P&T Committee Meeting Minutes

Commercial-Exchange-CHIP

May 12, 2026

Present (via Teams):	Absent:
Bret Yarczower, MD, MBA – Chair	Alyssa Cilia, RPh
Amir Antonious, Pharm.D.	Bhargavi Degapudi, MD
Leslie Astleford, Pharm.D.	Michael Dubartell, MD
Emily Bednarz, Pharm.D.	Michael Evans, RPh
Kristen Bender, Pharm.D.	Nichole Hossler, MD
Jeremy Bennett, MD	Emily Jacobson, Pharm.D.
Angela Bolesta, Pharm.D.	Kerry Ann Kilkenny, MD
Kim Castelnovo, RPh	Philip Krebs, R.EEG T
Kimberly Clark, Pharm.D.	Lauren Lesh, Pharm.D.
Keri Donaldson, MD, MSCE	Perry Meadows, MD
Kelly Faust, Pharm.D.	Jonas Pearson, RPh
Tricia Heitzman, Pharm.D.	Angela Scarantino
Jason Howay, Pharm.D.	Kirsten Smith, Pharm.D.
Keith Hunsicker, Pharm.D.	Jill Stone, Pharm.D.
Kelli Hunsicker, Pharm.D.	Luke Sullivan, DO
Dennis Janosczyk, Pharm.D.	Amanda Taylor, MD
Alexandra Kempf-Malys, MSW, BSc	
Briana LeBeau, Pharm.D.	
Lisa Manoski, Pharm.D.	
Ted Marines, Pharm.D.	
Lisa Mazonkey, RPh	
Tyreese McCrea, Pharm.D.	
Jamie Miller, RPh	
Mark Mowery, Pharm.D.	
Andrei Nemoianu, MD	
Kara Pabst, Pharm.D.	
Austin Paisley, Pharm.D.	
Kimberly Reichard, Pharm.D.	
Melissa Sartori, Pharm.D.	
Kristen Scheib, Pharm.D.	
Michael Shepherd, MD	
Aubrielle Smith-Masri, Pharm.D.	
Michael Spishock, RPh	
Todd Sponenberg, Pharm.D.	
Kevin Szczecina, RPh	
Ariana Wendoloski, Pharm.D.	
Brandon Whiteash, Pharm.D.	
Margaret Whiteash, Pharm.D.	
Abigail Chua, DO (non-voting participant)	
Jeremy Garris, Pharm.D. (non-voting participant)	

Call to Order:
Dr. Bret Yarczower called the meeting to order at 1:03 p.m., Tuesday, May 12, 2026.

Review and Approval of Minutes:
Dr. Bret Yarczower asked for a motion or approval to accept the March 10, 2026 minutes as written. Minutes approved unanimously. None were opposed.

DRUG REVIEWS

CARDAMYST (etripamil)

Review: Cardamyst is a calcium channel blocker nasal spray indicated for the conversion of acute symptomatic episodes of paroxysmal supraventricular tachycardia (PSVT) to sinus rhythm in adults. Cardamyst is an L-type calcium influx inhibitor, exerting its effect by modulating the influx of ionic calcium across the cell membrane of AV nodal cells allowing it to restore sinus rhythm in patients with PSVT. In addition, Cardamyst inhibits calcium influx across the cell membrane of arterial smooth muscles and contractile myocardial cells.

PSVT guidelines have not been updated to address Cardamyst. Current treatments are separated into acute and ongoing maintenance treatments. First line recommendations for acute treatment are vagal maneuvers and/or intravenous adenosine. Other options include cardioversion for non-hemodynamically stable patients and intravenous diltiazem, verapamil, or beta blockers for hemodynamically stable patients. Treatment guidelines reserve the acute use of oral medications for terminating PSVT to patients with infrequent episodes of PSVT caused by AVNRT (Class IIb, Level C).

Cardamyst is administered intranasally as soon as possible after PSVT symptom onset. One spray is given in each nostril for a total initial dose of 70 mg. After 10 minutes, a second dose may be administered in each nostril (70 mg total) if symptoms persist. If symptoms do not improve 20 minutes after a second dose, patients should contact their healthcare provider or seek emergency medical help. Cardamyst is supplied in cartons containing 2 disposable nasal spray devices with each device containing two sprays (70 mg etripamil).

The efficacy of Cardamyst was evaluated in a randomized, double-blind, placebo-controlled, event-driven, phase-3 study in 692 patients with a history of symptomatic PSVT. Patients were randomized 1:1 to Cardamyst 70 mg or placebo. Patients with an episode of perceived PSVT were to self-administer the study drug intranasally in a medically unsupervised setting and self-administer a second dose if symptoms persisted at 10 minutes after the first dose. Continuously obtained electrocardiographic data during the episode of PSVT was blindly adjudicated.
The primary endpoint was time-to-conversion of confirmed PSVT to sinus rhythm for at least 30 seconds within 30 minutes of the first dose. Two hundred and fifty-five patients perceived an episode of PSVT and self-administered the study drug. Of those, 184 (72%) were confirmed by blinded adjudication to be PSVT. Sixty-three percent (63%) of patients with confirmed PSVT episode were taking concomitant beta blocker or calcium channel blocker.

In primary analysis, patients with confirmed episodes of PSVT, Kaplan-Meier Estimates of those who converted to sinus rhythm within 30 minutes were 64% and 31% for Cardamyst and placebo, respectively (p-value <0.001). Median time-to-conversion was 17.2 minutes with Cardamyst versus 53.5 minutes with placebo. Estimates of conversion remained in favor of Cardamyst at 300 minutes. Results were generally consistent across all major subgroups including sex, age group, concomitant medications, and duration from onset to first dose.

Seventy-one patients who self-administered Cardamyst for a perceived episode of PSVT did not have PSVT confirmed due to missing ECG data (4%), resolution of PSVT prior to dosing (5%), or other rhythm diagnoses (19%).

Cardamyst is contraindicated in patients with hypersensitivity to Cardamyst, NYHA Class II to IV heart failure, Wolff-Parkinson-White (WPW), Lown-Ganong-Levine (LGL) syndromes or manifest pre-excitation

(delta wave) on a 12-lead electrocardiogram (ECG), sick-sinus syndrome without a permanent pacemaker, or second degree AV Mobitz 2 block or higher degree of AV block.
Warnings include risk of dizziness or syncope related to hemodynamic effects (blood pressure, heart rate, and cardiac conduction), particularly in those with a history of syncope, high-grade AV block or sinus node dysfunction, history of syncope during PSVT episodes, and those with a history of hypotensive episodes.

The majority of treatment-related adverse reactions reported in clinical studies have been related to local reactions at, or near the nasal administration site, including nasal discomfort, nasal congestion, throat irritation, oropharyngeal pain, lacrimation, rhinorrhea, bleeding from the nose, upper-airway cough syndrome, and sneezing.

The safety and efficacy of Cardamyst have not been established in pediatric patients. Cardamyst is structurally similar to another drug in the same class that is associated with a high risk of potentially non-reversible electromechanical dissociation or cardiovascular collapse in pediatric patients less than 1 year of age.

Of the total number of patients in clinical trials, 41% were 60 years of age and older and 14% were 70 years of age and older. No meaningful differences in safety or efficacy were observed between older and younger patients.

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 (32 approved, 0 rejected).

Financial Discussion: No comments or questions. The committee unanimously voted to accept the recommendations as presented. None were opposed (33 approved, 0 rejected).

Outcome: Cardamyst is a pharmacy benefit and will be added to following tiers on the Commercial, Marketplace, and GHP Kids formulary. The following prior authorization criteria will apply:

2 Tier/CHIP	3 Tier	4 Tier	ACA
Tier 2: Brand	Tier 3: Brand NP	Tier 4:Specialty	Tier 6: Specialty

GPI LEVEL: GPI-12

QUANTITY LIMIT: One carton (2 nasal spray units) per 28 days

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.

EXDENSUR (depemokimab-ulaa)

Review: Exdensur (depemokimab-ulaa) was approved by the FDA in December 2025 as an add-on maintenance treatment for severe asthma in patients 12 years or older with eosinophilic phenotype disease. Exdensur (depemokimab-ulaa) is supplied as a single use dose of 100mg/ml prefilled pen or syringe that is to be administered subcutaneously by a health care provider every 6 months in the upper arm, thigh or abdomen, It is considered the first ultra long-acting monoclonal antibody antagonist that targets interleukin 5 (IL-5) which prevents IL-5 from connecting with its receptor thus inhibiting and reducing eosinophil production and survival. This helps to modify the eosinophilic pathways involved in the inflammatory pathway implicated in eosinophilic asthma. The 2025 Global initiative for Asthma Guideline (GINA), recommends treatment modalities based on severity of disease. Using preferred track

1 of the GINA guidelines, Step 1-2(Mild asthma), recommends using a low dose inhaled corticosteroid (ICS)-formoterol inhaler as needed only. Step3(Moderate asthma), recommends use of maintenance low dose ICS-formoterol inhaler for daily use along with using it as needed, while Step 4 (Moderate asthma) guidelines suggest using medium dose ICS-formoterol for daily maintenance use in addition to using it as needed. Step 5(Severe asthma) is asthma that remains uncontrolled despite optimized treatment with high-dose ICS-Formoterol maintenance use, or disease that requires this treatment to prevent it from becoming uncontrolled. At this stage, providers may opt to add additional therapy for control such as a long-acting muscarinic agent (LAMA) and/or a biologic, like Tezspire, Dupixent, Fasenra, Cinqair, Nucala or Xolair depending on the phenotype of the disease. Exdensur can be considered for use in uncontrolled patients with Type 2 inflammatory disease associated with elevated eosinophils above 150 cells/microL or those that have had a previous elevation within a year of starting treatment of >300cells/microL. However, patients that are already stable on IL-5 targeting biologics, could consider switching to Exdensur due to its convenience in bi-yearly dosing. However, Exdensur did not prove non-inferiority to other IL-5 biologics, Nucala and Fasenra, during studies. The NIMBLE trial (NCT04718389) evaluated switching stable severe eosinophilic asthma patients from Nucala(mepolizumab) or Fasenra(benralizumab) to twice-yearly Exdensur(depemokimab). Over 52 weeks, Exdensur(depemokimab) showed a slightly higher exacerbation rate and did not meet non-inferiority statistically, though overall asthma control, lung function, and safety were similar between groups. Clinically, this suggests Exdensur(depemokimab) may be a reasonable convenience-driven option for stable patients, but without definitive equivalence to existing biologics.

Other biologics, with market availability such as Tezspire (MOA: TSLP(Thymic Stromal Lymphopoietin), Dupixent(MOA: IL-4r),Fasenra(MOA:IL-5), Cinqair,(MOA:IL-5) Nucala(MOA: IL-5) and Xolair(MOA:IgE) are currently acceptable treatments offering slightly different mechanisms of actions and selection criteria for use based on biomarkers such as IgE, eosinophil count, FeNO(fractional exhaled Nitric Oxide) and oral corticosteroid dependency. Biologic selection in Step 5 (Severe asthma) should be phenotypic driven, prioritizing IL5/IL-5R or IL/4/13 blockade for Type 2 inflammation with anti-TSLP reserved for non-eosinophilic or refractory disease.

The efficacy of Exdensur was determined in 2 trials, SWIFT-1 and SWIFT-2. These trials were phase 3, randomized, double-blind, placebo-controlled studies evaluating Exdensur (depemokimab) in patients aged ≥12 years with severe eosinophilic asthma. Key inclusion criteria included use of medium- to high-dose inhaled corticosteroids plus at least one additional controller, a history of ≥2 exacerbations in the prior year, and evidence of type 2 inflammation with blood eosinophil counts typically ≥150 cells/μL at screening or ≥300 cells/μL in the prior 12 months. Patients were not on other asthma biologics at baseline or required washout prior to enrollment. Major exclusion criteria included current smoking or significant smoking history, other clinically relevant lung diseases such as COPD, and unstable comorbid conditions and prior failure of a IL-5/5r Mab targeting biologic The primary endpoint in both SWIFT-1 and SWIFT-2 was the annualized rate of clinically significant asthma exacerbations over the 52-week treatment period. Clinically significant exacerbations were defined as worsening asthma requiring systemic corticosteroids (oral/IV), and/or an emergency department visit or hospitalization. Over 52 weeks, Exdensur (depemokimab) administered every 26 weeks reduced annualized exacerbation rates by approximately 50% compared to placebo (rate ratios ~0.46–0.56 across trials), significantly prolonged time to first exacerbation, and produced modest improvements in lung function (FEV_1) and asthma control, with a safety profile comparable to placebo. Overall, these results demonstrate that Exdensur(depemokimab) is an effective IL-5–targeted therapy, with twice-yearly dosing offering a meaningful reduction in treatment burden.

Safety considerations include adverse reactions with an incidence ≥4% and more common than placebo, were upper respiratory tract infection, allergic rhinitis, influenza, arthralgia, and pharyngitis. Injection site reactions occurred in 1% and <1% patients receiving Exdensur and placebo, respectively. Hypersensitivity reactions including anaphylaxis have been reported. Clinicians should not abruptly discontinue systemic or inhaled corticosteroids when starting Exdensur, as this may lead to withdrawal symptoms. Pre-existing helminth infections should be treated prior to initiating therapy due to potential effects on immune response.

Safety and efficacy in special populations to consider include pediatric patients less than age 12 years old, pregnant, and lactating women. There is insufficient evidence or lack of safety and efficacy data for use of Exdensur in these populations. For geriatric patients, there were no overall differences observed between these and younger patients.

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 asked to confirm that the definition of eosinophilic asthma in this policy is consistent with our other drug policies? Tyreese confirmed they are consistent. No additional comments or questions. The committee unanimously voted to accept the recommendations as presented. None were opposed (32 approved, 0 rejected).

Financial Discussion: Dr. Yarczower asked if there are rebate opportunities within this category given all of the competition or an opportunity within Risant for improved purchasing? Kim Clark commented that this category has not yet been evaluated but she will present it to the group for discussion. We will also work with Expion to determine if there is opportunity. Additionally, Kim Clark clarified that tiering for the 2 Tier/CHIP formulary will be tier 2 and the 3 Tier formulary will be tier 3. No additional comments or questions. The committee unanimously voted to accept the recommendations as presented. None were opposed (33 approved, 0 rejected).

Outcome: Exdensur (depemokimab) is a medical benefit that will be added to the medical cost share list and will require prior authorization with an allowance to be filled at Specialty on the following tiers requiring prior authorization:

2 Tier/CHIP	3 Tier	4 Tier	ACA
Tier 2 – Brand Tier	Tier 3 – Brand NP Tier	Tier 4 – Specialty tier	Tier 6 – Specialty tier

- Documentation of patient age >= 12 years **AND**
- Medical record documentation of a diagnosis of severe eosinophilic asthma **AND** that Exdensur(depemokimab) is being used as add-on maintenance treatment **AND**
- Prescription written by an allergist, immunologist or pulmonologist **AND**
- Medical record documentation of a blood eosinophil count of either > 300 cells/mcL (0.30 K/µl) during the 12-month period before screening and/or > 150 cells/mcL (0.15 K/µl) within 3 months of the start of therapy **AND**
- Medical record documentation of Intolerance to or not well controlled or very poorly controlled
- symptoms* despite at least a 3-month trial of: high-dose inhaled corticosteroids and/or oral systemic corticosteroids plus a long-acting beta agonist **OR**
- Two or more exacerbations in the previous 12 months requiring additional medical treatment (oral corticosteroids, emergency department or urgent care visits, or hospitalization) despite current therapy with high-dose inhaled corticosteroids plus a long-acting beta agonist **AND**
- Insured individuals must be adherent with current therapeutic regimen and must demonstrate appropriate inhaler technique **AND**
- Medical record documentation that the medication will not be used in combination with another biologic medication indicated for asthma treatment (e.g., Fasenra (benralizumab), Cinqair (reslizumab), Dupixent (dupilumab), Xolair (omalizumab), Tezspire (Tezepelumab), Nucala (Mepolizumab)

GPI LEVEL: GPI-10

QUANTITY LIMIT: 1 ml/6 month

AUTHORIZATION DURATION: Initial approval will be for 12 months. Continued authorization may be granted in 12-month cycles for patients demonstrating a documented clinical benefit, such as improvement in asthma symptoms, an increase in percent predicted FEV1 from baseline, reduced

reliance on rescue medication, and/or a decrease in the frequency or severity of asthma exacerbations.

RPH SIGNOFF REQUIRED: Yes

FORMULARY ALTERNATIVES: Fasenra (benralizumab), Cinqair (reslizumab), Dupixent (dupilumab), Xolair (omalizumab), Tezspire (Tezepelumab)

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

JAVADIN (clonidine hcl)

Review: Javadin is an immediate-release, ready-to-use oral clonidine HCl solution. It eliminates the need for compounding, tablet splitting/crushing, or variability seen with transdermal patches. It is an alpha2-adrenergic agonist that is FDA approved for the treatment of hypertension in adult patients. Clonidine stimulates alpha-2 adrenoceptors in the brain stem that activate an inhibitory neuron, which reduces sympathetic outflow. This decreases peripheral and vascular resistance, heart rate and blood pressure. The net effect is a reduction in blood pressure driven by central sympatholysis, rather than direct vascular smooth muscle relaxation. Onset of action occurs within 30 to 60 minutes but peaks around 2-4 hours after administration. It is metabolized hepatically and excreted renally, with a 12-16 hour elimination half-life.

Javadins' place in therapy for hypertension treatment is generally not first line. It is reserved as a later-line option, often as an adjunctive agent. We see its' most commonly in those with resistant hypertension. Dependent on patient age, comorbidities and race, first line agents can include angiotensin-converting enzyme inhibitors (ACEi), angiotensin II receptor blockers (ARBs), thiazides, and calcium channel blockers (CCBs). If hypertension treatment is resistant to an optimized regimen of 3 or more of the listed medications, then mineralcorticoid receptor antagonists (MRAs) are added. If still uncontrolled, beta blockers and central alpha agonists, like clonidine are considered; then hydralazine and minoxidil are considered are final line treatment options. Clonidine is not considered earlier in treatment since its lacks cardiovascular outcome superiority, has greater side effect risk, and requires strict adherence to avoid rebound hypertension. Very limited scenarios exist where clonidine use earlier in treatment algorithm is considered. Such possibilities include elevated resting heart rate, anxiety driven blood pressure spikes, when beta blockers are contraindicated or not tolerated, or most commonly when liquid formulation is needed (ie unable to swallow tablets, feeding tube administration, or compounding is unavailable).

Javadin is a mixed-berry flavor, clear oral solution that is available as 0.02mg/mL strength. It is supplied in a child-resistant closure bottle that contains 250mL. It is stored at room temperature, and unused medication should be discarded after 60 days of opening. Dosing is individualized based on patients' response. For oral administration, it is recommended to start at 0.1mg dose twice daily. Weekly interval titrations are suggested by increments of 0.1mg per day until blood pressure goal is achieved without producing side effects. It should always be administered twice daily, with an equal or higher split dose given at bedtime. Most common therapeutic doses are seen in the 0.2mg to 0.6mg per day in divided doses. Maximum dose is 2.4mg but doses this high are considered rare. It should be administered with a calibrated measuring device such as an oral syringe or oral dosing cup; a household tablespoon or teaspoon is not adequate. It can be given with or without food. If having a procedure or surgery, it may be administered up to 4 hours before, and may be resumed as soon as possible post-operatively.
Javadin does not have safety, efficacy or outcomes trials. Evidence supporting Javadin comes from historical data of other clonidine formulations. FDA approval is based only on a bioequivalence trial that was conducted against immediate-release oral clonidine tablets (ie Catapres). This trial showed comparable Cmax, AUC, and exposure.

Javadin is contraindicated in those with known hypersensitivity to clonidine. There are warning and precautions to monitor for. First, bradycardia, cardiac conduction abnormalities, and symptomatic

hypotension are possible, as clonidine may worsen sinus node dysfunction and atrioventricular (AV) block. Patients with a history of syncope, conduction abnormalities or bradycardia should have a much slower titration process while also assessing for and discontinuing other medications that can affect conduction. Second, rebound hypertension can occur with abrupt discontinuation due to resulting elevated catecholamines, especially if using higher clonidine doses or using concomitantly with beta blockers. Gradual taper over 2-4 days is recommended to avoid tachycardia, elevated blood pressure, headache, agitation or in worst case encephalopathy or stroke. Finally, sedation and somnolence are possible. Operation of heavy machinery and driving should be avoided until response to medication is known. It should not be used along with other CNS depressants as this can increase sedation risk even more. Other more common adverse reactions to monitor for include fatigue, headache, palpitation, anxiety, agitation, vivid dreams, insomnia, nausea/vomiting, constipation, hives, rash, weight gain, muscle/joint pain, and blurred vision.

Javadin has special considerations to remember. Caution should be exercised when starting concomitant use with other antihypertensives (increased hypotension risk), CNS depressants (increased sedation), drugs like CCBs and beta blockers that affect AV node conduction (increased bradycardia and AV block), and tricyclic antidepressants (increased blood pressure as hypotensive effects are counteracted). Use in pregnancy is not advised unless clinically necessary as studies are mixed on effects of development of embryo/fetus. Use in lactation is not advised; it has been found in breastmilk although on effect on infant has mixed evidence. Use has not been studied in pediatric populations, and use is limited to adults 18 years of age or older. Use in those renally impaired should start at lower doses and titrated more slowly since the half-life increases since renal excretion is slowed. For those receiving hemodialysis, minimal amount is removed during dialysis, thus no additional supplemental dose needs to be given. No elderly or hepatic considerations needed.

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 (29 approved, 0 rejected).

Financial Discussion: No comments or questions. The committee unanimously voted to accept the recommendations as presented. None were opposed (30 approved, 0 rejected).

Outcome: Javadin is a pharmacy benefit and will not be added to the Commercial, Exchange, or CHIP formularies. Javadin will be reviewed with the administrative policy for medical necessity and failure of formulary alternatives.

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.

OMLONTI (omidenepag isopropyl ophthalmic solution)

Review: Omlonti is indicated for the reduction of elevated intraocular pressure (IOP) in patients with open-angle glaucoma or ocular hypertension. Omlonti is a selective EP2 receptor agonist which is believed that increasing aqueous humor drainage through the conventional and uveoscleral outflow pathways and decreases intra-ocular pressure.

The recommended dosage of Omlonti is one drop into the affected eye(s) once daily in the evening. It is supplied in 2.5 milliliter bottles.

The efficacy and safety of Omlonti was evaluated in three randomized, controlled clinical trials in patients with open-angle glaucoma or ocular hypertension with an average baseline IOP of 24-26 mm Hg. The

trials consisted of a 3 month double-masked treatment period, followed by a 9-month open-label treatment period in the third study. Omlonti was compared to latanoprost (PEONY) and timolol (SPECTRUM 3, SPECTRUM 4). In the three studies, IOP reductions were observed for all treatment arms. Omlonti was determined to be noninferior to the comparator agent in the SPECTRUM 4 and PEONY studies, but not in the SPECTRUM 3 study. In the Omlonti arm, the reduction in IOP ranged from 5-7 mm Hg across all three studies. The corresponding reductions for the timolol and latanoprost arms were 5-7 mm Hg and 6-8 mm Hg, respectively.

Safety is consistent with other prostaglandin eye drops used to decrease intra-ocular pressure. Warnings and precautions include pigmentation, eyelash changes, ocular inflammation, macular edema, and risk of contamination and injury to eye. In clinical trials, the most common adverse reactions were conjunctival hyperemia, photophobia, blurred vision, dry eye, instillation site pain, eye pain, ocular hyperemia, punctate keratitis, headache, eye irritation, and visual impairment.

The safety and efficacy of Omlonti has not been established in pediatric patients. There were no overall differences in safety or efficacy of Omlonti observed between elderly and younger patients.

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

Clinical Discussion: Kim Clark mentioned that we may not be able to operationalize a step therapy edit on a non-formulary drug. If that is the case, we will move forward with only the criteria requiring medical record documentation. No additional comments or questions. The committee unanimously voted to accept the recommendations as presented. None were opposed (30 approved, 0 rejected).

Financial Discussion: No comments or questions. The committee unanimously voted to accept the recommendations as presented. None were opposed (32 approved, 0 rejected).

Outcome: Omlonti is a pharmacy benefit that will not be added to the Commercial, Marketplace, or GHP Kids formulary. Step therapy will be required and Omlonti will be added to Commercial Policy 506.0 for Iyuzeh and Vyzulta as follows:

- Electronic step therapy of on-line prescription drug claims history showing 15 days use of latanoprost (generic Xalatan), tafluprost (generic Zioptan), **AND** travoprost within the previous 180 days. If this electronic step is met, the claim will automatically adjudicate **OR**
- Medical record documentation of intolerance to, contraindication to, or therapeutic failure on latanoprost (generic Xalatan), tafluprost (generic Zioptan), **AND** travoprost

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.

VOYXACT (sibeprenlimab)

Review: Voyxact is indicated to reduce proteinuria in adults with primary immunoglobulin A nephropathy (IgAN) at risk for disease progression. This is an accelerated approval based on reduction of proteinuria. It has not been established whether Voyxact slows kidney decline long-term in patients with IgAN. Voyxact is the first inhibitor of A Proliferation Inducing Ligand (APRIL) which results in reduced level of serum galactose-deficient immunoglobulin A1 (Gd-IgA1) which is implicated in the pathogenesis of IgAN.

The recommended dosage of Voyxact is 400 mg subuctanously once every 4 weeks. Voyxact can be self-administered or administered by a healthcare provider. Voyxact is supplied as single-dose prefilled syringes containing 400 mg/ 2 mL.

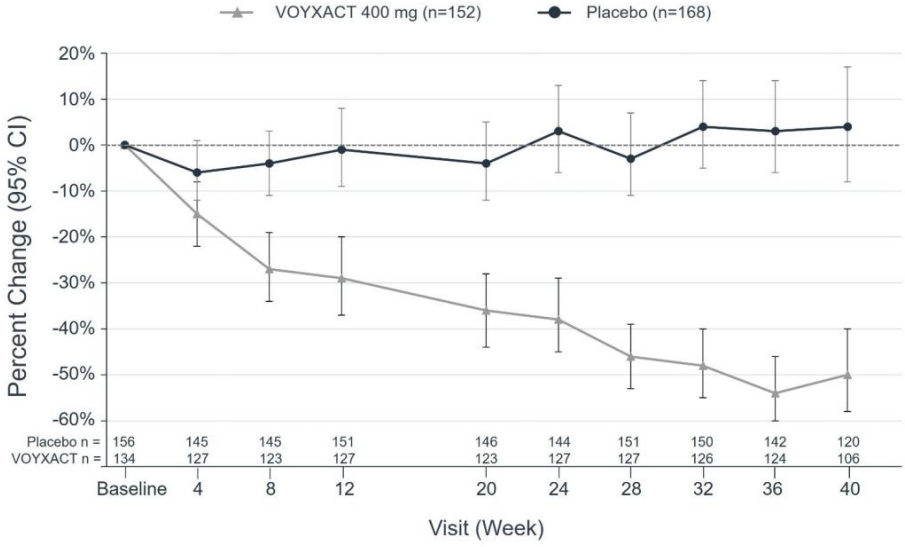
The efficacy and safety of Voyxact was evaluated in VISIONARY, a randomized, double-blind, placebo-

controlled trial in 510 adults with biopsy-confirmed IgAN, an eGFR ≥ 30 mL/min/1.73 m2, proteinuria (defined as uPCR-24h ≥ 0.75 g/g or urine protein ≥ 1.0 g/day), and on a stable and maximally tolerated dose of an angiotensin-converting enzyme inhibitor (ACEi) and/or angiotensin receptor blocker (ARB) with or without a sodium-glucose co-transporter 2 inhibitor (SGLT2i). Patients were randomized 1:1 to receive Voyxact or placebo. An interim efficacy analysis was conducted at the first 320 patients who reached Month 9 visit. Of the 320 patients, 152 were randomized to Voyxact while 168 were randomized to placebo.

At baseline, mean uPCR-24h was 1.5 g/g, mean eGFR was 63 mL/min/1.73 m2, and 74% had hematuria on urine dipstick. At baseline, 98% of patients were treated with an ACEi and/or ARB and 40% of patients were also on a SGLT2i.

The primary endpoint was relative change from baseline in uPCR-24h at Month 9. The mean estimated percent change from baseline in uPCR-24h was -50% in the Voyxact treatment group compared to 2% increase in the placebo. Figure 1 shows the percentage change compard to baseline over time in spot uPCR.

Figure 1. Percent Change Compared to Baseline in Spot uPCR Over Time in Patients with IgAN in the VISIONARY Study



CI = Confidence Interval
Spot uPCR at specific week is defined as spot uPCR/spot uPCRbaseline

The treatment effect was consistent across the subgroups and pre-specified stratification factors including sex, age, race, ethnicity, geographic region, baseline proteinuria (uPCR-24h), baseline eGFR, and SGLT2i use.

Warnings and precautions for Voyxact include immunosuppression based on the mechanism of action which in turn reduces antibody production and increases risk of interference with immune responses to vaccines as well as increasing the risk of infection with live vaccines. In clinical trials, the most common adverse reactions were infections (most commonly upper respiratory infection) and injection site reactions (most commonly erythema). Most adverse reactions were reported as mild or moderate in severity and resolved without treatment interruption or discontinuation.

The safety and efficacy of Voyxact in pediatric patients has not been established. Clinical studies did not include sufficient numbers of patients aged 65 years of age or older to determine whether they respond differently from younger adult patients. No clinically meaningful differences were observed between patients over 65 years of age compared to younger adult patients.

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 (30 approved, 0 rejected).

Financial Discussion: Dr. Yarczower suggested that we reach out to nephrology to review the recommendations. Kim Reichard will follow-up with them. No additional comments or questions. The committee unanimously voted to accept the recommendations as presented. None were opposed (27 approved, 0 rejected).

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

- Medical record documentation of age greater than or equal to 18 years **AND**
- Medical record documentation of primary immunoglobulin A nephropathy (IgAN) verified by biopsy **AND**
- Medical record documentation that Voyxact is prescribed by or in consultation with a nephrologist **AND**
- Medical record documentation that patient is at risk of disease progression, defined as proteinuria greater than 1 gram/day **AND**
- Medical record documentation of estimated glomerular filtration rate (eGFR) greater than or equal to 30 mL/min/1.73 m^2 **AND**
- Medical record documentation that member has received a stable dose of a renin-angiotensin system (RAS) Inhibitor (ACE inhibitor or ARB) at a maximally tolerated dose for greater than or equal to 90 days **AND**
- Medical record documentation that member has received greater than or equal to 90 days of optimized supportive care, including blood pressure management, lifestyle modification, and cardiovascular risk modification

GPI LEVEL: GPI-12

QUANTITY LIMIT: 2 mL per 28 days, 28 days supply per fill

AUTHORIZATION DURATION: Initial approval will be for 9 months. Subsequent authorizations will be for 12 months and will require:

- Medical record documentation of continued disease improvement or lack of disease progression according to prescriber (i.e., decreased levels of proteinuria from baseline or decreased urine protein-to-creatinine ratio (UPCR) from baseline)

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

REDEMPLO (plozasiran)

Review: Redemplo is an apolipoprotein C-III (apoC-III)-directed small interfering ribonucleic acid (siRNA) indicated for adults as an adjunct to diet to reduce triglycerides with familial chylomicronemia syndrome (FCS). Redemplo is available as a 25mg/0.5ml prefilled syringe, which is administered subcutaneously every 3 months. Patients and caregivers should be trained on proper preparation and administration. Redemplo should be refrigerated until use, but it can be kept at room temperature for up to 30 days. If a dose is missed, the next dose should be taken as soon as possible, and dosing every 3 months should resume from the date of the most recently administered dose.

FCS, also referred to as type 1 hyperlipoproteinemia, is a rare inherited autosomal recessive disorder

characterized by elevated triglyceride (TG) levels that can lead to acute pancreatitis (AP). The manufacturer estimates that there are approximately 6,500 patients affected in the United States. The condition is most commonly caused by mutations in both copies of the lipoprotein lipase (LPL) gene, resulting in absent or insufficient LPL enzyme activity. Mutations in other genes such as, apoA-V, apoC-II, GPIHBP1, and LMF1, can also contribute to LPL function but are less common. Impaired LPL activity causes chylomicrons, lipoproteins that transport TGs, to accumulate in the plasma, resulting in TG levels that may exceed 1,000 mg/dL compared to normal levels which are below 150 mg/dL. Redemplo interferes with the production of apoC-III. When present, apoC-III slows LPL activity and inhibits chylomicrons or TG clearance. By reducing apoC-III, clearance of chylomicrons and other TG lipoproteins are improved.

According to the American Association of Clinical Endocrinologists (AACE) diagnostic algorithm, a diagnosis of FCS should include fasting TG levels ≥880 mg/dL, patients refractory to standard TG lowering therapies, and an absence of secondary causes such as alcohol use, uncontrolled diabetes, medications, or other conditions known to increase TGs. Patients should also have a history of AP, history of recurrent abdominal pain without other known cause, or confirmation by genetic testing, though limited due to its complexity, lack of availability, and unknown number of FCS-causing variants. FCS also has similar clinical signs as multifactorial chylomicronemia syndrome (MCS), which is more common. To differentiate between the two, researchers have developed the North American FCS (NAFCS) Score, which incorporates eight attributes: age, onset of hypertriglyceridemia (HTG), body mass index, history of abdominal pain/pancreatitis, presence of secondary factors, TG levels, ratio of TG/total cholesterol, and ApoB level to assign probability of FCS. Scores ≥60 indicate definite classical FCS and scores ≥45 are very likely FCS.

Currently, the treatment goal for FCS is to lower TG levels enough to alleviate any signs or symptoms of AP, as well as reduce the risk. TG concentrations <750–880 mg/dL are thought to lower the risk, while lowering TG concentrations to <500 mg/dL are recommended by the AACE guidelines for the treatment of severe HTG (sHTG) to reduce the risk of AP. Patients are instructed to adhere to a low-fat diet (≤20 grams of fat per day) and to avoid alcohol and medications that raise TG levels. Traditional TG lowering treatments such as, statins, fibrates, and omega-3 fatty acids, are not effective for FCS due to impaired LPL activity. Plasmapheresis may be used to manage acute, life-threatening complications of FCS. Tryngolza, an antisense oligonucleotide (ASO) that reduces serum apoC-III, was approved in December 2024 as the first FDA-approved treatment for FCS. Both Tryngolza and Redemplo lower TGs by reducing apoC-III production but have different mechanism of actions with Tryngolza working by mRNA degradation and Redemplo working by RNA interference. A direct comparison between the two drugs has not been completed.

The efficacy of Redemplo was evaluated in a randomized, placebo-controlled, double-blind Phase 3 PALISADE trial. The PALISADE trial compared Redemplo to placebo given every 3 months for a 12 month period in 75 adults. Redemplo 25mg was given to 26 patients, Redemplo 50mg was given to 24 patients, and 25 patients received placebo. The 50mg dose was not included in the FDA approval, so the efficacy results for these patients are not included. All participants had fasting TG ≥880 mg/dL at screening, were refractory to standard lipid lowering therapy, and had a history of fasting TG >1,000 mg/dL at least three times. Participants were maintained on a low-fat diet (≤20 grams fat per day) and had prior genetic testing diagnostic of FCS or clinically diagnosed FCS which included one of the following: recurrent episodes of AP not caused by alcohol or cholelithiasis, recurrent hospitalizations for severe abdominal pain without other explainable cause, history of childhood pancreatitis, or family history of HTG-induced AP. Participants were excluded from the trial if any of the following was present: current use or use within the last year of any hepatocyte-targeted siRNA or ASO, Diabetes Mellitus newly diagnosed within 12 weeks of screening or HbA1c ≥9.0% at screening, AP within 12 weeks before Day 1 of trial, history of ACS event within 24 weeks of Day 1 of trial, uncontrolled hypertension, current treatment with HIV antiretroviral therapy and seropositive for HBV or HCV, or NYHA Class II, III, or IV heart failure. The primary endpoint was the median percent change of 59% for Redemplo treated patients from baseline in fasting TG level at month 10 as shown in Table 2.

Table 2: Baseline and Percent Changes from Baseline in Lipid/Lipoprotein Parameters in Patients with FCS at Month 10 in Trial 1

Parameter (mg/dL)	REDEMPLO 25 mg N=26		Placebo (pooled) N=25		REDEMPLO 25 mg vs. Placebo
	BL	% change at Month 10	BL	% change at Month 10	Treatment Difference % change (95% CI) at Month 10
Triglycerides[b]	2008	-80	2053	-17	-59[a] (-90, -28)
Non-HDL-C[c]	279	-39	268	4	-42 (-67, -18)
LDL-C[c]	24	112	28	20	92 (4, 180)
Total ApoB[c]	72	27	79	12	15 (-16, 46)
ApoB-48[c]	10	-61	11	45	-106 (-180, -33)

Abbreviations: ApoB = apolipoprotein B; CI= confidence interval; BL = baseline; FCS=familial chylomicronemia syndrome; non-HDL-C = non-high-density lipoprotein cholesterol; LDL-C = low-density lipoprotein cholesterol.
[a] Reached statistical significance (p value < 0.0001).
[b] Median; Hodges-Lehmann method was used to estimate the median difference (location shift) and its corresponding 95% confidence interval for percent changes. Missing data were imputed using washout imputation.
[c] Mean; Analysis of covariance (ANCOVA) model was used to estimate the mean difference and its corresponding 95% confidence interval for percent changes. Missing data were imputed using washout imputation.

Secondary endpoints showed median percent change in TG from baseline and median absolute TG values that consistently demonstrated a lowering effect throughout the 12 month period as shown in Figure 1 and 2.

Figure 1: Median Percent Change from Baseline in Fasting Triglycerides Over Time in Trial 1

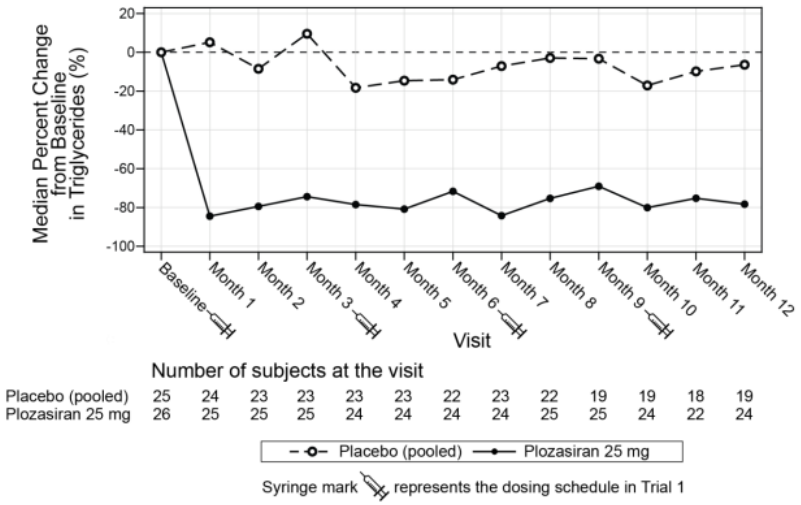
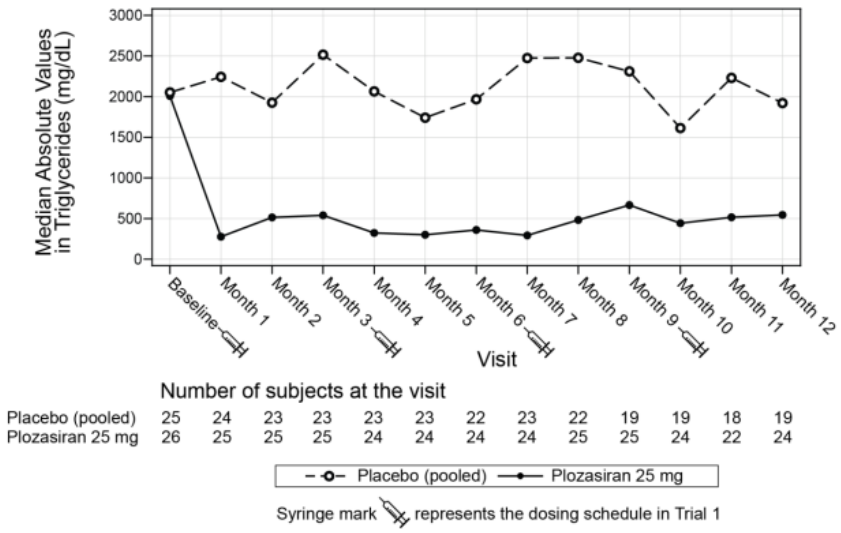


Figure 2: Median Absolute Fasting Triglyceride Levels (mg/dL) in Trial 1



Another secondary endpoint was the incidence of AP with 8% in patients treated with Redemplo 25 mg compared to 20% of placebo-treated patients.

The safety of Redemplo was evaluated in the PALISADE trial and included the Redemplo 50mg participants for a total of 75 patients. The most common adverse reactions were hyperglycemia in 20% of patients, headache in 16%, nausea in 14%, and injection site reaction in 10%. Treatment was discontinued in 6% of patients due to hyperglycemia and urticaria. There are no warnings or contraindications for Redemplo.

Safety and efficacy of Redemplo have not been established in pediatric patients. No differences were seen between patients 65 years and older and younger patients. There is insufficient data on the risk of major birth defects, miscarriage or other adverse maternal or fetal outcomes associated with the use of Redemplo in pregnant patients. The impact of severe renal impairment, end-stage renal impairment, or moderate to severe hepatic impairment is not known.

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 asked how we will evaluate members who had a significantly elevated LDL at baseline and is now somewhat improved, but still elevated. Would that be considered sufficient for approval? Kim Reichard commented that any reduction would be considered improvement, but we will reach out to specialists and evaluate treatment guidelines to determine what a clinically significant improvement would be considered. We will update the policy if necessary. Dr. Yarczower also asked if the approval for 12 months was appropriate. Kim Reichard commented that due to the administration every 3 months that is what we are recommending. Kim will additionally discuss with Kirsten who completed this review. No comments or questions. The committee unanimously voted to accept the recommendations as presented. None were opposed (28 approved, 0 rejected).

Financial Discussion: No comments or questions. The committee unanimously voted to accept the recommendations as presented. None were opposed (29 approved, 0 rejected).

Outcome: Redemplo will be a pharmacy benefit and will be added to the Commercial, Exchange, and CHIP Formulary. It is recommended to add Redemplo to the Commercial/Exchange/CHIP formularies at the Specialty tier or the Brand Non-Preferred tier for those with a three-tier benefit. The following prior authorization criteria will apply:

- Medical record documentation of ONE of the following:
    - A diagnosis of familial chylomicronemia syndrome (FCS) confirmed by genetic testing (variants in LPL, apoC-II, GPIHBP1, apoA-V, or LMF1) **OR**
    - If genetic testing is inconclusive, a diagnosis of familial chylomicronemia syndrome (FCS) confirmed by a North American FCS (NAFCS) Score ≥ 45 **AND**
- Medical record documentation of age greater than or equal to 18 years **AND**
- Medical record documentation that Redemplo is written by or in consultation with a lipidologist, endocrinologist, gastroenterologist, or cardiologist **AND**
- Medical record documentation of fasting triglycerides ≥ 880 mg/dL **AND**
- Medical record documentation that the member will adhere to a low-fat diet of ≤20 g of fat per day **AND**
- Medical record documentation that the member will NOT use concomitantly with Tryngolza

GPI LEVEL: GPI-12

QUANTITY LIMIT: 0.5mL per 90 days (1 syringe per 90 days)

Authorization Duration: Approval will be given for an initial duration of twelve (12) months or less if the reviewing provider feels it is medically appropriate. After the initial approval, subsequent approvals will be for a duration of twelve (12) months or less if the reviewing provider feels it is medically appropriate, and will require:

- Medical record documentation that the member has had a positive response to Redemplo (e.g. reduction in fasting triglycerides from baseline, reduction in acute pancreatitis episodes) **AND**
- Medical record documentation that the member is receiving a low-fat diet of ≤20 g of fat per day **AND**
- Medical record documentation that the member will NOT use concomitantly with Tryngolza

ADDITIONAL RECOMMENDATIONS: To ensure Redemplo is not concomitantly being used with Tryngolza, it is recommended to update the current Policy 860.0 Tryngolza for initial and renewal requests to include the following:

- Medical record documentation that the member will NOT use concomitantly with Redemplo.

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

RYONCIL (remestemcel-L-rknd)

Review: Ryoncil is indicated for the treatment of steroid-refractory acute graft versus host disease (SR-aGvHD) in pediatric patients 2 months of age and older. Ryoncil is comprised of culture-expanded mesenchymal stromal cells (MSCs) isolated from bone marrow of healthy humans and donors. The mechanism of action in the treatment of SR-aGvHD is unclear but may be related to immunomodulatory effects of MSCs which inhibit T cell activation and secretion of pro-inflammatory cytokines. Alloreactive donor-derived T cells in acute GvHD may trigger an immunological response and mediate systemic inflammation, cytotoxicity and potential end organ damage associated with aGVHD. Ryoncil is the first agent approved for SR-aGvHD in pediatric patients less than 12 years of age. Ryoncil will compete with Jakafi approved for SR-aGvHD in patients ≥ 12 years of age.

Ryoncil is administered by intravenous infusion with a recommended dosage of 2 x 106 mesenchymal stromal cell (MSC)/kg body weight given twice a week (at least 3 days apart) for 4 consecutive weeks for a total of 8 infusions. After 28 ± 2 days, patient response should be assessed to determine if further treatment is appropriate (Table 8).

Table 8. Recommended Treatment based on Day 28 Response

Response	Recommendation
Complete Response	No further treatment with RYONCIL
Partial or Mixed Response*	Repeat administration of RYONCIL once a week for additional 4 weeks (4 infusions total)
No Response	Consider alternative treatments
Recurrence of GvHD after complete response	Repeat administration of RYONCIL twice a week for an additional 4 consecutive weeks (8 infusions total)

*Partial response defined as organ improvement of at least one stage without worsening in any other organ, whereas mixed response was defined as improvement of at least one evaluable organ with worsening in another organ as per International Blood and Marrow Transplantation Registry Severity Index Criteria grading system.

RYONCIL is available as a cell suspension for intravenous infusion in a target concentration of 6.68 X 106 MSCs per mL in 3.8 mL at cryopreservation contained in a 6 mL cryovial. Each 6 mL cryovial contains approximately 25 x 106 MSCs. Cryopreserved MSCs are combined with Plasma-Lyte® A for administration.

The efficacy of Ryoncil was evaluated in MSB-GVHD, a prospective, single-arm study in 55 pediatric patients with SR-GvHD Grade B to D as per International Blood and Marrow Transplantation Registry Severity Index Criteria (IBMTR) after receiving allogeneic hematopoietic stem cell transplantation (HSCT). SR-aGvHD was defined as aGvHD that progressed within 3 days or did not improve within 7 consecutive days of treatment with methylprednisolone 2 mg/kg/day or equivalent. Patients who received a second line therapy for aGvHD prior to screening were excluded.

Fifty-four patients received Ryoncil at the recommended dosage twice a week for four consecutive weeks. Patients with partial or mixed response at Day 28 received Ryoncil once a week for an additional four consecutive weeks. Patients who had a complete response at Day 28 and experienced a recurrence of aGvHD received Ryoncil infusions twice a week for an additional four consecutive weeks.

The main efficacy outcome measures were Day-28 overall response rate (complete response rate and partial response rate) and the duration of response. Results are shown in Table 9.

Table 9. Efficacy Results for Study MSB-GVHD001

Response at Day 28	N=54
Overall Response Rate n (%) 95% CI[a] Duration (days) Median (range)	 38 (70%) 56.4, 82.0 54 (7, 159+)
Complete Response Rate n (%) 95% CI[a]	 16 (30%) 18.0, 43.6
Partial Response Rate[d] n (%) 95% CI[a]	 22 (41%) 27.6, 55.0

CI=confidence interval
[a] Two-sided exact binomial confidence interval at the 95% level
[b] Duration of response was calculated from Day-28 response to either progression (worsening by one stage in any organ without improvement in other organs in comparison to prior response assessment), new systemic therapy for aGvHD or death from any cause.
[c] Complete response was defined as resolution of aGvHD in all involved organs as per IBMTR grading system.
[d] Partial response was defined as organ improvement of at least one stage without worsening of any other organ as per IBMTR grading system.

Overall response rate at Day 28 by baseline disease severity is as follows: Grade B (3/6; 50%), Grade C (16/23; 70%), and Grade D (19/25; 76%). Among the 38 responders, the median time from Day-28 response to either death or need for systemic therapy for aGvHD (non-RYONCIL systemic therapy for aGvHD or increase in the dose of corticosteroids to methylprednisolone 2 mg/kg or equivalent) was 111.5 days.

Warnings and precautions include hypersensitivity and acute infusion reactions, including anaphylaxis, transmission of infectious disease or agents, and ectopic tissue formation. Serious adverse reactions occurred in 35 patients including pyrexia, respiratory failure, pneumatosis intestinalis, and staphylococcal bacteremia. Eight patients discontinued treatment due to acute infusion reactions (n=3), hypotension (n=1), gastroenteritis (n=1), and death (n=3). The most common reactions were viral infectious disorders, bacterial infectious disorders, infection – pathogen unspecified, pyrexia, hemorrhage, edema, abdominal pain and hypertension.

The safety and efficacy of Ryoncil for the treatment of SR-GvHD have been established in pediatric patients 2 months of age and older supported by evidence from an adequate and well controlled trial.

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 suggested that we reach out to transplant medicine for input. Kim Reichard commented that Ben Andrick does receive the P&T packet, but we will also reach out to transplant for input. No additional comments or questions. The committee unanimously voted to accept the recommendations as presented. None were opposed (28 approved, 0 rejected).

Financial Discussion: Dr. Yarczower asked if it would be appropriate to include a step through Jakafi for patients 12 years of age or older? Kim Reichard commented that she would ask transplant that question when she requested feedback. No additional comments or questions. The committee unanimously voted to accept the recommendations as presented. None were opposed (29 approved, 0 rejected).

Outcome: Ryoncil is a medical benefit for Commercial, Marketplace, and GHP Kids. It will be added to the medical cost share list. It will be excluded from Specialty pharmacy. The following prior authorization criteria will apply:

- Medical record documentation that Ryoncil is prescribed by a hematologist/oncologist or transplant specialist **AND**
- Medical record documentation of age greater than or equal to 2 months to less than 18 years **AND**
- Medical record documentation of a diagnosis of steroid refractory graft-versus-host disease (GVHD)

QUANTITY LIMIT:

- Initial Authorization: 2-month duration with a quantity limit of 12 doses
- Reauthorization: 1-month duration with a quantity limit of 8 doses

AUTHORIZATION DURATION: Initial approval will be for 2 months or less if the reviewing provider feels it is medically appropriate. One subsequent approval will be for an additional 1 month or less if the reviewing provider feels it is medically appropriate and will require documentation of the following:

- Medical record documentation of a complete response following initial treatment with Ryoncil **AND** documentation of recurrent steroid refractory graft-versus-host disease (GVHD)

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.

RYZNEUTA (efbemalenograstim alfa)

Review: Ryzneuta is a long acting leukocyte growth factor indicated to decrease the incidence of infection, as manifested by febrile neutropenia, in adult patients with non-myeloid malignancies receiving myelosuppressive anti-cancer drugs associated with a clinically significant incidence of febrile neutropenia. It is not indicated for the mobilization of peripheral blood progenitor cells for hematopoietic stem cell transplant. Ryzneuta binds specific cell surface receptors on hematopoietic cells and stimulates proliferation, differentiation, commitment, and end cell functional activation. It is the first non-pegylated G-CSF and will compete with Neupogen (filgrastim) and biosimilars, and Neulasta (pegfilgrastim) and biosimilars. It was thought Ryzneuta would have an advantage over pegylated G-CSF products in efficacy and safety, but at this time it does not appear to have any clinical advantages in safety or efficacy over other available treatments.

The recommended dosage of Ryzneuta is a single subcutaneous injection of 20 mg administered once per chemotherapy cycle at least 24 hours after cytotoxic chemotherapy. Ryzneuta should not be administered within 14 days before and < 24 hours after administration of cytotoxic chemotherapy. Ryzneuta should be administered by a healthcare professional. It is supplied as a 20 mg/mL prefilled syringe.

Ryzneuta safety and efficacy was evaluated in Study GC-627-04 and Study GC-627-05, two randomized, controlled studies in patients with nonmyeloid malignancies receiving myelosuppressive anti-cancer drugs.

Study GC-627-04 was a randomized, double-blind, placebo controlled study in 122 patients receiving doxorubicin and docetaxel for the treatment of metastatic or non-metastatic breast cancer. Patients were randomized to receive a single subcutaneous injection of Ryzneuta or placebo on day 2 of chemotherapy cycle 1. All patients received Ryzneuta on Day 2 of chemotherapy cycles 2-4. Efficacy was based upon the mean duration of severe (Grade 4) neutropenia in cycle 1 which was lower for the Ryzneuta treated patients as compared to placebo-treated patients (1.4 days vs. 4.3 days, respectively). The incidence of febrile neutropenia was also lower for Ryzneuta treated patients versus placebo-treated patients in Cycle 1 (4.8% vs 25.6%, respectively).

Study GC-627-05 was a randomized, active-controlled study comparing Ryzneuta to pegfilgrastim in 393 patients receiving docetaxel and cyclophosphamide for the treatment of non-metastatic breast cancer. Patients were randomized to receive a single subcutaneous injection of Ryzneuta (20 mg) or pegfilgrastim (6 mg) on day 2 of each chemotherapy cycle. Results showed that the mean days of severe (Grade 4) neutropenia in Ryzneuta treated patients did not exceed that of pegfilgrastim treated patients by more than 0.6 days in cycle 1 of chemotherapy. The mean days of severe neutropenia in cycle 1 were 0.2 days in both treatment groups.

The safety profile of Ryzneuta is comparable to the other G-CSF products. Warnings and precautions include risk of fatal splenic rupture, Acute respiratory distress syndrome (ARDS), serious allergic reactions including anaphylaxsis, sickle cell crisis in patients with sickle cell disease, glomerulonephritis, thrombocytopenia, capillary leak syndrome, myelodysplastic syndrome and acute myeloid leukemia. In clinical trials, the most common adverse reactions were nausea, anemia, thrombocytopenia, fatigue, and bone pain.

The safety and efficacy of pediatric patients have not been established. Clinical trials did not include sufficient numbers of patients aged 65 years or older to determine whether they respond differently from younger patients.

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 (28 approved, 0 rejected).

Financial Discussion: Kim Clark asked if there should be an authorization duration or quantity limit added? Kim Reichard suggested matching the Neulasta policy to allow 1 syringe per 14 days with a 6 month authorization duration. No additional comments or questions. The committee unanimously voted to accept the recommendations as presented. None were opposed (29 approved, 0 rejected).

Outcome: Ryzneuta is a medical benefit for Commercial, Marketplace, and GHP Kids. It will be added to the medical benefit cost share list. When processed at a Specialty pharmacy, Ryzneuta will process on the following tiers:

2 Tier/CHIP	3 Tier	4 Tier	ACA
Tier 2 – Brand Tier	Tier 3 – Brand NP Tier	Tier 4 – Specialty tier	Tier 6 – Specialty tier

The following prior authorization criteria will apply:

The use of Ryzneuta is considered medically necessary for the commercial, exchange, and CHIP lines of business in insured individuals with a diagnosis of cancer, and when any of the following FDA labeled indications or uses supported by clinical guidelines are present:

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

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

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

AND

- Medical record documentation of a therapeutic failure on, intolerance to, or contraindication to Ziextenzo, Udenyca, Nyvepria, Fylnetra, Stimufend, AND Fulphila.

OR

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

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

AND

- Medical record documentation of a therapeutic failure on, intolerance to, or contraindication to Ziextenzo, Udenyca, Nyvepria, Fylnetra, Stimufend, AND Fulphila.

Ryzneuta may also be considered medically necessary for any of the following:

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

- Medical record documentation of a therapeutic failure on, intolerance to, or contraindication to Ziextenzo, Udenyca, Nyvepria, Fylnetra, Stimufend, **AND** Fulphila

QUANTITY LIMIT: 1 syringe per 14 days

AUTHORIZATION DURATION: 6 months

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

KRESLADI (marnetegragene autotemcel)

Review: Kresladi is an autologous stem cell-based gene therapy indicated for the treatment of pediatric patients with severe leukocyte adhesion deficiency-I (LAD-I) due to biallelic variants in *ITGB2* without an available human leukocyte antigen (HLA)-matched sibling donor for allogenic hematopoietic stem cell transplant. This indication is approved under accelerated approval based on increase in neutrophil CD18 and CD11a surface expression as reported in clinical trial NCT03812263. Continued approval may be contingent upon verification and description of clinical benefit in a confirmatory trial(s).

Kresladi is prepared from the patient's HSCs, which are collected via apheresis procedure(s). The autologous cells are enriched for CD34+ cells, then transduced ex vivo with LV-RP-201 overnight in the presence of defined growth factors before harvest and suspended in a cryopreservation solution. LV-RP-201 is a replication-incompetent, self-inactivating lentivirus vector encoding for the CD18 β2 integrins (*ITGB2*). The ITGB2 gene is under the control of a human chimeric promotor.

Kresladi adds functional copies of the ITGB2 gene into the patient's hematopoietic stem cells (HSCs) through transduction of autologous CD34+ cells with LV-RP-201. After Kresladi infusion, transduced CD24+ HSCs engraft in the bone marrow and differentiates into various cell types, including leukocytes capable of expressing functional CD18 protein. Functional CD18 protein enables formation of the CD18/CD11a heterodimer, which facilitates leukocyte adhesion to endothelial surfaces and extravasation to infectious and inflammatory sites.

Leukocyte adhesion deficiency (LAD) is a primary immunodeficiency of both B and T cells. It is characterized by defects in the leukocyte adhesion process, marked leukocytosis, and recurrent infections, with first signs generally occurring in infancy or early childhood.

Major immunologic features of LAD include an inability to form pus, deficiency of various glycoproteins, and impaired leukocyte migration/adhesion to infection sites to kill invading microorganisms, due to mutations in the CD18 glycoprotein. Adhesion molecule deficiency results in an abnormal inflammatory response and eventually recurrent bacterial infections. There are currently three distinctly defined defects in the leukocyte adhesion cascade, each of which translates to different clinical presentations:

- LAD-I is characterized by life-threatening, recurrent bacterial infections
- LAD-II presents with leukocytosis, recurrent infections, severe growth delay, and intellectual deficit
- LAD-III (also called LAD-I variant) is characterized by both severe bacterial infections and a severe bleeding disorder

LAD-I is caused by mutations in the ITGB2 gene (21q22.3), encoding the beta-2-integrin CD18, which is essential for firm adhesion of leukocytes to the endothelium. LAD-I impacts approximately 1 in 1 million people, and the severity of the disease correlates with the degree of CD18 deficiency. Prognosis is LAD-I varies depending on the severity of the disease. Without HSCT, patients with severe LAD-I usually die from infection within the first 2 years of life, whereas those with moderate LAD-I typically have a longer disease course and typically survive childhood with recurrent skin and mucosal surface infections.

Severe LAD-I (<2% of normal levels of CD18-expressing neutrophils) is characterized by recurrent, life-threatening infections of the skin, mouth, and respiratory tract and substantial mortality (>60%) in patients younger than 2 years of age who do not receive allogenic HSCT. Current supportive management of severe LAD-I includes aggressive treatment of bacterial infections with antibiotics. The only currently available cure is HSCT.

Kresladi is for autologous use only and is given only as a one-time, intravenous single-dose. The recommended minimum dose is 2.8 x 106 CD34+ cells/kg. The dose is calculated based on the patient's weight prior to first apheresis. Kresladi is composed of one or two infusion bags which contain 0.34 to 6.1 x 106 CD34+ cells/ml suspended in a cryopreservation solution.

The efficacy of Kresladi was evaluated in one open-label, single-arm, multicenter study (RP-L201-0318; NCT03812263) in 9 pediatric patients with molecularly confirmed ITGB2-associated severe LAD-I. Severe LAD-I was defined as having neutrophil CD18 expression <2% or CD11a and/or CD11b expression <2% (if CD18 expression ≥ 2%), documented biallelic ITGB2 mutations, and clinical history consistent with severe LAD-I or a known family history. Patients were required to have had ≥ 1 prior significant bacterial or fungal infection. Patients with an available HLA-identical sibling donor for allogenic HSCT were excluded. Patients were also excluded who had significant hepatic, renal, or pulmonary dysfunction, evidence of active metastatic or locoregionally advanced malignancy for which survival is anticipated to be less than 3 years, serious infections at the time of trial entry, significant medical or psychiatric conditions, including documented HIV infection, poorly controlled diabetes, poorly controlled hypertension, poorly controlled cardiac arrhythmia or congestive heart failure, or thromboembolic events (including MI or stroke) within the 6 months prior.

The median age was 42 months (range: 9.8 months to 117 months). Three of the nine patients were siblings carrying the same pathogenic ITGB2 variant. No patients had a history of prior allogenic HSCT. Seven out of nine patients had baseline CD18 expression < 2% and all patients had baseline neutrophil CD11a expression < 2%. The surrogate endpoints for efficacy included improvement in CD18 and CD11a surface expression in neutrophils at Month 12 and sustained expression through Month 24 post-infusion.

Seven out of nine patients had baseline CD18 expression < 2% and thus were evaluable for post-treatment CD18 assessment. CD18 expression increased in all seven patients after Kresladi infusion with a median CD18 surface expression at Month 12 and Month 24 post-infusion of 54% (range: 20% to 87%) and 50% (range: 16% to 82%) respectively. Neutrophil CD18 expression was sustained through at least Month 42 post-infusion in all seven patients. Neutrophil CD11a surface expression increased after Kresladi infusion in all nine patients. Median CD11a surface expression at Month 12 and Month 24 post-infusion were 45% (range: 18% to 75%) and 39% (range: 17% to 65%) respectively. Neutrophil CD11a surface expression was sustained through at least month 42 in all nine patients. None of the nine treated patients received allogenic HSCT after Kresladi administration. The median duration of follow-up after Kresladi administration was 4.2 years (range: 3.6 to 5.7 years).

The most common non-laboratory adverse reactions (≥ 30%): mucositis, upper respiratory tract infection, viral infection, febrile neutropenia, skin lesion, nausea/vomiting, rash/dermatitis, pyrexia, device related infection, and skin infection. The most common laboratory adverse reactions (≥ 30%): hemoglobin decrease, platelet count decrease, neutrophil count decrease, leukocyte count decrease, aspartate aminotransferase increase, and alanine aminotransferase increase

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 asked about the criterion requiring that the member is an appropriate candidate for autologous transplantation of hematopoietic stem cells and if it should reflect that the member is **not** a candidate. Mark confirmed that is should state the member is **not** a candidate. Tricia Hetizman later clarified that the criterion was accurate as originally presented. Members must be able to undergo a similar procedure in order for this product to be administered. The clarification is that members do not have a medically-eligible human leukocyte antigen (HLA)-matched sibling stem cell donor OR a feasible HLA-matched sibling donor for stem cell collection is not identified which is captured in a separate criterion. No additional comments or questions. The committee unanimously voted to accept the recommendations as presented. None were opposed (27 approved, 0 rejected).

Financial Discussion: Dr. Yarczower asked if we have any members with this diagnosis? Mark confirmed that we currently have no members and none within the last 5 years with that ICD-10 codes. No additional comments or questions. The committee unanimously voted to accept the recommendations as presented. None were opposed (30 approved, 0 rejected).

Outcome: Kresladi will be 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 an age greater than or equal to 3 months and less than 18 years of age AND
- Medical record documentation that Kresladi is being prescribed by or in consultation with an immunologist, hematologist, oncologist, infectious disease specialist, or other providers with expertise in the diagnosis and treatment of leukocyte adhesion deficiency-I (LAD-I) AND
- Medical record documentation of a confirmed diagnosis of severe LAD-I demonstrated by **ONE** of the following:
    - Flow cytometry indicating CD18 expression on < 2% neutrophils (polymorphonuclear neutrophils [PMNs]) OR
    - For patients in which CD18+ PMNs are > 2%, one of the following:
        - <2% CD11a or CD11b expressing PMNs AND
        - Documented *ITGB2* mutation AND
        - Clinical history consistent with LAD-I **OR** documented known family history of LAD-I
- Medical record documentation that the patient is considered to be an appropriate candidate for autologous transplantation of hematopoietic stem cells AND
- Medical record documentation that the patient is **NOT** pregnant or breastfeeding AND
- Medical record documentation that the patient does **NOT** have a medically-eligible human leukocyte antigen (HLA)-matched sibling stem cell donor **OR** a feasible HLA-matched sibling donor for stem cell collection is not identified (e.g., donor is in utero, is a newborn from whom cord blood was not collected, or is unable to undergo donation procedure because of medical impairments) AND
- Medical record documentation that the patient does **NOT** have hepatic dysfunction as defined by bilirubin > 1.5 x the upper limit of normal OR alanine aminotransferase (ALT) or aspartate aminotransferase (AST) > 2.5 x the upper limit of normal AND
- Medical record documentation that the patient does **NOT** have renal dysfunction or the requirement for either peritoneal dialysis or hemodialysis AND
- Medical record documentation that the patient does **NOT** have pulmonary dysfunction as defined by either the need for supplemental oxygen during the prior 2 weeks (in absence of acute infection) **OR** oxygen saturation (by pulse oximetry) < 90% AND
- Medical record documentation that the patient does **NOT** have a serious, untreated infection with persistent bloodstream pathogens AND
- Medical record documentation that the patient does **NOT** have active or metastatic locoregionally advanced malignancy (including hematologic malignancy) for which survival is anticipated to be less than 3 years AND
- Medical record documentation that the patient does **NOT** have significant medical conditions including documented human immunodeficiency virus (HIV) infection, poorly controlled diabetes, poorly controlled hypertension, poorly controlled cardiac arrhythmia or heart failure, or arterial

thromboembolic events (including myocardial infarction or stroke) within the prior 6 months AND
- Medical record documentation that the patient has **NOT** received prior treatment with Kresladi

AUTHORIZATION DURATION: One (1) time approval (auth duration: 3 months) per lifetime. Requests for authorizations exceeding these limits will require the following 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 beyond the FDA-approved treatment duration.

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

ZEVASKYN (prademagene zamikeracel)

Review: Zevaskyn is indicated for the treatment of wounds in adult and pediatric patients with recessive dystrophic epidermolysis bullosa (RDEB). It is a gene therapy comprised of a patient's own cells genetically modified to express COL7A1 gene to produce C7 protein, which forms anchoring fibrils (AFS). In RDEB, both copies of the COL7A1 gene are mutated, resulting in low or absent levels of C7 protein and decreased formation of Afs. The lack of Afs disrupts the connection between the epidermis and dermis causing skin fragility and other symptoms of RDEB.

Zevaskyn combines the modified cells into cellular sheets for autologous topical application to wounds. After Zevaskyn is prescribed and once payer approval is obtained, two 8-mm skin punch biopsies are collected from the patient in the outpatient setting of the qualified treatment center (QTC).Zevaskyn is prepared by the manufacturer and shipped directly to the qualified treatment center for surgical application by a healthcare professional. The recommended dosage is based on the surface area of the wound. One sheet of Zevaskyn covers an area of 41.25 cm2. Up to 12 Zevaskyn sheets may be manufactured from the patient biopsies and supplied for potential use. Zevaskyn sheets are applied unaltered onto the would bed only by affixing with resorbable sutures. Zevaskyn should not be sutured to healthy intact skin, should not be overlapped, and all selected sheets should be applied in a single session. Due to Zevaskyn's autologous nature, in case of a manufacturing failure, a second manufacturing of Zevaskyn may be attempted and would require a repeat biopsy.

The efficacy of Zevaskyn was evaluated during the VIITAL trial, randomized, intrapatient-controlled study. The study compared Zevaskyn to standard of care treatment in patients with RDEB wounds. Patients were required to have at least one pair of matched, large (at least one wound ≥ 20 cm2 for treatment and at least one wound ≥ 20 cm2 for control) and chronic wounds (open for ≥ 6 months) associated with RDEB. Patients with current or history of squamous cell carcinoma (SCC) at the treatment site were excluded. Matched wound pairs were randomized in a 1:1 ratio to receive either Zevaskyn (up to 6 sheets) or control treatment (standard of care wound dressings).

A total of 86 wounds in 11 patients were enrolled and treated with Zevaskyn or standard of care in the study. The wounds assessed in the study at baseline had been open for a median of 5 years (range 0.5-21 years). The co-primary efficacy outcome measures were 1) proportion of randomized wound pairs with at least 50% healing at Month 6 with confirmation of wound healing two weeks later as assessed using baseline digital photography by the Investigator, and 2) pain reduction as assessed by the mean differences in patient-reported pain scores using the Wong-Baker FACES scale between randomized wound pairs at Month 6. Secondary endpoints were proportion of randomized wound pairs with complete wound healing defined as reepithelialization with no drainage or erosion and presence of only minor crusting from baseline at Month 3 and at Month 6 with confirmation of wound healing two weeks later. Efficacy results are shown in Table 4.

Table 4. Efficacy results for VIITAL Study (N=86 wounds)

Efficacy endpoint	ZEVASKYN (N=43 wounds)	Control (N=43 wounds)	P value
Proportion of randomized wound pairs healed ≥50% from baseline at Month 6[a] n (%)	35 (81%)	7 (16%)	<0.0001
Mean pain reduction from baseline at Month 6[b] Mean (SD)	-3.07 (3.19)	-0.90 (2.73)	0.0002
Proportion of randomized wound pairs completely healed from baseline at Month 3 n (%)	6 (14%)	0 (0%)	0.0316
Proportion of randomized wound pairs completely healed from baseline at Month 6[a] n (%)	7 (16%)	0 (0%)	0.0160

N=total number of observations; SD=Standard deviation; %=percentage
Complete wound healing is defined as re-epithelialization with no drainage or erosion and presence of only minor crusting.
[a] The proportion of wounds achieving success criteria at Month 6 must have been confirmed at least 2 weeks later.
[b] One wound was excluded from the control group due to missing baseline value.

Of note, no patients involved in clinical trials for Zevaskyn have received re-treatment on previously treated wounds, unlike Vyjuvek and Filsuvez, which have transient effects and require chronic application to open wounds.

Warnings and precautions include risk of severe hypersensitivity to vancomycin, amikacin, or product excipients with application, retroviral vector (RVV)-mediated insertional oncogenesis, and transmission of infections agents (manufactured process uses human and bovine-derived reagents). In clinical trials, the most common adverse reactions were procedural pain and pruritis.

The safety and efficacy of Zevaskyn has been established in pediatric patients, supported by evidence from clinical trials which included two pediatric patients aged 6 years and 16 years. The safety and efficacy of Zevaskyn has not been established in patients aged ≥ years of age.

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 (32 approved, 0 rejected).

Financial Discussion: Dr. Yarczower asked Discussion No comments or questions. The committee unanimously voted to accept the recommendations as presented. None were opposed (32 approved, 0 rejected).

Outcome: Zevaskyn is a medical benefit for Commercial, Marketplace, and GHP Kids. It will be added to the medical cost share list. It will be excluded from Specialty pharmacy. The following prior authorization criteria will apply:

- Medical record documentation that Zevaskyn is prescribed by or in consultation with a dermatologist or wound care specialist who specializes in epidermolysis bullosa (EB) management **AND**
- Medical record documentation of age greater than or equal to 6 years **AND**
- Medical record documentation of diagnosis of recessive dystrophic epidermolysis bullosa (RDEB) **AND**
- Medical record documentation of at least one clinical feature of RDEB (recessive dystrophic epidermolysis bullosa) including but not limited to blistering, scarring and skin wounds **AND**
- Medical record documentation of genetic testing confirming mutation(s) in both alleles in the collagen type VII alpha 1 chain (COL7A1) gene **AND**

- Medical record documentation of at least one open dystrophic epidermolysis bullosa (DEB) wound AND all of the following:
    - documentation of the presence of partial-thickness RDEB wounds open chronically for greater than or equal to 6 months **AND**
    - documentation that member does not have current evidence or a history of squamous cell carcinoma (SCC) in the wound area **AND**
    - documentation that the wound area has not been previously treated with Zevaskyn **AND**
- Medical record documentation that member does not have an immune response to C7 by indirect immunofluorescence (IIF) **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 that Zevaskyn will not be used concomitantly with another treatment indicated for dystrophic epidermolysis bullosa (DEB) (i.e. Vyjuvek, Filsuvez)

AUTHORIZATION DURATION: Approve for three months auth duration for one application of up to 12 gene-modified cellular sheet.

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

CLASS REVIEWS

NEW ONCOLOGY FORMULATIONS

New Oncology Formulations

Brand Name	Generic	Formulation	Manufacturer
Rybrevant Faspro	Amivantamab/ hyaluronidase-lpuj	New subcutaneous formulation of Rybrevant	Janssen Biotech, Inc.
Lunsumio Velo	Mosunetuzumab-axgb	Subcutaneous injection of Lunsumio	Genentech, Inc.
Jobevne	Bevacizumab-nwgd	Avastin Biosimilar	Biocon Biologics Inc.
Kyxata	Carboplatin	Multidose intravenous formulation of carboplatin	Avyxa Pharma, LLC
Ivra	Melphalan injection	Ready to dilute solution formulation of melphalan	Apotex Corp
Pemrydi RTU	Pemetrexed	Ready to use intravenous formulation of pemetrexed (no reconstitution or dilution)	Amneal Pharmaceuticals LLC
Boruzu	Bortezomib	Ready to use subcutaneous formulation of bortezomib, can be diluted for intravenous use	Amneal Pharmaceuticals LLC
Zusduri	Mitomycin	Intravesical instillation formulation of mitomycin	UroGen Pharma, Inc

Rybrevant Faspro

Rybrevant Faspro is a subcutaneous formulation of amivantamab (Rybrevant) indicated:

- in combination with lazertinib for the first-line treatment of adult patients with locally advanced or metastatic NSCLC with EGFR exon 19 deletions or exon 21 L858R substitution mutations, as detected by an FDA-approved test.
- in combination with carboplatin and pemetrexed for the treatment of adult patients with locally advanced or metastatic NSCLC with EGFR exon 19 deletions or exon 21 L858R substitution mutations, whose disease has progressed on or after treatment with an EGFR tyrosine kinase inhibitor.
- in combination with carboplatin and pemetrexed for the first-line treatment of adult patients with locally advanced or metastatic NSCLC with EGFR exon 20 insertion mutations, as detected by an FDA-approved test.
- as a single agent for the treatment of adult patients with locally advanced or metastatic NSCLC with EGFR exon 20 insertion mutations, as detected by an FDA approved test, whose disease has progressed on or after platinum-based chemotherapy

These indications are consistent with Rybrevant and are supported by previous clinical trials evaluating the safety and efficacy of Rybrevant as well as a PALOMA-3, an open-label, randomized trial in adult patients with NSCLC who were randomized to Rybrevant Faspro or intravenous admivantamab in combination with lazeritinib. Amivantamab exposure was comparable between the two treatment groups following administration. Rybrevant Faspro + Lazertinib demonstrated noninferiority to intravenous amivantamab + lazertinib, with a comparable safety profile and survival rate.

Rybrevant Faspro is administered subcutaneously by a healthcare professional. The following dosages are recommended for Rybrevant Faspro.

In Combination with Carboplatin & Pemetrexed

Rybrevant Faspro is given every 3 weeks based on baseline body weight (Table 1).

Table 1. Recommended Dosage for Rybrevant Faspro in Combination with Carboplatin and Pemetrexed (Every 3-Week Dosing)

Body Weight at Baseline*	Recommended Dose	Dosing Schedule
Less than 80 kg	1,600 mg amivantamab and 20,000 units hyaluronidase	First dose at Week 1 Day 1
	2,400 mg amivantamab and 30,000 units hyaluronidase	Weekly (total of 2 doses) from Weeks 2 to 3 • Weeks 2 to 3 – Injection on Day 1
		Every 3 weeks starting at Week 4 onwards
Greater than or equal to 80 kg	2,240 mg amivantamab and 28,000 units hyaluronidase	First dose at Week 1 Day 1
	3,360 mg amivantamab and 42,000 units hyaluronidase	Weekly (total of 2 doses) from Weeks 2 to 3 • Weeks 2 to 3 – Injection on Day 1
		Every 3 weeks starting at Week 4 onwards

* Dose adjustments not required for subsequent body weight changes.

In Combination with Lazertinib or as a Single Agent

Rybrevant is administered every two weeks based on body weight according to Table 2.

Table 2. Recommended Dosage for Rybrevant Faspro in Combination with Lazertinib or as a Single Agent (Every 2-Week Dosing)

Body Weight at Baseline*	Recommended Dose	Dosing Schedule
Less than 80 kg	1,600 mg amivantamab and 20,000 units hyaluronidase	Weekly (total of 4 doses) from Weeks 1 to 4 • Weeks 1 to 4 – Injection on Day 1
		Every 2 weeks starting at Week 5 onwards
Greater than or equal to 80 kg	2,240 mg amivantamab and 28,000 units hyaluronidase	Weekly (total of 4 doses) from Weeks 1 to 4 • Weeks 1 to 4 – Injection on Day 1
		Every 2 weeks starting at Week 5 onwards

* Dose adjustments not required for subsequent body weight changes.

No new safety signals have been identified with Rybrevant Faspro and the warnings and precautions are consistent with the known safety profile of Rybrevant. The safety and efficacy of Rybrevant Faspro has not been evaluated in pediatric patients.

In PALOMA-3, 35% of 206 patients with locally advanced or metastatic NSCLC treated with Rybrevant Faspro were 65 years of age or older and 9% were 75 years or older. No clinically important differences in safety or efficacy were observed between patients who were ≥ 65 years of age and younger patients.

Lunsumio Velo

Lunsumio Velo is a new subcutaneous formulation of Lunsumio, a bispecific CD20-directed CD4 T-cell engager indicated for treatment of adult patients with relapsed or refractory follicular lymphoma after two or more lines of systemic therapy.

Lunsumio Velo is administered by subcutaneous injection by a healthcare professional. Like Lunsumio, it is administered for 8 cycles unless patients experience unacceptable toxicity or disease progression. For patients with a partial response and/or stable disease after 8 cycles, an additional 9 cycles should be administered. The recommended dosage of Lunsumio is Cycle 1: Day 1: 5 mg, Day 8 and Day 15: 45 mg; then Cycle 2+: Day 1: 45 mg in 21 day cycles.

The efficacy of Lunsumio Velo was evaluated in GO29781, an open-label multicohort trial in patients with relapsed or refractory FL after at least two lines of systemic therapy. Patients received subcutaneous injections of Lunsumio Velo according the recommended dosage with each treatment cycle lasting 21 days. Patients received 8 cycles unless they experienced disease progression or unacceptable toxicity. Efficacy was evaluated as objective response rate and duration of response based on 2007 International

Working Group criteria. Efficacy results showed a 75% response rate, with 59% of patients achieving a complete response and 16% of patients achieving a partial response. The median duration of response was 22.4 months.

The safety profile of Lunusmio Velo is consistent with the known safety profile of Lunsumio. Additional risks may arise from the incorrect formulation being prescribed, dispensed, or administered since Lunsumio and Lunsumio Velo have different dosages and routes of administration.

Safety and efficacy of Lunsumio Velo has not been established in pediatric patients. Of the 94 patients treated with Lunsumio Velo in clinical trials, 51% of patients were 65 years or older. There was not a sufficient number of patients 65 years and older to determine if there were differences in safety or efficacy between older and younger patients.

Jobevne
Jobevne is a biosimilar to Avastin, with the following indications:

- Metastatic colorectal cancer, in combination with intravenous fluorouracilbased chemotherapy for first-or second-line treatment.
- Metastatic colorectal cancer, in combination with fluoropyrimidineirinotecan-or fluoropyrimidine-oxaliplatin-based chemotherapy for secondline treatment in patients who have progressed on a first-line bevacizumab product-containing regimen
  Limitations of Use: Jobevne is not indicated for adjuvant treatment of colon cancer.
- Unresectable, locally advanced, recurrent or metastatic non-squamous non-small cell lung cancer, in combination with carboplatin and paclitaxel for first-line treatment.
- Recurrent glioblastoma in adults.
- Metastatic renal cell carcinoma in combination with interferon alfa.
- Persistent, recurrent, or metastatic cervical cancer, in combination with paclitaxel and cisplatin, or paclitaxel and topotecan.
- Epithelial ovarian, fallopian tube, or primary peritoneal cancer:
  - in combination with carboplatin and paclitaxel, followed by Jobevne as a single agent, for stage III or IV disease following initial surgical resection
  - in combination with paclitaxel, pegylated liposomal doxorubicin, or topotecan for platinum-resistant recurrent disease who received no more than 2 prior chemotherapy regimens
  - in combination with carboplatin and paclitaxel or carboplatin and gemcitabine, followed by Jobevne as a single agent, for platinum-sensitive recurrent disease

The recommended dosage is consistent with Avastin and other biosimilars and is 5-15 mg/kg administered every two or three weeks depending on the indication.

No new clinical trials were conducted for Jobevne and approval is supported by comparative pharmacokinetic, safety, efficacy, nonclinical, structural, analytical and functional data which showed no clinically meaningful differences between Jobevne and Avastin.

No new safety signals were identified for Jobevne. The safety and efficacy has not been established in pediatric patients. In a pooled analysis of 1745 patients treated with bevacizumab, 35% of patients were 65 years and older. The overall incidence of arterial thrombotic events was increased in all patients receiving bevacizumab with chemotherapy as compared to those receiving chemotherapy alone, regardless of age; however, the increase in the incidence of ATE was greater in patients ≥ 65 years (8% vs. 3%) as compared to patients < 65 years (2% vs. 1%).

Kyxata
Kyxata is a new formulation of carboplatin that is indicated in adults:

- As part of a combination regimen, for the initial treatment of advanced ovarian carcinoma.
- As a single-agent for the treatment of ovarian carcinoma recurrent after prior chemotherapy.

The recommended dosage of Kyxata for initial treatment of advanced ovarian carcinoma is 300 mg/m^2 or AUC of 4 mg/mL-min to 6 mg/mL-min intravenously in combination with cyclophosphamide on Day 1 every 4 weeks for each cycle for up to 6 cycles or until disease progression of unacceptable toxicity. For patients with recurrent advanced ovarian carcinoma, the recommended dosage of Kyxata is 360 mg/m^2 or AUC of 4 mg/mL-min to 6 mg/mL-min intravenously on Day 1 every 4 weeks until disease progression or unacceptable toxicity. Kyxata is supplied as multiple-dose vials containing 80 mg/8 mL and 500 mg/50 mL

Kyxata is nearly identical to the listed carboplatin product, Paraplatin. No new clinical trials were conducted and no new clinical or non-clinical data was submitted for this approval. Kyxata was approved through the FDA 505(b)(2) pathway.

Ivra
Ivra is a ready-to-dilute formulation of melphalan, indicated for the palliative treatment of patients with multiple myeloma for whom oral therapy is not appropriate.

The recommended dose is 16 mg/m^2 administered intravenously over 15 to 20 minutes at 2-week intervals for 4 doses, then, after adequate recovery from toxicity, at 4-week intervals. Ivra is supplied as 90 mg/mL amber glass multiple-dose vial for dilution.

Compared to the listed product (Alkern), Ivra has the same active ingredient, route of administration, dosing regimen and concentration after dilution but is available as a ready to dilute solution compared to Alkern lyophilized powder injection for reconstitution.

The approval of Ivra is based on the clinical findings of safety and efficacy of Alkern as well as physiochemical properties, in vitro protein binding, and hemolysis data to establish a scientific bridge. The submitted data showed that differences in formulation and dosage form were unlikely to impact disposition or pharmacokinetics of melphalan when administered intravenously. Ivra was approved through the FDA 505(b)(2) pathway.

Pemrydi RTU
Pemrydi RTU is a ready-to-use formulation of pemetrexed (Alimta) indicated:

- in combination with pembrolizumab and platinum chemotherapy, for the initial treatment of patients with metastatic non-squamous non-small cell lung cancer (NSCLC), with no EGFR or ALK genomic tumor aberrations.
- in combination with cisplatin for the initial treatment of patients with locally advanced or metastatic, non-squamous NSCLC.
- as a single agent for the maintenance treatment of patients with locally advanced or metastatic, non-squamous NSCLC whose disease has not progressed after four cycles of platinum-based first-line chemotherapy.
- as a single agent for the treatment of patients with recurrent, metastatic non-squamous, NSCLC after prior chemotherapy.
  Limitations of Use: Pemrydi RTU is not indicated for the treatment of patients with squamous cell, non-small cell lung cancer.
- initial treatment, in combination with cisplatin, of patients with malignant pleural mesothelioma whose disease is unresectable or who are otherwise not candidates for curative surgery.

The recommended dosage of Pemrydi RTU is consistent with Alimta and is 500 mg/m^2 on Day 1 of a 21 day cycle. Duration of treatment is dependent on the indication.

Pemrydi RTU is supplied as a ready-to-use solution in a glass vial containing 100 mg/10 ML, 500 mg/50 mL, or 1000 mg/100 mL in single-dose vials. Other pemetrexed products are supplied as multi-dose vials that require dilution.

No clinical trials were conducted and approval is based on the listed product Alimta. Pemrydi RTU was approved through the FDA 505(b)(2) pathway.

Boruzu
Boruzu is a new ready-to-use formulation of bortezomib (Velacade) for subcutaneous administration that does not require dilution or reconstitution. Boruzu can also be diluted for intravenous administration. Boruzu is indicated for the treatment of adult patients with multiple myeloma or mantle cell lymphoma.

The recommended starting dosage of Boruzu is 1.3 mg/m^2 administered either as a 3 or 5 second bolus intravenous injection or subcutaneous injection. Each route of administration has a different final concentration. Boruzu is administered intravenously at a concentration of 1 mg/mL and a concentration of 2.5 mg/mL when administered subcutaneously. Boruzu is supplied as 3.5 mg/ 1.4 mL in a single-dose vial. In previously untreated MM, Boruzu is administered twice weekly for Cycles 1-4, then once weekly for Cycles 5 to 9. In previously untreated MCL, Boruzu is administered IV for 6, 3 week treatment cycles at a concentration of 1 mg/mL when administered intravenously twice weekly for two weeks, then a 10 day rest period on Days 12 to 21.

No new clinical or non-clinical data was submitted with this approval. Approval was based on the listed drug, Velcade. Boruzu was approved through the FDA 505(b)(2) pathway.

Zusduri
Zusduri is an intravesical formulation of mitomycin indicated for the treatment of adult patients with recurrent low-grade intermediate-risk non-muscle invasive bladder cancer (LG-IR-NMIBC).

The recommended dosage of Zusduri is 75 mg (56 mL) instilled once weekly for 6 weeks. It is reconstituted and then administered into the bladder via a urinary catheter. Each intravesical solution kit contains two 40 mg single-dose vials of powdered mitomycin and one single-dose vial of sterile, clear, colorless gel to be used as a vehicle for reconstitution. The hydrogel-based formulation of mitomycin is expected to increase mitomycin's dwell time and prolong exposure of the bladder tissue to mitomycin.

Most patients with LG-IR-NMIBC are initially treated with a transurethral resection of bladder tumor (TURBT) followed by immediate instillation of intravesical chemotherapy (mitomycin/gemcitabine) or immunotherapy (Bacillus Calmette–Guérin [BCG]) to eliminate any residual tumor cells. Zusduri has the potential to offer a more superficial, minimally invasive, and nonsurgical alternative to TURBT, as it can be administered without anesthesia or special equipment.

The efficacy of Zusduri was evaluated in ENVISION, a single-arm, multicenter trial in 240 patients with recurrent low-grade intermediate-risk non-muscle invasive bladder cancer (LG-IR-NMIBC), of whom 223 were evaluable for response. LG-IR-NMIBC was defined as Ta disease, histologically confirmed by biopsy, having one or two of the following: the presence of multiple tumors, a solitary tumor > 3 cm, and/or early or frequent recurrence (≥ 1 occurrence of LG-NMIBC within 1 year of the current diagnosis).

Patients received 75 mg via urinary catheter once a week for 6 weeks.

The major efficacy outcome measures were complete response rate (CR) at 3 months (defined as no detectable disease in the bladder by cystoscopy, biopsy [if indicated], and urine cytology) and duration of response.

Efficacy results showed a 78% complete response rate with a duration range from 0 to 25+ months and 79% of 173 patients with a response having a response lasting at least 12 months.

Warnings and precautions include risk in patients with perforated bladder or in whom the integrity of the bladder mucosa has been compromised. The most common adverse reactions in clinical trials were e increased creatinine, increased potassium, dysuria, decreased hemoglobin, increased aspartate aminotransferase, increased alanine aminotransferase, increased eosinophils, decreased lymphocytes, urinary tract infection, decreased neutrophils, and hematuria.

Clinical Discussion: No comments or questions. The committee unanimously voted to accept the recommendations as presented. None were opposed (30 approved, 0 rejected).

Financial Discussion: Dr. Yarczower asked if this was a rebated drug category to which Austin and Keith clarified that we are collecting rebates and the recommendations presented will optimize those opportunities. No additional comments or questions. The committee unanimously voted to accept the recommendations as presented. None were opposed (29 approved, 0 rejected).

Outcome:

Medication	Benefit Type	Recommendations

Rybrevant Faspro	Medical Benefit	Rybrevant Faspro will require a prior authorization, Add to Medical Benefit Policy 239.0 for all lines of business as follows:
		
		• Medical record documentation that Rybrevant or Rybrevant Faspro is prescribed by a hematologist or oncologist **AND**
		• Medical record documentation of age greater than or equal to 18 years **AND**
		• Medical record documentation of a diagnosis of with locally advanced or metastatic non-small cell lung cancer (NSCLC) **AND**
		• One of the following:
		  ○ Medical record documentation of epidermal growth factor receptor (EGFR) exon 20 insertion mutations as determined by an FDA approved test* **AND** one of the following:
		  ▪ Medical record documentation of disease progression on or following prior treatment with a platinum-based chemotherapy AND that Rybrevant or Rybrevant Faspro will be used as a single agent **OR**
		  ▪ Medical record documentation that Rybrevant or Rybrevant Faspro is being used as first line treatment AND that Rybrevant or Rybrevant Faspro will be used in combination with carboplatin and pemetrexed
		OR
		  ○ Medical record documentation of epidermal growth factor receptor (EGFR) exon 19 deletions or exon 21 L858R substitution mutations as determined by an FDA-approved test **AND** one of the following:
		  ▪ Medical record documentation that Rybrevant or Rybrevant Faspro is being used as first-line treatment AND Rybrevant will be used in combination with Lazcluze (Lazertinib) **OR**
		  ▪ Medical record documentation of disease progression on or following treatment with an epidermal growth factor receptor (EGFR) tyrosine kinase inhibitor AND Rybrevant or Rybrevant Faspro will be used in combination with carboplatin and pemetrexed
		
		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 if the reviewing provider feels it is medically appropriate and will require medical record documentation of continued disease improvement or lack of disease progression. The medication will no longer be covered if patient experiences toxicity or worsening of disease.
		
		***NOTE:** The FDA approved test for Rybrevant or Rybrevant Faspro to detect the presences of EGFR exon 20 insertion mutations is the Guardant360® CDx

Lunsumio Velo	Medical Benefit	Lunsumio Velo will require a prior authorization and should be added to Medical Benefit Policy 280.0 for all lines of business as follows: • Medical record documentation that Lunsumio or Lunsumio Velo is written by a hematologist or oncologist **AND** • Medical record documentation of age greater than or equal to 18 years of age **AND** • Medical record documentation of a diagnosis with relapsed or refractory follicular lymphoma **AND** • Medical record documentation of prior treatment with two or more lines of therapy

		AUTHORIZATION DURATION: Approval of Lunsumio or Lunsumio Velo will be given for an initial authorization of 6 months or less if the reviewing provider feels it is medically appropriate. One subsequent approval will be given for 12 months or less if the reviewing provider feels it is medically appropriate, not to exceed the limitations outlined below. Authorization of Lunsumio or Lunsumio Velo for the treatment of relapsed or refractory follicular lymphoma should not exceed the FDA-approved treatment duration of 8 total cycles for patients who are in complete remission following 8 cycles of Lunsumio treatment. Authorization of Lunsumio or Lunsumio Velo for the treatment of relapsed or refractory follicular lymphoma should not exceed the FDA-approved treatment duration of 17 total cycles for patients who are in partial remission or stable disease following 8 cycles of Lunsumio treatment. For requests exceeding the above limits, 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
Jobevne	Medical Benefit	Jobevne will not require a prior authorization (consistent with other bevacizumab biosimilars) and should be added to Medical Benefit Policy 309.0 for all lines of business as follows: For commercial, exchange, CHIP, and Medicaid lines of business, Alymsys (bevacizumab-maly), Mvasi (bevacizumab-awwb), Vegzelma (bevacizumab-adcd), Jobevne (bevacizumab-nwgd), and Zirabev (bevacizumab-bvzr) do not require prior authorization. Avastin (bevacizumab) used for intravitreal injection does NOT require prior authorization. Otherwise, Avastin (bevacizumab) will be considered medically necessary when ALL of the following criteria are met: • Medical record documentation of a therapeutic failure of, intolerance to, or contraindication to **all** of the following: Alymsys (bevacizumab-maly), Mvasi (bevacizumab-awwb), Vegzelma (bevacizumab-adcd), Zirabev (bevacizumab-bvzr), and Jobevne (bevacizumab-nwgd), **AUTHORIZATION DURATION**: For adjuvant treatment of Stage III or IV Epithelial Ovarian, Fallopian Tube or Primary Peritoneal Cancer following initial surgical resection: Authorization will be for one (1) 21 month approval. Authorization of Avastin for adjuvant treatment should not exceed the FDA-approved treatment duration of 21 months (28 cycles). For requests exceeding the above limit, medical record documentation of the following is required: • Peer-reviewed literature citing well-designed clinical trials to indicate that the member's healthcare outcome will be improved by dosing beyond the FDA-approved treatment duration For all other indications: Authorization will be open-ended
Kyxata	Medical Benefit	Kyxata will require a prior authorization for the medical benefit for all lines of business with the following prior authorization criteria: • Medical record documentation Kyxata is being used as part of a combination regimen for the initial treatment of advanced ovarian carcinoma OR as a single-agent for the treatment of ovarian carcinoma recurrent after prior chemotherapy AND • Medical record documentation of therapeutic failure, intolerance, or contraindication to generic carboplatin products Auth duration: 6 months
Ivra	Medical Benefit	Ivra will require a prior authorization for the medical benefit for all lines of business with the following prior authorization criteria:

		• Medical record documentation that Ivra will be used for the palliative treatment of patients with multiple myeloma for whom oral therapy is not appropriate AND • Medical record documentation of therapeutic failure, intolerance, or contraindication to generic melphalan products Auth duration: 6 months
Pemrydi RTU	Medical Benefit	Pemrydi RTU will require a prior authorization for the medical benefit for all lines of business with the following prior authorization criteria: • Medical record documentation that Pemrydi RTU will be used in combination with pembrolizumab and platinum chemotherapy for initial treatment of patients with metastatic non-squamous non-small cell lung cancer (NSCLC) AND documentation of no EGFR or ALK genomic tumor aberrations OR • Medical record documentation that Pemrydi RTU will be used in combination with cisplatin for the initial treatment of patients with locally advanced or metastatic, non-squamous NSCLC OR • Medical record documentation that Pemrydi RTU will be used as a single agent for the maintenance treatment of patients with locally advanced or metastatic, non-squamous NSCLC whose disease has not progressed after four cycles of platinum-based first-line chemotherapy OR • Medical record documentation that Pemrydi RTU will be used as a single agent for the treatment of patients with recurrent, metastatic non-squamous, non-small cell lung ancer (NSCLC) after prior chemotherapy OR • Medical record documentation that Pemrydi RTU will be used in combination with cisplatin for initial treatment of malignant pleural mesothelioma whose disease is unresectable or who are otherwise not candidates for curative surgery AND • Medical record documentation of therapeutic failure, intolerance, or contraindication to generic pemetrexed products Auth duration: 6 months
Boruzu	Medical Benefit	Boruzu will require a prior authorization for the medical benefit for all lines of business with the following prior authorization criteria: • Medical record documentation of age greater than or equal to 18 years AND • Medical record documentation of a diagnosis of multiple myeloma or mantle cell lymphoma AND • Medical record documentation of therapeutic failure, intolerance, or contraindication to generic bortezomib products Auth duration: 6 months
Zusduri	Medical Benefit	Zusduri will require a prior authorization for the medical benefit for all lines of business with the following prior authorization criteria: • Medical record documentation that Zusduri is prescribed by a hematologist/oncologist or urologist AND • Medical record documentation of a diagnosis of recurrent low-grade intermediate-risk non-muscle invasive bladder cancer (LG-IR-NMIBC) AND • Medical record documentation of age greater than or equal to 18 years **AUTHORIZATION DURATION**: Authorization will be for one 6 (six) month approval. Authorization of Zusduri for the treatment of LG-IR-NMIBC should not exceed the FDA-approved treatment duration of 6 weekly doses. 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

Rybrevant Faspro, Lunsumio Velo, Jobevne will be added to the medical cost share list. When processed at Specialty pharmacy, they will process on the following tiers:

2 Tier/CHIP	**3 Tier**	**4 Tier**	**ACA**
Tier 2 – Brand	Tier 3 – Brand NP	Tier 4 – Specialty	Tier 6 - Specialty

Kyxata, Ivra, Pemrydi RTU, Boruzu, and Zusduri will be added to the medical cost share list. They will be excluded from Specialty pharmacy.

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

FAST FACTS

WEGOVY TABLET (semaglutide)

Clinical Summary: Wegovy tablets, in combination with a reduced calorie diet and increased physical activity, are indicated: 1) to reduce the risk of major adverse CV events (CV death, non-fatal myocardial infarction, or non-fatal stroke) in adults with established CV disease and either obesity or overweight, and 2) to reduce excess body weight and maintain weight reduction long term in adults with obesity, or in adults with overweight in the presence of at least one weight-related comorbid condition.

Wegovy tablets are available in 1.5mg, 4mg, 9mg and 25mg strengths. The recommended starting dosage of Wegovy tablets is 1.5 mg taken orally once daily. The dosage escalation in the table below is recommended to reduce the risk of gastrointestinal adverse reactions. If patients do not tolerate a dose during dosage escalation, delaying dosage escalation could be considered. The recommended maintenance dosage of Wegovy tablets is 25 mg orally once daily. If patients do not tolerate the 25 mg once daily maintenance dosage, consider switching to Wegovy injection 1.7 mg once weekly.
Please see the table below for the titration schedule.

Treatment	Days	Once Daily Tablet Dosage
Starting Dosage	1 through 30	1.5 mg
Dosage Escalation	31through 60	4 mg
	61 through 90	9 mg
Maintenance	91 and onward	25 mg

OASIS 4: A phase III, randomized, double-blind, placebo-controlled 64-week trial of 307 adults with obesity (BMI ≥30 kg/m²) or overweight (BMI 27 kg/m²-29.9 kg/m²) and ≥1 weight-related comorbid condition, such as treated or untreated dyslipidemia or hypertension; patients with type 2 diabetes were excluded. Patients were randomized in a 2:1 ratio to either once-daily Wegovy® tablets 25 mg or placebo; both in conjunction with a reduced-calorie diet (~500 kcal/day deficit) and increased physical activity (recommended to a minimum of 150 min/week).
In OASIS 4, the doses used in escalation were 3 mg, 7 mg, and 14 mg. Each dose was taken once daily for 4 weeks. These doses are bioequivalent to 1.5 mg, 4 mg, and 9 mg, which are the commercially available, FDA-approved doses. The 25 mg dose was studied in OASIS 4 and is available as the maintenance dose.

Co-primary end points:

- Mean percentage change in body weight from baseline to week 64
- Percentage of patients achieving ≥5% weight loss from baseline to week 64

Secondary end points:

- Percentage of patients achieving ≥10% weight loss from baseline to week 64
- Percentage of patients achieving ≥15% weight loss from baseline to week 64
- Percentage of patients achieving ≥20% weight loss from baseline to week 64

Key Efficacy Findings:
Primary endpoint (64 weeks):

Mean body weight change was **−16.6%** in the oral Wegovy group vs. **−2.7%** in placebo (p<0.001)
≥20% weight loss: 30% of Wegovy patients vs. <3% in placebo
Cardiometabolic benefits: Significant reductions in BMI, waist circumference, HbA1c, lipids, and C-reactive protein
Glycemic control: In pre-diabetes, 71.1% of Wegovy patients achieved normal blood glucose vs. 33.3% in placebo

Safety Profile:

Serious adverse events: 3.9% vs. 8.8% in placebo

Most common AEs: Gastrointestinal (74% vs. 42% placebo), mostly mild/moderate and transient
Discontinuation due to AEs: 7% vs. 6%

Current Formulary Status: Wegovy is an excluded medication. It is reviewable for plans with weight loss benefit.

Recommendation: No changes recommended to the formulary placement of Wegovy at this time. It would remain excluded, but reviewable for members with weight loss benefit on their plan. It is recommended to add Wegovy tablets to the same tier as Wegovy subcutaneous injection and add to the existing Commercial/Marketplace/CHIP Policy 686.0.

Chronic Weight Management (Wegovy and Zepbound)

- ~~Medical record documentation that member has participated in comprehensive lifestyle modifications including reduced-calorie diet, physical activity, and behavioral health for at least 3 months prior to beginning Wegovy or Zepbound AND~~
- Medical record documentation of use as adjunct therapy to reduced calorie diet and increased physical activity for chronic weight management **AND**
- Medical record documentation of one of the following:
  - Medical record documentation of age greater than or equal to 18 years with one of the following:
    - Medical record documentation of body mass index (BMI) greater than or equal to 30 kg/m^2 **OR**
    - Medical record documentation of body mass index (BMI) greater than or equal to 27 kg/m^2 and at least one weight-related comorbid condition for the requested medication (e.g., Wegovy: hypertension, type 2 diabetes mellitus, dyslipidemia, or established cardiovascular disease*; Zepbound: hypertension, type 2 diabetes mellitus, or dyslipidemia
  - For Wegovy subcutaneous injection only: Medical record documentation of age greater than or equal to 12 years and less than 18 years with an initial body mass index (BMI) in the 95th percentile or higher for age and sex

NOTES:

- Wegovy and Zepbound are not indicated for treatment of chronic weight management:
  - In combination with semaglutide or tirzepatide containing products or any other GLP-1 receptor agonist
  - In combination with other products for weight loss, as safety and efficacy or coadministration has not been established
  - In patients with acute pancreatitis. Use in caution in patients with history of pancreatitis.
  - In patients with personal or family history of medullary thyroid C-cell carcinoma or Multiple Endocrine Neoplasia syndrome type 2
  - In known hypersensitivity to semaglutide or tirzepatide or any of the excipients
  - In pregnancy
- Established cardiovascular disease is defined as having one of the following:
  - Acute coronary syndromes
  - History of myocardial infarction
  - Ongoing angina (stable or unstable)
  - Prior coronary or other arterial revascularization
  - Prior stroke or transient ischemic attack
  - Peripheral arterial disease of atherosclerotic origin

MEDISPAN APPROVAL LEVEL: GPI-12

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

- QL FOR LETTER ONLY:
    - Wegovy 0.25 mg, 0.5 mg, and 1 mg: 2 mL per 180 days
    - Wegovy 1.7 mg and 2.4 mg: 3 mL per 28 days
    - Wegovy 1.5 mg, 4 mg, 9 mg: 30 tablets per 180 days
    - Wegovy 25 mg: 30 tablets per 30 days
    - Zepbound 2.5 mg: 2 mL per 180 days
    - Zepbound 5 mg, 7.5 mg, 10 mg, 12.5 mg, and 15mg: 2 mL per 28 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 that the member continues to experience clinical benefit from Wegovy or Zepbound based on the prescriber's assessment **AND**
- Medical record documentation that member has experienced at least a 5% reduction in weight from baseline **AND**
- Medical record documentation that member has titrated to the appropriate maintenance dosage based on patient response and tolerability

OR if the above criteria are NOT met:

- The plan may provide a one-time three (3) month authorization for the requested medication during a period of titration to the appropriate maintenance dose in accordance with the accepted standards of care and package labeling for patients requiring a slower titration based on tolerability.

NOTE: Wegovy 0.25 mg. 0.5 mg, and 1 mg subcutaneous injections are indicated for initiation and titration and are not recommended maintenance dosages. Wegovy 1.5 mg, 4 mg, and 9 mg tablets are indicated for initiation and titration and are not recommended maintenance dosages. Zepbound 2.5 mg is indicated for initiation only and is not indicated as a maintenance **dosage.**

Discussion: Kim Clark clarified that the recommendation to remove the lifestyle modification requirement was based on the ability to collect rebates if the criterion was removed. It was confirmed that in 2025 and 2026 only 14 cases were removed for that criterion but all but 12 were approved within days of the initial request due to the physician providing additional information. No additional comments or questions.

Outcome: The committee unanimously voted to accept the recommendations as presented. None were opposed (29 approved, 0 rejected).

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

EYLEA HD (aflibercept)

Clinical Summary: 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), Diabetic Retinopathy (DR), and as of November 19, 2025 has gained FDA approval for treatment of Macular Edema Following Retinal Vein Occlusion (RVO). RVO is a common cause of vision loss in adults and the second most common retinal vascular disease. RVO occurs when there is a blockage in a vein in the retina, which leads to a buildup of blood, restricted blood flow, increased pressure and sometimes pain in the eye. RVO may cause sudden blurry vision or vision loss and can ultimately result in serious complications like swelling in the eye called macular edema. Vascular endothelial growth factor (VEGF) is instrumental in causing the vascular leakage that leads to macular edema. When a vein in the retina is blocked, the levels of VEGF increase, which spurs new blood vessel growth. Too much VEGF can lead to the formation of abnormal blood vessels and may cause vision to become blurry. Anti-VEGF injections are commonly used to treat macular edema due to RVO.

The safety and efficacy of Eylea HD was assessed in the QUASAR trial, a multi-center double-masked, active-controlled Phase 3 trial in patients with treatment naïve macular edema secondary to RVO,

including those with central retinal vein occlusion (CRBV), branch retinal vein occlusion (BRVO), or hemiretinal vein occlusion HRVO). A total of 892 patients (425 with CRVO/HRVO and 467 with BRVO) were treated and analyzed for efficacy (591 with Eylea HD). Patients were randomized into three groups to receive either: Eylea HD every 8 weeks following 3 initial monthly doses; Eylea HD every 8 weeks following 5 initial monthly doses; or Eylea every 4 weeks. The trial also allowed for dosing interval of Eylea HD to be shortened to a minimum of every 4 weeks based on protocol-defined criteria for disease progression not being met or extended starting at week 32 for both treatment groups based on protocol-defined criteria starting at week 32 after 3 initial monthly doses or at week 40 for those who had 5 initial monthly doses of Eylea HD; patients were followed through week 64.

The primary endpoint was mean change in best corrected visual acuity (BCVA) from randomization through week 36, as measured by the Early Treatment Diabetic Retinopathy Study (ETDRS) letter score. Both Eylea HD groups were shown to be non-inferior and clinically equivalent to Eylea with respect to the change in BCVA score at week 36 using the pre-specified non-inferiority margin of 4 letters. 88% of patients were able to be maintained on every 8 week dosing interval in the 3 initial dose group vs 93 % in the 5 initial dose group. Efficacy results in all subgroups (e.g., age, gender, geographic region, ethnicity, race, baseline BCVA and RVO subtype) were generally consistent with those in the overall population.

Primary Outcome in QUASAR Study

Efficacy Outcomes	EYLEA HDq8/3	EYLEA HDq8/5	EYLEA 2q4
Full Analysis Set[a]	N=293	N=298	N=301
Mean change in BCVA as measured by ETDRS letter score from baseline (SD) at week 36[b]	17.0 (11.8)	19.1 (11.2)	17.8 (13.1)
LS mean (SE) change from baseline[c]	17.0 (0.7)	17.9 (0.6)	17.1 (0.7)
Difference in LS mean (95% CI)[c]	-0.1 (-2.0, 1.9)	0.8 (-1.1, 2.7)	

BCVA = Best Corrected Visual Acuity; ETDRS = Early Treatment Diabetic Retinopathy Study; SD = Standard Deviation; LS = Least Square; SE = Standard Error; CI = Confidence Interval; MMRM = Mixed Model for Repeated Measurements

a. Full Analysis Set (FAS) includes all randomized patients who received at least 1 dose of study medication
b. Observed values at week 36: n=260 for HDq8/3; n=248 for HDq8/5; n=264 for 2q4
c. Estimate based on the MMRM model, was computed for the differences of HDq8/3 minus 2q4 and HDq8/5 minus 2q4, respectively, with two-sided 95% CIs

The recommended dose for Eylea HD is 8 mg (0.07 mL) administered by intravitreal injection every 4 weeks (approximately every 28 days +/- 7 days) for the first three to five doses, followed by 8 mg (0.07 mL) once every 8 weeks, +/- 1 week. Some patients did not maintain a response with extended dosing intervals after successful response to the first three to five initial monthly doses. These patients may benefit from resuming every 4-week dosing (approximately every 28 days +/- 7 days).

The safety profile of Eylea HD was similar to Eylea in the QUASAR trial and remained generally consistent with the known safety profile of Eylea HD. Ocular treatment emergent adverse events (TEAEs) occurring in ≥5% of all EYLEA HD patients included increased ocular pressure (5%), and there was one case each of endophthalmitis and retinal vasculitis. The rate of intraocular inflammation was 0.5% for Eylea HD and 1.3% for Eylea. Hypertension at baseline was present in 66% of Eylea HD patients and 62% of Eylea patients. Hypertension during the trial was reported in 8.1% of Eylea HD patients and 4.7% of Eylea patients. Thromboembolic events (APTC) occurred in 0.5% of Eylea HD patients and 1.7% of Eylea patients.

Current Formulary Status: medical benefit requiring prior authorization

Recommendation: There are no changes recommended to the formulary placement of Eylea HD. It is recommended to change the prior authorization criteria for MBP 94.0 to include the new FDA approved diagnosis.

MBP: 94.0 Eylea (aflibercept), Eylea HD (aflibercept) and Pavblu (aflibercept-ayyh)

Eylea HD (aflibercept) will be considered medically necessary for commercial, exchange, and CHIP lines of business when ALL of the following criteria are met:

- 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 an adequate trial of intravitreal bevacizumab (Avastin) given at every four (4) week dosing intervals AND
- Medical record documentation of therapeutic failure on, intolerance to, or contraindication to one (1) of the following: a preferred aflibercept product*, Beovu*, a preferred ranibizumab product* 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 an adequate trial of intravitreal bevacizumab (Avastin) given at every four (4) week dosing intervals AND
- Medical record documentation of therapeutic failure on, intolerance to, or contraindication to one (1) of the following: a preferred aflibercept product*, Beovu*, a preferred ranibizumab product* AND
- Medical record documentation of therapeutic failure on, intolerance to, or contraindication to Vabysmo*

OR

- Medical record documentation of a diagnosis of macular edema following retinal vein occlusion **AND**
- Medical record documentation of therapeutic failure on, intolerance to, or contraindication to an adequate trial of intravitreal bevacizumab (Avastin) given at every four (4) week dosing intervals **AND**
- Medical record documentation of therapeutic failure on, intolerance to, or contraindication to one (1) additional intravitreal VEGF inhibitor (e.g. a preferred aflibercept product or a preferred ranibizumab product) **AND**
- Medical record documentation of therapeutic failure on, intolerance to, or contraindication to Vabysmo*

*Prior authorization required

AUTHORIZATION DURATION: Initial authorization approval will be for 12 months or less if the reviewing provider feels it is medically appropriate. Subsequent approvals will be for an additional 12 months or less if the reviewing provider feels it is medically appropriate. Medical record documentation of a beneficial clinical response based on objective clinical monitoring will be required for subsequent approvals. The medication will no longer be covered if the member experiences unacceptable toxicity or worsening of disease in a manner suggestive of lack of efficacy of the medication

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

Discussion: No comments or questions.

Outcome: The committee unanimously voted to accept the recommendations as presented. None were opposed (28 approved, 0 rejected).

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

TEVIMBRA (tislelizumab-jsgr)

Clinical Summary: Tevimbra is now approved for use in combination with platinum-containing chemotherapy for the first-line treatment of adults with unresectable or metastatic esophageal squamous cell carcinoma (ESCC) whose tumors express PD-L1 ≥ 1.

There are no changes to the recommended dosage of Tevimbra for the new indication. The recommended dosage for esophageal cancer is 150 mg every 2 weeks or 200 mg every 3 weeks or 300 mg every 4 weeks or 400 mg every 6 weeks until disease progression or unacceptable toxicity.

The efficacy of Tevimbra, in combination with chemotherapy, was evaluated in RATIONALE-306 (NCT03783442), a global, randomized, placebo-controlled, double-blind study in patients with unresectable, recurrent, or metastatic ESCC. Patients were enrolled regardless of their PD-L1 expression level. PD-L1 expression was evaluated using an assay that identified PD-L1 staining on both tumor and tumor-associated immune cells (Tumor Area Positivity or TAP). A retrospective scoring of tumor PD-L1 status using Combined Positive Score (CPS) was also conducted using the PD-L1-stained tumor specimens used for randomization.

Patients should not have received prior systemic therapy for advanced or metastatic disease. A treatment-free interval of at least 6 months was required if there was prior neoadjuvant/adjuvant therapy with platinum-based chemotherapy. Patients were randomized (1:1) to receive either Tevimbra 200 mg every 3 weeks or placebo in combination with investigator's choice of chemotherapy (ICC) on a 21-day cycle. Patients received Tevimbra until disease progression or unacceptable toxicity. Tumor assessments were performed every 6 weeks for the first 48 weeks, then every 9 weeks thereafter. The chemotherapy regimen consisted of:

- Platinum (cisplatin [60 to 80 mg/m2 IV, on Day 1] or oxaliplatin [130 mg/m2 IV on Day 1]) and a fluoropyrimidine (fluorouracil [750 to 800 mg/m2 IV, on Days 1 to 5] or capecitabine [1000 mg/m2 orally twice daily, on Days 1 to 14])

OR

- Platinum (cisplatin [60 to 80 mg/m2 IV, on Day 1 or 2] or oxaliplatin [130 mg/m2 IV on Day 1 or 2]) and (paclitaxel 175 mg/m2 IV, on Day 1)

The primary efficacy outcome measure was overall survival (OS) in the Intent-to-Treat (ITT) population. Secondary outcome measures included progression-free survival (PFS), objective response rate, and duration of response (DoR). Additional analyses of efficacy outcome measures were also conducted based on PD-L1 TAP ≥ 1% and CPS ≥ 1. A total of 649 patients were randomized. The median age was 64 years (range: 26 to 84 years). 86% had metastatic disease and 14% had locally advanced disease. 34% of patients had tumors that expressed PD-L1 TAP ≥ 10%, 74% had PD-L1 TAP ≥ 1%, and 74% had PD-L1 CPS ≥ 1.

RATIONALE-306 demonstrated a statistically significant improvement in OS for patients randomized to Tevimbra in combination with chemotherapy compared to placebo in combination with chemotherapy. Efficacy results are shown below in Table 1.

Table 1: Efficacy Results in RATIONALE-306

Efficacy Parameter	ENHERTU 5.4 mg/kg + Pertuzumab N = 383	THP[§] N = 387
Progression-Free Survival (PFS) per BICR		
Number of events (%)	118 (31)	172 (44)
Median, months (95% CI)	40.7 (36.5, NE)	26.9 (21.8, NE)
Hazard ratio (95% CI)	0.56 (0.44, 0.71)	
p-value[¶]	< 0.0001	
Confirmed Objective Response Rate (ORR) per BICR		
Patients with Measurable Disease at Baseline, N	374	371
ORR (95% CI)[‡]	87 (83, 90)	81 (77, 85)
Complete Response, %	15	8
Partial Response, %	72	73

CI = confidence interval; NE = not estimable, N = number
[¶] The stratified log-rank test p-value is compared with the allocated alpha of 0.00043 for this interim analysis (with 73% of the planned number of events for final analysis).
[‡] 95% CI was based on Clopper-Pearson method.
[§] THP = taxane (docetaxel or paclitaxel), trastuzumab,and pertuzumab

No new safety signals were identified and the adverse reactions reported were consistent with the known safety profile of Enhertu and pertuzumab.

Current Formulary Status: Medical Benefit, PA Required

Recommendation: No changes are recommended for the formulary placement or the authorization duration. The following changes are recommended to the Medical Benefit Policy 208.0 to incorporate the new indication.

Medical Benefit Policy 208.0 Enhertu
Breast Cancer

- Prescription written by a hematologist or oncologist **AND**
- Medical record documentation of patient age greater than or equal to 18 years **AND**
- Medical record documentation of unresectable or metastatic HER2-positive (IHC 3+ or ISH positive) breast cancer **AND**
- Medical record documentation of one of the following:
    - Documentation of a prior anti-HER2 based therapy in the metastatic setting **OR**
    - Documentation of a prior anti-HER2 based therapy in the neoadjuvant or adjuvant setting AND documentation of disease recurrence during or within 6 months of completing therapy **OR**
    - Documentation of first line treatment in combination with pertuzumab

OR

- Prescription written by a hematologist or oncologist **AND**
- Medical record documentation of patient age greater than or equal to 18 years **AND**
- Medical record documentation of unresectable or metastatic hormone-receptor (HR)-positive breast cancer **AND**
- Medical record documentation of one of the following:
    - Documentation that the tumor is HER2-low (IHC 1+ or IHC 2+/ISH-) as determined by an FDA-approved test **OR**
    - Documentation that the tumor is HER2-ultralow (IHC 0 with membrane staining) as deter-mined by an FDA-approved test

AND

- Medical record documentation that the patient has progressed on one or more endocrine therapies in the metastatic setting

OR

- Prescription written by a hematologist or oncologist **AND**
- Medical record documentation of patient age greater than or equal to 18 years **AND**
- Medical record documentation of unresectable or metastatic HER2-low (IHC 1+ or IHC 2+/ISH-) breast cancer, as detected by an Food and Drug Administration (FDA)-approved test **AND**
- Medical record documentation that Enhertu will be used as a single agent **AND**
- Medical record documentation of one of the following:
    - Documentation of a prior chemotherapy in the metastatic setting **OR**
    - Documentation of disease recurrence during or within 6 months of completing adjuvant chemotherapy

Discussion: No comments or questions.

Outcome: The committee unanimously voted to accept the recommendations as presented. None were opposed (29 approved, 0 rejected).

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

CEREZYME (imiglucerase)

Clinical Summary: Cerezyme is a hydrolytic lysosomal glucocerebrosidase-specific enzyme now indicated for the treatment of non-central nervous system (CNS) manifestations of Type 1 or Type 3 Gaucher disease in adults and pediatric patients. Previously, Cerezyme was indicated for the treatment of non-central nervous system (CNS) manifestations of Type 1 Gaucher disease only, in adults and pediatric patients.

The dosing of Cerezyme has remained the same for the new indication. The recommended dose is 2.5 units/kg IV three times weekly to 60 units/kg IV once every two weeks. For patients weighing greater than 20kg, Cerezyme is to be infused over 1-2 hours, and for patients weighing less than or equal to 20kg, Cerezyme is to be infused over 2 hours. No changes were made to how Cerezyme is supplied, and it is still available in a single-dose vial containing 400 units of Cerezyme.

The efficacy of Cerezyme in Type 1 and Type 3 Gaucher disease was evaluated in an observational study (Study 3, NCT00358943). The study used data from the International Collaborative Gaucher Group (ICGG) Gaucher Disease Registry, specifically patients who used Cerezyme as initial therapy with an index clinical assessment and one or more follow-ups. Patient ages ranged from 19 weeks to 87 years for Type 1 Gaucher disease and 7 weeks to 54 years for Type 3 Gaucher disease. Improvement was seen compared to baseline after 1-3 years of treatment in the following measures: hemoglobin, platelet count, liver volume, spleen volume, and height Z-score. The 2-year results are summarized in Table 1.

Table 1. Summarized 2-year results in Study 3

Clinical Parameter	Type 1 Gaucher Disease	Type 1 Gaucher Disease	Type 3 Gaucher Disease	Type 3 Gaucher Disease
Hemoglobin concentration (g/dL)	N	1,052	N	118
	Mean baseline	11.8	Mean baseline	10
	Mean change from baseline	+1.5	Mean change from baseline	+1.8
	95% CI	1.4, 1.5	95% CI	1.5, 2.1
Platelet count	N	1,053	N	116

(× 10^3 /mm^3)	Mean baseline	128	Mean baseline	149
	Mean change from baseline	+64	Mean change from baseline	+105
	95% CI	59.6, 67.9	95% CI	87.4, 122.4

No new contraindications, warning/precautions, or adverse reactions were added to the prescribing information with the new indication. New recommendations for mild to moderate hypersensitivity reactions were added, which recommend to consider decreasing infusion rate, temporarily stopping the infusion, and/or administering antihistamines, antipyretics, and/or corticosteroids for hypersensitivity reactions. The pediatric section of the prescribing information has been updated to state that Cerezyme for the treatment of non-CNS manifestations of Type 3 Gaucher disease is supported by evidence in adult and pediatric patients 12 years of age and older with Type 1 Gaucher disease, and that additional safety and efficacy data came from an observational study of Type 3 Gaucher disease.

Current Formulary Status: Medical benefit requiring prior authorization. If processed at a specialty pharmacy, Specialty tier or the Brand Non-preferred tier for members with a three tier benefit.

Recommendation: There are no changes recommended to the formulary placement or authorization duration of Cerezyme. It is recommended to update the prior authorization criteria for MBP 60.0 Cerezyme (imiglucerase).

MBP 60.0 Cerezyme (imiglucerase) – Commercial/Exchange/CHIP/Medicare

- Documentation of a diagnosis of Type 1 or Type 3 Gaucher disease along with at least one of the following conditions:
  - anemia OR
  - thrombocytopenia OR
  - bone disease OR
  - hepatomegaly or splenomegaly **AND**
- Cerezyme® is recommended by a metabolic specialist with experience in treating Gaucher disease **AND**
- **For Type 1 Gaucher disease only:** Medical record documentation of therapeutic failure on, intolerance to, or contraindication to Vpriv in patients 4 years of age and older

Discussion: No comments or questions.

Outcome: The committee unanimously voted to accept the recommendations as presented. None were opposed (29 approved, 0 rejected).

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

SUBLOCADE (buprenorphine extended-release injection)

Clinical Summary: Sublocade 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 product or who are already being treated with buprenorphine. Previously, Sublocade was indicated for the treatment of moderate to severe opioid use disorder in patients who have initiated treatment with a buprenorphine-containing product, followed by dose adjustment for a minimum of 7 days.

Updated Dosing for New indication: Patients not currently taking buprenorphine should receive an initial dose (e.g. 4 mg) of transmucosal buprenorphine before administering the first injection of Sublocade. Monitor patients in a healthcare setting after injection with Sublocade to assess for symptoms of worsening withdrawal or sedation. Patients' symptoms should be stable or improving prior to release from the healthcare setting. The second injection of Sublocade may be administered as early as one week

after the first injection. The recommended dose of Sublocade is two initial doses of 300 mg followed by 100 mg monthly maintenance doses. Increasing the maintenance dose to 300 mg monthly may be considered for patients in which the benefits outweigh the risks.

Summary of Updated Clinical Studies: Induction on Sublocade following a single dose of 4 mg transmucosal buprenorphine was compared to standard induction (minimum of 7 days of transmucosal buprenorphine) based on data from 723 treatment-seeking patients with moderate to severe Opioid Use Disorder (OUD) and high-risk opioid use. High-risk opioid use was defined as using five or more days per week either via IV injection, high doses (at least 500 mg IV heroin equivalent), or potent synthetic opioids (e.g., fentanyl). At induction, 77.5% of patients were fentanyl positive by urine drug screen (UDS).
In this open-label study, patients were randomized at a 2:1 ratio to Sublocade rapid induction or standard induction and stratified according to the same-day UDS result for fentanyl due to the potential for fentanyl use to impact the response to induction. For rapid induction, patients were observed at a minimum of 1 hour after receiving a single dose of 4 mg transmucosal buprenorphine to confirm tolerability before administering the first injection of 300 mg Sublocade. On induction day, up to an additional 8 mg of transmucosal buprenorphine could be administered to manage withdrawal symptoms. In both treatment groups, the second 300 mg injection was administered at 1 week after the first Sublocade injection and subsequent injections were scheduled every 4 weeks.

Rapid induction was effective, shown by the primary endpoint of participant retention at the second injection. The proportion of participants who received the second injection was 66.4% in the rapid induction arm and 54.5% in the standard induction arm; the estimated retention rate difference (rapid induction minus standard induction) in the overall population was 11.8% with a lower bound of multiplicity adjusted two-sided 95% confidence interval greater than the pre-specified non-inferiority margin of -10%. This demonstrated non-inferiority of rapid induction to standard induction.

Summary of Updated Safety Considerations: The proportion of patients who experienced an adverse event associated with opioid withdrawal was 31.4% in patients who received Sublocade injection after an initial dose of transmucosal buprenorphine (rapid induction) and 25.1% in those who first received transmucosal buprenorphine for at least 7 days (standard induction). Three fentanyl positive patients in the rapid induction arm had serious adverse events associated with opioid withdrawal, and none in the standard induction arm.

Current Formulary Status: Sublocade is on the Specialty Tier, with a min 26-day supply and max 34-day supply.

Recommendation: No changes to formulary placement are recommended at this time. It is recommended to add a QL to both strengths of Sublocade and update the day supply restrictions as noted below:

- Sublocade 100 mg/0.5 mL Syringe: 0.5 mL (1 syringe) per 28 days, Min Day Supply: 26, Max Day Supply: 34 days
- Sublocade 300 mg/1.5 mL Syringe: 3 mL (2 syringes) per 28 days, Min Day Supply: 26, Max Day Supply: 34 days

Discussion: No comments or questions.

Outcome: The committee unanimously voted to accept the recommendations as presented. None were opposed (29 approved, 0 rejected).

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

UPDATES

MIGRAINE PREVENTION AGENT UPDATE

Background: We were presented with a rebate opportunity if we were to remove the following language from our preferred CGRP antagonist policies.

- *Medical record documentation that CGRP antagonist will not be used in combination with botulinum toxin OR*
- *If the request is for use in combination with Botox, all of the following must be met:*
    - *Medical record documentation of a therapeutic failure on a minimum 3 month trial of at least one CGRP antagonists without the concomitant use of Botox AND*
    - *Medical record documentation of therapeutic failure on a minimum 6 month trial of Botox without the concomitant use of a CGRP antagonist*

Also, we need to remove any "documentation" notation in the policies and replace it with "attestation".

Migraines involve multiple pathways, neurotransmitters, neuropeptides, and receptors, therefore preventive treatment that focuses on a single mechanism of action may not completely eliminate migraines. The 2021 American Headache Society (AHS) consensus statement states that CGRP antagonists may be added to 1 or more established preventive treatment, based on clinical judgement in adults who meet International Classification of Headache Disorders, 3rd edition criteria for the following conditions: Migraine with/without aura (4–7 monthly migraine days [MMDs]) with at least moderate disability (Migraine Disability Assessment ≥11 or 6-item Headache Impact Test >50) and failure of an 8-week trial of ≥2 preventive treatments with established efficacy (e.g., topiramate, divalproex sodium, beta-blocker, tricyclic antidepressant, and others); Migraine with/without aura (8–14 MMDs) and failure of an 8-week trial of ≥2 established preventive treatments; chronic migraine (≥15 MMDs) with any level of disability and either failure of an 8-week trial of ≥2 established preventive treatments or inadequate tolerability or response to onabotulinumtoxinA for two quarterly injections. The recently updated AHS consensus statement suggests that the combination of CGRP targeted mABs and onabotulinumtoxinA in people with migraine is probably effective. Data on safety and efficacy of combination use are limited and have not been fully peer-reviewed. However, real world data suggests this may have a potential synergistic effect.

Recommendations:
Aimovig (Policy 511.0)

- ~~Medical record documentation of~~ Patient age greater than or equal to 18 years AND
- ~~Medical record documentation~~ Physician attestation of a diagnosis of migraine with or without aura AND
- ~~Medical record documentation~~ Physician attestation of number of baseline migraine or headache days per month AND
- ~~Medical record documentation~~ Physician attestation of therapeutic failure on, intolerance to, or contraindication to at least two (2) of the following:
    - One (1) beta blocker (metoprolol, propranolol, timolol, atenolol, nadolol)
    - Topiramate
    - Divalproex/sodium valproate
    - Amitriptyline
    - Venlafaxine AND
- ~~Medical record documentation~~ Physician attestation that Aimovig will not be used concomitantly with another calcitonin gene-related peptide (CGRP) receptor antagonist indicated for the preventive treatment of migraine ~~AND~~
- ~~Medical record documentation that Aimovig will not be used in combination with botulinum toxin OR~~
- ~~If the request is for use in combination with Botox, all of the following must be met:~~

- ~~Medical record documentation of a therapeutic failure on a minimum 3 month trial of at least one CGRP antagonists without the concomitant use of Botox AND~~
- ~~Medical record documentation of therapeutic failure on a minimum 6 month trial of Botox without the concomitant use of a CGRP antagonist~~

AUTHORIZATION DURATION: Initial approval will be for six (6) months and subsequent approvals will be for twelve (12) months. Requests for continuation of coverage will be approved for members who meet the following criteria:

- ~~Medical record documentation~~ Physician attestation of continued or sustained reduction in migraine or headache frequency or has experienced a decrease in severity or duration of migraine **AND**
- ~~Medical record documentation~~ Physician attestation that Aimovig will not be used concomitantly with another calcitonin gene-related peptide (CGRP) receptor antagonist indicated for the preventive treatment of migraine ~~**AND**~~
- ~~One of the following:~~
  - ~~Medical record documentation that Aimovig is not being used concurrently with botulinum toxin **OR**~~
  - ~~If the request is for use in combination with Botox, all of the following must be met:~~
    - ~~Medical record documentation of a therapeutic failure on a minimum 3 month trial of at least one CGRP antagonists without the concomitant use of Botox **AND**~~
    - ~~Medical record documentation of therapeutic failure on a minimum 6 month trial of Botox without the concomitant use of a CGRP antagonist~~

Emgality (Policy 533.0)
Migraine

- ~~Medical record documentation of~~ Patient age greater than or equal to 18 years AND
- ~~Medical record documentation~~ Physician attestation of a diagnosis of migraine with or without aura AND
- ~~Medical record documentation~~ Physician attestation of number of baseline migraine or headache days per month AND
- ~~Medical record documentation~~ Physician attestation of therapeutic failure on, intolerance to, or contraindication to at least two (2) of the following:
  - One (1) beta blocker (metoprolol, propranolol, timolol, atenolol, nadolol)
  - Topiramate
  - Divalproex/sodium valproate
  - Amitriptyline
  - Venlafaxine AND
- ~~Medical record documentation~~ Physician attestation that Emgality will not be used concomitantly with another calcitonin gene-related peptide (CGRP) receptor antagonist indicated for the preventive treatment of migraine ~~AND~~
- ~~Medical record documentation that Emgality will not be used in combination with botulinum toxin OR~~
- ~~If the request is for use in combination with Botox, all of the following must be met:~~
  - ~~Medical record documentation of a therapeutic failure on a minimum 3 month trial of at least one CGRP antagonists without the concomitant use of Botox AND~~
  - ~~Medical record documentation of therapeutic failure on a minimum 6 month trial of Botox without the concomitant use of a CGRP antagonist~~

AUTHORIZATION DURATION: Initial approval will be for six (6) months and subsequent approvals will be for twelve (12) months. Requests for continuation of coverage will be approved for members who meet the following criteria:

- ~~Medical record documentation~~ Physician attestation of continued or sustained reduction in migraine or headache frequency or has experienced a decrease in severity or duration of migraine AND

- ~~Medical record documentation~~ Physician attestation that Emgality will not be used concomitantly with another calcitonin gene-related peptide (CGRP) receptor antagonist indicated for the preventive treatment of migraine ~~AND~~
- ~~One of the following:~~
    - ~~Medical record documentation that Emgality is not being used concurrently with botulinum toxin OR~~
    - ~~If the request is for use in combination with Botox, all of the following must be met:~~
        - ~~Medical record documentation of a therapeutic failure on a minimum 3 month trial of at least one CGRP antagonists without the concomitant use of Botox AND~~
        - ~~Medical record documentation of therapeutic failure on a minimum 6 month trial of Botox without the concomitant use of a CGRP antagonist~~

Qulipta (Policy 696.0)

- ~~Medical record documentation of~~ Patient age greater than or equal to 18 years AND
- ~~Medical record documentation~~ Physician attestation of a diagnosis of migraine with or without aura AND
- ~~Medical record documentation~~ Physician attestation of number of baseline migraine or headache days per month AND
- ~~Medical record documentation~~ Physician attestation that Qulipta will not be used concomitantly with another calcitonin gene-related peptide (CGRP) receptor antagonist indicated for the preventive treatment of migraine AND
- ~~Medical record documentation~~ Physician attestation of therapeutic failure on, intolerance to, or contraindication to at least two (2) of the following:
    - One (1) beta blocker (metoprolol, propranolol, timolol, atenolol, nadolol)
    - Topiramate
    - Divalproex/sodium valproate
    - Amitriptyline
    - Venlafaxine ~~AND~~
- ~~Medical record documentation that Qulipta will not be used in combination with botulinum toxin for the preventive treatment OR~~
    - ~~Medical record documentation of therapeutic failure on a minimum 3 month trial of at least one CGRP antagonists without the concomitant use of Botox AND~~
    - ~~Medical record documentation of therapeutic failure on a minimum 6 month trial of Botox without the concomitant use of a CGRP antagonist~~

AUTHORIZATION DURATION: Initial approval will be for six (6) months and subsequent approvals will be for twelve (12) months. Requests for continuation of coverage will be approved for members who meet the following criteria:

- ~~Medical record documentation~~ Physician attestation of continued or sustained reduction in migraine or headache frequency or has experienced a decrease in severity or duration of migraine AND
- ~~Medical record documentation~~ Physician attestation that Qulipta will not be used concomitantly with another calcitonin gene-related peptide (CGRP) receptor antagonist indicated for the preventive treatment of migraine ~~AND~~
- ~~Medical record documentation that Qulipta will not be used in combination with botulinum toxin for preventive treatment OR~~
    - ~~Medical record documentation of a therapeutic failure on a minimum 3 month trial of at least one CGRP antagonists without the concomitant use of Botox AND~~
    - ~~Medical record documentation of therapeutic failure on a minimum 6 month trial of Botox without the concomitant use of a CGRP antagonist~~

Nurtec ODT (Policy 629.0)

Preventive Migraine Treatment

- ~~Medical record documentation of~~ Patient age greater than or equal to 18 years AND
- ~~Medical record documentation~~ Physician attestation of a diagnosis of migraine with or without aura AND
- ~~Medical record documentation~~ Physician attestation of number of baseline migraine or headache days per month AND
- ~~Medical record documentation~~ Physician attestation of diagnosis of episodic migraine (no more than 14 headache days per month) AND
- ~~Medical record documentation~~ Physician attestation of therapeutic failure on, intolerance to, or contraindication to at least two (2) of the following: o One (1) beta blocker (metoprolol, propranolol, timolol, atenolol, nadolol)
    - Topiramate
    - Divalproex/sodium valproate
    - Amitriptyline
    - Venlafaxine AND
- ~~Medical record documentation~~ Physician attestation that Nurtec ODT will not be used concomitantly with another calcitonin gene-related peptide (CGRP) receptor antagonist indicated for the preventive treatment of migraine ~~AND~~
- ~~Medical record documentation that Nurtec ODT will not be used in combination with botulinum toxin for preventive treatment OR~~
    - ~~Medical record documentation of a therapeutic failure on a minimum 3 month trial of at least one CGRP antagonists without the concomitant use of Botox AND~~
    - ~~Medical record documentation of therapeutic failure on a minimum 6 month trial of Botox without the concomitant use of a CGRP antagonist~~

AUTHORIZATION DURATION FOR PREVENTIVE TREATMENT: Initial approval will be for six (6) months and subsequent approvals will be for twelve (12) months. Requests for continuation of coverage will be approved for members who meet the following criteria:

- ~~Medical record documentation~~ Physician attestation of continued or sustained reduction in migraine or headache frequency or has experienced a decrease in severity or duration of migraine **AND**
- ~~Medical record documentation~~ Physician attestation that Nurtec ODT will not be used concomitantly with another calcitonin gene-related peptide (CGRP) receptor antagonist indicated for the preventive treatment of migraine ~~**AND**~~
- ~~Medical record documentation that Nurtec ODT will not be used in combination with botulinum toxin for preventive treatment **OR**~~
    - ~~Medical record documentation of a therapeutic failure on a minimum 3 month trial of at least one CGRP antagonists without the concomitant use of Botox **AND**~~
    - ~~Medical record documentation of therapeutic failure on a minimum 6 month trial of Botox without the concomitant use of a CGRP antagonist~~

Ajovy (Policy 532.0)

Prevention of Chronic Migraine in Adults

- Medical record documentation of age greater than or equal to 18 years AND
- Medical record documentation of a diagnosis of migraine with or without aura AND
- Medical record documentation of number of baseline migraine or headache days per month AND
- Medical record documentation of therapeutic failure on, intolerance to, or contraindication to at least two (2) of the following:
    - One (1) beta blocker (metoprolol, propranolol, timolol, atenolol, nadolol)
    - Topiramate
    - Divalproex/sodium valproate
    - Amitriptyline
    - Venlafaxine AND
- Medical record documentation of therapeutic failure on, intolerance to, or contraindication to two (2) of the following: Aimovig, Emgality, Nurtec ODT, and Qulipta AND

- Medical record documentation that Ajovy will not be used concomitantly with another calcitonin gene-related peptide (CGRP) receptor antagonist indicated for the preventive treatment of migraine ~~AND~~
- ~~Medical record documentation that Ajovy will not be used in combination with botulinum toxin OR~~
- ~~If the request is for use in combination with Botox, all of the following must be met:~~
    - ~~Medical record documentation of a therapeutic failure on a minimum 3 month trial of at least one CGRP antagonists without the concomitant use of Botox **AND**~~
    - ~~Medical record documentation of therapeutic failure on a minimum 6 month trial of Botox without the concomitant use of a CGRP antagonist~~

AUTHORIZATION DURATION: Initial approval will be for six (6) months and subsequent approvals will be for twelve (12) months. Requests for continuation of coverage will be approved for members who meet the following criteria:

- Medical record documentation of continued or sustained reduction in migraine or headache frequency or has experienced a decrease in severity or duration of migraine AND
- Medical record documentation that Ajovy will not be used concomitantly with another calcitonin gene-related peptide (CGRP) receptor antagonist indicated for the preventive treatment of migraine ~~AND~~
- ~~One of the following:~~
    - ~~Medical record documentation that Ajovy is not being used concurrently with botulinum toxin OR~~
    - ~~If the request is for use in combination with Botox, all of the following must be met:~~
        - ~~Medical record documentation of a therapeutic failure on a minimum 3 month trial of at least one CGRP antagonists without the concomitant use of Botox AND~~
        - ~~Medical record documentation of therapeutic failure on a minimum 6 month trial of Botox without the concomitant use of a CGRP antagonist~~

Vyepti (MBP 218.0)

- Prescription written by or in consultation with a neurologist or headache specialist AND
- Medical record documentation of the patient age greater than or equal to 18 years AND
- Medical record documentation of a diagnosis of migraine with or without aura, based on the ICHD-III diagnostic criteria AND
- Medical record documentation of the number of baseline migraine or headache days per month AND
- Medical record documentation of the patient experiencing 4 or more migraines per month AND
- Medical record documentation of therapeutic failure on, intolerance to, or contraindication to two of the following: Aimovig, Emgality, Nurtec ODT, Qulipta AND
- If the request is for Vyepti 300 mg every 3 months, medical record documentation of therapeutic failure on Vyepti 100 mg every 3 months AND
- ~~If the request is for use in combination with Botox, all of the following must be met:~~
    - ~~Medical record documentation of therapeutic failure on a minimum 3 month trial of at least one calcitonin gene-related peptide (CGRP) receptor antagonist without the concomitant use of Botox AND~~
    - ~~Medical record documentation of therapeutic failure on a minimum 6 month trial of Botox without the concomitant use of calcitonin gene-related peptide (CGRP) receptor antagonist AND~~
- Medical record documentation that Vyepti will not be used concomitantly with another calcitonin gene-related peptide (CGRP) receptor antagonist indicated for the preventive treatment of migraine (e.g. Aimovig, Ajovy, Emgality, Nurtec ODT, Qulipta)

Reauthorization Criteria:

- Medical record documentation of continued or sustained reduction in migraine or headache frequency AND
- If the request is for Vyepti 300 mg every 3 months, medical record documentation of therapeutic failure on Vyepti 100 mg every 3 months AND
- ~~If the request is for use in combination with Botox, all of the following must be met:~~
  - ~~Medical record documentation of therapeutic failure on a minimum 3 month trial of at least one calcitonin gene-related peptide (CGRP) receptor antagonist without the concomitant use of Botox AND~~
  - ~~Medical record documentation of therapeutic failure on a minimum 6 month trial of Botox without the concomitant use of calcitonin gene-related peptide (CGRP) receptor antagonist AND~~
- Medical record documentation that Vyepti will not be used concomitantly with another calcitonin gene-related peptide (CGRP) receptor antagonist indicated for the preventive treatment of migraine (e.g. Aimovig, Ajovy, Emgality, Nurtec ODT, Qulipta)

Botulinum Toxin and Derivatives (MBP 11.0)

1. Chronic Migraine Headache
   - Physician provided medical record documentation of a history of 15 or more migraine headache days per month that last 4 or more hours per day AND
   - Physician provided medical record documentation that Botox is prescribed by or in consultation with a neurologist or headache specialist AND
   - Physician provided medical record documentation of therapeutic failure on, intolerance to, or contraindication to at least two (2) of the following:
     - One (1) beta blocker (metoprolol, propranolol, timolol, atenolol, nadolol)
     - Topiramate
     - Divalproex/sodium valproate
     - Amitriptyline
     - Venlafaxine

     ~~AND~~
   - ~~Medical record documentation that Botox will not be used in combination with a CGRP antagonist OR~~
   - ~~If the request is for use in combination with a CGRP antagonist, all of the following must be met:~~
     - ~~Medical record documentation of a therapeutic failure on a minimum 3 month trial of at least one CGRP antagonists without the concomitant use of Botox AND~~
     - ~~Medical record documentation of therapeutic failure on a minimum 6 month trial of Botox without the concomitant use of a CGRP antagonist~~

AUTHORIZATION DURATION: Initial approval will be for 12 months or less if the reviewing provider feels it is medically appropriate. Subsequent approvals will be for an additional 12 months or less if the reviewing provider feels it is medically appropriate and will require medical record documentation of the following:

- For Chronic Migraines:
  - Medical record documentation of continued or sustained reduction in migraine or headache frequency or has experienced a decrease in severity or duration of migraine AND
  - ~~Medical record documentation that Botox will not be used in combination with a CGRP antagonist OR~~
  - ~~If the request is for use in combination with a CGRP antagonist, all of the following must be met:~~
    - ~~Medical record documentation of a therapeutic failure on a minimum 3 month trial of at least one CGRP antagonists without the concomitant use of Botox AND~~

- ~~Medical record documentation of therapeutic failure on a minimum 6 month trial of Botox without the concomitant use of a CGRP antagonist~~

Discussion: No comments or questions.

Outcome: The committee unanimously voted to accept the recommendations as presented. None were opposed (32 approved, 0 rejected).

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

FORMULARY RECOMMENDATIONS BASED ON SPECIALTY ROUTING TOOL

Background/Recommendations: I completed a comparison of the current commercial/exchange formulary and compared it to the most current specialty routing tool. Based on my review, I am recommending the following changes.

Commercial/Exchange/CHIP: For commercial plans, for a medication to process through specialty, it must be assigned a tier. If a medication is medical only, it should be excluded on the pharmacy formulary.

Drug Name	Current Formulary Status for Commercial/Exchange Formulary	Current Specialty Routing Tool Designation	Recommendations to Commercial/Exchange Formulary
Pemetrexed	Specialty tier (specifically NDC 480451601 & 480451501)	Buy and bill only	Exclude
Fludarabine Phosphate	Non-formulary	Buy and bill only	Exclude
Kebilidi	Non-formulary	Buy and bill only	Exclude
Paclitaxel Protein-Bound	Non-formulary	Buy and bill only	Exclude
Posfrea	Tier 2	Buy and bill only	Exclude
Acthar	Exchange: Non-formulary; Commercial: excluded	Specialty Designation	Exclude for Exchange

Adynovate	Excluded	Specialty Designation	Non-formulary for Commercial and Exchange
Akynzeo	Excluded	Specialty Designation	Non-formulary for Commercial and Exchange
Alphanine SD	Excluded	Specialty Designation	Non-formulary for Commercial and Exchange
Alprolix	Excluded	Specialty Designation	Non-formulary for Commercial and Exchange
Azacitidine	Excluded	Specialty Designation	Non-formulary for Commercial and Exchange
Benefix	Excluded	Specialty Designation	Non-formulary for Commercial and Exchange
Beyfortus	Excluded	Specialty Designation	Non-formulary for Commercial and Exchange
Byooviz	Excluded	Specialty Designation	Specialty tier or the Brand Non-preferred tier for members with a 3 tier benefit
Cladribine	Excluded	Specialty Designation	Non-formulary for Commercial and Exchange
Coagadex	Excluded	Specialty Designation	Non-formulary for Commercial and Exchange
Corifact	Excluded	Specialty Designation	Non-formulary for Commercial and Exchange

Cytarabine	Excluded	Specialty Designation	Non-formulary for Commercial and Exchange
Daunorubicin	Excluded	Specialty Designation	Non-formulary for Commercial and Exchange
Deflux	Commercial: Excluded; Exchange: Non-formulary	Specialty Designation	Non-formulary for Commercial
Egrifta	Commercial: Excluded; Exchange: Non-formulary	Specialty Designation	Exclude for exchange
Elzonris	Commercial: Excluded; Exchange: Non-formulary	Specialty Designation	Non-formulary for Commercial
Etopophos	Excluded	Specialty Designation	Non-formulary for Commercial and Exchange
Etoposide	Excluded	Specialty Designation	Non-formulary for Commercial and Exchange
Evomela	Excluded	Specialty Designation	Non-formulary for Commercial and Exchange
Feraheme	Commercial: Excluded; Exchange: Non-formulary	Specialty Designation	Non-formulary for Commercial
Fibryga	Excluded	Specialty Designation	Non-formulary for Commercial and Exchange
Idelvion	Commercial: Excluded; Exchange: Non-formulary	Specialty Designation	Non-formulary for Commercial

Imcivree	Commercial: Tier 3; Exchange: Excluded	Specialty Designation	Non-formulary for Exchange
Iron Sucrose	Excluded	Specialty Designation	Non-formulary for Commercial and Exchange
Ixinity	Commercial: Excluded; Exchange: Non-formulary	Specialty Designation	Non-formulary for Commercial
Levoleucovorin	Excluded	Specialty Designation	Non-formulary for Commercial and Exchange
Metopirone	Commercial: Excluded; Exchange: Non-formulary	Specialty Designation	Non-formulary for Commercial
Mitoxantrone	Excluded	Specialty Designation	Non-formulary for Commercial and Exchange
Myalept	Commercial: Excluded; Exchange: Non-formulary	Specialty Designation	Non-formulary for Commercial
Novoseven	Excluded	Specialty Designation	Non-formulary for Commercial and Exchange
Nuzyra	Excluded	Specialty Designation	Non-formulary for Commercial and Exchange
Orapeutic Gel	Commercial: Excluded; Exchange: Non-formulary	Specialty Designation	Exclude for Exchange
Orencia Solution	Excluded	Specialty Designation	Non-formulary for Commercial and Exchange

Ozurdex	Excluded	Specialty Designation	Non-formulary for Commercial and Exchange
Panhematin	Excluded	Specialty Designation	Non-formulary for Commercial and Exchange
Photorexa-Photorexa	Commercial: Excluded; Exchange: Non-formulary	Specialty Designation	Non-formulary for Commercial
Profilnine	Excluded	Specialty Designation	Non-formulary for Commercial and Exchange
Proleukin	Excluded	Specialty Designation	Non-formulary for Commercial and Exchange
Provenge	Commercial: Excluded; Exchange: Specialty tier	Specialty Designation	Exclude for exchange
Rebinyn	Excluded	Specialty Designation	Non-formulary for Commercial and Exchange
Remodulin	Excluded	Specialty Designation	Non-formulary for Commercial and Exchange
Revatio	Excluded	Specialty Designation	Non-formulary for Commercial and Exchange
Riastap	Excluded	Specialty Designation	Non-formulary for Commercial and Exchange
Rixubis	Commercial: Excluded; Exchange: Non-formulary	Specialty Designation	Non-formulary for Commercial

Rystiggo	Excluded	Specialty Designation	Non-formulary for Commercial and Exchange
Sandostatin solution	Excluded	Specialty Designation	Non-formulary for Commercial and Exchange
Sevenfact	Excluded	Specialty Designation	Non-formulary for Commercial and Exchange
Sildenafil solution	Excluded	Specialty Designation	Non-formulary for Commercial and Exchange
Sodium phenylbutyrate powder	Excluded	Specialty Designation	Non-formulary for Commercial and Exchange
Solesta	Commercial: Excluded; Exchange: Non-formulary	Specialty Designation	Non-formulary for Commercial
Tadalafil	Commercial: Tier 1; Exchange: Excluded	Specialty Designation	Generic tier for exchange
Temodar	Excluded	Specialty Designation	Non-formulary for Commercial and Exchange
Tepadina	Excluded	Specialty Designation	Non-formulary for Commercial and Exchange
Testopel	Excluded	Specialty Designation	Non-formulary for Commercial and Exchange
Tice BCG	Excluded	Specialty Designation	Non-formulary for Commercial and Exchange

Torisel	Commercial: Excluded; Exchange: Non-formulary	Specialty Designation	Non-formulary for Commercial
Tretten	Excluded	Specialty Designation	Non-formulary for Commercial and Exchange
Truxima	Excluded	Specialty Designation	Non-formulary for Commercial and Exchange
Veklury	Excluded	Specialty Designation	Non-formulary for Commercial and Exchange
Vidaza	Excluded	Specialty Designation	Non-formulary for Commercial and Exchange
Vincristine	Excluded	Specialty Designation	Non-formulary for Commercial and Exchange
Vonvendi	Excluded	Specialty Designation	Non-formulary for Commercial and Exchange
Vyepti	Excluded	Specialty Designation	Non-formulary for Commercial and Exchange
Yutiq	Excluded	Specialty Designation	Non-formulary for Commercial and Exchange
Zirabev	Excluded	Specialty Designation	Specialty tier or Brand Non-Preferred tier for members with a 3 tier benefit

Discussion: No comments or questions.

Outcome: The committee unanimously voted to accept the recommendations as presented. None were opposed (26 approved, 0 rejected).

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

LEVOCETIRIZINE UPDATE

Background/Recommendations: It is recommended to add levocetirizine solution (Rx only) to the commercial policy 855.0 Levocetirizine 5 mg Tablets (RX Formulation) and update the policy name to Levocetirizine Rx Formulations. The current prior authorization criteria will apply to both the Rx tablets and Rx solution.

Commercial/Marketplace/CHIP:
Current prior authorization criteria

- Medical record documentation of therapeutic failure on, intolerance to, or contraindication to three over-the-counter (OTC) antihistamines, one of which must be cetirizine

Discussion: No comments or questions.

Outcome: The committee unanimously voted to accept the recommendations as presented. None were opposed (26 approved, 0 rejected).

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

AUSTEDO XR UPDATE

Background/Recommendations: It is recommended to update the quantity limits for Austedo XR for Commercial/Marketplace/CHIP.

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

- QL FOR LETTER ONLY:
  - Austedo XR Titration Kit: 28 tablets per 180 days, 30 day supply per fill
  - Austedo 6 mg tablet: 2 tablets per day, 30 day supply per fill
  - Austedo 9 mg tablet: 4 tablets per day, 30 day supply per fill
  - Austedo 12 mg tablet: 4 tablets per day, 30 day supply per fill
  - Austedo XR 6 mg tablet: 1 tablet per day, 30 day supply per fill
  - Austedo XR 12 mg tablet: ~~2 tablets~~ 1 tablet per day, 30 day supply per fill
  - Austedo XR 18 mg tablet: ~~2 tablets~~ 1 tablet per day, 30 day supply per fill
  - Austedo XR 24 mg tablet: ~~2 tablets~~ 1 tablet per day, 30 day supply per fill
  - Austedo XR 30 mg tablet: 1 tablet per day, 30 day supply per fill
  - Austedo XR 36 mg tablet: 1 tablet per day, 30 day supply per fill
  - Austedo XR 42 mg tablet: 1 tablet per day, 30 day supply per fill
  - Austedo XR 48 mg tablet: 1 tablet per day, 30 day supply per fill

Discussion: No comments or questions.

Outcome: The committee unanimously voted to accept the recommendations as presented. None were opposed (27 approved, 0 rejected).

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

SPRAVATO UPDATE

Background: Spravato is indicated for the treatment of: 1) Treatment-resistant depression (TRD) in adults as monotherapy or in conjunction with an oral antidepressant, and 2) Depressive symptoms in adults with major depressive disorder (MDD) with acute suicidal ideation or behavior in conjunction with an oral antidepressant. The recommended dose of Spravato for TRD is 56 or 84mg twice weekly for 4 weeks, then once weekly or once every 2 weeks thereafter. The recommended dose of Spravato for MDD with suicidal ideation/behavior is 84mg twice weekly for 4 weeks (can decrease to 56mg if needed). Spravato was not evaluated for treatment beyond 4 weeks. Spravato is supplied as either a 56 mg kit (two 28mg devices) or an 84mg kit (three 28mg devices).

Recommendations: It is recommended to update the initial and reauthorization prior authorization criteria, and quantity limits for MBP 195.0 Spravato.

MBP 195.0 Spravato (esketamine) – commercial/exchange/CHIP
Spravato (esketamine) will be considered medically necessary for commercial, exchange, and CHIP lines of business when ALL of the following criteria are met:

For Treatment Resistant Depression

- Medical record documentation of age ≥ 18 **AND**
- Medical record documentation of diagnosis of major depression disorder (MDD), consistent with the FDA approved indication **AND**
- Medical record documentation of Spravato being used for treatment-resistant depression as defined by failure of at least two antidepressants from two different classes at an optimized dose for at least 6 weeks **AND**
- Medical record documentation of therapeutic failure on, intolerance to, or contraindication to at least one augmentation therapy (e.g., lithium, antipsychotic, stimulant) in combination with an antidepressant at an optimized dose for at least 6 weeks ~~olanzapine/fluoxetine capsules~~ **AND**
- ~~Medical record documentation that Spravato will be used as monotherapy OR in combination with a newly initiated antidepressant **AND**~~
- Medical record documentation of the patient's baseline depression status using an appropriate rating scale (e.g. PHQ-9, Clinically Useful Depression Outcome Scale, Quick Inventory of Depressive Symptomatology-Self Report 16 Item, MADRS, HAM-D) **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 that all potential drug interactions and other applicable safety concerns have been ~~addressed~~ assessed by the prescriber and addressed with the member when appropriate (such as discontinuation of the interacting drug, dose reduction of the interacting drug, ~~or~~ counseling of the beneficiary about the risks associated with the use of both medications when they interact, and education on potential adverse effects including the risk for abuse, misuse, and addiction).

For acute suicidal ideation and behavior

- Medical record documentation of age ≥ 18 years **AND**
- Medical record documentation that Spravato will be used in combination with an oral antidepressant **AND**
- Medical record documentation of diagnosis of major depression disorder (MDD) **AND**
- Medical record documentation of a recent hospital admission (within 4 weeks) due to depressive symptoms with acute suicidal ideation and behavior **AND**
- Medical record documentation that Spravato was started inpatient **AND**
- Medical record documentation that Spravato will not exceed the FDA-approved duration of 4 weeks **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 that all potential drug interactions and other applicable safety concerns have been ~~addressed~~ assessed by the prescriber and addressed with the member when appropriate (such as discontinuation of the interacting drug, dose reduction of the interacting drug, ~~or~~ counseling of the beneficiary about the risks associated with the use of both medications when they interact, and education on potential adverse effects including the risk for abuse, misuse, and addiction).

*Note to reviewer: The standard of care for patients with acute suicidal ideation and behavior is to hospitalize for safety. Spravato should be started inpatient for acute suicidal ideation requests.

Authorization Duration for treatment resistant depression:
Initial approval will be for 1 month or less if the reviewing provider feels it is medically appropriate. For continued coverage, the following criteria is required.

- Medical record documentation of clinical improvement in depression symptoms as measured by an appropriate rating scale (compared to previous measurement) **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

Subsequent approvals will be for an additional 12 months or less if the reviewing provider feels it is medically appropriate. For continued coverage, the following criteria is required.

- Medical record documentation of clinical improvement or lack of progression in depression symptoms as measured by an appropriate rating scale (compared to previous measurement) **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

Quantity Limits for treatment resistant depression:
For the initial 1 month authorization: ~~23~~ 24 devices per 28 days
For subsequent authorizations:

- 56 mg dose pack: 8 devices per 28 days
- 84 mg dose pack: 12 devices per 28 days

Authorization Duration for depressive episodes with acute suicidal ideation: Approval will be for one (1) 4 week approval for the FDA approved maximum of 24 devices. Requests for authorizations exceeding these limits will require the following medical record documentation of peer-reviewed literature citing well-designed clinical trials to indicate that the member's healthcare outcome will be improvement by dosing beyond the FDA-approved treatment duration.

Quantity Limits for depressive episodes with acute suicidal ideation:
~~56 mg dose pack: 16 devices per 28 days~~
~~84 mg dose pack:~~ 24 devices per 28 days

Discussion: No comments or questions.

Outcome: The committee unanimously voted to accept the recommendations as presented. None were opposed (26 approved, 0 rejected).

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

TEPEZZA POLICY UPDATE

Background: According to guidelines and UpToDate, Tepezza is the preferred product in patients with active moderate-to-severe TED with significant proptosis and/or diplopia.

Recommendations: It is recommended to update the criteria for MBP 217.0 Tepezza (teprotumumab-trbw) for the Medicaid, commercial, exchange, and CHIP lines of business:

MBP 217.0 Tepezza (teprotumumab-trbw) - Commercial/Exchange/CHIP/Medicaid

Tepezza (teprotumumab-trbw) will be considered medically necessary for the Medicaid line of business when ALL of the following criteria are met:

- Prescription written by an ophthalmologist **AND**
- Medical record documentation of the member being ≥ 18 years of age **AND**
- Medical record documentation of a diagnosis of Grave's disease **AND**
- Medical record documentation of moderate to severe Thyroid Eye Disease with documentation of one or more of the following: lid retraction of ≥ 2mm, moderate or severe soft-tissue involvement, proptosis ≥ 3 mm above normal values for race and sex, or periodic or constant diplopia **AND**
- Medical record documentation that the member is euthyroid or has mild hypo- or hyperthyroidism (free T4 and free T3 levels <50% above or below normal limits) prior to starting Tepezza therapy OR patient has been initiatedlo on anti-thyroid medication **AND**
- Medical record documentation that the member is being prescribed an appropriate dose and duration of Tepezza (10 mg/kg as a single dose, followed by 20 mg/kg IV every 3 weeks for 7 additional doses) **AND**
- Medical record documentation of therapeutic failure on, intolerance to, or contraindication to systemic steroids OR evidence of significant proptosis (≥ 3 mm above normal values for race and sex) and/or diplopia.

Tepezza (teprotumumab-trbw) will be considered medically necessary for the commercial, exchange, and CHIP lines of business when ALL of the following criteria are met:

- Prescription written by an ophthalmologist **AND**
- Medical record documentation of the member being ≥ 18 years of age **AND**
- Medical record documentation of a diagnosis of Grave's disease **AND**
- Medical record documentation of moderate to severe Thyroid Eye Disease with documentation of one or more of the following: lid retraction of ≥ 2mm, moderate or severe soft-tissue involvement, proptosis ≥ 3 mm above normal values for race and sex; and periodic or constant diplopia **AND**
- Medical record documentation that the member is euthyroid or has mild hypo- or hyperthyroidism (free T4 and free T3 levels <50% above or below normal limits) prior to starting Tepezza therapy **AND**
- Medical record documentation that the member is being prescribed an appropriate dose and duration of Tepezza (10 mg/kg as a single dose, followed by 20 mg/kg IV every 3 weeks for 7 additional doses) **AND**
- Medical record documentation of therapeutic failure on, intolerance to, or contraindication to systemic steroids OR evidence of significant proptosis (≥ 3 mm above normal values for race and sex) OR diplopia.

Discussion: No comments or questions.

Outcome: The committee unanimously voted to accept the recommendations as presented. None were opposed (30 approved, 0 rejected).

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

SHORT ACTING OPIOID POLICY UPDATE

Background: In the fall of 2018 it was announced by the state of Pennsylvania that all prescriptions for short acting opioid medications should require prior authorization when beyond five days' (adults) and three days' (children) worth of the drug (with possible exceptions for active cancer, sickle cell crisis, and palliative care and hospice patients) is required. These limits were implemented as directed at the time.

On January 1, 2024 those limits were updated to limit initial short acting opioid fills to ten days' (adults) and five days' (children) to be in alignment with the Department of Human Services guidelines for Medicaid plans.

It was recently discovered that the state of Pennsylvania is still referencing the 2018 guidance for Commercial insurance plans meaning limitations will need to be updated once again.

Recommendations: It is recommended that the limitations on short acting opioids are updated to reflect a prior authorization requirement for any fill beyond an initial five days' (adults) and three days' (children) worth of the drug.

Discussion: No comments or questions.

Outcome: The committee unanimously voted to accept the recommendations as presented. None were opposed (27 approved, 0 rejected).

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

DEXCOM RECEIVER QUANTITY LIMIT UPDATE

Background: It was recently discovered that the Dexcom Receiver quantity limit of 1 receiver per 2 years was limiting our ability to collect rebates on these claims. Although they typically last for several years, Dexcom receivers are only warrantied for 1 year from the date of shipment and in order to retain rebate eligibility the receiver quantity limit must be no more restrictive than 1 receiver per 365 days

Recommendations: It is recommended that the Dexcom Receiver quantity limit is updated to 1 receiver per 365 days.

Discussion: No comments or questions.

Outcome: The committee unanimously voted to accept the recommendations as presented. None were opposed (26 approved, 0 rejected).

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

DAPAGLIFLOZIN/METFORMIN UPDATE

Background: At the April P&T electronic vote dapagliflozin, generic Farxiga, was added to the Commercial, Exchange, and CHIP formularies on the generic tier.

Recommendations: It is recommended that dapagliflozin/metformin, generic Xigduo, is added to the formularies at parity with generic dapagliflozin.

Traditional (2 Tier)	Triple Tier	4th Tier	Marketplace	CHIP
Tier 1 (Generic)	Tier 1 (Generic)	Tier 1 (Generic)	Tier 3 (Generic Non-Preferred)	Tier 1 (Generic)

Discussion: No comments or questions.

Outcome: The committee unanimously voted to accept the recommendations as presented. None were opposed (27 approved, 0 rejected).

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

DUR UPDATE

Commercial/Exchange/TPAs (COMM, D6)

Ongoing

- DPP-4/GLP-1 Diabetes Duplicate Therapy Report
    - We receive this report monthly for all from Adam Kelchner. This report identifies members who potentially have duplicate therapy on a DPP-4/GLP-1 combination. Calls are made to the prescribers to discuss the lack of clinical evidence of this combination and/or duplicate therapy. Recommendations are made to discontinue one agent (ex. the DPP-4 if member on both a GLP-1 and DPP-4).
        - For 2026 we have resolved the following number of **c**ases of therapeutic duplication:
        - **COMM: 1 case** of therapeutic duplication resulting in a projected savings of **$485.18 per script** (this is savings to both member and the health plan)

- TNF and Oral Oncology Agent Report
    - We get this report monthly for the Commercial/Exchange, TPA, and CHIP LOBs from Adam Kelchner.
    - This report was generated in response to removing the renewal prior authorization requirement for these agents.
    - This report identifies members who are on a TNF or Oral Oncology agent and may not have been seen by their applicable specialist in the last 15 months.
    - We research these members and reach out to the offices/members as necessary to ensure the member has been seen within the last 15 months, an appointment has been scheduled or will be scheduled with the member to ensure the member continues to be able to receive their medication.
    - For 2026:
        - For COMM
            - Members Reviewed: **20**
            - Outreaches Made: **8**
            - Letters Sent: **1**
            - Negative Overrides Entered: **0**
        - For D6
            - Members Reviewed: **22**
            - Outreaches Made: **8**
            - Letters Sent: **2**
            - Negative Overrides Entered: **1**

- For TG48
  - Members Reviewed: **20**
  - Outreaches Made: **3**
  - Letters Sent: **2**
  - Negative Overrides Entered: **0**
- For TG51
  - Members Reviewed: **5**
  - Outreaches Made: **1**
  - Letters Sent: **0**
  - Negative Overrides Entered: **0**
  -
- For TGW2
  - Members Reviewed: **5**
  - Outreaches Made: **1**
  - Letters Sent: **0**
  - Negative Overrides Entered: **0**
- For TP45
  - Members Reviewed: **2**
  - Outreaches Made: **1**
  - Letters Sent: **1**
  - Negative Overrides Entered: **0**
- For TP56
  - Members Reviewed: **1**
  - Outreaches Made: **0**
  - Letters Sent: **0**
  - Negative Overrides Entered: **0**
- For SASE
  - Members Reviewed: **1**
  - Outreaches Made: **0**
  - Letters Sent: **0**
  - Negative Overrides Entered: **0**
- For SASN
  - Members Reviewed: **3**
  - Outreaches Made: **0**
  - Letters Sent: **0**
  - Negative Overrides Entered: **0**
- For TPM4
  - Members Reviewed: **1**
  - Outreaches Made: **0**
  - Letters Sent: **0**
  - Negative Overrides Entered: **0**

- <u>Cystic Fibrosis Adherence Report</u>
  - We get this report quarterly for all LOBs from Adam Kelchner. The report identifies patients who have a specific diagnosis of Cystic Fibrosis & outpatient/office visits within the past 2 years. Further the report calls out medication fill history for specific CF medications and the corresponding PDC.

        - For those members who are seen by a GHS provider we send their information to the CF coordinators to discuss their medication adherence
        - We send letters to non-GHS providers with the CF medication fill history for those members with a PDC less than 80%
        - And for all members we send a letter discussing the importance of medication adherence
        - For 2026, please see below for the number of **members** an adherence letter was sent to:
            - Letters are only sent to members every 6 months
                - For COMM: 1
                - For D6: 5
                - For TG48: 5
                - For SASN: 1
                - For WF89: 1
                - For TGW2: 1
        - Please see below for the number of letters sent to non-GHS pulmonologists
            - For D6: **0**
        - Please see below for the number of members referred to the CF coordinators:
            - For COMM: 0
            - For D6: 3
            - For TG48: 5
            - For SASN: 1
            - For WF89: 2

- <u>Duplicate Anticoagulant Report</u>
    - We get this report **<u>weekly</u>** for **all LOBs** flagging members filling duplicate anticoagulant medications. We personally reach out to the providers/members of the flagged members to confirm proper medication therapy.
    - For 2026:
        - For COMM (Commercial): **0 members** reviewed and **0 interventions** made
        - For D6 (Exchange): **6 members** reviewed and **0 interventions** made
        - For TG48/TG51: **5 members** reviewed and **0 intervention** made
        - For TP46: **2 members** reviewed and **0 interventions** made

- <u>Duplicate Specialty Therapy</u>
    - We run an in-house retrospective report **<u>quarterly</u>** for **all LOBs** with help from Adam Kelchner and Aubrielle Smith. These members are identified and written up and sent to a medical director if follow up is needed.
        - For Commercial/Exchange/TPA for 2026, **0 members** were reviewed by a pharmacist and **0 members** were referred to Medical Directors for additional follow-up.
            - For COMM: **0**
            - For D6: **0**
            - For TG48, TG51: **1** member reviewed and **0** interventions made
- <u>Duplicate Buprenorphine Therapy</u>
    - We get this report **<u>quarterly</u>** with help from Adam Kelchner. The report works to identify members who have at least a 7 day overlap period of generic Buprenorphine

and generic Buprenorphine/naloxone products. Members identified as being on both products are being forwarded to Dr. Meadows and Dr. Hossler for further outreach.
    - For Commercial/Exchange, TPAs for 2026, **0 members** have flagged on the report for review and **0 members** were referred to Dr. Meadows

- Suboxone with an Opioid Report
    - We get this report **weekly** for **all LOBs** from Adam Kelchner and we are writing up each new member that flags on the report. These members are being discussed at our weekly meeting with Dr. Meadows and Dr. Hossler. Both medical directors look into whether it is appropriate to end the opioid authorizations still in place or if further intervention is required.
    - For Commercial/Exchange/TPA for 2026, see below for the new members reviewed and those referred to the MDs:
        - For COMM: we have reviewed **0 new members** and **0 members** were referred to MDs
        - For D6: we have reviewed **0 new members** and **0 members** were referred to MDs

- Ending Opioid Authorizations
    - We are working on identifying members who have active opioid authorizations in place but have since started Buprenorphine therapy. The letter is sent to the members notifying them the opioid authorization has been ended due to the start of buprenorphine therapy.
    - For Commercial/Exchange/TPA for 2026, see below for the number of letters we sent to members notifying them that we are ending their opioid authorization(s):
        - For D6: **0**
        - For COMM: **0**
- Opioid Overutilization Report
    - We get this report **monthly** from Navitus and we write up each member that flags on the report. We have been monitoring the members that are continuously showing up on the report by any change in their MED. For those members we deem appropriate we will send a letter to their PCP.
    - For Commercial/Exchange/TPA for 2026, see below for the number of reviewed cases.
        - For COMM: we have reviewed **0 members** and sent **0 cases** to MDs for review
        - For D6: we have reviewed **1 member** and sent **0 cases** to MDs for review
- Fraud Waste Abuse Reports
    - We get this report **weekly** for **all LOBs** from Jeremy Baker. We prepare this report by determining which claims need to be verified, and our GHP technician makes calls to pharmacies to correct/verify claims.
    - We review claims for anti-hypertensives, statins, 1-day supply, and inhalers
        - For COMM for 2026, we have reviewed **8** cases and corrected claims, resulting in a potential **cost savings/avoidance of $1,876.79**
        - For D6 for 2026, we have reviewed **4** cases and corrected claims, resulting in a potential **cost savings/avoidance of $25.63**
        - For TG48 for 2026, we reviewed **8** cases and corrected claims, resulting in a potential **cost savings/avoidance of $203.69**
        - For ALM3 for 2026, we reviewed 1 case and corrected claims, resulting in a potential **cost savings/avoidance of $11.26**

        - For TP50 for 2026, we reviewed 1 case and corrected claims, resulting in a potential cost savings/avoidance of **$532.66**
        - For TP56 for 2026, we reviewed 1 case and corrected claims, resulting in a potential **cost savings/avoidance of $13.45**
        - For SASE for 2026, we reviewed **1** case and corrected claims, resulting in a potential **cost savings/avoidance of $0**

- Duplicate Antipsychotics
    - We get this report **quarterly**, and we send letters to the PCPs to address potential duplicate therapy issues.
        - We have sent the following provider letters in 2026
            - For COMM: **6**
            - FOR D6: **12**
            - FOR TG48, TG51: **24**
            - For SASK: **2**
            - For TP50: **2**
            - For WF89: **0**

- Tobacco Cessation Program
    - We get this report **monthly** to identify members on prolonged tobacco cessation treatment. We send a letter and resource pamphlet to provide additional behavioral health support through Geisinger Health and Wellness.
    - For Commercial/Exchange/TPA for 2026, we sent letters to the below number of members:
        - For COMM: **2**
        - For D6: **0**

- STENT Adherence Report
    - We get this report **monthly** to identify members on an antiplatelet medication and then flag for betablocker and statin medication claims.
    - In 2026, we have sent letters encouraging adherence to the below number of members:
        - **Members for Antiplatelet:**
            - COMM: **8**
            - D6: **22**
            - SASE: **3**
            - TG48, TG51: **11**
            - TP23: 1
            - TP33: **1**
        - **Members for Beta-Blocker:**
            - COMM: **11**
            - D6: **25**
            - SASE: **3**
            - TG48, TG51: **16**
            - SASX: **1**
            - TP45: **1**
            - TP56: **1**
            - WF89: **1**
        - **Members for Statin:**
            - COMM: **14**
            - D6: **21**
            - SASN: **4**
            - SASE: **1**
            - SAH1: **1**
            - TG48, TG51: **16**
            - TGW2: **1**
            - TP56: **1**
            - SASX: **2**
            - TP46: **1**
            - TP50: **3**

        - *member may flag for more than one measure and are included in the count for each measure
    - In 2026, we have attempted telephonic outreach to the below number of members non-adherent in all 3 measures and reached the below members to encourage adherence.
        - COMM:
            - Attempted: **1**
            - Reached: **1**
        - D6:
            - Attempted: **1**
            - Reached:**0**
- <u>Diabetes and Statin Adherence Report</u>
    - We get this report **<u>monthly</u>** to identify members on a Diabetes medication and a Statin medication who are non-adherent to one or both medications.
    - For 2026, we have sent letters to members encouraging adherence:
        - **Diabetes:**
            - COMM: **26**
            - D6: **19**
            - SASE: **1**
            - SASN: **1**
            - TG48, TG51: **24**
            - TGW2: **4**
            - TP45: **1**
            - TP56: **1**
        - **Statin:**
            - COMM: **3**
            - D6: **2**
            - TG48, TG51: **7**

- **<u>HEDIS Initiatives: *Using proactive HEDIS data*</u>**
- <u>Asthma Medication Ratio (AMR) Member Letters</u>
    - Adam Kelchner runs this report **<u>monthly,</u>** and we send letters to the flagged members who have a ratio of controller to total asthma medications of < 0.5.
        - For Commercial/Exchange for 2026, see below for the number of letters sent to members:
            - COMM: **1**
            - D6: **1**
- <u>Asthma Medication Ratio (AMR) Provider Letters</u>
    - Adam Kelchner runs this proactive HEDIS report **<u>quarterly,</u>** and we send letters to the MedInsight attributed PCP for members who have a ratio of controller to total asthma medications of < 0.5.
        - For Commercial/Exchange for 2026, we have sent letters to **providers** for the following number of members to encourage adherence.
            - COMM: **2**
            - D6: **2**

- <u>Asthma Medication Ratio (AMR) Member Calls</u>
    - Jeremy Baker runs this report **<u>weekly</u>** based off of proactive HEDIS reporting. Direct telephonic outreach is made to Commercial/Exchange members who have had a

controller or reliever medication filled in the past 3 months AND are past due for their controller medication.
    - For Commercial/Exchange for 2026, see below for the number of members we have outreached to and the number of members that have been reached:
        - COMM:
            - Outreached to: **2**
            - Reached: **0**
        - D6:
            - Outreached to: **0**
            - Reached: **0**
- Adherence to Antipsychotics for Individuals with Schizophrenia (SAA)
    - Adam Kelchner runs this report **monthly,** and we send letters to the flagged members who appear non-adherent to their antipsychotic medications.
        - For Commercial/Exchange for 2026, see below for the number of letters sent to members:
            - COMM: **0**
            - D6: **0**
- Statin Therapy for Patients with Cardiovascular Disease (SPC)
    - We get this report **monthly** to identify members with cardiovascular disease and who have not received a statin medication or who are non-adherent to statin therapy
        - For Commercial/Exchange in 2026, see below for the number of letters sent to **providers** to encourage statin therapy initiation**:**
            - COMM: 30
            - D6: **22**
        - For Commercial/Exchange in 2026, see below for the number of letters sent to **members** to promote statin adherence:
            - COMM: **1**
            - D6: **2**
- Statin Therapy for Patients with Diabetes (SPD)
    - We get this report **monthly** to identify members with cardiovascular disease and who have not received a statin medication or who are non-adherent to statin therapy
        - For Commercial/Exchange for 2026, see below for the number of letters sent to **members** to promote statin adherence:
            - COMM: **8**
            - D6: **3**
- Persistence of Beta-Blocker Treatment After a Heart Attack (PBH)
    - We get this report **monthly** to identify members with a diagnosis of AMI who received beta-blocker treatment for 6 months after discharge and who are non-adherent to beta-blocker therapy
        - For Commercial/Exchange for 2026, see below for the number of letters sent to **members:**
            - COMM: **0**
            - D6: **0**
- Use of Opioids from Multiple Providers (UOP)
    - We get this report quarterly to identify members 18 years of age and older with a total day supply of all opioid claims to be 15 days or greater

        - For Commercial/Exchange in 2026 we have identified the following number of members seeing 4 or more providers from **different offices** for their opioid prescriptions.
            - COMM: **7**
            - D6: **4**
        - For Commercial/Exchange in 2026 we have identified the following number of members seeing 4 or more providers within the **same office** for their opioid prescriptions.
            - COMM: **1**
            - D6: **1**
- We send letters to the MI attributed PCP of each member with the respective medication fill history to encourage medication evaluation of the opioid medications. Members are omitted from this report if an MI attributed PCP does not populate or if an MI attributed PCP address is not available.

Letters

- <u>Current Provider Letters</u>
    - Cystic Fibrosis Adherence Letter
    - TNF/Oral Oncology Letter
    - Opioid Overutilization
    - Duplicate Antipsychotic medication
    - HEDIS: Statin Therapy for Patients with Cardiovascular Disease (SPC)
    - SUPD/SPD Provider Letter
    - HEDIS: Asthma Medication Ratio (AMR)
    - HEDIS: Use of Opioids from multiple providers (UOP)
- <u>Current Member Letters</u>
    - Cystic Fibrosis Adherence Letter
    - TNF/Oral Oncology Letter
    - Ending Opioid Authorizations
    - Tobacco Cessation Letter
    - STENT Adherence Report
    - Diabetes and Statin Adherence Letters
    - HEDIS: Asthma Medication Ratio (AMR)
    - HEDIS: Adherence to Antipsychotics for Individuals with Schizophrenia (SAA)
    - HEDIS: Statin Therapy for Patients with Cardiovascular Disease (SPC)
    - HEDIS: Statin Therapy for Patients with Diabetes (SPD)
    - HEDIS: Persistence of Beta-Blocker Treatment After a Heart Attack (PBH)

CHIP (CHBQ)

- All of our Medicaid adherence/DUR reports include logic to identify the CHIP population

Ongoing

- DPP-4/GLP-1 Diabetes Duplicate Therapy Report
    - We receive this report monthly for all LOBs from Adam Kelchner. This report identifies members who potentially have duplicate therapy on a DPP-4/GLP-1 combination. Calls are made to the prescribers to discuss the lack of clinical evidence of this combination and/or duplicate therapy. Recommendations are made to discontinue one agent (ex. the DPP-4 if member on both a GLP-1 and DPP-4).
        - For 2026 we have resolved **0 cases** of therapeutic duplication.
- Cystic Fibrosis Adherence Report
    - We get this report **quarterly** for **all LOBs** from Adam Kelchner. The report identifies patients who have a specific diagnosis of Cystic Fibrosis & outpatient/office visits within the past 2 years. Further the report calls out medication fill history for specific CF medications and the corresponding PDC.
        - For those members who are seen by a GHS provider we send their information to the CF coordinators to discuss their medication adherence with the member
        - We send letters to non-GHS providers with the CF medication fill history for those members with a PDC less than 80%
        - And for all members we send a letter discussing the importance of medication adherence
        - For CHBQ for 2026, we sent **0 members** an adherence letter
            - Letters are only sent to members every 6 months
            - There were **0 members** who saw a non-GHS pulmonologist and a letter was sent to that pulmonologist
            - There were **0 members** who saw GHS pulmonologists and were sent to the CF coordinators for follow up
- Duplicate Anticoagulant Report
    - We get this report **weekly** for **all LOBs** flagging members filling duplicate anticoagulant medications. We personally reach out to the providers/members of the flagged members to confirm proper medication therapy.
        - For CHBQ in 2026, we have reviewed **0 members** and have made interventions for **0 members**
- Duplicate Specialty Therapy
    - We run an in-house retrospective report **quarterly** for **all LOBs** with help from Adam Kelchner and Aubrielle Smith. These members are identified and written up and sent to a medical director if follow up is needed.
        - For CHBQ for 2026, **0 members** were reviewed by pharmacists and **0 members** were referred to Medical Directors for additional follow-up.
- Duplicate Buprenorphine Therapy
    - We get this report **quarterly** with help from Adam Kelchner. The report works to identify members who have at least a 7 day overlap period of generic Buprenorphine and generic Buprenorphine/naloxone products. Members identified as being on both products are being forwarded to Dr. Meadows and Dr. Hossler for further outreach.
        - For CHBQ for 2026, we have reviewed **0 members** and **0 members** were referred to MDs
- Suboxone with an Opioid Report

    - We get this report **weekly** for **all LOBs** from Adam Kelchner and we are writing up each member that flags on the report. These members are being discussed at our weekly meeting with Dr. Meadows and Dr. Hossler. Both MDs look into whether it is appropriate to end the opioid authorizations still in place or if further intervention is required.
        - For CHBQ for 2026, we have reviewed **0 new members**, and **0 members** were referred to MDs
- Ending Opioid Authorizations
    - We are working on identifying members who have active opioid authorizations in place but have since started Buprenorphine therapy. The letter is sent to the members notifying them the opioid authorization has been ended due to the start of buprenorphine therapy.
        - For CHBQ for 2026, we sent **0 members** a letter notifying them of the end of their opioid authorization(s).
- Fraud Waste Abuse Reports
    - We get this report **weekly** for **all LOBs** from Jeremy Baker. We prepare this report by determining which claims need to be verified, and our GHP technician makes calls to pharmacies to correct/verify claims.
    - We review claims for anti-hypertensives, statins, 1-day supply, and inhalers
        - For CHBQ for 2026, we have reviewed **8** cases and corrected claims, resulting in a potential **cost savings/avoidance of $1,245.71**
- TNF and Oral Oncology Agent Report
    - We get this report monthly for the Commercial/Exchange, TPA, and CHIP LOBs from Adam Kelchner.
    - This report was generated in response to removing the renewal prior authorization requirement for these agents.
    - This report identifies members who are on a TNF or Oral Oncology agent and may not have been seen by their applicable specialist in the last 15 months.
    - We research these members and reach out to the offices/members as necessary to ensure the member has been seen within the last 15 months, an appointment has been scheduled or will be scheduled with the member to ensure the member continues to be able to receive their medication.
    - For 2026:
        - For CHBQ
            - Members Reviewed: **0**
            - Outreaches Made: **0**
            - Letters Sent: **0**
            - Negative Overrides Entered: **0**
- Tobacco Cessation Program
    - We get this report **monthly** to identify members on prolonged tobacco cessation treatment. We send a letter and resource pamphlet to provide additional behavioral health support through Geisinger Health and Wellness.
        - For CHBQ for 2026, we have not sent any letters
- STENT Adherence Report
    - We get this report **monthly** to identify members on an antiplatelet medication and then flag for betablocker and statin medication claims.
    - For CHBQ for 2026, we have sent letters encouraging adherence to:
        - Members for Antiplatelet:

        - CHBQ: **0**
    - Members for Beta-blocker:
        - CHBQ: **0**
    - Members for Statin:
        - CHBQ: **0**
    - *member may flag for more than one measure and are included in the count for each measure
- Antipsychotic with Opioid Report
    - We get this report **quarterly** to identify **CHIP** members with an overlap of 8 or more days between an opioid and antipsychotic medication.
    - We send a letter with claims data to both the opioid prescriber and the antipsychotic prescriber to encourage collaboration in medication management.
        - For CHBQ for 2026, we sent **0 letters** to **opioid and antipsychotic prescribers**
- Duplicate Antipsychotics
    - We get this report **quarterly**, and we send letters to the PCPs to address potential duplicate therapy issues.
        - For CHBQ in 2026, we have sent letters to **2 providers**
- Diabetes and Statin Adherence Report
    - We get this report **monthly** to identify members on a Diabetes medication and a Statin medication who are non-adherent to one or both medications.
        - For CHBQ in 2026, we have sent letters to members encouraging adherence:
            - For Diabetes: **0 letters**
            - For Statins: **0 letters**

- **HEDIS Initiatives: *Using proactive HEDIS data***
- Asthma Medication Ratio (AMR) Member Letters
    - Adam Kelchner runs this proactive HEDIS report **monthly,** and we send letters to the flagged members who have a ratio of controller to total asthma medications of < 0.5.
        - For CHBQ for 2026, we sent **0 letters** to members

- Asthma Medication Ratio (AMR) Provider Letters
    - Adam Kelchner runs this proactive HEDIS report **quarterly,** and we send letters to the MedInsight attributed PCP for members who have a ratio of controller to total asthma medications of < 0.5.
        - For CHBQ for 2026, we have sent letters to **providers** for the following number of members to encourage adherence.
            - CHBQ: **1**

- Asthma Medication Ratio (AMR) Member Calls
    - Jeremy Baker runs this report **weekly** based off of proactive HEDIS reporting. we send CHIP members who have had a controller or reliever medication filled in the past 3 months AND are past due for their controller medication to the Respiratory Therapists for direct telephonic outreach.
        - For CHBQ for 2026, our pharmacy technician and the STAR reps have outreached to **1 member** and reached **0 members**
- Adherence to Antipsychotics for Individuals with Schizophrenia (SAA)

- Adam Kelchner runs this report **monthly,** and we send letters to the flagged members who appear non-adherent to their antipsychotic medications.
    - For CHBQ for 2026, we have sent **0 letters** to members
- Statin Therapy for Patients with Cardiovascular Disease (SPC)
    - This is a **monthly** report to identify members with cardiovascular disease and who have not received a statin medication or who are non-adherent to statin therapy
        - For CHBQ for 2026, we have sent **0 letters** to providers
        - For CHBQ for 2026, we have sent **0 letters** to members
- Statin Therapy for Patients with Diabetes (SPD)
    - This is a **monthly** report to identify members with cardiovascular disease and who have not received a statin medication or who are non-adherent to statin therapy
        - For CHBQ for 2026, we have sent **0 letters** to members
- Persistence of Beta-Blocker Treatment After a Heart Attack (PBH)
    - This is a **monthly** report to identify members with a diagnosis of AMI who received beta-blocker treatment for 6 months after discharge and who are non-adherent to beta-blocker therapy
        - For CHBQ for 2026, we have sent **0 letters** to members

Letters

- Current Provider Letters
    - Cystic Fibrosis Adherence Letter
    - TNF/Oral Oncology Letter
    - Duplicate Antipsychotic medication
    - HEDIS: Statin Therapy for Patients with Cardiovascular Disease (SPC)
    - SUPD/SPD Provider Letter
    - HEDIS: Asthma Medication Ratio (AMR)
- Current Member Letters
    - Cystic Fibrosis Adherence Letter
    - TNF/Oral Oncology Letter
    - Ending Opioid Authorizations
    - Tobacco Cessation Letter
    - STENT Adherence Report
    - Diabetes and Statin Adherence Letters
    - HEDIS: Asthma Medication Ratio (AMR)
    - HEDIS: Adherence to Antipsychotics for Individuals with Schizophrenia (SAA)
    - HEDIS: Statin Therapy for Patients with Cardiovascular Disease (SPC)
    - HEDIS: Statin Therapy for Patients with Diabetes (SPD)

Geisinger Gold (H3954, H3924, H2064)

Ongoing

- DPP-4/GLP-1 Diabetes Duplicate Therapy Report
    - We receive this report monthly for all LOBs from Adam Kelchner. This report identifies members who potentially have duplicate therapy on a DPP-4/GLP-1 combination. Calls are made to the prescribers to discuss the lack of clinical evidence of this combination and/or duplicate therapy. Recommendations are made to discontinue one agent (ex. the DPP-4 if member on both a GLP-1 and DPP-4).
        - For 2026 we have resolved the following number of **c**ases of therapeutic duplication:

        - **H3924: 1 case** of therapeutic duplication resulting in a projected savings of $357.96 per script (this is savings to both member and the health plan)
        - **H3954: 3 cases** of therapeutic duplication resulting in a projected savings of **$1,548.02 per script** (this is savings to both member and the health plan)
- <u>Cystic Fibrosis Adherence Report</u>
    - We get this report quarterly for all LOBs from Adam Kelchner. The report identifies patients who have a specific diagnosis of Cystic Fibrosis & outpatient/office visits within the past 2 years. Further the report calls out medication fill history for specific CF medications and the corresponding PDC.
        - For those members who are seen by a GHS provider we send their information to the CF coordinators to discuss their medication adherence
        - We send letters to non-GHS providers with the CF medication fill history for those members with a PDC less than 80%
        - And for all members we send a letter discussing the importance of medication adherence
        - For 2026, please see below for the number of **members** an adherence letter was sent to:
            - For H3954: **2**
            - For H3924: **3**
        - There were **0** letters sent to a non-GHS provider
            - For H3954: **1**
            - For H3924: **0**
        - Please see below for the number of members referred to the CF coordinators:
            - For H3954: 3
            - For H3924: **2**

- <u>Duplicate Anticoagulant Report</u>
    - We get this report **<u>weekly</u>** for **all LOBs** flagging members filling duplicate anticoagulant medications. We personally reach out to the providers/members of the flagged members to confirm proper medication therapy.
    - For 2025:
        - For H3954: **58 members** have been reviewed, and **0 interventions** made
        - For H3924: **20 members** have been reviewed, and **2 interventions** made
        - For H2064: **1 member** has been reviewed, and **0 interventions** made
- <u>Duplicate Antipsychotics</u>
    - We get this report **<u>quarterly</u>**, and we send letters to the PCPs to address potential duplicate therapy issues.
        - We have sent the following provider letters in 2026:
            - For H3954: **276** letters sent
            - For H3924: **62** letters sent
            - H2064: **5** letters sent
- <u>Duplicate Specialty Therapy</u>

- We run an in-house retrospective report **quarterly** for **all LOBs** with help from Adam Kelchner and Aubrielle Smith. These members are identified and written up and sent to a medical director if follow up is needed.
    - For Gold for 2026, **9 members** were reviewed by pharmacists and **1 member** was referred to Medical Directors for additional follow-up.
        - For H3954: **7 members reviewed, 1 member referred**
        - For H3924: **2 members reviewed, 0 members referred**
        - For H2064: **0 members reviewed, 0 members referred**

- Duplicate Buprenorphine Therapy
    - We get this report **quarterly** with help from Adam Kelchner. The report works to identify members who have at least a 7 day overlap period of generic Buprenorphine and generic Buprenorphine/naloxone products. Members identified as being on both products are being forwarded to Dr. Meadows and Dr. Hossler for further outreach.
        - For Gold in 2026, we have reviewed **0 members** and **0 members** were referred to Dr. Meadows
            - For H3954: **0**
            - For H3924: **0**
- Suboxone with an Opioid Report
    - We get this report **weekly** for **all LOBs** from Adam Kelchner and we write up each member that flags on the report. These members are being discussed at our weekly meeting with Dr. Meadows and Dr. Hossler. Both MDs look into whether it is appropriate to end the opioid authorizations still in place or if further intervention is required.
    - For Gold for 2026:
        - For H3954: we have reviewed **38 members**, and **5 member**s were referred to MDs
        - For H3924: we have reviewed **10 members**, and **0 members** were referred to MDs
        - For H2064: we have reviewed **0 new member**, and **0 members** were referred to MDs

- Fraud Waste Abuse Reports
    - We get this report **weekly** for **all LOBs** from Jeremy Baker. We prepare this report by determining which claims need to be verified, and our GHP technician makes calls to pharmacies to correct/verify claims.
    - We review claims for anti-hypertensives, statins, 1-day supply, and inhalers.
        - For H3954 for 2026, we have reviewed **40** cases and corrected claims, resulting in a potential **cost savings/avoidance of $2,916.89**
        - For H3924 for 2026, we have reviewed **11** cases and corrected claims, resulting in a potential **cost savings/avoidance of $691.47**
        - For H2064 for 2026, we have reviewed **3** cases and corrected claims, resulting in a potential **cost savings/avoidance of $59.97**
- Tobacco Cessation Program
    - We get this report **monthly** to identify members on prolonged tobacco cessation treatment. We send a letter and resource pamphlet to provide additional behavioral health support through Geisinger Health and Wellness.
        - For Gold for 2026, we have sent letters to the below number of members:
            - For H3954: **0**

        - For H3924: **0**
        - For H2064: **0**
- STENT Adherence Report
    - We get this report **monthly** to identify members on an antiplatelet medication and then flag for betablocker and statin medication claims.
    - For GOLD for 2026, we have sent letters encouraging adherence to:
        - Members for Antiplatelet:
            - H3954: **346**
            - H3924: **135**
            - H2064 (LIFE Geisinger): **4**
        - Members for Beta-blocker:
            - H3954: **444**
            - H3924: **172**
            - H2064 (LIFE Geisinger): **4**
        - Members for Statin:
            - H3954: **521**
            - H3924: **174**
            - H2064 (LIFE Geisinger): **3**
        - *member may flag for more than one measure and are included in the count for each measure
    - For 2026, we have attempted telephonic outreach to the below number of members non-adherent in all 3 measures and reached the below members to encourage adherence.
        - H3954:
            - Attempted: **1**
            - Reached: **1**
        - H3924:
            - Attempted: **0**
            - Reached: **0**
        - H2064:
            - Attempted: **0**
            - Reached: **0**

- Diabetes and Statin Adherence Report
    - We get this report **monthly** to identify members on a Diabetes medication and a Statin medication who are non-adherent to one or both medications.
        - For GOLD for 2026, we have sent letters to members encouraging adherence:
            - **Diabetes:**
                - H3954: **112**
                - H3924: **32**
                - H2064: **3**
            - **Statins:**
                - H3954: **21**
                - H3924: **9**
                - H2064: **1**

- **HEDIS Initiatives: *Using proactive HEDIS data***

- Adherence to Antipsychotics for Individuals with Schizophrenia (SAA)
    - Adam Kelchner runs this report **monthly,** and we send letters to the flagged members who appear non-adherent to their antipsychotic medications.
        - For H3954, we have sent **7 letters** to members
        - For H3924, we have sent **0 letter**s to members
- Statin Therapy for Patients with Cardiovascular Disease (SPC)
    - We get this report **monthly** to identify members with cardiovascular disease and who have not received a statin medication or who are non-adherent to statin therapy
        - For GOLD members for 2026, see below for the number of letters sent to **providers** to encourage statin therapy initiation**:**
            - H3954: **873**
            - H3924: **307**
        - For GOLD members for 2026, see below for the number of letters sent to **members** to promote statin adherence:
            - H3954: **9**
            - H3924: **4**
- Statin Therapy for Patients with Diabetes (SPD)
    - We get this report **monthly** to identify members with cardiovascular disease and who have not received a statin medication or who are non-adherent to statin therapy
        - For GOLD members for 2026, see below for the number of letters sent to **members** to promote statin adherence:
            - H3954: **22**
            - H3924: **8**
- Persistence of Beta-Blocker Treatment After a Heart Attack (PBH)
    - We get this report **monthly** to identify members with a diagnosis of AMI who received beta-blocker treatment for 6 months after discharge and who are non-adherent to beta-blocker therapy
        - For H3954, we sent **1 letter** to members
        - For H3924, we sent **1 letter** to members
- Use of Opioids from Multiple Providers (UOP)
    - We get this report quarterly to identify members 18 years of age and older with a total day supply of all opioid claims to be 15 days or greater
        - In 2026 we have identified the following number of members seeing 4 or more providers from **different offices** for their opioid prescriptions.
            - H3924: **152**
            - H3954: **297**
        - In 2026 we have identified the following number of members seeing 4 or more providers within the **same office** for their opioid prescriptions.
            - H3924: **8**
            - H3954: **26**
        - We send letters to the MI attributed PCP of each member with the respective medication fill history to encourage medication evaluation of the opioid medications. Members are omitted from this report if an MI attributed PCP does not populate or if an MI attributed PCP address is not available.
- Use of High-Risk Medications in Older Adults (DAE)
    - We get this report quarterly to identify Medicare members 67 and older with High-Risk Medications Claims per proactive HEDIS data.

- For 2026 we have identified the following number of members for this mailing:
  - H3954: **4,669**
  - H3924: **2,003**
  - We send letters to the MI attributed PCP of each member with the respective medication fill history to encourage medication evaluation of the opioid medications. Members are omitted from this report if an MI attributed PCP does not populate or if an MI attributed PCP address is not available.

Letters

- Current Provider Letters
  - Cystic Fibrosis Adherence Letter
  - Duplicate Antipsychotic medication
  - SUPD/SPD Provider Letter
  - HEDIS: High Risk Meds in the Elderly (DAE)
  - HEDIS: Statin Therapy for Patients with Cardiovascular Disease (SPC)
  - HEDIS: Use of Opioids from multiple providers (UOP)
- Current Member Letters
  - Cystic Fibrosis Adherence Letter
  - Tobacco Cessation Letter
  - HEDIS: Adherence to Antipsychotics for Individuals with Schizophrenia (SAA)
  - HEDIS: Statin Therapy for Patients with Cardiovascular Disease (SPC)
  - HEDIS: Statin Therapy for Patients with Diabetes (SPD)
  - HEDIS: Persistence of Beta-Blocker Treatment After a Heart Attack (PBH)
  - STENT Adherence Report
  - Diabetes and Statin Adherence Letters

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

Meeting adjourned at 4:31 pm.

The next bi-monthly scheduled meeting will be held on May 12th, 2026 at 1:00 p.m.

Meeting will be held virtually via phone/Microsoft Teams.