Geisinger

P&T Committee Meeting Minutes
Commercial-Exchange-CHIP
September 9, 2025

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

Ariana Wendoloski, Pharm.D. Brandon Whiteash, Pharm.D. Margaret Whiteash, Pharm.D. Jeremy Garris, Pharm.D. (non-voting participant) Tiffany O'Hagan, Pharm.D., MBA (non-voting participant) Abigail Chua Lacey Blauser – Pharmacy resident (non-voting)	

Call to Order:
Dr. Bret Yarczower called the meeting to order at 1:03 p.m., Tuesday, September 9, 2025.

Review and Approval of Minutes:
Dr. Bret Yarczower asked for a motion or approval to accept the July 8, 2025, and August 2025 e-vote minutes as written. Minutes approved unanimously. None were opposed.

DRUG REVIEWS

OCREVUS ZUMOVO (ocrelizumab and hyaluronidase-ocsq)

Review:
Ocrevus Zunovo is a new subcutaneous formulation of Ocrevus indicated for the treatment of adults with relapsing forms of multiple sclerosis (MS), to include clinically isolated syndrome, relapsing-remitting disease, and active secondary progressive disease and primary progressive MS. It is a line extension of Ocrevus, which is available for intravenous administration.

Ocrevus Zunovo includes ocrelizumab and hyaluronidase-ocsq and is administered by subcutaneous injection in the abdomen. At this time, it must be administered by a healthcare professional. Prior to the administration of Ocrevus Zunovo, patients should receive premedication with dexamethasone and an antihistamine. The recommended dosage of Ocrevus Zunovo is 23 mL (920 mg ocrelizumab and 23,000 units of hyaluronidase) subcutaneously in the abdomen over approximately 10 minutes every 6 months. It is supplied as single dose vials containing 920 mg and 23,000 units/23 mL (40 mg and 1,000 units/mL) of ocrelizumab and hyaluronidase-ocsq.

The approval of Ocrevus Zunovo is based on previous clinical trials of Ocrevus and Study 4, a randomized, open-label, parallel arm trial comparing bioavailability, pharmacokinetics, pharmacodynamics, safety, and immunogenicity for Ocrevus Zunovo to intravenous ocrelizumab in 236 patients with RMS or PPMS. Ocrevus Zunovo demonstrated non-inferiority to intravenous ocrelizumab and similar clinical and imaging measures.

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

Clinical Discussion: Bret asked if rituximab was preferred before Ocrevus – for medical, yes. Bret also asked if providers were interested in this formulation – few cases have been received – but there is some interest. No additional comments or questions. The committee unanimously voted to accept the recommendations as presented. None were opposed (38 approved, 0 rejected).

Financial Discussion: Bret asked if this price has increased significantly over the years and if there are rebate opportunities. Prices have not increased abnormally. No rebate available, due to requiring failure of rituximab. No additional comments or questions. The committee unanimously voted to accept the recommendations as presented. None were opposed (38 approved, 0 rejected).

Outcome: Ocrevus Zunovo is a medical benefit and will require prior authorization. Ocrevus Zunovo will be added to the medical benefit cost share list. When processed at a specialty pharmacy, it will process

on the Specialty tier or Brand NP tier for members with a three-tier benefit. It will be added to the existing Ocrevus Medical Benefit Policy 155.0 with the following changes:

Ocrevus (ocrelizumab) or Ocrevus Zunovo (ocrelizumab/hyaluronidase-ocsq) 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 age > 18 years **AND**
- Medical record documentation Ocrevus or Ocrevus Zunovo is prescribed by a neurologist **AND**
- Medical record documentation of hepatitis B screening **AND**
- One of the following:
    - Medical record documentation of a diagnosis of primary progressive MS (PPMS) **OR**
    - Medical record documentation of a diagnosis of a relapsing form of multiple sclerosis, including clinically isolated syndrome, relapsing-remitting disease, and active secondary progressive disease **AND**
- For members with a diagnosis of a relapsing form of multiple sclerosis:
    - Medical record documentation that member has failed, is intolerant to, or has a contraindication to a preferred rituximab product **AND**
    - If intolerant to the preferred rituximab product, documentation of previous history of severe or potentially life-threatening adverse event during or following administration and the adverse event cannot be managed using pre-medication(s) or adjusting the rate of infusion

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

QUANTITY LIMIT:
Ocrevus:
Initial authorization: 12-month duration with quantity limit of 3 doses
Re-authorization: 12-month duration with quantity limit of 2 doses
Ocrevus Zunovo:
Initial authorization and Re-authorization: 12-month duration with quantity limit of 2 doses

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

ENCELTO (revakinagene taroretcel-lwey)

Review:
Encelto is an allogeneic encapsulated cell-based gene therapy indicated for the treatment of adults with idiopathic macular telangiectasia type 2 (MacTel). Encelto is the first FDA-approved treatment for MacTel type 2. Encelto is a surgically implanted, allogeneic encapsulated cell-based gene therapy that continually delivers recombinant human ciliary neurotrophic factor (rhCNTF) to the retina to slow disease progression. Exogenous CNTF is thought to initially target Muller glia to trigger a cascade of signaling events that may promote photoreceptor survival; however, the mechanism of action for Encelto is not completely understood

Encelto is administered via surgical intravitreal implantation by a qualified ophthalmologist. The recommended dose is one Encelto implant per affected eye. Each implant contains 200,000 to 440,0000 allogeneic retinal pigment epithelial cells expressing rhCNTF.

There are two primary forms of macular telangiectasia have been identified. Both are associated with blood vessel abnormalities in the retina. MacTel type 1 is a very rate congenital disorder that occurs unilaterally and almost exclusively in males. There are no FDA approved treatments for MacTel type 1. MacTel type 2 is the more common form of macular telangiectasia with a US prevalence of about 0.1% in individuals over 40 years of age. This form is typically diagnosed in middle age, is more common in females, occurs bilaterally even though each eye may be affected differently. In its early phases, MacTel type 2 is believed to be a neurodegenerative disease associated with the loss of Muller cells. Muller cells are important to maintain the blood retinal barrier. They surround the neurons and provide them with nutrition. Nutritional deprivation may be a major factor leading to the loss of retinal transparency commonly seen in MacTel. Overtime, it may progress to a proliferative form, affecting the macular vasculature ultimately leading to macular degeneration. While it does not cause total blindness, it significantly impacts quality of life due to progressive central vision loss.

Encelto was studied in two studies. Study 1 was a randomized, multi-center, sham-controlled study which enrolled adults with MacTel. Patients were required to have a photoreceptor inner segment/outer segment (IS/OS PR) break (loss) in ellipsoid zone (EZ) between 0.16 and 2.00 mm2 measured by spectral domain-optical coherence tomography (SD-OCT) and best corrected visual acuity (BCVA) of 54-letter score or better (20/80 or better) as measured by the Early Treatment Diabetic Retinopathy Study (ETDRS) chart at screening. Patients were also required to have at least one study eye with MacTel type 2, fluorescein leakage, and at least one other characteristic such as hyperpigmentation outside a 500-micron radius from the fovea center, retinal opacification, crystalline deposits, right-angle vessels, or inner/outer lamellar cavities. Patients with neovascular MacTel were excluded. Patients were randomized to receive either Encelto intravitreal implant (n=58) or sham procedure (n=57) under standard operative procedures. Majority of the patients (96%) had the procedure and were included in the analysis. The primary efficacy outcome measure was the rate of change in the area of EZ loss (IS/OS, macular PR loss) over 24 months, as measured by SD-OCT. The secondary outcome measure was the mean change in aggregate sensitivity loss of microperimetry within the EZ break area from baseline to Month 24. For both outcomes, the Encelto treated patients had statistically significant less change than the sham patient group. Study 2 was a randomized, multi-center, sham-controlled study which enrolled adults with MacTel. Patients were required to have a photoreceptor inner segment/outer segment (IS/OS PR) break (loss) in EZ between 0.16 and 2.00 mm2 measured by SD-OCT and BCVA of 54-letter score or better (20/80 or better) as measured by the ETDRS chart at screening. Patients were also required to have at least one study eye with MacTel type 2, fluorescein leakage, and at least one other characteristic such as hyperpigmentation outside a 500-micron radius from the fovea center, retinal opacification, crystalline deposits, right-angle vessels, or inner/outer lamellar cavities. Patients with neovascular MacTel were excluded. Patients were randomized to receive either Encelto intravitreal implant (n=59) or sham procedure (n=54) under standard peri-operative procedures. Majority of the patients, 95%, underwent the assigned procedure and were included in the efficacy evaluation. The primary efficacy outcome measured was the rate of change in the area of EZ loss (IS/OS, macular PR loss) over 24 months, as measured by SD-OCT. The secondary outcome measure was the mean change in aggregate sensitivity loss of microperimetry within the EZ break area from baseline to Month 24. The rate of change in EZ area loss form baseline over 24 months was statistically significantly less with Encelto compared to sham. There was not a statistically significant difference in the mean change in aggregate retinal sensitivity loss from baseline to month 24 when comparing Encelto and sham.

Encelto is contraindicated in patients with active or suspected ocular or periocular infections and known hypersensitivity to Endothelial serum free media. Encelto has been associated with severe vision loss, infectious endophthalmitis, retinal tears and/or detachment, vitreous hemorrhage, implant extrusion, cataract formation, suture related complications, and delayed dark adaptation. Vitreous hemorrhages occurring greater than one year from implantation could be a sign of Encelto extrusion. The most common adverse reactions (incidence ≥2%) were conjunctival hemorrhage, delayed dark adaptation, foreign body sensation, eye pain, suture related complications, miosis, conjunctival hyperemia, eye pruritus, ocular discomfort, vitreous hemorrhage, blurred vision, headache, dry eye, eye irritation, cataract progression or formation, vitreous floaters, severe vision loss, eye discharge, anterior chamber cell, iridocyclitis. The safety and effectiveness of Encelto have not been established in pediatric patients. There are no data on the use of Encelto in pregnant women. Also there is no data on the presence of

Encelto in human milk, its effects on the breastfed infant, or its impact on milk production. Clinical studies of Encelto did not include sufficient numbers of patients aged 65 and over to determine whether they respond differently than younger patients.

Per IPD review, Encelto is the 1st FDA approved product to treat MacTel type 2, Encelto may offer patients an opportunity to slow progression of the condition and maintain sharper central vision for a longer period of time. Neurotech has indicated that microperimetry data pooled across three clinical trials showed a nearly 35% reduction in aggregate retinal sensitivity loss. The data appear positive; however it is difficult to see how truly impactful Encelto is for maintaining vision and quality of life over time.

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

Clinical Discussion: Bret asked if there were any differences between proliferative and non-proliferative MacTel type 2. Neovascular MacTel type 2 patients were not studied and are usually prescribed VEGF inhibitors. No additional comments or questions. The committee unanimously voted to accept the recommendations as presented. None were opposed (35 approved, 0 rejected).

Financial Discussion: No comments or questions. The committee unanimously voted to accept the recommendations as presented. None were opposed (37 approved, 0 rejected).

Outcome: Encelto will be a medical benefit only. Encelto will be excluded through pharmacy. The following prior authorization criteria will apply (medical benefit):

- Medical record documentation that Encelto is prescribed by an ophthalmologist **AND**
- Medical record documentation of age greater than or equal to 18 years **AND**
- Medical record documentation of a diagnosis of idiopathic macular telangiectasia type 2 (MacTel) type 2 as evident by the following:
    - Evidence of fluorescein leakage and <u>one</u> of the following **AND**
        - Hyperpigmentation outside a 500-micron radius from the fovea center,
        - Retinal opacification,
        - Crystalline deposits,
        - Right-angle vessels,
        - Or inner/outer lamellar cavities **AND**
- Medical record documentation that the patient has not previously received an Encelto implant in the requested eye **AND**
- Medical record documentation of photoreceptor inner segment/outer segment (IS/OS PR) break (loss) in ellipsoid zone (EZ) between 0.16 and 2.00 mm^2 **AND**
- Medical record documentation of best corrected visual acuity (BCVA) of 54-letter score or better (20/80 or better) **AND**
- Medical record documentation that the member does NOT have neovascular MacTel type 2

Authorization Duration: One (1) time approval per eye 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.

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.

HEMICLOR (chlorthalidone)

Review: On March 17, 2025, the United States Food and Drug Administration (FDA) approved Hemiclor (chlorthalidone), an oral thiazide-like diuretic, for the treatment of hypertension in adults. This is a line extension of chlorthalidone, offering a new low dose 12.5mg strength.

The recommended starting dose is 12.5mg or 25mg orally once daily with food. The dose may be doubled after 2 to 4 weeks as needed based on individual response, up to a maximal dose of 100mg once daily. Hemiclor is available as a 12.5mg tablet.

Hypertension is persistently elevated blood pressure, typically defined as ≥130/80 mmHg (ACC/AHA 2017) or ≥140/90 mmHg (WHO and ESC guidelines), affecting about 119.9 million adults in the U.S. Common symptoms of hypertension are headache, dizziness and chest pain. Lowering blood pressure reduces the risk of fatal and nonfatal cardiovascular events, primarily strokes and myocardial infarctions.

Hemiclor is the first FDA-approved low-dose formulation of a thiazide-like diuretic available in the U.S. for treating hypertension in adults. Chlorthalidone (generic formulation) has long been recommended in both 2017 ACC/AHA Hypertension Guideline and 2023 ESH Guideline. Initial therapeutic choices include angiotensin-converting enzyme (ACE) inhibitors, angiotensin-receptor blockers (ARBs), thiazide or thiazide-like diuretics, and calcium channel blockers. Chlorthalidone is also used for edema or general volume overload, and used off-label for the prevention of calcium nephrolithiasis.

The efficacy of a once daily dose of chlorthalidone 12.5 mg for the treatment of hypertension in adults is derived from a published randomized, double-blind, multinational study along with other supportive studies from published literature.

- The efficacy of chlorthalidone 12.5mg once daily was based on data from a randomized, double-blind, phase 3 study, which compared fixed-dose combinations of azilsartan, medoxomil, and chlorthalidone (12.5mg and 25mg) with individual monotherapies.
- The combination of azilsartan, medoxomil, and chlorthalidone demonstrated higher effectiveness than azilsartan alone in lowering blood pressure. Azilsartan and chlorthalidone 12.5 mg demonstrated a 15.8 mmHg reduction in systolic blood pressure; Azilsartan and chlorthalidone 25 mg demonstrated a 21mmHg reduction in systolic blood pressure. Both combination treatments show strong efficacy in hypertension management.
- The Hypertension Detection and Follow-up Program (HDFP), Multiple Risk Factor Intervention Trial (MRFIT), the Systolic Hypertension in the Elderly Program (SHEP), and Antihypertensive and Lipid-Lowering to Prevent Heart Attack Trial (ALLHAT) primarily used chlorthalidone as initial therapy and more consistently demonstrated reductions in cardiovascular events compared to studies that primarily used hydrochlorothiazide (HCTZ). However, a randomized trial to prove any differences in outcome did not perform.
- Both HCTZ and chlorthalidone have demonstrated risk reduction in clinical trials, however there is not strong evidence to support the use of chlorthalidone over HCTZ. It is suggested that clinicians use one of these medications as the preferred diuretic in the treatment of hypertension.

Safety summary:

- Contraindications: Chlorthalidone is contraindicated in patients with anuria, or hypersensitivity to chlorthalidone or other sulfonamide-derived drugs.
- Warnings and precautions: Acute kidney injury, electrolyte abnormalities, metabolic disturbances, and systemic lupus erythematosus.
- Adverse reactions: Acute kidney injury, electrolyte abnormalities and metabolic disturbances
- Drug interactions: Insulin and oral hypoglycemic agent dosages may require adjustments, lithium, tubocurarine, and norepinephrine
- Pregnant/Lactating: Use not recommended.
- Geriatric population: Dose selection for an elderly patient should be cautious, usually starting at the low end of the dosing range, reflecting the greater frequency of decreased hepatic, renal or cardiac function, and of concomitant disease or other drug therapy.
- Renal impairment: Risk of toxicity in patients with impaired renal function.

    - In patients with CrCl ≥10 mL/minute, no dose adjustment is necessary. In patients with CrCl <10 mL/minute, use is not recommended.
- Hepatic impairment: Minor alterations of fluid and electrolyte in patients with impaired hepatic function or progressive liver disease

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 (36 approved, 0 rejected).

Financial Discussion: No comments or questions. The committee unanimously voted to accept the recommendations as presented. None were opposed (37 approved, 0 rejected).

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

- Medical record documentation of a therapeutic failure on, intolerance to, or contraindication to 3 thiazide and/or thiazide-like diuretic formulary alternatives, one of which must be generic chlorthalidone

Formulary Alternatives: chlorthalidone, diuril, hydrochlorothiazide, indapamide, metolazone
Authorization Duration: Open-ended
GPI Level: GPI-12
Quantity Limits: 8 tablets per day
Require RPH Sign off: No

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

ENSACOVE (ensartinib)

Review: Ensacove is indicated for the treatment of adult patients with anaplastic lymphoma kinase (ALK)-positive locally advanced or metastatic non-small cell lung cancer (NSCLC) who have not previously received an ALK-inhibitor. Ensacove is a kinase inhibitor of ALK as well as MET and ROS1. In vitro, it inhibits phosphorylation of ALK and its downstream signaling proteins AKT, ERK, and S6, blocking ALK-mediated signaling pathways and proliferation in cell lines harboring ALK fusions and mutations. In vivo, it showed anti-tumor activity in mouse xenograft models of human NSLCL harboring ALK fusion.

The recommended dosage of Ensacove is 225 mg orally once daily, with or without food, until disease progression or unacceptable toxicity. In the case of adverse reactions, Ensacove can be reduced to 200 mg orally once daily, then 150 mg orally once daily, then permanently discontinued for patients unable to tolerate 150 mg once daily. Once the dose has been reduced for adverse reactions, the dosage should not be subsequently increased. Ensacove is supplied as 25 mg and 100 mg capsules.

The efficacy of Ensacove was evaluated in the eXALT3 study, an open-label, randomized, active-controlled, multicenter study in adult patients with locally advanced (stage IIIB following prior chemotherapy or chemoradiation or not amenable to curative intent therapy) or metastatic ALK-positive NSCLC. Patients could have received one prior chemotherapy regimen, but no ALK-targeted therapies. Patients with asymptomatic, untreated brain metastases who were not on corticosteroids and patients with asymptomatic, treated brain metastases who were on stable or decreasing dose of corticosteroids were eligible. Patients were required to have completed radiation therapy at least 2 weeks, or chemotherapy at least 4 weeks, prior to enrollment. Patients with leptomeningeal disease were ineligible.

Patients were randomized 1:1 to receive Ensacove 225 mg orally once daily or crizotinib 250 mg orally twice daily in 28-day cycles until disease progression or unacceptable toxicity.

The major efficacy endpoint was progression-free survival evaluated by BICR according to RECIST v1.1. Secondary efficacy outcome measures were overall survival (OS), CNS response rate, time to CNS progression, and overall response rate (ORR).

Results in eXALT3 demonstrated a statistically significant improvement in PFS for patients randomized to Ensacove compared to crizotinib. Results are shown in Table 5.

Table 5. Efficacy results for eXALT3 study according to BICR assessment

Efficacy Parameter	**ENSACOVE N=143**	**Crizotinib N=147**
Progression-free survival		
Number of events, n (%)	59 (41%)	80 (54%)
Progressive disease, n (%)	51 (36%)	77 (52%)
Death, n (%)	8 (6%)	3 (2%)
Median, months (95% CI)	25.8 (21.8, NE)	12.7 (9.2, 16.6)
Hazard ratio (95% CI)	0.56 (0.40, 0.79)	
p-value[a]	0.0007	
Overall response rate		
Overall response rate % (95% CI)	74% (66, 81)	67% (58, 74)
Complete response %	12%	5%
Partial response %	62%	61%
Duration of response		
Number of responders, n	106	98
Median, months (95% CI)	NE (22.0, NE)	27.3 (12.9, NE)

CI = Confidence Interval; NE=not estimable; BICR = Blinded Independent Central Review

[a] p-value based on unstratified log-rank test

At the time of the primary PFS analysis, OS results were immature. At the time of final analysis of OS, there were no statistically significant differences between Ensacove and crizotinib. Median OS was 63.2 months in the Ensacove arm and 55.7 months in the crizotinib arm.

Results for the pre-specified analysis of CNS response rate by BICR in patients with baseline CNS disease are summarized in Table 6.

Table 6. CNS ORR and DOR by BICR in patients with baseline measurable CNS disease in eXALT3 study.

Efficacy Parameter	**ENSACOVE N=17**	**crizotinib N=24**
CNS overall response rate % (95% CI)	59% (33, 82)	21% (7, 42)
Complete response %	24%	8%
Partial response %	35%	13%
Duration of Response		
Number of responders, n	10	5
Patients with DOR ≥ 12 months	30%	40%

BICR = Blinded Independent Central Review; CI = Confidence Interval

Warnings and precautions for Ensacove include interstitial lung disease/pneumonitis, hepatotoxicity,

dermatologic reactions, bradycardia, hyperglycemia, visual disturbances, increased creatine phosphokinase, hyperuricemia, and embryo-fetal toxicity. Serious adverse reactions occurred in 23% of patients, including pneumonia, hemorrhage, rash, and cellulitis. Permanent discontinuation occurred in 12% of patients, most commonly due to increased ALT, increased AST, pneumonitis/ILD, increased blood bilirubin, and increased conjugated bilirubin. Dose interruptions and dose reductions due to adverse reactions occurred in 41% and 24% of patients, respectively. The most common reactions in the eXALT3 study were rash, musculoskeletal pain, constipation, pruritus, cough, nausea, edema, vomiting, fatigue, and pyrexia. The most frequent Grade 3 or 4 laboratory abnormalities (≥2%) were increased uric acid, decreased lymphocytes, increased alanine aminotransferase, decreased phosphate, increased gamma glutamyl transferase, increased magnesium, increased amylase, decreased sodium, increased glucose, decreased hemoglobin, increased bilirubin, decreased potassium, and increased creatine phosphokinase.

The safety and efficacy of Ensacove in pediatric patients has not been established. Of the 458 patients enrolled in clinical studies, 16% of patients were aged 65 years or older. Clinical studies did not include sufficient number of patients aged 65 years or older to determine if they respond differently from younger patients. Exploratory analysis suggests a higher incidence of serious adverse events (43% vs. 27%), more frequent adverse reactions leading to discontinuation (18% vs 10%), and dose modifications (34% vs 16%) in patients 65 years or older compared to 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: Bret suggested a class review of the alk inhibitors and possible preference of a particular medication (even if only via the clinical enterprise). Kim believes there is a law in PA in those with metastatic disease cannot step through other agents. Kim will do some additional research. Keith also recommended reaching out to OncoHealth for input. No additional comments or questions. The committee unanimously voted to accept the recommendations as presented. None were opposed (35 approved, 0 rejected).

Financial Discussion: No comments or questions. The committee unanimously voted to accept the recommendations as presented. None were opposed (37 approved, 0 rejected).

Outcome: Ensacove is a pharmacy benefit and will be added to the following tiers of Commercial, Marketplace, and GHP Kids formularies. It will require prior authorization for new starts only. The following prior authorization criteria will apply:

2 Tier/CHIP	3 Tier	4 Tier	ACA
Tier 2 – Brand	Tier 3 – Brand NP	Tier 3 – Brand NP	Tier 1 – Brand NP (Oral Oncology $0 Copay)

- Medical record documentation that Ensacove 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 locally advanced or metastatic non-small cell lung cancer **AND**
- Medical record documentation of anaplastic lymphoma kinase (ALK) fusion or mutation **AND**
- Medical record documentation that member has not previously received an anaplastic lymphoma kinase (ALK) inhibitor

MediSpan Authorization Level: GPI-12

Quantity Limits: 25 mg and 100mg capsules: 2 capsules per day

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

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

the prescribing specialist

Formulary Alternatives: Alecensa*, Alunbrig*, Lorbrena*

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

IBTROZI (taletrectinib)

Review:
Ibtrozi is a kinase inhibitor indicated for the treatment of adult patients with locally advanced or metastatic ROS1-positive non-small cell lung cancer (NSCLC). Ibtrozi inhibits tyrosine kinase ROS1, including ROS1 resistance mutations as well as inhibitory effects on tropomyosin receptor kinases (TRKs) TRKA, TRKB, and TRKC. Ibtrozi inhibited growth of cancer cells expressing ROS1 fusion genes and mutations. In vitro, mice subcutaneously implanted with tumors harboring ROS1 fusions, including G2032R mutation, administration of Ibtrozi inhibited tumor growth. Ibtrozi had anticancer activity in intracranial NSCLC xenograft model harboring a ROS1 fusion.

The recommended dosage of Ibtrozi is 600 mg orally once daily on an empty stomach (no food for at least 2 hours before and 2 hours after taking Ibtrozi) until disease progression or unacceptable toxicity. In the event of adverse reactions, Ibtrozi can be reduced to 400 mg once daily, then 200 mg once daily, then permanently discontinued in patients unable to tolerate 200 mg once daily. Ibtrozi is supplied as 200 mg capsules.

The safety and efficacy of Ibtrozi was evaluated in TRUST-I and TRUST-II, two single-arm, open-label trials in 270 patients with ROS-1 positive locally advanced or metastatic NSCLC. Patients included in the trial had histologically confirmed, locally advanced or metastatic, ROS1-positive NSCLC, ECOG performance status of 0 or 1, and measurable disease per Response Evaluation Criteria in Solid Tumors (RECIST) v1.1. Patients received Ibtrozi 600 mg orally once daily.

The major efficacy endpoint was confirmed overall response rate (ORR) and duration of response (DOR) according to RECIST v1.1 as assessed by BICR. Intracranial response according to modified RECIST v1.1. The efficacy populations included 157 patients naïve to treatment with a ROS1 TKI and 113 patients who received one prior ROS1 TKI. Patients could be chemotherapy-naïve or have received prior chemotherapy for locally advanced disease.

In TRUST-1, 91% of patients had metastatic disease; 17 % of patients had CNS metastases by BICR; 96% had adenocarcinoma; and 19% of patients had prior platinum-based chemotherapy for advanced disease. In TRUST-II, 91% of patients had metastatic disease, 35% of patients had CNS metastases by BICR; 98% had adenocarcinoma; and 19% of patients had prior platinum-based chemotherapy for advanced disease.

Efficacy results are shown in Table 5 in TKI treatment naïve patients and Table 6 in patients previously treated with a TKI.

Table 5. Efficacy Results in ROS1-Positive TKI-Naïve NSCLC Patients per BICR Assessment

Efficacy Parameters	ROS1 TKI-Naïve N=157	
	TRUST-I	TRUST-II
	n=103	*n=54*
Response Rate, % (95% CI)	90% (83, 95)	85% (73, 93)
Complete Response	5%	7%
Partial Response	85%	78%
Duration of Response (DOR)	n= 93	n= 46
Median DOR (95% CI)	NR (30.4, NR)	--[a]
Range (months)	1.1, 46.9+	1.4+, 30.4+
% with DOR[b] ≥12 months	72	63

Abbreviations: CI = Confidence interval; NR = Not reached; "+" indicating ongoing response
[a] Median DOR not included for TRUST-II given the shorter duration of follow-up.
[b] Based on observed duration of response

Table 6. Efficacy Results in ROS1-Positive TKI-Pretreated NSCLC Patients per BICR Assessment

Efficacy Parameters	ROS1 TKI-Pretreated N=113	
	TRUST-I	TRUST-II
	n=66	*n=47*
Response Rate, % (95% CI)	52% (39, 64)	62% (46, 75)
Complete Response	0%	11%
Partial Response	52%	51%
Duration of Response (DOR)	n= 34	n= 29
Median DOR (95% CI)	13.2 (7.7, 24.9)	--[a]
Range (months)	1.4, 38.7+	1.7+, 30.4+
% with DOR[b] ≥6 months	74	83
% with DOR[b] ≥12 months	44	45

Abbreviations: CI = Confidence interval; "+" indicating ongoing response
[a] Median DOR not included for TRUST-II given the shorter duration of follow-up.
[b] Based on observed duration of response.

Of the 15 treatment naïve patients in TRUST-I and TRUST-II with measurable CNS metastases at baseline, 11 patients had response in intracranial lesions. Of the 24 patients previously treated with TKI with measurable CNS metastases at baseline, 15 patients had responses in intracranial lesions. Of 32 patients who had re-biopsied samples tested after failure of prior ROS1 TKI, 15 had resistance mutations. Response were observed in 8 of these 15 patients. All responding patients had tumors with solvent front mutation G2032R.

Warnings and precautions for Ibtrozi include risk of hepatotoxicity, including drug-induced liver failure and fatal adverse reactions, interstitial lung disease/pneumonitis, QTc interval prolongation, hyperuricemia, myalgia with creatine phosphokinase elevation, skeletal fractures, and embryo-fetal toxicity. In TRUST-I and TRUST-II, serious adverse reactions occurred in 31% of patients, including pneumonia, pleural effusion, and hepatotoxicity. Fatal adverse reactions occurred in 18 (5%) patients and included pneumonia, multiple organ dysfunction syndrome, hepatotoxicity, cardia arrest, cardiac failure,

cardiopulmonary failure, respiratory failure, and death not otherwise specified. Permanent discontinuation was required in 7% of patients due to adverse reactions. Dose interruptions and dose reductions due to adverse reactions occurred in 41% and 29% of patients, respectively. The most common adverse reactions were diarrhea, nausea, vomiting, dizziness, rash, constipation, and fatigue. The most frequently reported Grade 3 or 4 laboratory abnormalities were increased ALT, increased AST, decreased neutrophils, and increased creatine phosphokinase.

The safety and efficacy of Ibtrozi in pediatric patients has not been established. Of 352 patients who received Ibtrozi 600 mg orally once daily, 88 (25%) patients were 65 years of age or older and 14 (4%) were 75 years of age or older. There were no clinically meaningful differences in safety and efficacy 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 (34 approved, 0 rejected).

Financial Discussion: No comments or questions. The committee unanimously voted to accept the recommendations as presented. None were opposed (37 approved, 0 rejected).

Outcome: Ibtrozi is a pharmacy benefit and will be added to the following tiers of Commercial, Marketplace, and GHP Kids formularies. It will require prior authorization for new starts only. The following prior authorization criteria will apply:

- Medical record documentation that Ibtrozi 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 locally advanced or metastatic non-small cell lung cancer **AND**
- Medical record documentation of ROS1 rearrangement

Medispan Authorization Level: GPI-12
Quantity Limits: 3 capsules per day, 30 day supply per fill

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

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

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

ENFLONSIA (clesrovimab-cfor)

Review:
Enflonsia is a respiratory syncytial virus (RSV) F protein-directed fusion inhibitor indicated for the prevention of RSV lower respiratory tract disease in neonates and infants who are born during or entering their first RSV season. Enflonsia is a monoclonal antibody with anti-RSV activity.

The recommended dose of Enflonsia is 105mg administered as a single intramuscular (IM) injection by a healthcare professional. For patients born during RSV season, it is recommended to give Enflonsia once starting from birth. For patients born outside of the RSV season, it is recommended to give Enflonsia once prior to the start of their first RSV season, considering the duration of protection provided by Enflonsia. Enflonsia is supplied in a single-dose prefilled syringe containing 105mg/0.7mL (NDCs: 0006-5073-01, 0006-5073-02). Enflonsia is to be stored under refrigeration (26-26 degrees Fahrenheit) and

may be kept at room temperature for a maximum of 48 hours. For infants entering their first RSV season and undergoing cardiac surgery with cardiopulmonary bypass during, one additional dose of Enflonsia is recommended to be administered once the infant is stable after surgery, to ensure adequate serum levels.

Patients at risk of developing more severe illness from RSV include infants, young children, and older adults. Of all children infected, up to 3% of children are hospitalized due to RSV in their first year of life in the United States. Currently available products for RSV include Pfizer's Abrysvo and Sanofi's Beyfortus. Abrysvo is a single-dose IM vaccine for pregnant individuals, and Beyfortus is a single dose IM vaccine for neonates, infants and toddlers in both their first and second RSV seasons. These available products lowered hospitalization rates by 28% to 43% when comparing the 2024/2025 season to rates from 2018-2020. Synagis is also still available however a publication from the American Academy of Pediatrics (AAP) states Synagis is no longer routinely recommended for use and will be discontinued as of 12/31/2025.

The AAP and CDC both recommend Abrysvo to be given at 32-36 weeks of pregnancy from September to January to provide the newborn protection during RSV season. The guidelines also recommend Beyfortus in infants born during or entering their first RSV season when the parent did not get Abrysvo, vaccine status unknown, or when the infant was both within 14 days of the vaccine. Per the latest AAP publication, patients aged 8 to 19 months at high risk of RSV, entering their second season, may get Beyfortus regardless of parent vaccine status. High risk is defined as 1) Children with chronic lung disease of prematurity who required medical support (chronic corticosteroid therapy, diuretic therapy, or supplemental oxygen) at any time during the 6-month period before the start of the second RSV season, 2) Children with severe immunocompromise, 3) Children with cystic fibrosis who have either manifestations of severe lung disease (previous hospitalization for pulmonary exacerbation in the first year of life or abnormalities on chest imaging that persist when stable) OR weight-for-length that is less than the 10th percentile, and 4) American Indian or Alaska Native children. The AAP publication does state that Enflonsia is not approved in children 8 through 19 months entering their second RSV season.

No head-to-head trials have been completed between Enflonsia, Beyfortus, and Abrysvo. When attempting to compare similar endpoints in individual trials, it appears Enflonsia may have a slightly greater impact on hospitalization rates than Beyfortus and Abrysvo, however Enflonsia may have higher rates of injection site reactions compared to Beyfortus. Table 3 above compares the three products. Beyfortus and Synagis are the only options currently available for children entering their second RSV season, however Merck is collecting data on safety and serum concentration of Enflonsia during the second RSV season. Two products in the pipeline are Trinomab's retavibart (IM vaccine entering first RSV season) which can be approved as soon as 2027 and Sanofi's SP0125 (intranasal vaccine in patients 6-21 months old) which can also be approved in 2027.

The efficacy and safety of Enflonsia was evaluated in two trials titled Trial 004 (NCT04767373) and Trial 007 (NCT04938830). Trial 004 was a Phase 2b/3, randomized, double-blind placebo-controlled, multi-site trial in early and moderate preterm infants and late preterm and full-term infants (≥29 weeks GA). The median age of infants was 3.1 months (range: 0-12 months) and participants were randomized 2:1 to receive Enflonsia or placebo. The primary endpoint was incidence of RSV-associated Medically Attended Lower Respiratory Infection (MALRI) defined as cough or difficulty breathing plus requiring ≥1 indicator of LRI (wheezing, rales/crackles) or severity (chest wall in-drawing/retractions, hypoxemia, tachypnea, dehydration due to respiratory symptoms) through 150 days after dosing. Table 4 summarizes the efficacy results.

Table 4. Incidence of RSV-Associated Disease in Infants Born at ≥29 Weeks GA Days 1 Through 150 Post-Dose (Trial 004)

RSV-Associated Endpoint	ENFLONSIA (n=2,411)		Placebo (n=1,203)		Efficacy* (95% CI)†
	Number of cases	Incidence Rate over 5 months	Number of cases	Incidence Rate over 5 months	
MALRI (requiring ≥1 indicator of LRI or severity)	60	0.026	74	0.065	60.5% (44.2, 72.0)‡
Hospitalization	9	0.004	28	0.024	84.3% (66.7, 92.6)‡

n=Number of participants eligible for inclusion in the full analysis set population.
*Efficacy for MALRI (requiring ≥1 indicator of LRI or severity) and hospitalization based on relative risk reduction against placebo adjusted for hemisphere at randomization, gestational age group and age group at randomization.
†Estimate and 95% CI of efficacy were estimated from the modified Poisson regression with robust variance method.
‡($p<0.001$)

The efficacy and safety of Enflonsia was also evaluated in Trial 007, a Phase 3, randomized, partially-blind, palivizumab-controlled, multi-site trial in early or moderate preterm infants (29-35 weeks GA) and infants with chronic lung disease of prematurity or congenital heart disease and any GA, at high risk of RSV. The median age of infants was 2.5 months (range: 0-12 months) and patients were randomized to receive either Enflonsia then placebo, or Synagis. Efficacy was extrapolated from the previous trial, Trial 004, based on similar pharmacokinetic exposure. The incidence rate of RSV-associated MALRI through 150 days after dosing was comparable between Enflonsia and Synagis (incidence rate=3.6%, 95% CI: 2.0, 6.0, incidence rate=2.9%, 95% CI: 1.5, 5.2 respectively). The incidence rate of RSV-associated hospitalization through 150 days after dosing was generally comparable between Enflonsia and Synagis (incidence rate=1.3%, 95% CI: 0.4, 2.9, incidence rate=1.5%, 95% CI: 0.5, 3.2, respectively).

There are no black box warnings for Enflonsia. Contraindication is significant for infants with a history of serious hypersensitivity reactions, including anaphylaxis, to any component of Enflonsia. Warnings and precautions are significant for hypersensitivity including anaphylaxis, and RSV diagnostic test interference. Adverse reactions reported at an incidence higher than placebo in Trial 004 included

injection site erythema, swelling, and rash. The safety profile of Enflonsia in Trial 007 was similar to Synagis and consistent with the safety profile of Enflonsia in Trial 004. Enflonsia is not indicated for use in females of reproductive potential. The safety and effectiveness of Enflonsia has not been established in children older than 12 months 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 (31 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: Enflonsia is a medical benefit and will not require prior authorization, however will have an age and quantity limit. Enflonsia will be added to the medical benefit cost share list. Enflonsia will not be added to the commercial pharmacy formulary. The following limits will apply:

- **Age limit:** younger than 8 months (<8 months old)
- **Quantity limit:** 1 injection per lifetime

Other Recommendations (Beyfortus)
A review of the U.S. Center for Disease Control and Prevention's (CDC's) article titled RSV Immunization Guidance for Infants and Young Children was completed. It was found that the CDC firmly recommends administration of RSV antibody during October through March. The article states: "Administration of infant RSV antibody is recommended during October through March in most of the U.S. The optimal timing for infant RSV antibody administration is shortly before the RSV season begins (e.g., October–November), or within a baby's first week of life if born October through March (ideally during the birth hospitalization.)"

In addition, the American Academy of Pediatrics (AAP) also released a publication on 8/19/25 with a statement that RSV immunization may be administered from October through the end of March. The AAP went on to define "high risk" with new criteria compared to previous publications.

Beyfortus Recommendations: It is recommended to update the authorization duration of MBP 297.0 Beyfortus to more closely align with CDC and AAP's recommendations to allow administration of Beyfortus starting in the month of October. It is also recommended to update the high risk criteria to more closely align with AAP's definition.

- For Children 8 through 19 months of age, medical record documentation of:
  - Chronic lung disease of prematurity who required medical support (chronic corticosteroid therapy, diuretic therapy, or supplemental oxygen) at any time during the 6-month period before the start of the second RSV season **OR**
  - Severe immunocompromise **OR**
  - Cystic fibrosis, with either:
    - Manifestations of severe lung disease, denied as previous hospitalization for pulmonary exacerbation in the first year of life or abnormalities on chest imaging that persist when stable **OR**
    - Weight-for-length that is less than the 10th percentile **OR**
  - American Indian or Alaska Native children

AND

- Medical record documentation that member has not received Synagis during the current RSV season

- ~~Infants ≤ 12 months of age, and born before < 29 weeks gestation at the onset of RSV season **OR**~~
- ~~Infants < 12 months of age, who have a diagnosis of a congenital abnormality of the airway or a diagnosis of a neuromuscular condition that compromises handling of respiratory secretions **OR**~~
- ~~Infants and children < 24 months of age who will be profoundly immunocompromised during the RSV season (e.g., severe combined immunodeficiency or severe acquired immunodeficiency~~

~~syndrome)~~ ~~**OR**~~

- ~~Infants < 12 months of age, born at < 32 weeks gestation, with chronic lung disease of prematurity, defined as > 21% oxygen for at least 28 days after birth~~ ~~**OR**~~
- ~~Infants and children < 24 months of age with chronic lung disease (CLD) who have required at least 28 days of supplemental oxygen after birth and who continue to require medical intervention (supplemental oxygen, chronic steroid use, bronchodilator use or diuretic use)~~ ~~**OR**~~
- ~~Infants < 12 months of age with hemodynamically significant acyanotic heart disease who:~~
  - ~~are receiving medication to control congestive heart failure; or~~
  - ~~have moderate to severe pulmonary hypertension~~

~~**OR**~~

- ~~Infants < 12 months of age with cyanotic heart disease who have been evaluated and recommended for treatment by a cardiologist~~ ~~**OR**~~
- ~~Infants or children who have been receiving prophylaxis and undergo cardiopulmonary bypass during RSV season should receive an additional dose of Beyfortus post-operatively as soon as possible after procedure (even if sooner than a month from previous dose) when medically stable (serum concentrations decrease by a mean of 58% following by-pass)~~ ~~**OR**~~
- ~~Children less than two years of age who undergo cardiac transplantation during the RSV season~~ ~~**OR**~~
- ~~Infants in the first year of life with CF and clinical evidence of CLD and/or nutritional compromise~~ ~~**OR**~~
- ~~Infants in the second year of life with CF and who have severe lung disease (previous hospitalization for pulmonary exacerbation in the first year of life or abnormalities on chest radiography or chest computed tomography that persist when stable) or whose weight for length is less than the 10th percentile.~~

AUTHORIZATION DURATION: Prophylaxis of 1 dose should be initiated on or after October 1 ~~on November 1~~ (prior to RSV season). Listed indications would need to be met on October 1 ~~November 1~~ of the calendar year that prophylaxis is initiated. Members born after October 1 ~~November 1~~ during RSV season who meet criteria will receive one dose of prophylaxis.

In the event of an atypical RSV season (i.e. unpredicted, early, or late, high rates of RSV circulation), prophylaxis of 1 dose should be initiated on dates deemed appropriate by Geisinger Health Plan in conjunction with guidance from the American Academy of Pediatrics (AAP) and other applicable clinical resources. Members born after the start of the atypical RSV season who meet criteria will receive 1 dose on the date deemed appropriate by Geisinger Health Plan in conjunction with guidance from the American Academy of Pediatrics (AAP) and other applicable clinical resources.

Dosing beyond 1 dose will be reviewed on a case-by case basis based on CDC surveillance reports, state/local health department recommendations, and other current medical literature.

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

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

VYKAT XR (diazoxide choline)

Review:
Vykat XR (diazoxide choline extended-release) is a new FDA-approved therapy indicated for the treatment of hyperphagia in adults and pediatric patients aged 4 years and older with Prader-Willi Syndrome (PWS). Approved in March 2025, Vykat XR represents a significant therapeutic advancement as the first and only medication approved for hyperphagia associated with PWS—a rare, complex neurodevelopmental disorder characterized by neurobehavioral, endocrine, and metabolic abnormalities.

This review is being conducted as a new drug evaluation of diazoxide, which has historically been used in its immediate-release formulation for the treatment of hyperinsulinemic hypoglycemia. The focus of this evaluation is to assess the clinical value, safety profile, and appropriate place in therapy for the newly approved extended-release formulation, which represents both a new dosage form and a new therapeutic indication.

Prader-Willi Syndrome is caused by the loss of function of paternally inherited genes on chromosome 15 (15q11-q13) and affects approximately 1 in 15,000 live births. Clinical features include hypotonia and poor feeding in infancy, developmental delays, short stature, hypogonadism, intellectual disability, behavioral challenges, and hyperphagia. Hyperphagia is one of the most challenging and potentially life-threatening symptoms of PWS. It typically begins around age 3 and progresses to severe, persistent hyperphagia between the ages of 5 and 13, continuing throughout life. It is driven by hypothalamic dysfunction, resulting in an inability to sense satiety, obsessive food-seeking behaviors, and emotional distress when food is restricted. Key features include persistent food preoccupation, compulsive food-seeking (e.g., foraging, hoarding), lack of satiety, and behavioral outbursts. Management of hyperphagia often requires strict environmental controls such as locking food storage areas and constant supervision. If left untreated, hyperphagia can lead to severe obesity, metabolic syndrome, type 2 diabetes, and complications like gastric rupture. Historically, there have been no FDA-approved pharmacologic treatments for hyperphagia in PWS. Management has relied solely on behavioral strategies, structured routines, and dietary restriction. The approval of Vykat XR offers a novel pharmacologic option that directly targets this core symptom, addressing a major unmet need in this patient population.
The mechanism of action of diazoxide choline in hyperphagia is not fully understood. It is theorized to act as a potassium channel activator that modulates neuronal signaling related to appetite regulation, potentially reducing the excessive hunger and food preoccupation seen in PWS. Vykat XR is administered once daily, with or without food. It is available in 25 mg, 75 mg, and 150 mg tablet strengths. Dosing is weight-based and titrated slowly to minimize adverse effects. Tablets must be swallowed whole and should not be crushed or split.

Efficacy data for Vykat XR are derived from Study 2-RWP (also known as Study C602-RWP), a phase 3, multicenter, randomized, double-blind, placebo-controlled trial. This study included a 16-week randomized withdrawal phase involving 77 participants who had previously received open-label diazoxide choline extended-release tablets for two to four years. Participants were randomized 1:1 to either continue treatment (n=38) or switch to placebo (n=39). The primary endpoint of the study was to assess changes in hyperphagia-related behaviors from baseline, using the Hyperphagia Questionnaire for Clinical Trials (HQ-CT). This is a validated, caregiver-completed, nine-item questionnaire designed specifically to evaluate hyperphagic symptoms. Secondary endpoints included the Clinical Global Impression of Severity (CGI-S) and the Clinical Global Impression of Improvement (CGI-I), both of which were used by investigators to assess overall illness severity and perceived improvement. The study results revealed a significant worsening in hyperphagia-related behaviors among participants who switched to placebo compared to those who continued with diazoxide choline treatment. At week 16, the placebo group showed a mean change from baseline in HQ-CT total score of 5.0 points, with a P-value of .0022, indicating both a statistically significant and clinically meaningful difference favoring the active treatment. Additionally, secondary outcome measures supported this trend, with the placebo group showing signs of deterioration in both CGI-S and CGI-I scores. Although these did not reach conventional levels of statistical significance, with P-values of .08 and .09 respectively, the findings still suggest a consistent pattern of clinical worsening upon withdrawal from diazoxide choline extended-release tablets.

Common adverse events of Vykat XR include hypertrichosis (36%), edema (27%), hyperglycemia (17%), and rash (12%). Rare but serious events include diabetic ketoacidosis and erythema multiforme (frequency not defined). The drug is contraindicated in patients with hypersensitivity to diazoxide, its components, or thiazides. Clinicians should monitor for hyperglycemia, fluid overload, and potential drug interactions. Strong CYP1A2 inhibitors can increase Vykat XR levels, requiring dose adjustments. Concomitant use with CYP1A2 substrates is not recommended. Rifampin should be avoided, and caution is advised with CYP3A4 inhibitors/inducers, phenytoin, and vitamin K antagonists.

Special population considerations for Vykat XR include limited data in geriatric patients and no established safety or efficacy in children under 4 years of age. The medication is not recommended for use in patients with renal or hepatic impairment due to a lack of clinical studies in these populations. Diazoxide, the active ingredient in Vykat XR, crosses the placenta, and although outcome data during pregnancy are limited, adverse effects such as altered carbohydrate metabolism, hyperbilirubinemia, thrombocytopenia, alopecia, and hypertrichosis lanuginosa (frequency not defined) have been reported in neonates following maternal use during late pregnancy. Additionally, diazoxide is present in human milk; therefore, the decision to breastfeed during therapy should weigh the potential risk of infant exposure against the benefits of breastfeeding and the therapeutic needs of the mother.

Currently, there are no formal guidelines from national organizations that have incorporated Vykat XR into their recommendations, but as the only FDA-approved therapy for hyperphagia in PWS, it is expected to become a standard adjunct to behavioral and nutritional management. In pediatric populations, it provides a long-needed pharmacologic option for a symptom previously managed only through environmental control. Overall, Vykat XR represents a new and clinically meaningful advancement for the treatment of hyperphagia in PWS, addressing a previously unmet need and offering measurable benefits in symptom management.

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

Clinical Discussion: Bret asked if we need to evaluate for “failure of medication” in the reauthorization. Difficult to define. May need to consult expert or one of the primary investigators. If there is no failure, why wouldn’t we just approve indefinitely? Dr. Nemoianu asked what the end points were of the study – all were related to amount of hyperphagia. No other 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 (30 approved, 0 rejected).

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

- Medical record documentation of age greater than or equal to 4 years **AND**
- Medical record documentation of a diagnosis of hyperphagia in Prader Willi Syndrome **AND**
- Medical record documentation of diagnosis of Prader Willi Syndrome confirmed by genetic testing (such as DNA methylation analysis to detect deletion of the chromosome 15q11-q13 region, uniparental disomy in chromosome 15, or imprinting, translocation, or inversion mutations involving chromosome 15) **AND**
- Medical record documentation that VYKAT XR is being prescribed by or in collaboration with a neurologist, psychiatrist, endocrinologist, or physician with expertise in the treatment of PWS **AND**
- Medical record documentation that the patient and/or caregiver have been counseled on appropriate non-pharmacologic strategies, including dietary restriction, exercise, and behavioral modification **AND**
- Medical record documentation of HbA1c or glucose monitoring at baseline **AND**
- Medical record documentation that patient’s dose will be titrated appropriately based on patient’s weight **OR** that maintenance dose is appropriate based on patient’s weight.

Vykat XR Dosing Chart

Weight (kg)	Starting Dosage	Titration Dosage	Titration Dosage	Target Maintenace Dosage
	Weeks 1 and 2	Weeks 3 and 4	Weeks 5 and 6	
20 to <30 kg	25 mg	50 mg	75 mg	100 mg

30 to <40 kg	75 mg	150 mg	150 mg	150 mg
40 to <65 kg	75 mg	150 mg	225 mg	225 mg
65 to <100 kg	150 mg	225 mg	300 mg	375 mg
100 to <135 kg	150 mg	300 mg	375 mg	450 mg
≥135 kg	150 mg	300 mg	450 mg	525 mg

MediSpan authorization level: GPI-12

Quantity Limits: 3 tablets per day for each tablet strength (25 mg, 75 mg, and 150 mg tablet strengths); 84 tablets per 28-day fill; 28-day supply per fill

Authorization Duration: 12 months

Reauthorization info:

- Documentation or provider assessment of improvement in patient's hyperphagia symptoms (for example, but not limited to, decrease in food-seeking behaviors; decrease/maintenance in patient weight; etc.) **AND**
- Medical record documentation of appropriate dosing based on patient's weight **AND**
- Medical record documentation of HbA1c and/or glucose monitoring within the last 6 months

Require RPH Sign off: Yes. Rph Signoff will be required to ensure appropriate utilization.

Formulary alternatives: none

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

SYMBRAVO (meloxicam/rizatriptan)

Review: Symbravo is a combination product of meloxicam, a nonsteroidal anti-inflammatory drug (NSAID) and rizatriptan, a serotonin receptor agonist (also known as a triptan medication). It is indicated for the acute treatment of migraine with or without aura in adult patients. It should not be used for migraine prevention or for cluster headaches. Currently, Treximet (sumatriptan/naproxen), is the only other FDA-approved NSAID/triptan combination product used for migraine treatment.

The mechanism of Symbravo is based on its individual components. Meloxicam reversibly inhibits cyclooxygenase-1 (COX-1) and cyclooxygenase-2 (COX-2) enzymes to reduce the synthesis of pro-inflammatory prostaglandins. Rizatriptan selectively activates intracranial serotonin receptors (5-HT1B and 5-HT1D) to induce vasoconstriction, thus reducing blood flow and pain. Symbravo is available as an oral tablet containing 20 mg meloxicam and 10 mg rizatriptan. The standard dose is one tablet daily as needed for migraine treatment. Currently, safety and efficacy data regarding the effect of a second dose is lacking. Additionally, the safety of treating more than 7 migraines in a 30-day period has not been established. Symbravo also has a warning for medication overuse headaches, which can occur when migraine agents are used as monotherapy or in combination for more than 10 days per month.

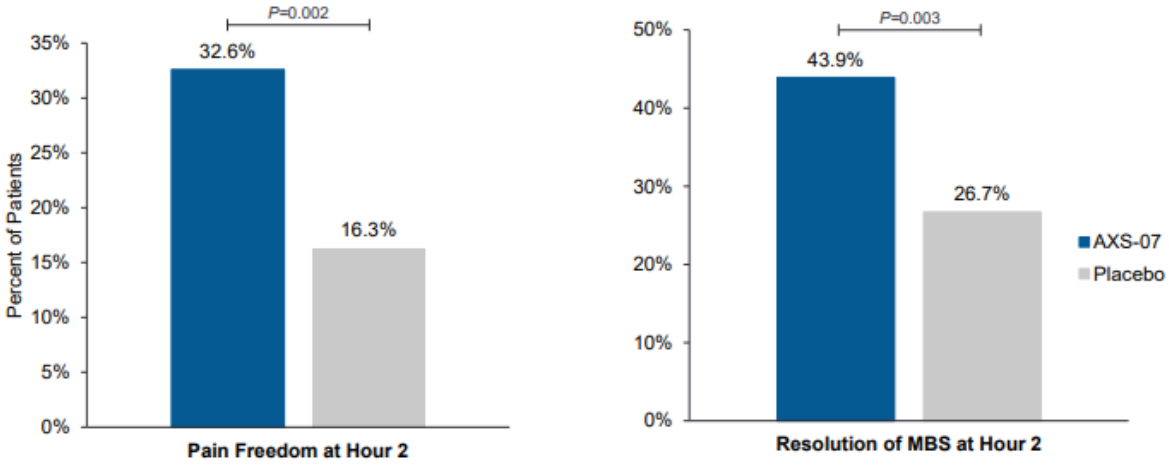
Current migraine management strategies are outlined in guidelines published by the American Academy of Family Physicians (AAFP), the American Headache Society (AHS), and the United States Department of Veterans Affairs/Department of Defense (VA/DoD). AAFP guidelines, updated April 2025, and AHS guidelines, updated February 2021, stratify abortive treatment based on migraine severity. In cases of mild to moderate migraines, NSAIDs, acetaminophen, or other simple analgesics are recommended. For moderate to severe migraines, a targeted migraine medication should be taken at symptom onset. Targeted migraine medications include triptan medications, calcitonin gene-related peptide receptor (CGRP) antagonists (-gepant medications), and 5-HT1F receptor agonists (-ditan medications). Among

targeted migraine medications, triptans are first line and other options should only be considered if contraindication or intolerance to triptans, or an inadequate response to two different triptans. VA/DoD guidelines, published September 2023, also have a strong recommendation for triptan medications as a first line therapy; this is regardless of migraine severity. Although none of the guidelines specifically mention Symbravo, the other NSAID/triptan combination product, Treximet, is classified as a first line treatment option in both the AAFP and VA/DoD guidelines.

Symbravo's safety and efficacy profile was studied in two clinical trials conducted prior to FDA approval. The first study, INTERCEPT, was a double-blind, placebo-controlled, phase 3 trial. The study involved 302 patients randomized 1:1 to receive either a single dose of AXS-07 (Symbravo) or placebo at the onset of mild migraine pain. Both male and female patients, ages 18-65 years, were included in the trial. All included patients were required to have an established migraine diagnosis (for at least 1 year) with or without aura, as defined by International Classification of Headache Disorders 3rd Edition (ICHD-3) criteria, and have an average of 2-8 migraines per month. Patients were excluded if they experienced non-migraine headaches (tension headaches, cluster headaches), had a history of significant cardiovascular disease, or had uncontrolled hypertension. Co-primary efficacy endpoints were freedom from migraine pain 2 hours post-dose and freedom from most bothersome symptoms (MBS), as self-identified by patients, 2 hours post-dose. The most commonly reported MBS were photophobia, nausea, and phonophobia.

Study results revealed that a significantly greater percentage of patients achieved freedom from migraine pain in the Symbravo group compared to placebo 2 hours after a single dose was administered (32.6% vs. 16.3%, p = 0.002). The other co-primary endpoint was also significant, as a higher percentage of patients achieved freedom from their most bothersome symptoms in the Symbravo group versus placebo 2 hours post-dose (43.9% vs. 26.7%, p = 0.003).

Figure 1: Results of Co-Primary Efficacy Endpoints Studied in the INTERCEPT Trial



Co- Primary Endpoints	Difference AXS-07 - Placebo	*P*-Value
Pain Freedom 2 Hours after Dose	16.3%	0.002
Resolution of Most Bothersome Symptom 2 Hours after Dose	17.3%	0.003

Most Bothersome Symptom = nausea, photophobia, or phonophobia

The trial's safety evaluation showed a higher percentage of treatment-emergent adverse effects in the Symbravo group compared to placebo (17.9% vs. 7.7%). The most common adverse effects reported in the Symbravo group versus placebo were somnolence (4.3% vs. 2.1%), dizziness (2.9% vs. 1.4%), and paresthesia (2.1% vs. 0%). There were no serious adverse effects reported in the trial.

The second study, MOMENTUM, was a double-blind, active- and placebo-controlled, phase 3 trial. The study included 1,594 patients randomized 2:1:2:2 to 4 treatment arms: AXS-07 (Symbravo), placebo, meloxicam 20 mg, and rizatriptan 10 mg. Participants were male and female adult (ages 18-65 years) patients with an established migraine diagnosis (for at least 1 year) according to ICHD-3 criteria, with or without aura. Included patients also had an average of 2-8 moderate to severe migraines per month and a history of inadequate response to prior treatments. Exclusion criteria included history of non-migraine headaches, significant cardiovascular disease, or uncontrolled hypertension. Co-primary efficacy endpoints were freedom from migraine pain 2 hours post-dose and freedom from self-identified MBS 2 hours post-dose. Similar to the first study, the highest reported MBS were photophobia, nausea, and phonophobia.
The results of the study showed the highest percentage of patients experienced freedom from migraine pain 2 hours post-dose in the Symbravo group versus placebo, meloxicam, and rizatriptan, respectively. (19.9% vs. 6.7% vs. 11.6% vs. 17.4%). There was a statistically significant difference in the Symbravo group compared to placebo (p <0.001). For the other co-primary endpoint, the highest percentage of patients experienced freedom from MBS 2 hours after dose administration in the Symbravo group versus placebo, meloxicam, and rizatriptan, respectively. (36.9% vs. 24.4% vs. 32.5% vs. 35.8%). Once again, there was a statistically significant difference in the Symbravo group compared to placebo (p = 0.002)

Figure 2: Results of Co-Primary Efficacy Endpoints Studied in the MOMENTUM Trial

Endpoints	AXS-07 (n=428)	Placebo (n=209)	Difference	*P*-Value
Co-Primary Endpoint 1: *Pain Freedom 2 Hours after Dose, %*	19.9%	6.7%	-13.2%	<0.001
Co-Primary Endpoint 2: *Absence of Most Bothersome Symptom 2 Hours after Dose, %*	36.9%	24.4%	-12.5%	0.002

The study's safety analysis revealed treatment-emergent adverse effects occurring in 11.1% of the Symbravo group, 6% of the placebo group, 11.5% of the meloxicam group, and 15.4% of the rizatriptan group. The most common adverse events reported in the Symbravo group compared to placebo, meloxicam, and rizatriptan groups, respectively, were nausea (2.7% vs. 3.7% vs. 3.2% vs. 4.8%), dizziness (1.6% vs. 1.2% vs. 1.2% vs. 2.1%), and somnolence (1.4% vs. 1.4% vs. 2.3% vs. 2.1%).

Studies involving Symbravo use in special populations, including pregnant patients, pediatric patients, and geriatric patients are limited. Symbravo has not been specifically studied in pregnant patients, although data pertaining to its individual components is available and may be used to guide prescribing decisions. Meloxicam, as an NSAID, has a risk of renal dysfunction and premature closure of the ductus arteriosus in the fetus. The risk is greatest further into pregnancy, so Symbravo's labeling recommends limiting dose and duration of the medication between 20-30 weeks gestation and avoiding after 30 weeks. The other active ingredient, rizatriptan, has insufficient human clinical trial data available. Ultimately, weighing the risks and benefits of Symbravo usage in pregnant individuals is important, as mothers experiencing migraines may have an increased risk of perinatal outcomes, such as pre-eclampsia and gestational hypertension. Regarding pediatric and geriatric patients, Symbravo has not been studied in these populations, as available safety and efficacy studies were limited to patients aged 18-65 years. In

general, geriatric patients have a higher risk of experiencing characteristic side effects of NSAIDs, including cardiovascular, renal, and gastrointestinal complications. Thus, caution should be exercised, and the risks and benefits should be weighed when considering Symbravo use in geriatric 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 (31 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: Symbravo is a pharmacy benefit and will not be added to the Commercial, Exchange, or GHP Kids formularies. Requests for coverage will require the following:

- Medical record documentation of a diagnosis of migraine **AND**
- Medical record documentation of age greater than or equal to 18 years **AND**
- Medical record documentation of therapeutic failure on, intolerance to, or contraindication to at least 2 formulary triptans (one of which must be rizatriptan) with concurrent use of meloxicam

Formulary Alternatives: sumatriptan/naproxen, sumatriptan, naratriptan, rizatriptan, zolmitriptan, meloxicam

GPI Level: GPI-12

Authorization Duration: Open-ended

Quantity Limit: 0.3 tablets per day (9 doses per 30 days) – maximum dose

Require RPH Signoff: No

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

LYNOZYFIC (linvoseltamab-gcpt)

Review:
Lynozyfic is a bispecific B-cell maturation antigen (BCMA)-directed CD3 T-cell engager indicated for the treatment of adult patients with relapsed or refractory multiple myeloma who have received at least four prior lines of therapy, including a proteasome inhibitor, an immunomodulatory agent, and an anti-CD38 monoclonal antibody. This was based on response rate and durability of response.

The recommended step-up schedule and maintenance dosage of Lynozyfic is shown in Table 8. Lynozyfic is administered through intravenous infusion according the step-up schedule to reduce the incidence and severity of cytokine release syndrome (CRS). Patients should receive pretreatment with acetaminophen, diphenhydramine, and dexamethasone prior to each dose of the step-up dosing schedule and if indicated, subsequent treatment doses. Patients who experience CRS, ICANS, or neurologic adverse reactions may require dose delays and adjusted doses for restarting therapy (Table 9).

Table 8. Lynozyfic Dosing Schedule

Dosing Schedule	Day[a]	LYNOZYFIC Dose		Duration of Infusion
Step-up Dosing Schedule	Day 1	Step-up dose 1	5 mg	4 hours
	Day 8	Step-up dose 2	25 mg	
	Day 15	First treatment dose	200 mg	
Weekly Dosing Schedule	One week after Day 15 treatment dose and once weekly from Week 4 to Week 13 for 10 treatment doses	Second and subsequent treatment doses	200 mg	1 hour for the second treatment dose, and 30 minutes for subsequent doses[b]
Biweekly (Every 2 Weeks) Dosing Schedule	Week 14 and every 2 weeks thereafter	Subsequent treatment doses	200 mg	30 minutes
Patients who have achieved and maintained VGPR or better at or after Week 24 and received at least 17 doses of 200 mg				
Every 4 Weeks Dosing Schedule	At Week 24 or after and every 4 weeks thereafter		200 mg	30 minutes

[a] Weekly doses should be at least 5 days apart. Biweekly doses should be at least 10 days apart. Every 4-week doses should be at least 24 days apart.

[b] For patients who experienced CRS with the previous dose of LYNOZYFIC, the duration of infusion should be maintained at the duration of the previous infusion; reduce the duration of infusion sequentially in subsequent doses in patients who do not experience CRS (e.g., 4 hours, 1 hour, then 30 minutes).

Table 9. Recommendations for Restarting Therapy with Lynozyfic After a Dose Delay

Last Dose Administered	Time since the last dose administered[a]	Action for next dose. (For CRS/IRR or ICANS, refer to the dose modifications in Table 3, Table 4, and Table 5.)
5 mg	14 days or less	Administer 25 mg
	Greater than 14 days	Restart step-up dosing from 5 mg
25 mg	14 days or less	Administer 200 mg
	Greater than 14 days and less than or equal to 28 days	Restart step-up dosing from 25 mg
	Greater than 28 days	Restart step-up dosing from 5 mg
200 mg	49 days or less	Administer 200 mg
	Greater than 49 days	Restart step-up dosing from 5 mg

NOTE: Administer pre-treatment medications prior to step-up dose 1, step-up dose 2, the first treatment dose, the second treatment dose, and if indicated, subsequent treatment doses *[see Dosage and Administration (2.3)]*.

[a] Consider benefit-risk of restarting LYNOZYFIC in patients who require a dose delay of more than 30 days.

The safety and efficacy of Lynozyfic was evaluated in LINKER-MM1, an open-label, multi-cohort study in patients with relapsed or refractory multiple myeloma. The study included patients who had previously received at least 3 prior therapies, including a proteasome inhibitor (PI), an immunomodulatory agent (IMiD), and an anti-CD38 antibody. The study excluded patients with known multiple myeloma brain lesions or meningeal involvement, history of a neurodegenerative condition, history of seizure within 12 months prior to study enrollment, active infection, a history of an allogeneic or autologous stem cell transplantation within 12 weeks, prior BCMA-directed bispecific antibody therapy, prior bispecific T-cell engaging therapy, or prior BCMA CAR-T cell therapy.

Patients received a step-up dose of 5 mg on Day 1, 25 mg on Day 8, and the first treatment dose of 200 mg on Day 15 of Lynozyfic by intravenous infusion. Then, patients received 200 mg of Lynozyfic weekly from Week 4 to Week 13, followed by 200 mg every other week thereafter. After at least 24 weeks, the Phase 2 patients who achieved a very good partial response (VGPR) or greater received 200 mg of Lynozyfic every 4 weeks. Patients were treated until disease progression or unacceptable toxicity.

The efficacy population included 80 patients who had received at least four prior lines of therapy. Sixty-five percent of patients received prior stem cell transplantation. Seventy-nine percent of patients were triple-class refractory (refractory to a proteasome inhibitor, an immunomodulatory agent, and an anti-CD38 monoclonal antibody). Thirteen percent of patients were previously treated with a BCMA antibody-drug conjugate.

Efficacy was based on objective response rate (ORR) determined by BICR, as measured using the International Myeloma Working Group (IMWG) criteria. The median time to first response was 0.95 months. Estimated duration of response was 89% at 9 months and 72% at 12 months. Table 10 shows efficacy results.

Table 10. Efficacy Results in LINKER-MM1

Efficacy Endpoints	**LYNOZYFIC N=80**
Objective Response Rate (ORR) % (n) (95% CI)	70% (56) (59,80)
Complete response (CR) or better, % (n) (95% CI)	45% (36) (34,57)
Efficacy Endpoints	**LYNOZYFIC N=80**
Stringent complete response (sCR), % (n)	39% (31)
Complete response (CR), % (n)	6% (5)
Very good partial response (VGPR) % (n)	19% (15)
Partial response (PR), % (n)	6% (5)
Duration of Response (DOR)[a]	
Median, months (95% CI)	NR (12, NE)
CI=confidence interval; NE=not estimable [a] Based on Kaplan-Meier estimation.	

Safety concerns are similar to other BCMA-targeted therapies and include black box warnings for cytokine release syndrome, neurologic toxicity, including immune effector cell-associated neurotoxicity syndrome. These include serious and life-threatening reactions which can be mitigated with step-up dosing, pre treatment when appropriate, and withholding/discontinuing medication based on severity of symptoms. Because of the risk of CRS and neurologic toxicity including ICANS, Lynozyfic is only available through Lynozyfic REMS.

Other warnings and precautions include risk of infections, neutropenia, hepatotoxicity, and embryofetal toxicity. In LINKER-MM1, serious adverse reactions occurred in 74% of patients treated with Lynozyfic, including CRS, pneumonia, COVID-19, and acute kidney injury. Fatal adverse reactions occurred in 7% of patients, including sepsis, chronic kidney disease, pneumonia, tumor lysis syndrome, and encephalopathy. Permanent discontinuation occurred in 16% of patients. Dosage interruptions/delays occurred in 74% of patients. The most common adverse reactions were musculoskeletal pain, cytokine release syndrome, cough, upper respiratory tract infection, diarrhea, fatigue, pneumonia, nausea, headache, and dyspnea. The most common Grade 3 to 4 laboratory abnormalities were decreased lymphocyte count, decreased neutrophil count, decreased hemoglobin, and decreased white blood cell count.

The safety and efficacy of Lynozyfic has not been established in pediatric patients. Of the 117 patients with relapsed or refractory multiple myeloma treated with Lynozyfic, 42 (36%) were 65 to 74 years old and 31 (26%) were 75 years of age and older. No overall differences in safety or efficacy were observed in patients 65 years or older compared to 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 (30 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: Lynozyfic is a medical benefit drug and will be added to the medical benefit cost share list. Lynozyfic will be excluded from processing at Specialty pharmacies and will be buy-and-bill only. The following prior authorization criteria will apply:

- Medical record documentation of age greater than or equal to 18 years **AND**
- Medical record documentation that Lynozyfic is prescribed by a hematologist or oncologist **AND**
- Medical record documentation of relapsed or refractory multiple myeloma **AND**
- Medical record documentation of treatment with at least four (4) prior lines of therapy, including a proteasome inhibitor, an immunomodulatory agent and an anti-CD38 monoclonal antibody

MediSpan Authorization Level: GPI-12

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 the member experiences unacceptable toxicity or worsening of disease.

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

TEZRULY (terazosin)

Review: Tezruly is a cherry flavored terazosin oral solution. Tezruly is an alpha-1 adrenergic receptor blocker and is FDA approved for the treatment of benign prostatic hyperplasia (BPH) and hypertension. Tezruly can be used alone or with other antihypertensive agents to lower blood pressure. Tezruly works by selectively blocking the alpha 1 receptor in both vascular and smooth muscle tissues. In the treatment of hypertension, this leads to vasodilation, reducing peripheral resistance and decreasing the cardiac workload. In BPH, it relaxes smooth muscle in the bladder neck and prostate, improving urine flow and

alleviating lower urinary tract symptoms. Tezruly is available in a 1 mg/ml strength that is packaged in a 150 ml bottle. The recommended initial dose for both BPH and hypertension is 1 mg once daily at bedtime to minimize possible side effects such as hypotension. For BPH, the dose is titrated slowly every few weeks based on response and tolerability, with a usual maintenance dose of 10 mg once daily and a maximum of 20 mg once daily, if there is no symptom control after 4-6 weeks. For hypertension, Tezruly can be titrated to a maximum of 20 mg daily, administered once daily or in two divided doses.

According to the 2023 American Urological Association (AUA) guidelines, alpha 1 blockers like terazosin are first line agents for moderate to severe lower urinary tract symptoms due to BPH. In hypertension, according to the 2023 ACC/AHA guidelines, alpha 1 blockers are not recommended as first line agents but may be used as an adjunct to other antihypertensive agents if first line treatment fails. Since Tezruly is in a liquid form this formulation may improve adherence and offers an alternative to patients who have trouble swallowing medication. In addition, individualized dosing is easily prepared with the liquid formulation being 1mg/ml, allowing for a more precise dose titration.

Tezruly is an oral solution formulation of terazosin and was approved in July 2024 for the treatment of hypertension and BPH. The safety profile of Tezruly is consistent with terazosin capsules. Common adverse effects (≥ 1% of patients and at a higher incidence that placebo) include asthenia, flu syndrome, postural hypotension, nausea, somnolence, vertigo, dyspnea, nasal congestion/rhinitis, blurred vision/amblyopia and erectile dysfunction. In the treatment of hypertension, the most common adverse reactions were those with an incidence of ≥5% on terazosin, those occurring at least ≥ 2% more often with a placebo, or those considered of particular clinical interest were asthenia, back pain, pain in the extremities, headache, palpitations, postural hypotension, tachycardia, nausea, edema, peripheral edema, weight gain, depression, dizziness, decreased libido, nervousness, paresthesia, somnolence, dyspnea, nasal congestion, sinusitis, blurred vision and erectile dysfunction. Orthostatic hypotension may occur mainly after the first dose or with a dose increase, this is called first-dose effect. To minimize the side effects, the dose is given at bedtime and blood pressure should be monitored. Warnings for terazosin may include priapism, and intraoperative floppy iris syndrome. Terazosin is listed in the Beers Criteria and should be used with caution in the treatment of BPH but avoided for the management of hypertension.

No clinical trials were conducted for Tezruly specifically, but terazosin capsules have been studied in clinical trials. Terazosin has been studied in 1222 men with symptomatic BPH across three placebo-controlled studies. Terazosin was administered in varying doses from 1mg to 20 mg, titrated to response or fixed dose up to 10 mg. When compared to placebo, terazosin improved urinary symptoms (measured by Boyarsky Index) and peak urine flow rates as early as 2 weeks with effects maintained throughout the study duration of up to 24 weeks and sustained over two years in long term follow-ups seen in a long-term, open-label, non-placebo controlled clinical trial with 181 men. Improvements were seen in both obstructive symptoms such as hesitancy, weak stream and irritative urinary function improvement in terazosin treated patients. When looking at the secondary measures of blood pressure changes in normotensive vs hypertensive patients, terazosin modestly lowered blood pressure in hypertensive patients, and it did not cause clinically significant hypotension in normotensive patients.

Terazosin has been studied in patients with mild to moderate hypertension with once daily dosing or twice daily regimens with total doses ranging from 5-20 mg/day. When measured 24 hours after dosing, terazosin showed consistent decreases in systolic (5-10 mmHg) and diastolic (3.5-8 mmHg) pressures when compared to the placebo with slightly larger effects when standing up. Heart rate remained unchanged at trough but increased by 6-10 beats per minute during peak plasma concentrations in the first few hours after the dose. About 12.5 % of patients experienced significant orthostatic hypotension shortly after dosing compared to 4% with placebo. In addition, lipid profiles showed a modest decrease in total cholesterol and LDL/VLDL fractions without affecting HDL or triglycerides.

There is insufficient data on the risk of major birth defects, miscarriage or other adverse maternal or fetal outcomes associated with terazosin. There are no available data on the presence of terazosin in breast milk, effects on the breast fed infant or effects on milk production. Safety and efficacy have not been established in pediatrics. Patients with renal impairment has significant effect on the elimination of

terazosin. No dose adjustments are needed for the removal of about 10% during hemodialysis. For individuals with liver impairment, there are no dosage adjustments provided in the manufacturer's labeling.

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 (27 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: Tezruly will be a pharmacy benefit and will not be added to the commercial, exchange and CHIP formularies. The following prior authorization criteria will apply:

- Medical record documentation of age greater than or equal to 18 years **AND**
- Medical documentation of a diagnosis of either benign prostatic hyperplasia **OR** hypertension **AND**
- Medical record documentation of contraindication to, intolerance to or therapeutic failure to 3 alternative alpha blockers on the formulary, one of which must be terazosin capsules

Formulary Alternatives: Terazosin capsules, prazosin capsules, doxazosin and tamsulosin capsules

Authorization Duration: Open-ended

GPI Level: GPI-12

Quantity Limits: 20mL per day (600mL per 30 days)

Require RPH sign off: No

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

CLASS REVIEWS

DENOSUMAB BIOSIMILAR CLASS REVIEW

Review:

FDA Approved Denosumab Biosimilars[1-13]				
Brand Name	**Manufacturer**	**How Supplied**	**Indications**	**Available?**
Prolia Biosimilars				
Conexxence (denosumab-bnht)	Fresenius Kabi USA, LLC	60 mg/mL single dose PFS	For treatment: • Of postmenopausal women with osteoporosis at high risk of fracture • To increase bone mass in men with osteoporosis at high risk of fracture • Of glucocorticoid-induced osteoporosis in men & women at high risk for fracture • To increase bone mass at high risk for fracture receiving androgen deprivation therapy for nonmetastatic prostate cancer • to increase bone mass in women at high risk for fracture receiving adjuvant aromatase inhibitor therapy for breast cancer	Yes
Jubbonti (denosumab-bbdz)	Sandoz Inc.	60 mg/mL single dose PFS		Yes
Ospomyv (denosumab-dssb) Denosumab-dssb	Samsung Bioepis Co., Ltd.	60 mg/mL single dose PFS		No
Stoboclo (denosumab-bmwo)	Celltrion, Inc	60 mg/mL single dose PFS		Yes
Xgeva Biosimilars				
Bomyntra (denosumab-bnht)	Fresenius Kabi USA, LLC	120 mg / 1.7 mL (70 mg/mL) Single dose vial 120 mg / 1.7 mL (70 mg/mL) Single-dose PFS	• Prevention of skeletal-related events in patients with multiple myeloma and in patients with bone metastases from solid tumors • Treatment of adults and skeletally mature adolescents with giant cell tumor of bone that is unresectable or where surgical resection is likely to result in severe morbidity • Treatment of hypercalcemia of malignancy refractory to bisphosphonate therapy	Yes Yes
Osenvelt (denosumab-bmwo)	Celltrion, Inc	120 mg / 1.7 mL (70 mg/mL) Single dose vial		
Xbryk (denosumab-dssb) Denosumab-dssb	Samsung Bioepis Co., Ltd.	120 mg / 1.7 mL (70 mg/mL) Single dose vial		No
Wyost (denosumab-bbdz)	Sandoz Inc.	120 mg / 1.7 mL (70 mg/mL) Single dose vial		Yes

Summary of Clinical Trials:
Conexxence/Bomyntra: FDA approval is supported by a clinical trial evaluating pharmacokinetics, pharmacodynamics, and immunogenicity in healthy volunteers and one efficacy, pharmacodynamic and

immunogenicity study in women with postmenopausal osteoporosis (LUMIADE-3 Study, NCT 04934072). LUMIADE-3 was a double-blind, randomized, multiple-dose, 2-arm parallel group study comparing Conexxence (n=277) to Prolia (n=276) in 553 postmenopausal women. Outcomes evaluating percentage change from baseline in bone mineral density, pharmacokinetics, and treatment-emergent adverse events demonstrated non-inferiority for Conexxence compared to Prolia for efficacy outcomes and no clinically meaningful differences in efficacy, safety, or immunogenicity.

Jubbonti/Wyost: FDA approval is based on pharmacokinetic analysis in health subjects between Jubbonti/Wyost and Prolia/Xgeva and one randomized, double-blind, comparative clinical study comparing efficacy, pharmacokinetics, and immunogenicity of Jubbonti and Prolia in 527 postmenopausal women with osteoporosis (Study CGP24112301). Study CGP24112301 demonstrated no clinically meaningful differences between treatment groups in terms of efficacy, pharmacokinetics, and immunogenicity.

Ospomyv/Xbryk/Denosumab-dssb: FDA approval was based on results of a randomized double-blind, three-arm, parallel group study in healthy male participants showing pharmacokinetic equivalence between Ospomyv US-Prolia, and EU-Prolia. In addition, a randomized, double-blind, Phase 3 study comparing safety, efficacy, pharmacokinetics, and immunogenicity of Ospomyv and Prolia in postmenopausal osteoporosis patients demonstrated comparable results for change from baseline in lumbar spine bone mineral density, safety, pharmacokinetics, and immunogenicity.

Stoboclo/Osenvelt: FDA approval is based on results from Phase III clinical trials in postmenopausal women which demonstrated equivalent efficacy for Stoboclo to Prolia in terms of efficacy, pharmacodynamics, pharmacokinetics, safety, and immunogenicity.

Clinical Summary: All of the approved denosumab biosimilars have shown pharmacokinetic similarities and no clinically meaningful differences have been identified between the biosimilars, Prolia, and Xgeva in terms of efficacy, safety, and immunogenicity for all indications. Ospomyv, Xbryk, and denosumab-dssb FDA approved but are not currently available. Commercial and Medicare approval rates for brand Prolia and Xgeva from June 2024 to June 2025 were 92% and 93%, respectively.

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 (31 approved, 0 rejected).

Outcome: Conexxence, Bomyntra, Jubbonti, Wyost, Stoboclo, and Osenvelt are medical benefits. Based on clinical comparisons, a biosimilar first approach, and previous approval rates of the brand Prolia and Xgeva, the biosimilars will not require prior authorization. They will be added to the medical benefit cost share list. When processed at a specialty pharmacy, they will process on the specialty tier or brand non-preferred tier for members with a three tier benefit. Ospomyv and Xbryk are not currently available, but when available will be reviewed based on clinical and financial information and if appropriate will not require prior authorization to match the other biosimilars.

Quantity Limit for Conexxence, Jubbonti, Ospomyv (when available), and Stoboclo:
QUANTITY LIMIT:

- QL FOR AUTHORIZATION: 1 ml (1 syringe) every 180 days
- QL FOR LETTER: 1 ml (1 syringe) every 180 days

To align with the biosimilar first approach, the following changes should be added to Medical benefit policy 81.0 for Prolia, Medical Benefit Policy 89.0 for Xgeva:

Medical Benefit Policy 81.0 Prolia

1. **For post-menopausal women at high risk for fractures:**
   - Physician provided documentation of a diagnosis of post-menopausal osteoporosis **AND**
   - One of the following:
     - Physician provided documentation of previous osteoporotic fracture* OR
     - Physician provided documentation of high risk of fracture (defined as a spine or hip DXA T-score of less than or equal to -2.5, supporting clinical factors, and/or FRAX calculation showing a >3% probability of hip fracture OR >20% probability of major osteoporosis-related fracture) **OR**
     - Physician provided documentation of a failed attempt of therapy with or contraindication to one oral bisphosphonate

AND

- Medical record documentation of a therapeutic failure on, intolerance to, or contraindication to two of the following: denosumab-bnht (Conexxence), denosumab-bbdz (Jubbonti), or denosumab-bmwo (Stoboclo)

2. **For increasing bone mass in women at high risk for fracture receiving adjuvant aromatase inhibitor therapy for breast cancer:**
   - Physician provided documentation that patient is receiving adjuvant aromatase inhibitor therapy for breast cancer AND
   - One of the following:
     - Physician provided documentation of previous osteoporotic fracture* OR
     - Physician provided documentation of high risk of fracture (defined as a spine or hip DXA T-score of less than or equal to -2.5, supporting clinical factors, and/or FRAX calculation showing a >3% probability of hip fracture OR >20% probability of major osteoporosis-related fracture) OR
     - Physician provided documentation of a failed attempt of therapy with or contraindication to one oral bisphosphonate

AND

- Medical record documentation of a therapeutic failure on, intolerance to, or contraindication to two of the following: denosumab-bnht (Conexxence), denosumab-bbdz (Jubbonti), or denosumab-bmwo (Stoboclo)

3. **For increasing bone mass in men at high risk for fracture receiving androgen deprivation therapy for non-metastatic prostate cancer:**
   - Physician provided documentation that patient is receiving androgen deprivation therapy for non-metastatic prostate cancer **AND**
   - One of the following:
     - Physician provided documentation of previous osteoporotic fracture* OR
     - Physician provided documentation of high risk of fracture (defined as a spine or hip DXA T-score of less than or equal to -2.5, supporting clinical factors, and/or FRAX calculation showing a >3% probability of hip fracture OR >20% probability of major osteoporosis-related fracture) OR
     - Physician provided documentation of a failed attempt of therapy with or contraindication to one oral bisphosphonate

AND

- Medical record documentation of a therapeutic failure on, intolerance to, or contraindication to two of the following: denosumab-bnht (Conexxence), denosumab-bbdz (Jubbonti), or denosumab-bmwo (Stoboclo)

4. For the treatment of men at high risk for fractures:
   - Physician provided documentation of a diagnosis of osteoporosis AND
   - One of the following:
     - Physician provided documentation of previous osteoporotic fracture* OR

- Physician provided documentation of high risk of fracture (defined as spine or hip DXA T-score of less than or equal to -2.5, supporting clinical factors, and/or FRAX calculation showing a >3% probability of hip fracture OR >20% probability of major osteoporosis-related fracture) **OR**
- Physician provided documentation of a failed attempt of therapy with or contraindication to one oral bisphosphonate

AND

- Medical record documentation of a therapeutic failure on, intolerance to, or contraindication to two of the following: denosumab-bnht (Conexxence), denosumab-bbdz (Jubbonti), or denosumab-bmwo (Stoboclo)

5. For the treatment of glucocorticoid-induced osteoporosis:

- Medical record documentation of a diagnosis of glucocorticoid-induced osteoporosis **AND**
- Medical record documentation that the patient is initiating or continuing systemic glucocorticoids in a daily dosage equivalent to 7.5 mg or greater of prednisone **AND**
- Medical record documentation that the patient is going to remain on systemic glucocorticoid therapy for at least 6 months **AND**
- One of the following:
  - Medical record documentation of previous osteoporotic fracture* OR
  - Medical record documentation of high risk of fracture defined as DXA T-score of less than or equal to -2.0 at the lumbar spine, total hip, or femoral neck, supporting clinical factors and/or FRAX calculation showing a >3% probability of hip fracture OR >20% probability of major osteoporosis-related fracture; **OR**
  - Medical record documentation of a failure on, intolerance to, or contraindication to one oral bisphosphonate

AND

- Medical record documentation of a therapeutic failure on, intolerance to, or contraindication to two of the following: denosumab-bnht (Conexxence), denosumab-bbdz (Jubbonti), or denosumab-bmwo (Stoboclo)

*Note:
Per the American Association of Clinical Endocrinologists/American College of Endocrinology
Osteoporotic fracture (low-trauma fracture, fragility fracture) - A fracture usually sustained from force similar to a fall from a standing position or less that would not have occurred in healthy bone, excepting fractures of the skull, face, fingers, and toes.

Per UpToDate
Osteoporotic fracture (fragility fracture) – Fracture at the spine, hip, wrist, humerus, and pelvis, without measurement of BMD. Fractures occurring from a fall from a standing height or less, without major trauma such as a motor vehicle accident. Fractures at some skeletal sites (including the skull, cervical spine, hands, and feet) are not considered fragility fractures. Stress fractures are also not considered fragility fractures as they are due to repetitive injury, often in individuals with otherwise healthy bones. Rib fractures may present as fragility fractures but more commonly result from trauma.

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

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

FAST FACTS

ENHERTU (fam-trastuzumab deruxtecan-nxki)

Clinical Summary:
Enhertu is now approved for adult patients with unresectable or metastatic hormone receptor (HR)-positive, HER2-low (IHC 1+ or IHC 2+/ISH-) or HER2-ultralow (IHC 0 with membrane staining) breast cancer, as determined by an FDA-approved test, that has progressed on one of more endocrine therapies in the metastatic setting. This new indication is added to the label that also includes other forms of breast cancer, non-small cell lung cancer, gastric or gastroesophageal junction cancer, and solid tumors.

Updated Dosing for New indication
The dosing for this new indication remains consistent with the dosing for all other forms of breast cancer for which Enhertu is approved. The dosing is 5.4 mg/kg given as an intravenous infusion once every 3 weeks (21-day cycle) until disease progression or unacceptable toxicity.

Current Formulary Status: Enhertu is a medical benefit requiring prior authorization. When processed at a specialty pharmacy, it is on the specialty tier or brand non preferred tier.

Recommendation: No changes recommended to the formulary placement or authorization duration of Enhertu at this time. However, it is recommended to update policy Medical Benefit Policy 208.0 to include the following highlighted changes:

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

- 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 determined 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 a 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.

UPDATES

OCREVUS

Background: In order to align our policies with the Geisinger Health System Multiple Sclerosis Carepath, updated guidelines, and for overall drug cost reduction it is recommended to require that the preferred rituximab product be used for the treatment of Multiple Sclerosis before using Ocrevus.

Recommendation: Update MBP 155.0 to require step through of the preferred rituximab product for the treatment of clinically isolated syndrome, relapsing-remitting disease, and active secondary progressive disease.

Ocrevus – MBP 155.0

Ocrevus (ocrelizumab) 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 age > 18 years **AND**
- Medical record documentation Ocrevus is prescribed by a neurologist **AND**
- Medical record documentation of hepatitis B screening **AND**
- One of the following:
    - Medical record documentation of a diagnosis of primary progressive MS (PPMS) **OR**
    - Medical record documentation of a diagnosis of a relapsing form of multiple sclerosis, including clinically isolated syndrome, relapsing-remitting disease, and active secondary progressive disease **AND**
- For members with a diagnosis of a relapsing form of multiple sclerosis:
    - Medical record documentation that member has failed, is intolerant to, or has a contraindication to a preferred rituximab product **AND**
    - If intolerant to the preferred rituximab product, documentation of previous history of severe or potentially life-threatening adverse event during or following administration and the adverse event cannot be managed using pre-medication(s) or adjusting the rate of infusion.

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.

BRIUMVI

Background: In order to align our policies with the Geisinger Health System Multiple Sclerosis Carepath, updated guidelines, and for overall drug cost reduction it is recommended to require that the preferred rituximab product be used for the treatment of Multiple Sclerosis before using Briumvi.

Recommendation: Update MBP 295.0 to require step through of the preferred rituximab product for the treatment of clinically isolated syndrome, relapsing-remitting disease, and active secondary progressive disease.

Briumvi – MBP 295.0

Briumvi (ublituximab)) 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 age > 18 years **AND**
- Medical record documentation Briumvi is prescribed by a neurologist **AND**
- Medical record documentation of hepatitis B screening **AND**
- Medical record documentation of a diagnosis of a relapsing form of multiple sclerosis, including clinically isolated syndrome, relapsing-remitting disease, and active secondary progressive disease **AND**
- Medical record documentation that member has failed, is intolerant to, or has a contraindication to a preferred rituximab product **AND**
- If intolerant to the preferred rituximab product, documentation of previous history of severe or potentially life-threatening adverse event during or following administration and the adverse event cannot be managed using pre-medication(s) or adjusting the rate of infusion.

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.

SPEVIGO (spesolimab-sbzo)

Background:
Spevigo is now available in a subcutaneous formulation for the treatment of generalized pustular psoriasis (GPP) in adults and pediatric patients 12 years of age and older and weighing at least 40 kg. Spevigo prefilled syringes are recommended for subcutaneous treatment when not experiencing a flare.

The recommended subcutaneous dosage is a loading dose of 600 mg followed by 300 mg subcutaneously 4 weeks after and every 4 weeks thereafter. The recommended dosage for subcutaneous Spevigo following a GPP flare treated with IV Spevigo is 300 mg four weeks after IV Spevigo followed by 300 mg every 4 weeks (no loading dose is needed). Spevigo is supplied as 150 mg/mL and 300 mg/2 mL prefilled syringes. When using Spevigo 150 mg/mL prefilled syringe, if required the 600 mg loading dose must be administered by a health care professional. For subsequent 300 mg doses and for Spevigo 300 mg/2mL prefilled syringes, the dosage can be self-administered if determined to be appropriate by the healthcare professional.

If a patient experiences a GPP flare while receiving subcutaneous Spevigo, the GPP flare may be treated with intravenous Spevigo.

Drug	Dosing	AWP/MAC per unit ($)
Spevigo IV 450 mg/ 7.5 mL	For treatment of GPP flare	$66,968 / 7.5 mL
Spevigo PFS 150 mg/mL, 300 mg/2 mL	For treatment of GPP after treatment of flare/when not experiencing a flare	$11,161 / 150 mg/mL $22,323 / 300 mg / 2 mL

Recommendation: Spevigo SC is a medical benefit (for loading dose of Spevigo SC 150 mg/mL PFS only) or a pharmacy benefit (for maintenance doses). It is recommended that Spevigo SC be added to the formulary for Commercial, Exchange and CHIP as follows:

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

It is recommended that separate criteria be added to the medical benefit policy for Spevigo SC be created since Spevigo IV is used for treating GPP flares, while Spevigo SC can be used for maintenance treatment of GPP while not experiencing flares. A commercial policy with the following criteria will be created for Spevigo SC.

Medical Benefit Policy Spevigo SC Prior Authorization Criteria:

- Medical record documentation that Spevigo is prescribed by a dermatologist **AND**
- Medical record documentation of age greater than or equal to 12 years **AND**
- Medical record documentation of a diagnosis of generalized pustular psoriasis (GPP) **AND**
- Medical record documentation of a dose and duration of therapy that is consistent with FDA-approved package labeling, nationally recognized compendia, or peer-reviewed medical literature

Quantity Limit:
One-time authorization for 28 days of 4 milliliters per 28 days for the loading dose of Spevigo SC 150 mg/mL PFS only (Spevigo SC 300 mg/2mL PFS loading dose can be self-administered) followed by 2 milliliters per 28 days for the requested Spevigo SC dose (through the pharmacy benefit)

Commercial Policy Spevigo SC Prior Authorization Criteria:

- Medical record documentation that Spevigo is prescribed by a dermatologist **AND**
- Medical record documentation of age greater than or equal to 12 years **AND**
- Medical record documentation of a diagnosis of generalized pustular psoriasis (GPP) **AND**
- Medical record documentation of a dose and duration of therapy that is consistent with FDA-approved package labeling, nationally recognized compendia, or peer-reviewed medical literature **AND**
- If the request is for Spevigo 150 mg/mL prefilled syringe: Medical record documentation of continuation following a GPP flare treated with intravenous spesolimab-sbzo OR documentation that member has received a loading dose of 600 mg subcutaneous spesolimab-sbzo

Authorization Duration: Approval will be given for a duration of twelve (12) months. For continuation of coverage, medical record documentation of clinical improvement or lack of progression in signs and symptoms of treated condition on ustekinumab therapy is required.

Quantity Limit:
Spevigo 300 mg/2 mL prefilled syringe: Initial loading dose approved 600 mg, followed by 300 mg 4 weeks later, then every 4 weeks:

1. In PA Hub: Add Treat as “Include” Process Modifier, Ignore Misc Handler, enter 1 in max number of claims authorized, max quantity dispensed 4, maximum day supply 28 with a duration of 28 days.
2. In NCRx: Add Treat as “Include” Process Modifier, Ignore Misc Handler, max quantity dispensed 2, maximum day supply 28 for the remainder of the authorization
    - QL FOR LETTER: Loading dose: 4 mL per 28 days for 1 fill
        - Maintenance dose: 2 mL per 28 days, 28 day supply per fill

Spevigo 150 mg/mL prefilled syringe: Maintenance dose 300 mg 4 weeks after initial loading dose administered through medical benefit, then 300 mg every 4 weeks:

1. In PA Hub: Add Treat as “Include” Process Modifier, Ignore Misc Handler, max quantity dispensed 2, max script days 28.
    - QL FOR LETTER:
        - Maintenance dose: 2 mL per 28 days, 28 day supply per fill

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.

ACTEMRA MEDICAL BENEFIT POLICY UPDATE

Recommendations: It is recommended to update prior authorization criteria to require appropriate preferred alternatives for rheumatoid arthritis and to align with the pharmacy commercial policy for the indication of polyarticular juvenile idiopathic arthritis.

MBP 76.0 Actemra IV (tocilizumab), Tofidence IV (tocilizumab-bavi), Tyenne IV (tocilizumab-aazg)

1. Adults with moderate to severe rheumatoid arthritis
   - Medical record documentation that member is 18 years of age or greater **AND**
   - Prescription written by a rheumatologist **AND**
   - Physician provided documentation of a diagnosis of moderate to severe rheumatoid arthritis (made in accordance with the American College of Rheumatology Criteria for the Classification of Diagnosis of Rheumatoid Arthritis) **AND**
   - Medical record documentation that Actemra or tocilizumab biosimilars are not being used concurrently with a TNF blocker or other biologic agent **AND**
   - Medical record documentation of a therapeutic failure on, contraindication to or intolerance to 12 weeks of a preferred adalimumab poduct ~~Humira~~*, Rinvoq*, Enbrel* OR Xeljanz* **AND**
   - For tocilizumab reference product requests (i.e. Actemra IV), medical record documentation of a therapeutic failure on, intolerance to, or contraindication to tocilizumab-bavi (Tofidence*) and tocilizumab-aazg (Tyenne*).

   *Requires prior authorization

2. Active polyarticular juvenile idiopathic arthritis (PJIA)
   - Medical record documentation that member is 2 years of age or greater **AND**
   - Prescription is written by a rheumatologist **AND**
   - Medical record documentation of a diagnosis active polyarticular juvenile idiopathic arthritis or juvenile rheumatoid arthritis **AND**
   - Medical record documentation that Actemra or tocilizumab biosimilars are not being used concurrently with a TNF blocker or other biologic agent **AND**
   - Physician provided documentation of a therapeutic failure on, contraindication to or intolerance to a minimum 3 month trial of two (2) preferred formulary biologics for the treatment of juvenile idiopathic arthritis or juvenile rheumatoid arthritis ~~4 month trial of Humira*~~ **AND**
   - For tocilizumab reference product requests (i.e. Actemra IV), medical record documentation of a therapeutic failure on, intolerance to, or contraindication to tocilizumab-bavi (Tofidence*) and tocilizumab-aazg (Tyenne*).

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.

SITE OF CARE UPDATE

Background: Currently, the below medication (highlighted in green) is a medical benefit that requires prior authorization for the commercial line of business and is not on the Site of Care Program. After review of the respective FDA-approved labels, it has been determined that the below medication is an acceptable candidate for the Site of Care program.

Recommendations: It is recommended the following change (highlighted in green) be made to MBP 181.0 so that this policy may reflect the addition of the below medication to the Site of Care Program. The addition of Ryplazim to the self-injected drug list is also recommended.

MBP 181.0 Site of Care

I. Policy:

Site of Care Review Guidelines for Infusion Drugs and Specialty Medications

II. Purpose/Objective:

To provide a policy of coverage regarding the use of hospital-based outpatient facilities as a site of care for drugs that require administration via intravenous infusion or injection. This policy applies to these medications:

1. Abatacept (Orencia IV)
2. ADAMTS13 [Recombinant] (Adzynma)
3. Agalsidase Beta (Fabrazyme)
4. Alglucosidase Alfa (Lumizyme)
5. Alpha1-Proteinase Inhibitor [Human] products
6. Anifrolumab-fnia (Saphnelo)
7. Avalglucosidase alfa-ngpt (Nexviazyme)
8. Axatilimab (Niktimvo) [effective 1-1-26]
9. Belimumab (Benlysta IV)
10. Benralizumab (Fasenra)
11. Beremagene Geperpavec (Vyjuvek)
12. Burosumab (Crysvita)
13. C1 esterase Inhibitor [Human] (Cinryze)
14. Canakinumab (Ilaris)
15. Casimersen (Amondys 45)
16. Certolizumab (Cimzia)
17. Cipaglucosidase alfa (Pombiliti)
18. Crizanlizumab (Adakveo)
19. Crovalimab (PiaSky) [effective 1-1-26]
20. Denosumab & denosumab biosimilars [effective 1-1-26]
21. Eculizumab & eculizumab biosimilars [effective 1-1-26]
22. Edaravone (Radicava)
23. Elapegademase-lvlr (Revcovi)
24. Elosulfase alfa (Vimizim)
25. Emapalumab (Gamifant) [effective 1-1-26]
26. Eptinezumab (Vyepti)
27. Efgartigimod Alfa (Vyvgart & Vyvgart Hytrulo)
28. Eteplirsen (Exondys 51)
29. Evinacumab (Evkeeza)
30. Galsulfase (Naglazyme)
31. Givosiran (Givlaari)
32. Golodirsen (Vyondys 53)
33. Golimumab (Simponi Aria)
34. Idursulfase (Elaprase)
35. Immune Globulin (IVIG)
36. Imiglucerase (Cerezyme)

37. Inclisiran (Leqvio)
38. Inebilizumab (Uplizna)
39. Infliximab & infliximab biosimilar products
40. Laronidase (Aldurazyme)
41. Lumasiran (Oxlumo)
42. Mepolizumab (Nucala)
43. Natalizumab & natalizumab biosimilars [effective 1-1-26]
44. Ocrelizumab (Ocrevus & Ocrevus Zunovo) [effective 1-1-26]
45. Olipudase alfa-rpcp (Xenpozyme)
46. Omalizumab (Xolair)
47. Patisiran (Onpattro)
48. Pegunigalsidase Alfa (Elfabrio)
49. Plasminogen (Ryplazim)
50. Pozelimab (Veopoz)
51. Ravulizumab (Ultomiris)
52. Reslizumab (Cinqair) [effective 1-1-26]
53. Romosozumab (Evenity)
54. Rozanolixizumab (Rystiggo)
55. Sebelipase alfa (Kanuma)
56. Secukinumab (Cosentyx IV)
57. Sutimlimab (Enjaymo)
58. Taliglucerase alfa (Elelyso)
59. Teprotumumab (Tepezza)
60. Testosterone udecanoate (Aveed)
61. Tezepelumab (Tezspire)
62. Tildrakizumab (Ilumya)
63. Tocilizumab IV & tocilizumab IV biosimilars [effective 1-1-26]
64. Ublituximab-xiiy (Briumvi)
65. Vedolizumab (Entyvio)
66. Velaglucerase alfa (Vpriv)
67. Velmanase alfa (Lamzede)
68. Vestronidase alfa-vjbk (Mepsevii)
69. Viltolarsen (Viltepso)
70. Vutrisiran (Amvuttra)

III. Responsibility:

A. Medical Directors
B. Medical Management
C. Pharmacy Department

IV. Required Definitions

1. Attachment – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. Exhibit – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. Devised – the date the policy was implemented.
4. Revised – the date of every revision to the policy, including typographical and grammatical changes.
5. Reviewed – the date documenting the annual review if the policy has no revisions necessary.
6. Site of Care – choice of physical location for administration of intravenous infusions or injections. Site of care locations include hospital inpatient, hospital based outpatient facilities, physician's office, ambulatory infusion centers, or home infusion services.
7. Alternative less intensive site of care facilities include non-hospital affiliated outpatient infusion centers such as ambulatory infusion centers or physician's offices and home infusion
8. Hospital based outpatient facilities include ER services, intravenous drug infusions or injections,

observation services, outpatient surgery, lab tests, or x-rays, or any other hospital services where the patient is not admitted as an inpatient.

V. Additional Definitions

Medical Necessity or Medically Necessary means Covered Services rendered by a Health Care Provider that the Plan determines are:

a. appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
b. provided for the diagnosis and the direct care and treatment of the Member's condition, illness disease or injury;
c. in accordance with current standards good medical treatment practiced by the general medical community;
d. not primarily for the convenience of the Member, or the Member's Health Care Provider; and
e. the most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient

DESCRIPTION:

Specific intravenous and injectable drugs must meet applicable medical necessity criteria for coverage. If these criteria are met, this coverage policy will be used to determine the medical necessity of administration in the hospital based outpatient setting. If medical necessity criteria for administration in the hospital based outpatient setting are not met, an alternative less intensive site of care facility should be utilized.

CRITERIA FOR USE: Requires Prior Authorization by Medical Director or Designee

Administration in the hospital-based outpatient setting will be considered medically necessary and LIMITED to a duration of 60 days (for Xolair (omalizumab), a duration of up to 90 days if the reviewing provider determines it is medically appropriate) when one of the following criteria are met:

- This is the initial medication infusion **OR**
- Member is reinitiating treatment after not receiving any treatments for at least 6 months.

AUTHORIZATION DURATION: Initial approval will be for a duration of 60 days (for Xolair, up to 90 days). Administration in the hospital-based outpatient setting for longer than the initially approved amount will be required to meet the authorization criteria in the section below.

Administration in the hospital-based outpatient setting will be considered medically necessary for a <u>duration of greater than 60 days</u> when one of the following criteria are met:

- The medication has a site of care restriction for administration per the FDA approved label **OR**
- Documented previous history of severe or potentially life-threatening adverse event during or following administration and the adverse event cannot be managed using pre-medication(s) or adjusting the rate of infusion **OR**
- All of the following:
    - All alternate non-hospital outpatient settings are not within a reasonable distance from the member's home (within 50 miles) **AND**
    - Home healthcare or infusion provider has determined that the patient, home caregiver, or home environment is not appropriate for home infusion or home infusion services are not available due to limited network access **AND**
    - For request of a provider administered drug, for which a self-administered formulation is available, including but not limited to abatacept, belimumab, benralizumab, certolizumab, golimumab, mepolizumab, omalizumab, plasminogen, secukinumab, tezepelumab, and

tocilizumab & tocilizumab biosimilar products-[effective 1-1-26]: medical record documentation of a therapeutic failure of or intolerance to a 3 month trial of the self-administered formulation of the respective product.

OR

- For IVIG any of the above criteria **OR**
    - Change of immune globulin products (one infusion will be permitted in the hospital outpatient setting) **OR**
    - Laboratory confirmed immunoglobulin A (IgA) deficiency with anti-IgA antibodies

OR

- For Xgeva (denosumab) or Xgeva biosimilars any of the above criteria **OR**
    - Patient is receiving Xgeva or Xgeva biosimilars concomitantly with intravenous chemotherapy as part of the same encounter

AUTHORIZATION DURATION: Initial approval will be for the same length of time as the authorization of the specific drug being administered. Subsequent approvals will be required if the specific drug requires subsequent authorizations.

NOTE: To prevent a delay in care and allow adequate transition time for members to an alternate infusion site, members already established on therapy who do not meet any of the above criteria will be given a 60-day transition auth to allow them to continue receiving therapy at their current hospital based outpatient facility while they transition to a different infusion site.
Discussion: No comments or questions.

Outcome: The committee unanimously voted to accept the recommendations as presented. None were opposed (31 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 2025 we have resolved the following number of **c**ases of therapeutic duplication:
        - **COMM: 2 cases** of therapeutic duplication resulting in a projected savings of **$1,405.40 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 2025:
    - For COMM
        - Members Reviewed: **22**
        - Outreaches Made: **5**
        - Letters Sent: **3**
        - Negative Overrides Entered: **1**
    - For D6
        - Members Reviewed: **45**
        - Outreaches Made: **11**
        - Letters Sent: **1**
        - Negative Overrides Entered: **0**
    - For TG48
        - Members Reviewed: **24**
        - Outreaches Made: **5**
        - Letters Sent: **2**
        - Negative Overrides Entered: **0**
    - For TG51
        - Members Reviewed: **10**
        - Outreaches Made: **2**
        - Letters Sent: **0**
        - Negative Overrides Entered: **0**
    - For TGW2
        - Members Reviewed: **3**
        - Outreaches Made: **2**
        - Letters Sent: **0**
        - Negative Overrides Entered: **0**
    - For TP50
        - Members Reviewed: **2**
        - Outreaches Made: **1**
        - Letters Sent: **0**
        - Negative Overrides Entered: **0**
    - For TP56
        - Members Reviewed: **1**
        - Outreaches Made: **1**
        - 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: **4**
        - Outreaches Made: **0**

        - Letters Sent: **0**
        - Negative Overrides Entered: **0**
- 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
        - 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 2025, 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: 2
                - For D6: 8
                - For TG48: 10
                - For WF89: 2
        - 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: 9
            - For TG48: 12
            - For WF89: 3
- 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 2025:
        - For COMM (Commercial): **4 members** reviewed and **0 interventions** made
        - For D6 (Exchange): **13 members** reviewed and **0 interventions** made
        - For TG48/TG51: **6 members** reviewed and **0 intervention** made
        - For TGW2: **2 members** reviewed and **0 intervention** made
        - Fopr TPN2: **1 member** reviewed and **1 intervention** made
- Duplicate Specialty Therapy
    - We run an in-house retrospective report **quarterly** for **all LOBs** with help from Adam Kelchner and Aubrielle Smith. These members are identified and written up and sent to a medical director if follow up is needed.
        - For Commercial/Exchange/TPA for 2025, **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**
- 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 Commercial/Exchange, TPAs for 2025, **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 2025, 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 2025, 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 **(Report was on hold for first quarter)**
    - 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 2025, 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 2025, we have reviewed **14** cases and corrected claims, resulting in a potential **cost savings/avoidance of $3,271.55**
        - For D6 for 2025, we have reviewed **12** cases and corrected claims, resulting in a potential **cost savings/avoidance of $239.83**
        - For TG48, TG51 for 2025, we reviewed **19** cases and corrected claims, resulting in a potential **cost savings/avoidance of $1,864.12**
        - For TGW2 for 2025, we reviewed 1 case and corrected claims, resulting in a potential **cost savings/avoidance of $0.00**

        - For TP23 for 2025, we reviewed 1 case and corrected claims, resulting in a potential cost savings/avoidance of **$150.45**
        - For TP45 for 2025, we reviewed 3 cases and corrected claims, resulting in a potential **cost savings/avoidance of $230.18**
        - For TP46 for 2025, we reviewed 1 case and corrected claims, resulting in a potential **cost savings/avoidance of $6.68**
        - For SAH1 for 2025, we reviewed 1 case and corrected claims, resulting in a potential cost savings/avoidance of **$187.04**
        - For SASE for 2025, we reviewed **2** cases and corrected claims, resulting in a potential **cost savings/avoidance of $4.54**
        - For SASN for 2025, we reviewed 4 cases and corrected claims, resulting in a potential **cost savings/avoidance of $84.03**
- 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 2025
            - For COMM: **10**
            - FOR D6: **16**
            - FOR TG48, TG51: **21**
            - For SASK: **3**
            - For TP50: **3**
- 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 2025, we sent letters to the below number of members:
        - For COMM: **10**
        - For D6: **10**
        - For SASE: **3**
        - For SASN: **2**
        - For TG48**: 9**
        - For TP50: **2**
        - For TG51: **2**
        - For TPH2: **1**
        - For TP46: **1**
        - For TGW2: **1**
        - For WF89: **1**
- 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 2025, we have sent letters encouraging adherence to the below number of members:
        - **Members for Antiplatelet:**
            - COMM: **34**
            - D6: **54**
            - ALH4: **1**
            - SASE: **2**
            - SASN: **5**
            - TG48, TG51: **22**
            - TGW2: **5**
            - TP33: **1**
            - TP45: **1**
            - TP50: **1**

        - TPH2: **1**
    - **Members for Beta-Blocker:**
        - COMM: **41**
        - D6: **73**
        - ALH4: **1**
        - SASE: **4**
        - SASN: **6**
        - TG48, TG51: **36**
        - SASX: **2**
        - TP45: **3**
        - TP46: **2**
        - TP56: **2**
        - TPF0: **1**
        - TPT2: **1**
        - TGW2: **5**
        - WF89: **1**
    - **Members for Statin:**
        - COMM: **49**
        - D6: **75**
        - ALH4: **1**
        - SASE: **4**
        - SASN: **4**
        - TG48, TG51: **41**
        - TGW2: **6**
        - TP45: **2**
        - TP56: **2**
        - TPT2: **1**
        - TPU1: **2**
        - WF89: **3**
    - *member may flag for more than one measure and are included in the count for each measure
- In 2025, 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: **0**
    - D6:
        - Attempted: **4**
        - Reached:**1**

- 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 2025, we have sent letters to members encouraging adherence:
        - **Diabetes:**
            - COMM: **42**
            - D6: **42**
            - ALQ3: **1**
            - SASE: **5**
            - SASN: **2**
            - TG48, TG51: **47**
            - TP23: **1**
            - TP33: **1**
            - TP45: **1**
            - TP50: **2**
            - TPV2: **2**
            - WF89: **4**
        - **Statin:**
            - COMM: **9**
            - D6: **7**
            - SASE: **1**
            - SASN: **1**
            - TG48, TG51: **16**
            - TP33: **1**
            - TPV2: **1**
            - WF89: **2**
- **HEDIS Initiatives: *Using proactive HEDIS data***
- Asthma Medication Ratio (AMR) Member Letters
    - Adam Kelchner runs this report **monthly,** and we send letters to the flagged members who have a ratio of controller to total asthma medications of < 0.5.
        - For Commercial/Exchange for 2025, see below for the number of letters sent to members:

        - COMM: **4**
        - D6: **2**
- 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 Commercial/Exchange for 2025, we have sent letters to **providers** for the following number of members to encourage adherence.
            - COMM: **48**
            - D6: **30**
- Asthma Medication Ratio (AMR) Member Calls
    - Jeremy Baker runs this report **weekly** based off of proactive HEDIS reporting. The RPHs call 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 2025, see below for the number of members we have outreached to and the number of members that have been reached:
        - COMM:
            - Outreached to: **38**
            - Reached: **17**
        - D6:
            - Outreached to: **33**
            - Reached: **16**
- 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 2025, see below for the number of letters sent to members:
            - COMM: **1**
            - 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 2025, see below for the number of letters sent to **providers** to encourage statin therapy initiation**:**
            - COMM: 1**9**
            - D6: **24**
        - For Commercial/Exchange in 2025, see below for the number of letters sent to **members** to promote statin adherence:
            - COMM: **15**
            - D6: **7**
- 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 2025, see below for the number of letters sent to **members** to promote statin adherence:
            - COMM: **19**
            - D6: **18**

- 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 2025, see below for the number of letters sent to **members:**
            - COMM: **1**
            - 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 2025 we have identified the following number of members seeing 4 or more providers from **different offices** for their opioid prescriptions.
            - COMM: **14**
            - D6: **9**
        - For Commercial/Exchange in 2025 we have identified the following number of members seeing 4 or more providers within the **same office** for their opioid prescriptions.
            - COMM: **0**
            - D6: **0**
- 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
    - 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)
- 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)
    - 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 2025 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 2025, 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 2025, 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 2025, **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 2025, 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 2025, 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 2025, 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 2025, we have reviewed **10** cases and corrected claims, resulting in a potential **cost savings/avoidance of $987.27**
- 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 2025:
        - 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 2025, 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 2025, 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 2025, we sent **1 letter** 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 2025, we have sent letters to **0 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 2025, 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 2025, we sent **2 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 2025, we have sent letters to **providers** for the following number of members to encourage adherence.
            - CHBQ: **16**
- 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 2025, our pharmacy technician and the STAR reps have outreached to **15 members** and reached **3 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 2025, 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 2025, we have sent **0 letters** to providers
    - For CHBQ for 2025, 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 2025, 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 2025, 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)
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    - 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)

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

Meeting adjourned at 3:47 pm.

The next bi-monthly scheduled meeting will be held on November 11th, 2025 at 1:00 p.m.

Meeting will be held virtually via phone/Microsoft Teams.