has similar efficacy compared to Ubrelvy and Nurtec.

In two clinical trials carried out to study zavegepant, dysgeusia, nasal discomfort, and nausea were the most common adverse effects experienced by study participants. In both studies, dysgeusia was the most common side effect and occurred significantly more often in the treatment groups than in the placebo group. Neither study demonstrated evidence of hepatotoxicity. Hypersensitivity reactions and urticaria have occurred in patients treated with zavegepant.

Safety and efficacy in pediatric patients have not been established. There is not sufficient data for use in geriatric patients, as clinical studies did not include sufficient number of patients over the age of 65. Within the small population of geriatric patients that were studied, there were no clinically significant pharmacokinetic differences.

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: Kimberly Clark, Pharm.D., asked if there is a reason we are not requiring step through Nurtec ODT or Ubrelvy. Leslie Shumlas, Pharm.D., stated we did not hear back from rebating company in time to make that recommendation so wanted to have them step through at least triptans before getting this medication. Leslie will follow-up with rebating vendor to see if we are able to have them step through other CGRPs first. Aubrielle Smith-Masri, Pharm.D., questioned if we should include criteria stopping members from using Zavzpret in combination with other acute CGRPs. Taylor Warner, Pharm.D., confirmed this would be appropriate. Derek Hunt, Pharm.D., asked if we would also review concomitant use with “ditan” drugs. Keith Hunsicker, Pharm.D., suggested that the “ditan” recommendation be brought to a future P&T meeting, as it would require multiple policy updates. The committee unanimously voted to accept the recommendations as presented. None were opposed.

Outcome: Zavzpret is a pharmacy benefit and will not be added to the Commercial/Exchange/CHIP formularies. Zavzpret will require prior authorization with the following criteria:

- Medical record documentation of a diagnosis of migraine with or without aura **AND**
- Medical record documentation that member is 18 years of age or older **AND**
- Medical record documentation of one of the following:
    - Medical record documentation that member is experiencing nausea and vomiting associated with migraine **AND** medical record documentation of therapeutic failure on intolerance to, or contraindication to one formulary intranasal triptan **OR**
    - Medical record documentation of therapeutic failure on, intolerance to, or contraindication to three formulary triptans, one of which must be an intranasal formulation

GPI LEVEL: GPI-12

QUANTITY LIMIT: 8 actuations per 30 days

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

EYLEA HD (aflibercept)

Review: Eylea HD is a vascular endothelial growth factor (VEGF) inhibitor indicated for the treatment of patients with Neovascular (Wet) Age-Related Macular Degeneration (nAMD), Diabetic Macular Edema (DME), and Diabetic Retinopathy (DR). The recommended dose of Eylea HD for nAMD and DME is 8mg every 4 weeks (±7 days) for the first 3 doses, followed by 8mg every 8 to 16 weeks (±1 week). The recommended dose of Eylea HD for DR is 8mg every 4 weeks for the first 3 doses, followed by 8mg every 8 to 12 weeks.

Eylea HD is supplied as one of two different preparations. One preparation is a vial kit (NDC 61755-050-01) that contains a single dose glass vial, a filter needle for withdrawal of contents, a needle for intravitreal injection, and a syringe for administration. A second preparation is the single dose glass vial only (NDC 61755-051-01).

Eylea HD is the eighth VEGF inhibitor FDA approved for macular degeneration. Other VEGF inhibitors and their FDA-approved indications are listed in Table 1 below. Eylea HD is the high-dose formulation of Eylea, previously approved in 2011. Eylea HD is expected to compete with Vabysmo, as both are indicated for nAMD and DME, and both can be given at intervals of 8 to 16 weeks. Other competitors will be short dosing interval products like Lucentis and Eylea. Eylea biosimilars are also expected sometime in 2024.

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: Eylea HD is a medical benefit and will require prior authorization. Eylea HD will be added to the medical benefit cost share list when processed on the medical benefit. If processed at a specialty pharmacy, Eylea HD will process 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 a diagnosis of neovascular age-related macular degeneration **AND**
- Medical record documentation of therapeutic failure on, intolerance to, or contraindication to intravitreal bevacizumab (Avastin) **AND**
- Medical record documentation of therapeutic failure on, intolerance to, or contraindication to one (1) of the following: Eylea, Beovu, Lucentis, Byooviz, or Cimerli **AND**
- Medical record documentation of therapeutic failure on, intolerance to, or contraindication to Vabysmo

OR

- 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) **AND**
- Medical record documentation of therapeutic failure on, intolerance to, or contraindication to one (1) of the following: Eylea, Beovu, Lucentis, Byooviz, or Cimerli **AND**
- Medical record documentation of therapeutic failure on, intolerance to, or contraindication to Vabysmo

NOTE: Indicators of intravitreal bevacizumab (Avastin) failure may include:

- Worse or unchanged intraretinal or subretinal fluid.

- Persistent subretinal or intraretinal fluid.
- Recurrent intraretinal or subretinal fluid at current interval or extended interval.
- New subretinal hemorrhage
- In the absence of subretinal fluid, intraretinal fluid, or subretinal hemorrhage a failure documented as evidence of growth of the neovascular membrane on clinical exam or multimodal imaging.
- Any ocular or systemic adverse event thought related to the use of intravitreal bevacizumab.

FORMULARY ALTERNATIVES: Avastin, Eylea, Lucentis, Byooviz, Cimerli, Beovu, Vabysmo

GPI LEVEL: GPI-12

QUANTITY LIMIT: 0.14mL (16mg) per 21 days (8mg per eye per 21 days)

RPH SIGNOFF REQUIRED: No

OTHER RECOMMENDATIONS: With the approval of Eylea HD, Eylea 2mg and Eylea HD now share the same GPI-12. For this reason, it is recommended that Eylea 2mg be approved by GPI-14 to ensure the preferred product is being used when approved.

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

BRENZAVVY (bexagloflozin)

Review: Brenzavvy is a sodium-glucose cotransporter 2 (SGLT2) inhibitor that is FDA approved to use as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus. Like other SGLT2-Inhibitors, the transporter allows for reabsorption of most of the glucose from the renal glomerular filtrate in the proximal tubule, thus reducing reabsorption of glucose and increasing urinary glucose excretion. Limitations of use include not using in patients with type 1 diabetes mellitus due to increased risk of diabetic ketoacidosis.

Brenzavvy is supplied as blue, caplet-shaped, biconvex, bevel-edged tablets containing 20 mg of bexagliflozin. They come in bottles of 30 or of 90. Recommended dosing is 20mg once daily in the morning with or without food. Renal function should be assessed before initiation; It is not recommended to start Benzavvy if eGFR is less than 30 mL/min/1.73m2 or in patients experiencing volume depletion. It is also recommended to hold Brenzavvy at least 3 days before any major surgery or procedure associated with prolonged fasting.

Initiation of a SGLT2 inhibitor in those with type 2 diabetes is dependent on patient specific factors and needs such as desire for weight loss, presence of or high risk of atherosclerotic cardiovascular disease (ASCVD), presence of heart failure, or chronic kidney disease as supported by eGFR less than 60 mL/min/1.73m2 or albuminuria (ACR greater than or equal to 30 mg/g). Current SGLT2-inhibitors that have shown provided benefit in ASCVD on MACE scores, heart failure, and CKD include Jardiance (empagliflozin) and Invokana (canagliflozin). Current SGLT2-inhibitors that have shown provided benefit in heart failure, and CKD include Farxiga (dapagliflozin). Current SGLT2-inhibitors that have shown provided benefit in heart failure include Steglatro (ertugliflozin).

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: Brenzavvy will be a pharmacy benefit and will not be added to Commercial/Exchange/CHIP formularies. Brenzavvy will require a prior authorization with the following criteria:

- Medical record documentation of a diagnosis of type 2 diabetes mellitus (T2DM) **AND**
- Medical record documentation of therapeutic failure on, intolerance to, or contraindication to Jardiance **AND** Farxiga

FORMULARY ALTERNATIVES: Jardiance, Farxiga

GPI LEVEL: GPI-12
QUANTITY LIMIT: 30 tablets per 30 days

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

OLPRUVA (sodium phenylbutyrate)

Review: Olpruva is a nitrogen-binding agent indicated for urea cycle disorders (UCDs) specifically involving deficiencies of carbamylphosphate synthetase (CPS), ornithine transcarbamylase (OTC), or argininosuccinic acid synthetase (AS), as adjunctive therapy to standard of care, which includes dietary management for adult and pediatric patients weighing 20kg or greater and with a body surface area (BSA) of 1.2 m2 or greater. Olpruva is available as 2g, 3g, 4g, 5g, 6 g, and 6.67g oral powder packets to be prepared for oral suspension via oral administration only. The recommended dosing of Olpruva is 9.9 to 13 g/m2 per day divided into three to six doses with food. Each dose of Olpruva should be rounded to the nearest available dosage strength. Plasma ammonia levels should be monitored to adjust the dose accordingly and the maximum recommended dosage is 20gm per day. Olpruva should be used in combination with dietary protein restriction and in some cases, amino acid supplementation.

UCD is caused by a deficiency of an enzyme in the metabolic pathway that transforms nitrogen to urea for excretion from the body. All UCDs cause hyperammonemia, except for one enzyme deficiency (arginase), and life-threatening metabolic decompensations. UCD occur in approximately 1 in 8,200 live births in the United States. According to the National Institutes of Health (NIH) Rare Diseases Clinical Research Network, UCDs have an overall prevalence of 1 in 35,000 with two-thirds presenting initial symptoms after the newborn period.

Olpruva is the first and only FDA-approved sodium phenylbutyrate oral packet for oral suspension formulation. Sodium phenylbutyrate was originally approved in 1996 for the treatment of urea cycle disorders but has only been available in oral powder or oral tablet formulations. Olpruva metabolizes to phenylacetate and conjugates with glutamine, which promotes urinary clearance for waste nitrogen. The efficacy of Olpruva is based upon pharmacokinetic studies in healthy adults under fasting conditions which demonstrated similar absorption to the powder/tablets after a dose of Olpruva. There were no other direct clinical trials completed for Olpruva.

The safety profile of Olpruva is similar to other sodium phenylbutyrate products. Signs and symptoms of neurotoxicity (such as, vomiting, nausea, headache, somnolence, or confusion) should be monitored due to an increased exposure of phenylacetate from Olpruva. Serum potassium should also be monitored due to increased risk of hypokalemia from renal excretion of phenylacetylglutamine which may induce urinary loss of potassium. Patients with conditions associated with edema, such as heart failure, cirrhosis, or nephrosis, should be monitored due to the presence of sodium in Olpruva. The most common adverse reactions are acidosis, amenorrhea, hypoalbuminemia, and menstrual disease.

There is insufficient data on the risk of major birth defects, miscarriage or adverse maternal outcomes associated with the use of Olpruva in pregnant women, but there are serious maternal and fetal risks associated with untreated UCDs. The safety and efficacy in pediatric patients have been established in patients weighing 20kg or greater and with a body surface area 1.2m2 or greater. There was an insufficient number of patients aged 65 years and older in clinical studies to establish if geriatric patients respond differently than younger patients. No studies were completed in patients with renal or hepatic impairment, but it is recommended to start at a lower dose and maintain dosing on the lowest dose necessary.

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: Olpruva will be 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 use for urea cycle disorders (UCDs) involving deficiencies of carbamylphosphate synthetase (CPS), ornithine transcarbamylase (OTC), or argininosuccinic acid synthetase (AS) **AND**
- Medical record documentation of adjunctive therapy to a protein-restricted diet **AND**
- Medical record documentation of increased blood ammonia levels b
- Medical record documentation of patient weighing 20 kg or greater and with a body surface area (BSA) of 1.2 m^2 or greater **AND**
- Medical record documentation of contraindication to, intolerance to, or therapeutic failure on sodium phenylbutyrate powder AND sodium phenylbutyrate tablets

GPI LEVEL: GPI-12

QUANTITY LIMIT:

- For 2gm dose: 10 packets per day
- For 3gm dose: 6 packets per day
- For 4gm dose: 5 packets per day
- For 5gm dose: 4 packets per day
- For 6gm and 6.67gm dose: 3 packets per day

RPH SIGNOFF REQUIRED: Yes

FORMULARY ALTERNATIVES: sodium phenylbutyrate powder*, sodium phenylbutyrate tablet* (*prior authorization required)

AUTHORIZATION DURATION: Initial approval will be for 6 months. Subsequent approvals will be for an additional 6 months and will require medical record documentation of improvement in either fasting ammonia levels, 24 hour AUC, or number of hyperammonemic crises.

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

Vyjuvek (beremagene geperpavec-svdt)

Review: Vyjuvek is a herpes-simplex virus type 1 (HSV-1) vector-based gene therapy indicated for the treatment of wounds in patients 6 months of age and older with dystrophic epidermolysis bullosa with

mutation(s) in the collagen type VII alpha 1 chain (COL7A1) gene. Dystrophic epidermolysis bullosa (DEB) is one of four major types of epidermolysis bullosa (EB), a heterogenous group of hereditary mechanobullous diseases characterized by varying degrees of skin and mucosa fragility caused by mutations that affect skin structural proteins. In the United States fewer than 5,000 people are diagnosed with DEB. Currently there is no targeted therapy for EB and the management of patients with EB is largely supportive (wound care, control of infection, nutritional support, and prevention and treatment of complications). A multidisciplinary team approach is required for the management of patients with EB. Care plans are individualized according to age, severity, symptoms, complications, and patient priorities. Overlap of symptoms can make it difficult to distinguish between types and subtypes of EB, therefore genetic testing is important to confirm diagnosis. Although genetic testing is guideline-recommended by DEBRA International Clinical Practice Guidelines, it is estimated that only 56% of patients with EB have had genetic testing to confirm type. Genetic testing can be done by analyzing blood, saliva, or buccal smear. Biopsy can also be useful in diagnosing DEB, however, does not definitively distinguish between DEB subtypes (DDEB and RDEB).
All DEB subtypes are caused by mutations in the COL7A1 gene on chromosome 3p23.31 which codes for the alpha-1 chain of type VII collagen. Collagen VII is the main constituent of the anchoring fibrils. Anchoring fibrils are located below the basal lamina at the dermoepidermal basement membrane zone and anchor the epidermal basement membrane to the dermis. Insufficient formation of anchoring fibrils disrupts adhesion of the epidermis to the dermis, resulting in fragility of epithelial-lined tissues and ultimately chronic and recurrent wounds. The four major subtypes of DEB include localized dominant dystrophic epidermolysis bullosa (DDEB), intermediate DDEB, intermediate recessive dystrophic epidermolysis bullosa (RDEB) and severe RDEB. Clinical presentations of DEB are skin fragility, blistering, scarring, nail changes, and milia formation in areas of healed blistering. Blistering can also occur in the mucus membranes and upper third of the esophagus.

RDEB is generally the more severe form of DEB. Infants with RDEB will have widespread blistering and areas of missing skin. As blisters heal severe scarring results, leading to additional complications such as: chronic malnutrition and slow growth due to esophageal strictures, fusion of the skin between the fingers and toes, loss of fingernails and toenails, joint deformities, eye inflammation and ulceration, and infection of open wounds. The major cause of death in those with RDEB is early onset of aggressive squamous cell carcinomas (SCC) which occurs at chronic wound sites. The risk of SCC is estimated to be greater than 90 percent by the age of 55 in patients with severe RDEB. DDEB is considered the milder form of DEB, although severity can vary. Blisters may be present at birth but typically appear during early childhood at vulnerable sites such as knees, ankles, elbows, and knuckles. Blisters generally become less frequent in adulthood and scars fade. Mild cases of DEB are often not fatal, however patients with severe disease have a life expectancy that ranges from infancy to mid-thirties.

Vyjuvek is the first FDA-approved treatment for DEB. Vyjuvek contains a genetically modified, replication deficient, herpes simplex virus (HSV-1) that delivers wildtype copies of COL7A1 to skin wounds and ultimately results in production and secretion of COL7 proteins and anchoring fibrils thus improving skin integrity. It is applied once weekly to open wounds by a healthcare professional either in a healthcare setting or home. It is applied in small droplets that are evenly spaced (1cm x 1cm apart) on the selected wounds to form a thin film after a hydrophobic dressing is applied. Because there is a maximum weekly dose, wound treatment prioritization may be required. Patients will use no more than 1 vial weekly.

Application continues once weekly to open wounds until closure. The cycle of applying Vyjuvek continues indefinitely as wounds close and reopen. Vyjuvek only works locally at the site of application and does not heal or prevent new wounds in other areas of the skin or visceral mucosa. It is available as a single-use vial (1.0mL) that contains a nominal concentration of 5x109 PFU/mL that requires mixing with an excipient gel (1.5mL). Vyjuvek must be prepared in a pharmacy. For patients 6 months to 3 years of age, up to two 0.4mL Vyjuvek gel syringes will be prepared. For patients 3 years of age and older, up to four 0.4mL Vyjuvek gel syringes will be prepared. Once gel is prepared, syringes can be stored in the refrigerator for up to 48 hours and can be maintained at room temperature for 8 hours.

Vyjuvek will be available to prescribers to buy and bill. Vyjuvek will also be available through a limited distribution specialty pharmacy network which includes Orsini Specialty Pharmacy and Option Care

Health. Through this pharmacy network, prescribers may have Vyjuvek delivered unmixed to a pharmacy of their choice for preparation. Option Care may also mix and deliver ready-for-use Vyjuvek to either a healthcare or home setting.

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

Clinical Discussion: Dr. Yarczower questioned if we should keep the "dermatologist who specializes in EB management" vs just a dermatologist. Briana LeBeau, Pharm.D., stated she questioned this herself and ran utilization confirming the rare incidence of disease. Keith Hunsicker, Pharm.D., stated he would be in favor of just "dermatologist" since we require genetic testing confirming the diagnosis. 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: Vyjuvek is a medical benefit and will require prior authorization. Vyjuvek will be added to the medical benefit cost share list when processed on the medical benefit. If processed at a specialty pharmacy, Vyjuvek will process at the Specialty tier, or the Brand Non-preferred tier for members with a three-tier benefit. Vyjuvek will also be added to MBP 181 Site of Care, as part of the Site of Care Program.

- Medical record documentation that Vyjuvek is prescribed by or in consultation with a dermatologist who specializes in epidermolysis bullosa (EB) management **AND**
- Medical record documentation of age greater than or equal to 6 months **AND**
- Medical record documentation of diagnosis of dystrophic epidermolysis bullosa (DEB) **AND**
- Medical record documentation of genetic testing confirming mutation(s) in the COL7A1 gene **AND**
- Medical record documentation of at least one open dystrophic epidermolysis bullosa (DEB) wound **AND**
- Medical record documentation of a prescribed dose and administration that is consistent with FDA-approved package labeling, nationally recognized compendia, or peer-reviewed medical literature

AUTHORIZATION DURATION: 6 months

REAUTHORIZATION CRITERIA: Subsequent approvals will be for an additional 6 months and will require medical record documentation of clinical response to prior dystrophic epidermolysis bullosa (DEB) wounds treated with Vyjuvek therapy and lack of toxicity.

QUANTITY LIMIT: 2.5 mL (1 vial) per week, or 10 mL (4 vials) every 28 days

GPI LEVEL: GPI-12

RPH SIGNOFF REQUIRED: Yes

FACETS RX COUNT: 9999

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

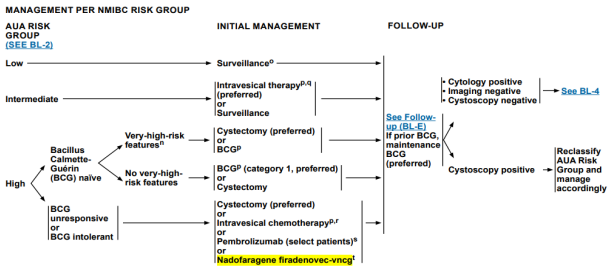
Adstiladrin (nadofaragene firadenovec-vncg)

Review: Adstiladrin is a non-replicating adenoviral vector-based gene therapy indicated for the treatment of adult patients with high-risk Bacillus Calmette-Guerin (BCG)-unresponsive non-muscle invasive

bladder cancer (NMIBC) with carcinoma in situ (CIS) with or without papillary tumors. This is the first and only FDA-approved medication of its kind.

Adstiladrin is designed to deliver a copy of a gene encoding a human interferon-alfa 2b (INFα2b) to the bladder urothelium. Intravesical instillation of Adstiladrin results in cell transduction and transient local expression of the INFα2b protein that is anticipated to have anti-tumor effects.

NCCN recommendation for use of Adstiladrin:



Dr. Heinric Williams, urology physician, stated that patients that would be candidates for Adstiladrin are quite difficult to manage medically. These patients are often advised to undergo cystectomies if they fail intravesical treatments.

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: Adstiladrin will be a medical benefit and will be added to the medical benefit cost share list. If processed at a specialty pharmacy, Adstiladrin will process at the Specialty tier or the Brand Non-preferred tier for members with a three-tier benefit. The following prior authorization criteria will apply:

- Medical record documentation of an age greater than or equal to 18 **AND**
- Medical record documentation that Adstiladrin is being prescribed by or in consultation with a hematologist, oncologist, or urologist **AND**
- Medical record documentation of high-risk Bacillus Calmette-Guerin (BCG)-unresponsive non-muscle invasive bladder cancer (NMIBC) with carcinoma in situ (CIS) with or without papillary tumors **AND**
- Medical record documentation of a prescribed dose and administration that is consistent with FDA-approved package labeling, nationally recognized compendia, or peer-reviewed medical literature

NOTE: There is currently no defined duration of therapy for Adstiladrin. In current clinical trial CS-003, patients without evidence of high-grade recurrence were allowed to continue Adstiladrin treatment every 3 months, with no specified limit.

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

RPH SIGNOFF REQUIRED: Yes

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

AKEEGA (niraparib-abiraterone acetate)

Review: Akeega is indicated with prednisone for the treatment of adult patients with deleterious or suspected deleterious BRCA-mutated (BRCAm) metastatic castration-resistant prostate cancer (mCRPC). The recommended dose of Akeega is 200 mg niraparib/1,000 mg abiraterone acetate orally once daily in combination with 10 mg prednisone daily until disease progression or unacceptable toxicity. Patients receiving Akeega should also receive a GnRH analog concurrently or should have had bilateral orchiectomy. A statistically significant improvement in rPFS for niraparib plus abiraterone compared to placebo plus abiraterone was observed in BRCAm patients, and the Cohort 1 intention to treat (ITT) population. In an exploratory analysis in the subgroup of 198 (47%) patients with non-BRCA mutations, the rPFS hazard ratio was 0.99 (95% CI: 0.67, 1.44) and the OS hazard ratio was 1.13 (95% CI: 0.77, 1.64), indicating that the improvement in the ITT population was primarily attributed to the results seen in the subgroup of patients with BRCAm.
There are no contraindications associated with the use of Akeega. Akeega has warnings and precautions for: Myelodysplastic Syndrome (MDS)/Acute Myeloid Leukemia (AML); Myelosuppression; Hypokalemia, Fluid Retention, and Cardiovascular Adverse Reactions; Hepatotoxicity; Adrenocortical Insufficiency; Hypoglycemia; Increased Fractures and Mortality in Combination with Radium 223 Dichloride; Posterior Reversible Encephalopathy Syndrome (PRES); and Embryo-Fetal Toxicity. The most common adverse reactions occurring ≥ 10%, including laboratory abnormalities are: decreased hemoglobin, decreased lymphocytes, decreased white blood cells, musculoskeletal pain, fatigue, decreased platelets, increased alkaline phosphatase, constipation, hypertension, nausea, decreased neutrophils, increased creatinine, increased potassium, decreased potassium, increased AST, increased ALT, edema, dyspnea, decreased appetite, vomiting, dizziness, COVID-19, headache, abdominal pain, hemorrhage, urinary tract infection, cough, insomnia, increased bilirubin, weight decreased, arrhythmia, fall, and pyrexia. Use of Akeega in patients with moderate or severe hepatic impairment should be avoided.

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: Akeega is a pharmacy benefit that will be added to the Commercial, Exchange, 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 of a diagnosis of metastatic castration-resistant prostate cancer (mCRPC) **AND**
- Medical record documentation of deleterious or suspected deleterious BRCA-mutation (BRCAm) as detected by an FDA-approved test **AND**
- Medical record documentation that Akeega will be given in combination with prednisone **AND**
- Medical record documentation of one of the following:
    - Medical record documentation that Akeega will be given concurrently with a gonadotropin-releasing hormone (GnRH) **OR**
    - Medical record documentation that member has had bilateral orchiectomy **AND**
- Medical record documentation that member is 18 years of age or older **AND**
- Medical record documentation that Akeega is prescribed by an oncologist or urologist

QUANTITY LIMIT:

- 50 mg/500 mg Tablets: 60 tablets per 30 days
- 100 mg/500 mg Tablets: 60 tablets per 30 days

GPI LEVEL: GPI-12

AUTHORIZATION DURATION: Initial approval will be for **12 months**. Subsequent approvals will be for an additional **12 months** and will require medical record documentation of continued disease improvement or lack of disease progression. The medication will no longer be covered if the member experiences unacceptable toxicity or worsening of disease.

RPH SIGNOFF REQUIRED: yes

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

TPOXX (tecovirimat)

Review: Tecovirimat (Tpoxx) is the first drug approved for the treatment of human smallpox disease caused by the variola virus. It works by targeting and inhibiting the activity of the orthopoxviral VP37 protein and blocks its interaction with cellular Rab9 GTPase and TIP47, which prevents the formation of egress-competent enveloped virions necessary for cell-to-cell and long-range dissemination of virus. Tecovirimat (Tpoxx) was first approved in 2018 as an oral dosage form and is indicated for the treatment of smallpox disease in pediatric and adult patients weighing greater than 13 kg. Tecovirimat (Tpoxx) also became FDA approved intravenously in 2022 as an option for patients unable to take the oral formulation and can be used in patients weighing as little as 3 kg. However, due to the public health risk of what a smallpox outbreak could signify, there are oral dosing considerations available based on weight for patients less than 3 kg which uses manipulation of oral capsules. Tecovirimat (Tpoxx) is not commercially available due to the eradication of smallpox and is part of the Strategic National Stockpile. Currently there is an off-label indication for use in the treatment of Mpox using an EA-IND (Emergency Use Authorization Investigational New Drug) which was approved in May 2023. The National Institute of Allergy and Infectious Diseases, part of the National Institutes of Health, is now sponsoring the Study of Tecovirimat for Human Mpox Virus (STOMP). The STOMP trial is designed to assess whether tecovirimat is safe and effective for treating Mpox in people with the disease.

Smallpox is a highly contagious disease caused by the variola virus. Patients with smallpox develop fever along with a distinctive, progressively worsening skin rash that resembles chickenpox in its initial stages. Approximately 30% of patients with smallpox die. Those who survive typically have significant scarring because of the rash. The disease can also cause blindness. The global eradication of smallpox was officially announced in 1979, marking one of the greatest achievements of modern medicine. However, there remains continued interest in this virus because of the concern regarding smallpox as a potential agent of bioterrorism.

Tecovirimat is supplied as a 200 mg capsule and as an undiluted single-dose vial with a 200 mg/20 mL (10 mg/mL) concentration. Capsules should be administered 30 mins after a moderate to high fat meal. If using tecovirimat (Tpoxx) intravenously, it should be infused over 6 hours using an infusion pump.

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: Tecovirimat (Tpoxx) will be non-formulary, as it is not commercially available. If Tecovirimat (Tpoxx) becomes commercially available, it will be added to formulary as both a medical and pharmacy benefit without requiring prior authorization. As a pharmacy benefit, it will be added to brand non-preferred.

QUANTITY LIMIT:

- Oral: 200 mg capsules (9 capsules per day for 14-day supply per 365 days)
- Intravenous: 200 mg/20 mL per 20 ml vial: (80 ml per day for 14-day supply per 365 days)

GPI LEVEL: GPI-10

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

Altuviiio (antihemophilic factor [recombinant], Fc-VWF-XTEN fusion protein-ehtl)

Review: Altuviiio (antihemophilic factor [recombinant], Fc-VWF-XTEN fusion protein-ehtl) is indicated for the treatment for use in adults and children with hemophilia A. Hemophilia is an X-linked inherited bleeding disorder caused by deficiency of coagulation factor VIII (hemophilia A) or factor IX (hemophilia B). Due to this, men are primarily affected compared to females. Hemophilia occurs in about 1 of every 5,000 male births. Hemophilia A is about four times as common as hemophilia B.

Disease severity is determined by the amount of factor in the blood. The lower the amount of factor, the more likely that bleeding is to occur. Severity is defined as:

- Severe hemophilia: factor activity < 1%, which corresponds to < 0.01 IU/mL.
- Moderate hemophilia: factor activity ≥ 1% of normal and ≤ 5% of normal, which corresponds to ≥ 0.01 and ≤ 0.05 IU/mL.
- Mild hemophilia: factor activity > 5% of normal and < 40% of normal, which corresponds to ≥ 0.05 and <0.40 IU/mL.
-

Signs and symptoms of hemophilia include bleeding into the joints, tissues, and other organs. Individuals with more severe hemophilia are more likely to have spontaneous bleeding, severe bleeding, and an earlier age of first bleeding episode. Those with moderate hemophilia often bleed in response to invasive procedures or trauma, and bleeding is less frequent than in severe hemophilia. Individuals with mild hemophilia generally only bleed in response to injury or trauma; spontaneous bleeding is rare.

Treatment of hemophilia includes replacing missing coagulation factors so that blood can clot properly. Individuals with hemophilia A are treated with factor VIII products or emicizumab (Hemlibra). Two types of clotting factor include plasma derived and recombinant. Currently, 75% of patients utilize a recombinant factor VIII product. Emicizumab is an option for prophylaxis for patients who develop antibodies to factor VIII.

Altuviiio is a recombinant fusion protein that replaces coagulation factor VIII, and it has demonstrated a 3- to 4-fold prolonged half-life compared to other standard and extended half-life factor VIII products. It is independent of endogenous von Willebrand Factor (VWF) to overcome the half-life limit Imposed by factor VIII-VWF interactions. Altuviiio is given once weekly for prophylaxis, and it can be utilized for on-demand treatment.

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: Dr. Yarczower asked if we have a count of hemophilia patients at the health plan. Leslie Shumlas, Pharm.D., stated we would pull the information and get back to Dr. Yarczower. The committee unanimously voted to accept the recommendations as presented. None were opposed.

Outcome: Altuviiio is a medical benefit and will require prior authorization. Altuviiio will be added to the medical benefit cost share list when processed on the medical benefit. If processed at a specialty pharmacy, Altuviiio will be processed 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 a diagnosis of hemophilia A **AND**
- Prescribed by or in consultation with a hematologist **AND**
- Medical record documentation for use as a treatment for one of the following:
    - Routine prophylaxis to reduce the frequency of bleeding episodes
    - On-demand treatment and control of bleeding episodes
    - Perioperative management of bleeding

  AND
- Medical record documentation of therapeutic failure on, intolerance to, or contraindication to Advate **AND**
- If being used for routine prophylaxis of Hemophilia A, medical record documentation of therapeutic failure on, intolerance to, or contraindication to Hemlibra.

GPI LEVEL: GPI-12

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

CLASS REVIEWS

HUMIRA BIOSIMILAR CLASS REVIEW

With the expiration of the Humira patent, several biosimilar products have launched to the market. All biosimilars are citrate free at this time and a majority of them are available in the original concentration (50 mg/mL). In addition, three manufacturers currently have a high concentration formulation on the market (Hadlima, Hyrimoz/Adalimumab adaz [unbranded Hyrimoz], and Yuflyma). Three additional manufacturers have high concentration formulations in development (Amjevita [Amgen], Cyltezo [BI], Yusimry [Coherus]). Available Dosages and Formulations vary from product to product.

Brand Name	Manufacturer	Concentration	Dosage/ Formulation
Humira	AbbVie, Inc.	Original (50 mg/ml)	**Prefilled-Pen, PFS, Peds Chrons Starter, Crohns Starter, Ps/UV/Adol HS Starter:** 40 mg / 0.8 mL,
		HC (100 mg/ml)	**Prefilled-Pen, PFS, Ped Crohns starter, Ps/UV, Starter, CD/UC/HS Starter, Ped UC Starter:** 40 mg / 0.4 mL, 80 mg / 0.8 mL **PFS:** 20 mg 0.2 mL, 10 mg / 0.1 mL
Abrilada	Pfizer, Inc.	Original (50 mg/ml)	**PFS:** 40 mg / 0.8 mL, 20 mg / 0.4 mL **Auto-injector:** 40 mg / 0.8 mL
Amjevita	Amgen, Inc.	Original (50 mg/ml):	**PFS:** 40 mg / 0.8 mL, 20 mg / 0.4 mL, 10 mg / 0.2 mL **Auto-injector:** 40 mg / 0.8 mL
		HC (100 mg/ml)	HC product launch 2023-2024
Cyltezo	Boehringer Ingelheim	Original (50 mg/ml)	**PFS:** 40 mg / 0.8 mL, 20 mg / 0.4 mL, 10 mg / 0.2 mL **Auto-injector, Psoriasis Starter Auto-injector, CD/UC/HS Starter Autoinjector:** 40 mg/0.8 mL
		HC (100 mg/ml)	HC product launch 2023-2024
Adalimumab-adbm (unbranded Cyltezo)	Boehringer Ingelheim	Original (50 mg/ml)	**PFS:** 20 mg / 0.4 mL, 10 mg / 0.2 mL **Auto-injector:** 40 mg / 0.8 mL
Hadlima	Samsung Bioepsis Co., Ltd	Original (50 mg/ml)	**PFS, PushTouch Auto-injector:** 40 mg / 0.8 mL
		HC (100 mg/ml)	**PFS, PushTouch Auto-injector:** 40 mg / 0.4 mL
Hulio	Mylan Pharmaceuticals, Inc.	Original (50 mg/ml)	**PFS:** 40 mg / 0.8 mL, 20 mg / 0.4 mL **Auto-injector:** 40 mg / 0.8 mL
Adallimumab-fkjp (unbranded Hulio)	Mylan Pharmaceuticals, Inc.	Original (50 mg/ml)	**PFS:** 40 mg / 0.8 mL, 20 mg / 0.4 mL **Auto-injector:** 40 mg / 0.8 mL
Hyrimoz	Sandoz, Inc.	Original (50 mg/ml)	**PFS:** 40 mg / 0.8 mL

			Auto-injector: 40 mg / 0.8 mL
		HC (100 mg/ml)	**Crohns/UC Starter Auto-injector:** 80 mg / 0.8 mL **Auto-injector, Peds Crohns Starter Auto-injector, Plaque Psoriasis Starter Auto-injector:** 80 mg / 0.8 mL, 40 mg / 0.4 mL **PFS:** 40 mg / 0.4 mL, 20 mg / 0.2 mL, 10 mg / 0.1 mL
Adalimumab-adaz (unbranded Hyrimoz HCF)	Sandoz, Inc.	HC (100 mg/ml)	**Auto-injector:** 40 mg / 0.4 mL
Idacio	Fresenius Kabi USA, LLC.	Original (50 mg/ml)	**Auto-injector, PFS, Crohns Disease/UC Auto-injector Kit, Ps Auto-injector Kit :** 40 mg / 0.8 mL
Yuflyma	Celltrion, Inc.	HC (100 mg/ml)	**Auto-injector, 2-Pen Auto-injector Kit, 1-Pen Auto-injector Kit, 2 Syringe PFS Kit :** 40 mg / 0.4 mL
Yusimry	Coherus Biosciences, Inc.	Original (50 mg/ml)	**Auto-injector:** 40 mg / 0.8 mL
		HC (100 mg/ml)	HC product launch TBD

Abbreviations PFS: Prefilled Syringe

All approved biosimilars share most indications with brand Humira. Three indications are missing from labels of all biosimilar products due to Orphan Drug Exclusivity (ODE) patents that have yet to expire:

- Pediatric uveitis: protected by ODE until September 28, 2025
- Adolescent hidradenitis suppurativa (HS): protected by ODE until October 16, 2025
- Pediatric ulcerative colitis (UC): protected by ODE until February 24, 2028

In June 2023, the ODE patent for Humira's adult uveitis indication expired. All biosimilars with the exception of Yuflyma received approval for this indication.

FDA Approved Indications													
Product	RA	JIA	PsA	AS	Adult CD	Ped CD	Adult UC	Ped UC	Ps	Adult HS	Adolescent HS	Adult UV	Ped UV
Humira	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
Abrilada	✓	✓	✓	✓	✓	✓	✓		✓	✓		✓	
Amjevita	✓	✓	✓	✓	✓	✓	✓		✓	✓		✓	
Cyltezo	✓	✓	✓	✓	✓	✓	✓		✓	✓		✓	
Adalimumab-adbm (unbranded Cyltezo)	✓	✓	✓	✓	✓	✓	✓		✓	✓		✓	
Hadlima	✓	✓	✓	✓	✓	✓	✓		✓	✓		✓	
Hulio	✓	✓	✓	✓	✓	✓	✓		✓	✓		✓	
Adallimumab-fkjp (unbranded Hulio)	✓	✓	✓	✓	✓	✓	✓		✓	✓		✓	
Hyrimoz	✓	✓	✓	✓	✓	✓	✓		✓	✓		✓	
Adalimumab-adaz (unbranded Hyrimoz HCF)	✓	✓	✓	✓	✓	✓	✓		✓	✓		✓	
Idacio	✓	✓	✓	✓	✓	✓	✓		✓	✓		✓	
Yuflyma	✓	✓	✓	✓	✓	✓	✓		✓	✓			
Yusimry	✓	✓	✓	✓	✓	✓	✓		✓	✓		✓	

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: All Humira biosimilars have shown pharmacokinetic similarities and no clinically meaningful differences have been identified between any of the biosimilars and US-Humira in terms of efficacy, safety, and immunogenicity. Clinically, there are no advantages for the Humira biosimilars over Humira. Each biosimilar has a variety of formulations and concentrations to compare to the brand Humira. At this time, only Brand Humira is indicated for pediatric uveitis, pediatric ulcerative colitis, and adolescent hidradenitis suppurativa (HS).

Preferred Humira biosimilars (Adalimumab-fkjp (unbranded Hulio), Hadlima, and Ysumiry) will be determined based on cost and will be added to formulary to match the current placement of Humira, will require a prior authorization for new starts only, and will be added to Commercial Policy 84.0 with the following criteria. Non-preferred Humira biosimilars will remain non-formulary and will require a prior authorization with the following criteria:

Policy 84.0 Humira & Preferred Biosimilars (Adalimumab-fkjp (unbranded Hulio), Hadlima, and Ysumiry)

For Adult Rheumatoid Arthritis

An exception for coverage of BIWEEKLY (every other week) administration may be made for members who meet all the following criteria:

- Medical record documentation of a diagnosis of moderate to severe rheumatoid arthritis (made in accordance with the American College of Rheumatology Criteria for the Classification and Diagnosis of Rheumatoid Arthritis) AND
- Medical record documentation that Humira or adalimumab biosimilar is prescribed by a rheumatologist AND
- Medical record documentation of an inadequate response to a minimum 3 month trial of methotrexate or other disease modifying anti-rheumatic drug (DMARD) if methotrexate is not tolerated or contraindicated OR medical record documentation of a therapeutic failure on or intolerance to prior biologic therapy AND
- Medical record documentation of age greater than or equal to 18 years AND
- Medical record documentation that Humira or adalimumab biosimilar is not being used concurrently with a tumor necrosis factor (TNF) blocker or other biologic agent

An exception for coverage of WEEKLY administration may be made for members who meet the following criteria:

- Medical record documentation of a diagnosis of moderate to severe rheumatoid arthritis (made in accordance with the American College of Rheumatology Criteria for the Classification and Diagnosis of Rheumatoid Arthritis) AND
- Medical record documentation that Humira or adalimumab biosimilar is prescribed by a rheumatologist AND
- Medical record documentation of age greater than or equal to 18 years AND
- Medical record documentation of an inadequate response to a minimum 3 month trial of methotrexate or other disease modifying anti-rheumatic drug (DMARD) if methotrexate is not tolerated or contraindicated OR medical record documentation of a therapeutic failure on or intolerance to prior biologic therapy AND
- Medical record documentation that the member has been compliant with BIWEEKLY administration of Humira or adalimumab biosimilar AND

- Medical record documentation of a contraindication to, intolerance to, or therapeutic failure on BIWEEKLY (every other week) administration of Humira or adalimumab biosimilar AND
- Medical record documentation that Humira or adalimumab biosimilar is not being used concurrently with a tumor necrosis factor (TNF) blocker or other biologic agent

For treatment of polyarticular juvenile idiopathic arthritis or juvenile rheumatoid arthritis
An exception for coverage of BIWEEKLY (every other week) may be made for members who meet all the following criteria:

- Medical record documentation of age greater than or equal to 2 years AND
- Medical record documentation that Humira or adalimumab biosimilar is prescribed by a rheumatologist AND
- Medical record documentation of a diagnosis of active polyarticular juvenile idiopathic arthritis or juvenile rheumatoid arthritis AND
- Medical record documentation of an inadequate response to a minimum 3 month trial of both nonsteroidal anti-inflammatory drug (NSAID) therapy AND methotrexate or other disease modifying anti-rheumatic drug (DMARD) if methotrexate therapy is contraindicated OR medical record documentation of a therapeutic failure on or intolerance to prior biologic therapy AND
- Medical record documentation that Humira or adalimumab biosimilar is being dosed at a maximum of 40 mg every other week OR medical record documentation of peer-reviewed literature citing well-designed clinical trials to indicate that the member's healthcare outcome will be improved by dosing that exceeds Food and Drug Administration (FDA) approved labeling AND
- Medical record documentation that Humira or adalimumab biosimilar is not being used concurrently with a tumor necrosis factor (TNF) blocker or other biologic agent

For Psoriatic Arthritis
An exception for coverage of BIWEEKLY (every other week) administration may be made for members who meet all the following criteria:

- Medical record documentation of a diagnosis of moderately to severely active psoriatic arthritis which must include documentation of either active psoriatic lesions or a documented history of psoriasis AND
- Medical record documentation that Humira or adalimumab biosimilar is prescribed by a rheumatologist or dermatologist AND
- Medical record documentation of age greater than or equal to 18 years AND
- For peripheral disease: Medical record documentation of an intolerance to, contraindication to, or therapeutic failure on methotrexate AND an adequate trial of at least two (2) formulary nonsteroidal anti-inflammatory drugs (NSAIDs) OR medical record documentation of a therapeutic failure on or intolerance to prior biologic therapy OR
- For axial disease: Medical record documentation of an intolerance to, contraindication to, or therapeutic failure to an adequate trial of at least two (2) formulary nonsteroidal anti-inflammatory drugs (NSAIDs) OR medical record documentation of a therapeutic failure on or intolerance to prior biologic therapy AND
- Medical record documentation that Humira or adalimumab biosimilar is being dosed at a maximum of 40 mg every other week OR medical record documentation of peer-reviewed literature citing well-designed clinical trials to indicate that the member's healthcare outcome will be improved by dosing that exceeds Food and Drug Administration (FDA) approved labeling AND
- Medical record documentation that Humira or adalimumab biosimilar is not being used concurrently with a tumor necrosis factor (TNF) blocker or other biologic agent

For Ankylosing Spondylitis
An exception for coverage of **BIWEEKLY (every other week)** administration may be made for members who meet all the following criteria:

- Medical record documentation that Humira or adalimumab biosimilar is prescribed by a rheumatologist **AND**
- Medical record documentation of age greater than or equal to 18 years **AND**
- Medical record documentation of a diagnosis of ankylosing spondylitis **AND**
- Physician documentation of a therapeutic failure on, contraindication to, or intolerance to an adequate trial of at least two (2) nonsteroidal anti-inflammatory drugs (NSAIDS) **OR** medical record documentation of a therapeutic failure on or intolerance to prior biologic therapy **AND**
- Medical record documentation that Humira or adalimumab biosimilar is being dosed at a maximum of 40 mg every other week **OR** medical record documentation of peer-reviewed literature citing well-designed clinical trials to indicate that the member's healthcare outcome will be improved by dosing that exceeds Food and Drug Administration (FDA) approved labeling **AND**
- Medical record documentation that Humira or adalimumab biosimilar is not being used concurrently with a tumor necrosis factor (TNF) blocker or other biologic agent
- **For Crohn's Disease**
  An exception for coverage of **BIWEEKLY (every other week) administration** may be made for members who meet all the following criteria:

- Medical record documentation that Humira or adalimumab biosimilar is prescribed by a gastroenterologist **AND**
- Medical record documentation of age greater than or equal to 6 years **AND**
- Medical record documentation of a diagnosis of moderately or severely active Crohn's disease **AND**
- Medical record documentation of one of the following:
    - Medical record documentation of therapeutic failure on, intolerance to, or contraindication to corticosteroids **AND** immunomodulators (e.g. azathioprine and 6-mercaptopurine) **OR** medical record documentation of a therapeutic failure on or intolerance to prior biologic therapy **OR**
    - Medical record documentation of moderate/high risk patient as defined by age at initial diagnosis less than 30 years, extensive anatomic involvement, perianal and/or severe rectal disease, deep ulcers, prior surgical resection, and structuring and/or penetrating behavior **AND**
- Medical record documentation that Humira or adalimumab biosimilar is not being used concurrently with a tumor necrosis factor (TNF) blocker or other biologic agent

An exception for coverage of **WEEKLY administration** may be made for members who meet the following criteria:

- Medical record documentation that Humira or adalimumab biosimilar is prescribed by a gastroenterologist **AND**
- Medical record documentation of age greater than or equal to 6 years **AND**
- Medical record documentation of a diagnosis of moderately or severely active Crohn's disease **AND**
- Medical record documentation of one of the following:
    - Medical record documentation of therapeutic failure on, intolerance to, or contraindication to corticosteroids **AND** immunomodulators (e.g. azathioprine and 6-mercaptopurine) **OR** medical record documentation of a therapeutic failure on or intolerance to prior biologic therapy **OR**
    - Medical record documentation of moderate/high risk patient as defined by age at initial diagnosis less than 30 years, extensive anatomic involvement, perianal and/or severe rectal disease, deep ulcers, prior surgical resection, and structuring and/or penetrating behavior **AND**
- Medical record documentation that Humira or adalimumab biosimilar is not being used concurrently with a tumor necrosis factor (TNF) blocker or other biologic agent **AND**
- Medical record documentation of a contraindication to, intolerance to, or therapeutic failure on BIWEEKLY (every other week) administration of Humira or adalimumab biosimilar **AND**

- Medical record documentation that the member has been compliant with BIWEEKLY administration of Humira or adalimumab biosimilar **AND**
- Medical record documentation of inadequate drug trough level (less than 7.5mcg/mL) to support weekly dosing, per American Gastroenterological Association (AGA) guidelines

NOTE:
- For patients with an adequate drug trough, American Gastroenterological Association (AGA) does not recommend antibody levels to guide therapy. Patients should be switched to another agent.
- For patients with an inadequate drug trough & undetectable antibodies, a dose increase may be warranted.
- For patients with an inadequate drug trough & detectable antibodies, a switch to another agent is recommended. However, patients with low antibody levels may be considered for a dose increase, in hopes of overcoming antibody level and achieving response.

For the treatment of moderate to severe Plaque Psoriasis
An exception for coverage of **BIWEEKLY (every other week) administration** may be made for members who meet all the following criteria:

- Medical record documentation that Humira is prescribed by a dermatologist **AND**
- Medical record documentation of age greater than or equal to 18 years **AND**
- Medical record documentation of a diagnosis of moderate to severe plaque psoriasis characterized by greater than or equal to 5% of body surface area involved or disease involving crucial body areas such as the hands, feet, face, or genitals **AND**
- Medical record documentation of a therapeutic failure on, intolerance to, or contraindication to topical corticosteroids **AND** at least two to three months of systemic therapy (including but not limited to methotrexate and/or cyclosporine) or phototherapy **OR** medical record documentation of a therapeutic failure on or intolerance to prior biologic therapy **AND**
- Medical record documentation that Humira or adalimumab biosimilar is being dosed at a maximum of 40 mg every other week **OR** medical record documentation of peer-reviewed literature citing well-designed clinical trials to indicate that the member's healthcare outcome will be improved by dosing that exceeds Food and Drug Administration (FDA) approved labeling **AND**
- Medical record documentation that Humira or adalimumab biosimilar is not being used concurrently with a tumor necrosis factor (TNF) blocker or other biologic agent

For Ulcerative Colitis
An exception for coverage of BIWEEKLY (every other week) administration may be made for members who meet all the following criteria:
- Medical record documentation of a diagnosis of moderate to severe ulcerative colitis AND
- Medical record documentation that Humira or adalimumab biosimilar is prescribed by a gastroenterologist AND
- Medical Record documentation of one of the following:
    a. For Requests for Humira: Medical record documentation of age greater than or equal to 5 years AND
    b. For Requests for adalimumab-fkjp, Hadlima, or Ysumiry:Medical record documentation of age greater than or equal to 18 years

AND
- Medical record documentation of therapeutic failure on, intolerance to, at least one conventional therapy: corticosteroids, aminosalicylates, or immunomodulators (azathioprine or 6-mercaptopurine (6-MP)) AND
- Medical record documentation that Humira or adalimumab biosimilar is not being used concurrently with a tumor necrosis factor (TNF) blocker or other biologic agent

An exception for coverage of WEEKLY administration may be made for members who meet all the following criteria:

- Medical record documentation of a diagnosis of moderate to severe ulcerative colitis AND
- Medical record documentation that Humira or adalimumab biosimilar is prescribed by a gastroenterologist AND
- Medical Record documentation of one of the following:
    c. For Requests for Humira: Medical record documentation of age greater than or equal to 5 years AND
    d. For Requests for adalimumab-fkjp, Hadlima, or Ysumiry: Medical record documentation of age greater than or equal to 18 years
- Medical record documentation of therapeutic failure on, intolerance to, or contraindication to at least one conventional therapy: corticosteroids, aminosalicylates, or immunomodulators (e.g. 6-mercaptopurine or azathioprine) AND
- Medical record documentation that Humira or adalimumab biosimilar is not being used concurrently with a tumor necrosis factor (TNF) blocker or other biologic agent AND
- Medical record documentation of one of the following:
    - For an adult:
        - Medical record documentation of a contraindication to, intolerance to, or therapeutic failure on BIWEEKLY (every other week) administration of Humira or adalimumab biosimilar AND
        - Medical record documentation that the member has been compliant with BIWEEKLY administration of Humira AND
        - Medical record documentation of inadequate drug trough level (less than 7.5mcg/mL) to support weekly dosing, per American Gastroenterological Association (AGA) guidelines OR
        - Medical record documentation that weekly dosing was initiated prior to the member turning 18 years and the member is well-controlled on this dose
    - For Humira requests for a member less than or equal to 18 years of age:
        - Medical record documentation that the member is less than 18 years of age and receiving an appropriate dose based on body weight

NOTE:

- For patients with an adequate drug trough, American Gastroenterological Association (AGA) does not recommend antibody levels to guide therapy. Patients should be switched to another agent.
- For patients with an inadequate drug trough & undetectable antibodies, a dose increase may be warranted.
- For patients with an inadequate drug trough & detectable antibodies, a switch to another agent is recommended. However, patients with low antibody levels may be considered for a dose increase, in hopes of overcoming antibody level and achieving response.

For Hidradenitis Suppurativa (HS)

An exception for coverage of WEEKLY administration may be made for members who meet all the following criteria:

- Medical record documentation that Humira or adalimumab biosimilar is prescribed by a dermatologist AND
- Medical Record documentation of one of the following:
    a. For Requests for Humira: Medical record documentation of age greater than or equal to 12 years AND
    b. For Requests for adalimumab-fkjp, Hadlima, or Ysumiry: Medical record documentation of age greater than or equal to 18 years
- Medical record documentation of a diagnosis of moderate to severe hidradenitis suppurativa (HS), defined as Stage II or III on the Hurley staging system* AND
- Medical record documentation of at least 3 abscesses or inflammatory nodules AND
- Medical record documentation of concomitant use of oral or systemic antibiotics AND
- Medical record documentation that the member has received counseling on weight management (if overweight) and smoking cessation (if the member is an active smoker) AND

- For members 12 to 18 years of age weighing 30 to less than 60 kg: medical record documentation of Humira being dosed at a maximum dose of 40 mg every other week AND
- Medical record documentation that Humira is not being used concurrently with a tumor necrosis factor (TNF) blocker or other biologic agent

*Hurley staging system:
- Stage I: A single lesion without sinus tract formation.
- Stage II: More than one lesion or area, but with limited tunneling.
- Stage III: Multiple lesions, with more extensive sinus tracts and scarring.

For the treatment of Non-Infectious Intermediate, Posterior and Panuveitis
An exception for coverage of **BIWEEKLY (every other week) administration** may be made for members who meet all the following criteria:

- Medical record documentation that Humira or adalimumab biosimilar is prescribed by an ophthalmologist or rheumatologist **AND**
- Medical Record documentation of one of the following:
    a. For Requests for Humira: Medical record documentation of age greater than or equal to 2 years AND
    b. For Requests for adalimumab-fkjp, Hadlima, or Ysumiry: Medical record documentation of age greater than or equal to 18 years
- Medical record documentation of a diagnosis of non-infectious intermediate, posterior or panuveitis **AND**
- Medical record documentation of:
    - Therapeutic failure on, intolerance to, or contraindication to local/systemic corticosteroids **AND** an immunosuppressant (methotrexate, azathioprine, mycophenolate, cyclosporine, or tacrolimus) **OR**
    - For members 2-18 years of age: therapeutic failure on, intolerance to, or contraindication to local/systemic corticosteroids **AND** methotrexate **AND**
- For members 2-18 years of age: medical record documentation that Humira or adalimumab biosimilar is being given in combination with methotrexate **OR** medical record documentation of contraindication to methotrexate **AND**
- Medical record documentation that member is receiving appropriate dose of Humira based on weight and age **AND**
- Medical record documentation that Humira or adalimumab biosimilar is not being used concurrently with a tumor necrosis factor (TNF) blocker or other biologic agent
-

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

Non-Preferred Humira Biosimilar Commercial Policy

For Adult Rheumatoid Arthritis

An exception for coverage of BIWEEKLY (every other week) administration may be made for members who meet all the following criteria:
- Medical record documentation of a diagnosis of moderate to severe rheumatoid arthritis (made in accordance with the American College of Rheumatology Criteria for the Classification and Diagnosis of Rheumatoid Arthritis) AND
- Medical record documentation that adalimumab is prescribed by a rheumatologist AND
- Medical record documentation of age greater than or equal to 18 years AND

- Medical record documentation that adalimumab is not being used concurrently with a tumor necrosis factor (TNF) blocker or other biologic agent

An exception for coverage of WEEKLY administration may be made for members who meet the following criteria:

- Medical record documentation of a diagnosis of moderate to severe rheumatoid arthritis (made in accordance with the American College of Rheumatology Criteria for the Classification and Diagnosis of Rheumatoid Arthritis) AND
- Medical record documentation that adalimumab is prescribed by a rheumatologist AND
- Medical record documentation of age greater than or equal to 18 years AND
- Medical record documentation that the member has been compliant with BIWEEKLY administration of adalimumab AND
- Medical record documentation of a contraindication to, intolerance to, or therapeutic failure on BIWEEKLY (every other week) administration of adalimumab AND
- Medical record documentation that adalimumab is not being used concurrently with a tumor necrosis factor (TNF) blocker or other biologic agent

For treatment of polyarticular juvenile idiopathic arthritis or juvenile rheumatoid arthritis
An exception for coverage of BIWEEKLY (every other week) may be made for members who meet all the following criteria:

- Medical record documentation of age greater than or equal to 2 years AND
- Medical record documentation that adalimumab is prescribed by a rheumatologist AND
- Medical record documentation of a diagnosis of active polyarticular juvenile idiopathic arthritis or juvenile rheumatoid arthritis AND
- Medical record documentation that adalimumab is being dosed at a maximum of 40 mg every other week OR medical record documentation of peer-reviewed literature citing well-designed clinical trials to indicate that the member's healthcare outcome will be improved by dosing that exceeds Food and Drug Administration (FDA) approved labeling AND
- Medical record documentation that adalimumab is not being used concurrently with a tumor necrosis factor (TNF) blocker or other biologic agent

For Psoriatic Arthritis
An exception for coverage of BIWEEKLY (every other week) administration may be made for members who meet all the following criteria:

- Medical record documentation of a diagnosis of moderately to severely active psoriatic arthritis which must include documentation of either active psoriatic lesions or a documented history of psoriasis AND
- Medical record documentation that adalimumab is prescribed by a rheumatologist or dermatologist AND
- Medical record documentation of age greater than or equal to 18 years AND
- Medical record documentation that adalimumab is being dosed at a maximum of 40 mg every other week OR medical record documentation of peer-reviewed literature citing well-designed clinical trials to indicate that the member's healthcare outcome will be improved by dosing that exceeds Food and Drug Administration (FDA) approved labeling AND
- Medical record documentation that adalimumab is not being used concurrently with a tumor necrosis factor (TNF) blocker or other biologic agent

For Ankylosing Spondylitis
An exception for coverage of **BIWEEKLY (every other week)** administration may be made for members who meet all the following criteria:

- Medical record documentation that adalimumab is prescribed by a rheumatologist **AND**
- Medical record documentation of age greater than or equal to 18 years **AND**
- Medical record documentation of a diagnosis of ankylosing spondylitis **AND**
- Medical record documentation that adalimumab is being dosed at a maximum of 40 mg every other week **OR** medical record documentation of peer-reviewed literature citing well-designed clinical trials to indicate that the member's healthcare outcome will be improved by dosing that exceeds Food and Drug Administration (FDA) approved labeling **AND**
- Medical record documentation that adalimumab is not being used concurrently with a tumor necrosis factor (TNF) blocker or other biologic agent

For Crohn's Disease

An exception for coverage of **BIWEEKLY (every other week) administration** may be made for members who meet all the following criteria:

- Medical record documentation that Humira is prescribed by a gastroenterologist **AND**
- Medical record documentation of age greater than or equal to 6 years **AND**
- Medical record documentation of a diagnosis of moderately or severely active Crohn's disease **AND**
- Medical record documentation that adalimumab is not being used concurrently with a tumor necrosis factor (TNF) blocker or other biologic agent

An exception for coverage of **WEEKLY administration** may be made for members who meet the following criteria:

- Medical record documentation that Humira is prescribed by a gastroenterologist **AND**
- Medical record documentation of age greater than or equal to 6 years **AND**
- Medical record documentation of a diagnosis of moderately or severely active Crohn's disease **AND**
- Medical record documentation that Humira is not being used concurrently with a tumor necrosis factor (TNF) blocker or other biologic agent **AND**
- Medical record documentation of a contraindication to, intolerance to, or therapeutic failure on BIWEEKLY (every other week) administration of adalimumab **AND**
- Medical record documentation that the member has been compliant with BIWEEKLY administration of adalimumab **AND**
- Medical record documentation of inadequate drug trough level (less than 7.5mcg/mL) to support weekly dosing, per American Gastroenterological Association (AGA) guidelines

NOTE:

- For patients with an adequate drug trough, American Gastroenterological Association (AGA) does not recommend antibody levels to guide therapy. Patients should be switched to another agent.
- For patients with an inadequate drug trough & undetectable antibodies, a dose increase may be warranted.
- For patients with an inadequate drug trough & detectable antibodies, a switch to another agent is recommended. However, patients with low antibody levels may be considered for a dose increase, in hopes of overcoming antibody level and achieving response.

For the treatment of moderate to severe Plaque Psoriasis

An exception for coverage of **BIWEEKLY (every other week) administration** may be made for members who meet all the following criteria:

- Medical record documentation that adalimumab is prescribed by a dermatologist **AND**
- Medical record documentation of age greater than or equal to 18 years **AND**
- Medical record documentation of a diagnosis of moderate to severe plaque psoriasis characterized by greater than or equal to 5% of body surface area involved or disease involving crucial body areas such as the hands, feet, face, or genitals **AND**

- Medical record documentation that adalimumab is being dosed at a maximum of 40 mg every other week **OR** medical record documentation of peer-reviewed literature citing well-designed clinical trials to indicate that the member's healthcare outcome will be improved by dosing that exceeds Food and Drug Administration (FDA) approved labeling **AND**
- Medical record documentation that adalimumab is not being used concurrently with a tumor necrosis factor (TNF) blocker or other biologic agent

For Ulcerative Colitis
An exception for coverage of BIWEEKLY (every other week) administration may be made for members who meet all the following criteria:
- Medical record documentation of a diagnosis of moderate to severe ulcerative colitis AND
- Medical record documentation that adalimumab is prescribed by a gastroenterologist AND
- Medical record documentation of age greater than or equal to 18 years

AND
- Medical record documentation that adalimumab is not being used concurrently with a tumor necrosis factor (TNF) blocker or other biologic agent

An exception for coverage of WEEKLY administration may be made for members who meet all the following criteria:
- Medical record documentation of a diagnosis of moderate to severe ulcerative colitis AND
- Medical record documentation that adalimumab is prescribed by a gastroenterologist AND
- Medical record documentation of age greater than or equal to 18 years
- Medical record documentation that adalimumab is not being used concurrently with a tumor necrosis factor (TNF) blocker or other biologic agent AND
- Medical record documentation of one of the following:
    - For an adult:
        - Medical record documentation of a contraindication to, intolerance to, or therapeutic failure on BIWEEKLY (every other week) administration of adalimumab AND
        - Medical record documentation that the member has been compliant with BIWEEKLY administration of adalimumab AND
        - Medical record documentation of inadequate drug trough level (less than 7.5mcg/mL) to support weekly dosing, per American Gastroenterological Association (AGA) guidelines OR
        - Medical record documentation that weekly dosing was initiated prior to the member turning 18 years and the member is well-controlled on this dose

NOTE:
- For patients with an adequate drug trough, American Gastroenterological Association (AGA) does not recommend antibody levels to guide therapy. Patients should be switched to another agent.
- For patients with an inadequate drug trough & undetectable antibodies, a dose increase may be warranted.
- For patients with an inadequate drug trough & detectable antibodies, a switch to another agent is recommended. However, patients with low antibody levels may be considered for a dose increase, in hopes of overcoming antibody level and achieving response.

For Hidradenitis Suppurativa (HS)
An exception for coverage of WEEKLY administration may be made for members who meet all the following criteria:

- Medical record documentation that adalimumab is prescribed by a dermatologist AND\
- Medical record documentation of age greater than or equal to 18 years
- Medical record documentation of a diagnosis of moderate to severe hidradenitis suppurativa (HS), defined as Stage II or III on the Hurley staging system* AND
- Medical record documentation of at least 3 abscesses or inflammatory nodules AND

- Medical record documentation of concomitant use of oral or systemic antibiotics AND
- Medical record documentation that the member has received counseling on weight management (if overweight) and smoking cessation (if the member is an active smoker) AND
- For members 12 to 18 years of age weighing 30 to less than 60 kg: medical record documentation of adalimumab being dosed at a maximum dose of 40 mg every other week AND
- Medical record documentation that adalimumab is not being used concurrently with a tumor necrosis factor (TNF) blocker or other biologic agent

*Hurley staging system:
- Stage I: A single lesion without sinus tract formation.
- Stage II: More than one lesion or area, but with limited tunneling.
- Stage III: Multiple lesions, with more extensive sinus tracts and scarring.

For the treatment of Non-Infectious Intermediate, Posterior and Panuveitis
An exception for coverage of **BIWEEKLY (every other week) administration** may be made for members who meet all the following criteria:

- Medical record documentation that adalimumab is prescribed by an ophthalmologist or rheumatologist **AND**
- Medical record documentation of age greater than or equal to 18 years
- Medical record documentation of a diagnosis of non-infectious intermediate, posterior or panuveitis **AND**
- Medical record documentation that member is receiving appropriate dose of adalimumab based on weight and age **AND**
- Medical record documentation that adalimumab is not being used concurrently with a tumor necrosis factor (TNF) blocker or other biologic agent

AUTHORIZATION DURATION (for all indications): Initial therapy (or dose increases from biweekly to weekly), if approved, is approved for **12 months** of therapy. For continuation of coverage, there must be medical record documentation of clinical improvement or maintenance of condition. Subsequent approvals for coverage will be for a duration of **12 months**. Reevaluation of coverage will require medical record documentation of improvement of signs and symptoms or maintenance of condition.

QUANTITY LIMIT: Quantity limits should be set up to match the currently Humira quantity limits set in Commercial Policy 84:

Drug Description	GPI	Quantity Limit Amount	Quantity Limit Days
Abrilada Prefilled Syringe 40 mg/0.8 mL	6627001507F820	2	28 days
Abrilada Prefilled Syringe 20 mg / 0.4 mL	6627001507F810	2	28 days
Abrilada Auto-Injector 40 mg/0.8 mL	6627001507F520	2	28 days
Amjevita Prefilled Syringe 40 mg/0.8 mL	6627001510E520	1.6 mL	28 days
Amjevita Prefilled Syringe 20 mg/0.4 mL	6627001510E510	0.8 mL	28 days
Amjevita Prefilled Syringe 10 mg/ 0.2 mL	6627001510E505	0.4 mL	28 days
Amjevita Auto-Injector 40 mg/0.8 mL	6627001510D520	1.6 mL	28 days

Cyltezo Prefilled Syringe 40 mg/0.8 mL	6627001505F820		2	28 days
Cyltezo Prefilled Syringe 20 mg/0.4 mL	6627001505F810		2	28 days
Cyltezo Prefilled Syringe 10 mg/0.2 mL	6627001505F805		2	28 days
Cyltezo Auto-injector 40 mg/0.8 mL	6627001505F520	00597-0375-97	2	28 days
Cyltezo Psoriasis Starter Auto-injector 4 x 40 mg/0.8 mL		00597-0375-23	4	28 days
Cyltezo CD/UC/HS Starter Auto-injector 6 x 40 mg/0.8 mL		00597-0375-16	6	28 days
Adalimumab-adbm (unbranded Cyltezo) Prefilled Syringe 20 mg/0.4 mL	6627001505F810		2	28 days
Adalimumab-adbm (unbranded Cyltezo) Prefilled Syringe: 10 mg/0.2 mL	6627001505F805		2	28 days
Adalimumab-adbm (unbranded Cyltezo) Prefilled Syringe 40 mg/0.8 mL	6627001505F820		2	28 days
Adalimumab-adbm (unbranded Cyltezo) Autoinjector 40 mg/0.8 mL Kit – 2 Boxes	6627001505F520	00597-0545-22	2	28 days
Adalimumab-adbm (unbranded Cyltezo) Autoinjector 40 mg/0.8 mL Kit – 4 Boxes		00597-0545-44	4	28 days
Adalimumab-adbm (unbranded Cyltezo) Autoinjector 40 mg/0.8 mL Kit – 6 Boxes		00597-0545-66	6	28 days
Hadlima Prefilled Syringe 40 mg/0.8 mL	6627001520E520		1.6 mL	28 days
Hadlima PushTouch Auto-injector 40 mg/0.8 mL	6627001520D520		1.6 mL	28 days
Hadlima Prefilled Syringe 40 mg/0.4 mL	6627001520E510		0.8 mL	28 days
Hadlima PushTouch Auto-injector 40 mg/0.4 mL	6627001520D510		0.8 mL	28 days
Hulio Prefilled Syringe 40 mg/0.8 mL	6627001535F820		2	28 days
Hulio Prefilled Syringe 20 mg/0.4 mL	6627001535F810		2	28 days
Hulio Auto-Injector 40 mg/0.8 mL	6627001535F520		2	28 days
Adalimumab-fkjp (unbranded Hulio) Prefilled Syringe 40 mg/0.8 mL	6627001535F820		2	28 days
Adalimumab-fkjp (unbranded Hulio) Prefilled Syringe 20 mg/0.4 mL	6627001535F810		2	28 days
Adalimumab-fkjp (unbranded Hulio) Auto-injector 40 mg/0.8 mL	6627001535F520		2	28 days

Hyrimoz Prefilled Syringe 40 mg/0.8 mL	6627001504E520		1.6 mL	28 days
Hyrimoz Auto-injector 40 mg/0.8 mL	6627001504D520		1.6 mL	28 days
Hyrimoz Auto-injector 40 mg/0.4 mL	6627001504D515		0.8 mL	28 days
Hyrimoz Auto-injector 80 mg/0.8 mL	6627001504D540	61314-0454-20	1.6 mL	28 days
Hyrimoz Crohns/UC Starter Auto-injector Kit 80 mg/0.8 mL		61314-0454-36	2.4 mL	28 days
Hyrimoz Peds Crohn's Starter Auto-injector Kit (3 x 80 mg/0.8 mL)	6627001504E540		2.4 mL	28 days
Hyrimoz Peds Crohn's Starter Auto-injector Kit (1 x 80 mg/0.8 mL, 1 x 40 mg/0.4 mL)	6627001504E560		1.2 mL	28 days
Hyrimoz Plaque Psoriasis Starter Auto-injector Kit (1 x 80 mg/0.8 mL, 2 x 40 mg/0.4 mL)	6627001504D560		1.6 mL	28 days
Hyrimoz Prefilled Syringe 40 mg/0.4 mL	6627001504E515		0.8 mL	28 days
Hyrimoz Prefilled Syringe 20 mg/0.2 mL	6627001504E513		0.4 mL	28 days
Hyrimoz Prefilled Syringe 10 mg/0.1 mL	6627001504E508		0.2 mL	28 days
Adalimumab-adaz (unbranded Hyrimoz HCF) Auto-injector 40 mg/0.4 mL	6627001504D515		0.8 mL	28 days
Adalimumab-adaz (unbranded Hyrimoz HCF) Prefilled Syringe 40 mg/0.4 mL	6627001504E515		0.8 mL	28 days
Idacio Auto-injector 40 mg/0.8 mL Kit – 1 tray (2 x 40 mg/0.8 mL)	6627001502F540	65219-0554-08	1 box	28 days
Idacio Plaque Psoriasis Auto-injector Kit – 2 Trays (4 x 40 mg/0.8 mL)		65219-0554-28	2 boxes	28 days
Idacio Crohn's/UC Starter Auto-injector Kit – 3 Trays (6 x 40 mg/0.8 mL)		65219-0554-38	3 boxes	28 days
Iadcio Pre-filled Syringe 40 mg/0.8 mL Kit – 1 tray (2 x 40 mg/0.8 mL)	6627001502F840		1 box	28 days
Yuflyma Auto-injector 40 mg/0.4 mL 2-pen Kit	6627001503F530	72606-0030-10	1 box	28 days
Yuflyma Auto-injector 40 mg/0.4 mL 1-pen Kit		72606-0030-09	2 boxes	28 days
Yuflyma Prefilled Syringe 40 mg/0.4mL 2-syringe Kit	6627001503F830		1 box	28 days
Yusimry Pen-injector 40 mg/0.8 mL	6627001509D240		1.6 mL	28 days

No changes will be made to Humira at this time.

Adalimumab-fkjp (unbranded Hulio), Hadlima, and Ysumiry will be added to the Specialty tier or Brand NP tier for members with a three tier benefit for Commercial, Marketplace, & CHIP. They will require a prior authorization and will be added to Commercial Policy 84.0.

Abrilada, Amjevita, Cyltezo, Adalimumab-adbm (unbranded Cyltezo), Hulio, Hyrimoz, Adalimumab-adaz (unbranded Hyrimoz), Idacio, and Yuflyma will be nonformulary. The following additional prior authorization criteria will be required:

- Medical record documentation of therapeutic failure of, intolerance to, or contraindication to three of the following: Humira, Adalimumab-fkjp, Hadlima, and Ysumiry

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

FAST FACTS

Prevnar 20 (pneumococcal 20-valent conjugate vaccine)

Clinical Summary: Prevnar 20 is now indicated for active immunization for the prevention of invasive disease caused by *Streptococcus pneumoniae* serotypes 1, 3, 4, 5, 6A, 6B, 7F, 8, 9V, 10A, 11A, 12F, 14, 15B, 18C, 19A, 19F, 22F, 23F, and 33F in individuals 6 weeks of age and older. Previously this indication was for adult patients 18 years of age and older. Prevnar 20 is also now indicated for active immunization for the prevention of otitis media caused by S. pneumoniae serotypes 4, 6B, 9V, 14, 18C, 19F, and 23F in individuals 6 weeks through 5 years of age. There are no changes to the Prevnar 20 indication for active immunization for the prevention of pneumonia caused by S. pneumoniae serotypes 1, 3, 4, 5, 6A, 6B, 7F, 8, 9V, 10A, 11A, 12F, 14, 15B, 18C, 19A, 19F, 22F, 23F, and 33F in individuals 18 years of age and older.

Prevnar 20 is administered for individuals 6 weeks through 15 months of age as a 4-dose series at 2, 4, 6, and 12 through 15 months of age (at least 2 months after the third dose). The first dose may be given as early as 6 weeks of age. For individuals 7 months through 17 years of age who have never received a conjugate vaccine Prevnar 20 is administered according to Table 1.

Table 1. Catch-Up Vaccination Schedule for Individuals Initiating Vaccination at 7 Months Through 17 Years of Age[a]

Study

Age at First Dose	Total Number of 0.5-mL Doses
7 through 11 months of age	3[b]
12 through 23 months of age	2[c]
24 months of age and above	1

[a] The vaccination schedule is based on the catch-up schedule for Prevnar 13 (Pneumococcal 13-valent Conjugate Vaccine [Diphtheria CRM$_{197}$ Protein]).
[b] The first 2 doses at least 4 weeks apart; third dose after the one-year birthday, separated from the second dose by at least 2 months.
[c] Two doses at least 2 months apart.

Individuals 15 months through 17 years of age previously vaccinated with one or more doses of a lower valency pneumococcal conjugate vaccine should receive a single dose of Prevnar 20. The dose of Prevnar 20 should be administered at least 8 weeks after the last dose of the lower valency pneumococcal conjugate vaccine.

The dosage of Prevnar 20 in adult patients 18 years of older is unchanged (single dose).

Current Formulary Status: Medical or Pharmacy benefit covered as preventive vaccine ($0 copay), Age Limit: 19 years to 999 years

Recommendation: No changes to formulary placement. Remove the age limit to incorporate the new indication for pediatric patients 6 weeks and older.

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

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

VISCOSUPPLEMENTATION UPDATE

Background: As part of the TriVisc, Triluron, & Synojoynt drug review, a recommendation to change the "Step 1 Drugs" for the Part B Step Therapy document was made based on ASP pricing outlined within the review. Clarification to the recommendations made regarding the medical benefit policy (MBP) 13.0 Viscosupplementation, is needed.

Recommendations: It is recommended to update the verbiage within MBP 13.0 Viscosupplementation to reflect changes that were made in the Part B Step Therapy document, and to accurately summarize the agents that do and do not require prior authorization across each line of business (LOB). Preferred agents/Step 1 Drugs for the Medicare LOB include Durolane, Euflexxa, Gelsyn-3, GenVisc, Hyalgan, Orthovisc, Supartz, Synvisc, Synvisc-One, and Visco-3. Nonpreferred agents for the Medicare LOB include Gel-One, Hymovis, Monovisc, Synojoynt, Triluron, and TriVisc.

NOTE: For commercial, exchange, and CHIP~~, and Medicare~~ lines of business, Durolane, Euflexxa, Gelsyn-3, Supartz FX, Synvisc, and Synvisc One are preferred agents and DO NOT Require Prior Authorization.

Gel-One, GenVisc 850, Hyalgan, Hymovis, Monovisc, Orthovisc, Synojoynt, Triluron, TriVisc, and **Visco-3** require Prior Authorization and will be considered medically necessary for the commercial, exchange and CHIP lines of business when all of the following criteria are met:
[see policy for clinical criteria]

NOTE: For the Medicare line of business, Durolane, Euflexxa, Gelsyn-3, GenVisc, Hyalgan, Orthovisc, Supartz, Synvisc, Synvisc-One, and Visco-3 are preferred agents and DO NOT require Prior Authorization.

Gel-One, Hymovis, Monovisc, Synojoynt, Triluron, and TriVisc require Prior Authorization and will be considered medically necessary for the Medicare line of business when all of the following criteria are met:
[see policy for clinical criteria]

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

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.

BLENREP UPDATE

Background: On November 22, 2022 the Biologic License Application (BLA) was voluntarily withdrawn. The confirmatory phase 3 trial DREAMM-3 failed to meet the primary end point of superior progression-free survival. Per the Federal Register, the BLA was revoked as of February 2, 2023 and published in the register March 30, 2023.

Recommendation: It is recommended to retire Medical Benefit Policy (MBP) 223.0 Blenrep (belantamab mafodotin-blmf).

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.

OLUMIANT & LITFULO FOR ALOPECIA AREATA

Background: Alopecia areata is a disease that affects men and women of all ages. The disease is characterized by loss of hair in any part of the body, due to an immunological response that is directed at the hair follicle. Hair loss mostly occurs in small round patches, approximately the size of a quarter, but can be more extensive and progressive in the pediatric patient population.

Patients with a history of certain autoimmune diseases, such as psoriasis, vitiligo or thyroid disease, are at higher risk of developing this disease. Alopecia areata is classified into three types: Patchy alopecia which is characterized by quarter sized patches on any part of the body, alopecia totalis which is nearly or total hair loss confined to the scalp, and alopecia universalis which is nearly or total hair loss of the scalp, face and body. This condition can also come with some emotional and mental implications for the patient and the families of those affected. A study published by the British Journal of Dermatology in 2022 found that adult patients with alopecia areata were up to 38% more likely to be diagnosed with depression as a cause of their disease. This population was noted to experience higher rates of anxiety and depression, similar to those who suffer from psoriasis and atopic dermatitis.

FDA Approved Therapies: Treatment for this disease has been off label up until 2018 when the FDA approved baricitinib (Olumiant) for adults 18 years of age and older. Studies showed up to 22% of patients taking the 2mg once daily were noted to have 80% scalp coverage and 26% of patients taking the 4 mg once daily saw 90% or greater scalp coverage at 36 weeks of treatment.5 In June 2023 the FDA approved ritlecitinib (Litfulo) which expands treatment coverage to adolescents starting at the age of 12. Studies showed 23% of patients taking 50 mg once daily saw 80% or greater scalp coverage at 6 months (~24 weeks).

Recommendation: Based on the coverage offered by competitor plans and the fact that alopecia areata is classified as an autoimmune condition, it is recommended to move Olumiant 4 mg and Litfulo from excluded to non-formulary. The following prior authorization criteria should apply:

Olumiant

- Medical record documentation of a diagnosis of severe alopecia areata, defined as at least 50% scalp hair lose as measured by the Severity of Alopecia Tool (SALT) **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 one of the following:
    - Systemic therapy used for at least 3 months (for example, corticosteroids, methotrexate, cyclosporine) **OR**
    - Prescription topical corticosteroids used for at least 28 days **OR**
    - Intralesional corticosteroids used for at least 3 months **AND**
- Medical record documentation that member does not have hair loss due to androgenetic alopecia (includes male and female pattern hair loss), chemotherapy-induced hair loss, or other causes of hair loss other than alopecia areata **AND**
- Medical record documentation that Olumiant is not prescribed in combination with other Janus kinase inhibitors, biologic immunomodulators, cyclosporine, or other potent immunosuppressants

Litfulo

- Medical record documentation of a diagnosis of severe alopecia areata, defined as at least 50% scalp hair lose as measured by the Severity of Alopecia Tool (SALT) **AND**
- Medical record documentation of age greater than or equal to 12 years **AND**
- Medical record documentation of therapeutic failure on, intolerance to, or contraindication to one of the following:
    - Systemic therapy used for at least 3 months (for example, corticosteroids, methotrexate, cyclosporine) **OR**
    - Prescription topical corticosteroids used for at least 28 days **OR**
    - Intralesional corticosteroids used for at least 3 months **AND**
- Medical record documentation that member does not have hair loss due to androgenetic alopecia (includes male and female pattern hair loss), chemotherapy-induced hair loss, or other causes of hair loss other than alopecia areata **AND**
- Medical record documentation that Olumiant is not prescribed in combination with other Janus kinase inhibitors, biologic immunomodulators, cyclosporine, or other potent immunosuppressants

QUANTITY LIMIT:

- Olumiant: 1 tablet per day, 30 day supply per fill
- Litfulo: 1 tablet per day, 28 day supply per fill

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

- Medical record documentation of tolerability and positive clinical response to Olumiant defined as improvement from baseline in extent and density of scalp hair as measured by the Severity of Alopecia Tool (SALT)
- Medical record documentation that Olumiant/Litfulo is not prescribed in combination with other Janus kinase inhibitors, biologic immunomodulators, cyclosporine, or other potent immunosuppressants

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.

OPZELURA FOR NON-SEGMENTAL VITILIGO

Background: Non-segmental vitiligo is a chronic skin disorder characterized by the loss of pigmentation in patches, resulting in white patches on the skin. Unlike segmental vitiligo, which affects only one side or segment of the body, non-segmental vitiligo can occur on any part of the body.

The exact cause of non-segmental vitiligo is still unknown, but it is believed to be an autoimmune condition. Non-segmental vitiligo typically starts as small, pale patches that gradually enlarge over time. There is no cure for non-segmental vitiligo, but various treatment options are available to help manage the condition and improve the appearance of the affected skin. Treatment options for non-segmental vitiligo include topical corticosteroids, calcineurin inhibitors, and depigmentation for widespread cases. Phototherapy, using ultraviolet (UV) light, can also be effective in repigmenting the affected areas. In some cases, surgical interventions such as skin grafting or tattooing may be considered. Living with non-segmental vitiligo can have a significant impact on individuals, both physically and emotionally. A systemic literature review looking at studies published from 1979 to 2021 showed that depression and anxiety are two of the major psychological disorders present in greater than 50% of this patient

population. It is important for patients to receive support and counseling to cope with the psychological and social effects of the condition.

Ruxolitinib (Opzelura) phase three studies noted that 1 in 3 patients achieved as least 75% improvement in the facial vitiligo at 24 weeks. Improvement was noted using the face vitiligo area score index (F-VASI) which is an estimate of the baseline percentage of vitiligo involvement in each body region.

Recommendation: Based on the coverage offered by competitor plans and the fact that non-segmental vitiligo is classified as an autoimmune condition, it is recommended to add this indication to the existing Opzelura policy. There are no changes recommended to the current formulary status, tiering, or quantity limits. The following prior authorization criteria should apply:

- Medical record documentation of a diagnosis of non-segmental vitiligo **AND**
- Medical record documentation that Opzelura is prescribed by or in consultation with a dermatologist, allergist, or immunologist **AND**
- Medical record documentation of age greater than or equal to 12 years **AND**
- Medical record documentation that other causes of depigmentation have been ruled out* **AND**
- Medical record documentation that affected areas do not exceed 10% of body surface area **AND**
- Medical record documentation that Opzelura is NOT being used in combination with therapeutic biologics, other JAK inhibitors or potent immunosuppressants such as azathioprine or cyclosporine **AND**
- Medical record documentation of therapeutic failure on, intolerance to, or contraindication to one formulary topical corticosteroid unless deemed inadvisable due to potential risks such as use on sensitive skin areas (face, axillae, groin) **AND** one topical calcineurin inhibitor

AUTHORIZATION DURATION: Initial approval will be for 6 months. Subsequent approvals will be for an additional 6 months and will require the following:

- Medical record documentation of tolerability and positive clinical response to Opzelura **AND**
- Medical record documentation of symptomatic nonsegmental vitiligo that requires additional treatment with Opzelura **AND**
- Medical record documentation that Opzelura is NOT being used in combination with therapeutic biologics, other JAK inhibitors or potent immunosuppressants such as azathioprine or cyclosporine

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.

SHORT-ACTING OPIOID INITIAL DAY SUPPLY LIMIT UPDATE

Review: Initial fills for short-acting opioids currently require the following criteria:

For short-acting opioid requests to exceed an initial 3 day supply for a member under the age of 18 years or for greater than a 5 day supply for a member greater than or equal to 18 years:

- Medical record documentation of prescriber attestation that greater than a 3 day supply for members under the age or 18 or greater than a 5 day supply for members 18 years of age and older is medically necessary to treat the member's pain **OR**
- Medical record documentation that member is already established on opioid therapy

The Department of Human Services recently updated their short-acting opioid policy to allow members under the age of 18 up to a 5 day supply and members 18 years of age or older a 10 day supply on initial fill.

Recommendations: To improve consistency and reduce provider confusion it is recommended that the short-acting opioid section of Policy 488.0 Opioid Use be updated to allow up to a 5 day supply for members under the age of 18 and a 10 day supply for members 18 years of age and older:

For short-acting opioid requests to exceed an initial ~~3~~5 day supply for a member under the age of 18 years or for greater than a ~~5~~10 day supply for a member greater than or equal to 18 years:

- Medical record documentation of prescriber attestation that greater than a ~~3~~5 day supply for members under the age or 18 or greater than a ~~5~~10 day supply for members 18 years of age and older is medically necessary to treat the member's pain **OR**
- Medical record documentation that member is already established on opioid 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.

PREVYMIS UPDATE

Review: Prevymis received a new indication for prophylaxis of cytomegalovirus (CMV) disease in high-risk adult patients (donor CMV seropositive/recipient CMV seronegative) undergoing kidney transplant. The 2024 prior authorization review by CMS identified this as an area of concern within our current prior authorization criteria.

Recommendations: To address concerns identified by CMS, the following changes are proposed to Commercial Policy 505.0 Prevymis:

Stem Cell Transplant

- Medical record documentation that Prevymis is prescribed by or in consultation with a hematologist/oncologist, infectious disease, and/or transplant specialist **AND**
- Medical record documentation of age greater than or equal to 18 years **AND**
- Medical record documentation that member is a recipient of an allogeneic hematopoietic stem cell transplant **AND**
- Medical record documentation that member is a confirmed cytomegalovirus (CMV) seropositive recipient (R+) **AND**
- Medical record documentation that Prevymis is being used for cytomegalovirus (CMV) prophylaxis **AND**
- Medical record documentation that Prevymis is being initiated between Day 0 and Day 28 post-transplantation **AND**
- Medical record documentation that Prevymis is not being used in combination with pimozide, ergot alkaloids (ergotamine and dihydroergotamine), and/or pitavastatin and simvastatin (if co-administered with cyclosporine).

OR

Kidney Transplant

- Medical record documentation that Prevymis is prescribed by or in consultation with a transplant specialist **AND**
- Medical record documentation of age greater than or equal to 18 years **AND**
- Medical record documentation that member is a recipient of a kidney transplant **AND**
- Medical record documentation that member is at high risk of CMV [defined as CMV seropositive donor and CMV seronegative recipient (D+/R-)] **AND**
- Medical record documentation that Prevymis is being used for cytomegalovirus (CMV) prophylaxis **AND**
- Medical record documentation that Prevymis is being initiated between Day 0 and Day 7 post-transplantation **AND**
- Medical record documentation that Prevymis is not being used in combination with pimozide, ergot alkaloids (ergotamine and dihydroergotamine), and/or pitavastatin and simvastatin (if co-administered with cyclosporine).

AUTHORIZATION DURATION:

- **Stem Cell Transplant:** 100 days
- **Kidney Transplant:** 200 days

MBP 177.0 Prevymis IV (letermovir)

Prevymis IV (letermovir) will be considered medically necessary for Commercial, Exchange, CHIP, and Medicaid lines of business when ALL of the following criteria are met:

Stem Cell Transplant

- Prescription written by or in consultation with a hematologist/oncologist, infectious disease, or transplant specialist **AND**
- Medical record documentation of age greater than or equal to 18 years **AND**
- Medical record documentation that the member is a recipient of an allogeneic hematopoietic stem cell transplant **AND**
- Medical record documentation that the member is a confirmed CMV seropositive recipient (R+) **AND**
- Medical record documentation that Prevymis is being used for CMV prophylaxis **AND**
- Medical record documentation that Prevymis is being initiated between Day 0 and Day 28 post-transplantation **AND**
- Medical record documentation that Prevymis is not being used in combination with pimozide, ergot alkaloids (ergotamine and dihydroergotamine), and/or pitavastatin and simvastatin (if co-administered with cyclosporine) **AND**
- Medical record documentation of intolerance to or contraindication to Prevymis tablets

OR

Kidney Transplant

- Medical record documentation that Prevymis is prescribed by or in consultation with a transplant specialist **AND**
- Medical record documentation of age greater than or equal to 18 years **AND**
- Medical record documentation that member is a recipient of a kidney transplant **AND**
- Medical record documentation that member is at high risk of CMV [defined as CMV seropositive donor and CMV seronegative recipient (D+/R-)] **AND**
- Medical record documentation that Prevymis is being used for cytomegalovirus (CMV) prophylaxis **AND**
- Medical record documentation that Prevymis is being initiated between Day 0 and Day 7 post-transplantation **AND**

- Medical record documentation that Prevymis is not being used in combination with pimozide, ergot alkaloids (ergotamine and dihydroergotamine), and/or pitavastatin and simvastatin (if co-administered with cyclosporine) **AND**
- Medical record documentation of intolerance to or contraindication to Prevymis tablets.

AUTHORIZATION DURATION:

- **Stem Cell Transplant:** If approved, a one-time authorization for 100 days with a maximum of 100 doses will apply.
- **Kidney Transplant:** If approved, a one-time authorization for 200 days with a maximum of 200 doses will apply.

QUANTITY LIMIT:

- **Stem Cell Transplant:** 100 doses per 100 days
- **Kidney Transplant:** 200 doses per 200 days

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.

INSULIN DELIVERY SYSTEM UPDATE

Review: A class review for Insulin Delivery Systems was taken to September P&T with a recommendation to add products to formulary. Tiering recommendations were not given for drugs that were recommended to add to formulary.

Recommendations: The following tiering recommendations should apply:

Commercial (Traditional)/ Exchange (Marketplace)/ CHIP (Kids)	
Medication	**Recommendations**
V-Go 20	Recommend adding V-Go to formulary at the Brand Preferred Tier.
V-Go 30	
V-Go 40	
Omnipod 5	Recommend adding Omnipod to formulary at the Brand Preferred Tier.

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.

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

Meeting adjourned at 5:02 pm.

The next bi-monthly scheduled meeting will be held on January 16th, 2024 at 1:00 p.m.

Meeting will be held virtually via phone/Microsoft Teams.