P&T Committee Meeting Minutes
Commercial, Exchange, CHIP
April 2026 e-Vote

FAST FACTS

AUSTEDO XR (deutetrabenazine extended release)

Clinical Summary: Austedo XR is an extended release formulation of Austedo. Austedo XR has the same FDA approved indications as Austedo – to treat chorea associated with Huntington's disease in adults and to treat tardive dyskinesia in adults.

The recommended dosage for Austedo XR is 12mg once daily and then titrating at weekly intervals by 6 mg per day based on reduction of chorea or tardive dyskinesia, and tolerability, up to a maximum recommended daily dosage of 48 mg. Austedo XR is administered once daily with or without food.

The efficacy of Austedo XR is based on a relative bioavailability study comparing Austedo XR tablets administered once daily and Austedo tablets administered twice daily.

Warnings and precautions for Austedo XR remain the same as Austedo.

Current Formulary Status: Austedo and Austedo XR are pharmacy benefit drugs requiring prior authorization and marked as a specialty drug. Quantity limits apply for Austedo. Austedo is non-formulary. Austedo XR is pending.

Recommendation: Recommend Austedo XR move from the pending tier to the non-formulary tier to match Austedo. It is recommended to update the pharmacy benefit policy 464.0 to account for Austedo XR and require the same criteria as Austedo since the cost of Austedo XR is not significantly higher than Austedo. It is recommended to add quantity limits to Austedo XR.

Policy 464.0 Austedo and Austedo XR

PROCEDURE:

A formulary exception for coverage of Austedo and Austedo XR may be made for members who meet the following criteria:

Huntington's Disease

- Medical record documentation of age greater than or equal to 18 years AND
- Medical record documentation that Austedo is prescribed by, or in consultation with, a neurologist or movement disorder specialist AND
- Medical record documentation of a diagnosis of Huntington's Disease AND
- Medical record documentation of symptoms of chorea AND
- Medical record documentation of that patient's baseline Total Maximal Chorea Score prior to initiating therapy AND
- One of the following:
    - If patient has a history of prior suicide attempt, bipolar disorder, or major depressive disorder: Medical record documentation that patient was evaluated and treated by a psychiatrist OR
    - For all others: Medical record documentation of a mental health evaluation performed by the prescriber AND
    - Medical record documentation of therapeutic failure on, intolerance to, or contraindication to tetrabenazine

Tardive Dyskinesia

- Medical record documentation of age greater than or equal to 18 years AND

- Medical record documentation that Austedo is prescribed by, or in consultation with, a psychiatrist or neurologist AND
- Medical record documentation of a diagnosis of tardive dyskinesia (TD) as evidenced by one of the following:
    - Moderate to severe abnormal body movement (AIMS score 3 or 4) in greater than or equal to 1 body area **OR**
    - Mild abnormal body movements (AIMS score 1 or 2) in greater than or equal to 2 body areas **AND**
- Medical record documentation that the member was assessed for and determined to have no other causes of involuntary movements **AND**
- Medical record documentation of the member's baseline AIMS score prior to initiating therapy **AND**
- One of the following:
    - If patient has a history of prior suicide attempt, bipolar disorder, or major depressive disorder: Medical record documentation that patient was evaluated and treated by a psychiatrist **OR**
    - For all others: Medical record documentation of a mental health evaluation performed by the prescriber **AND**
- If member's symptoms are related to use of a first-generation antipsychotic, medical record documentation that a switch to a second-generation antipsychotic has been attempted and did not resolve tardive dyskinesia symptoms **OR** provider rationale as to why a switch to a second-generation antipsychotic would not be appropriate for the member **AND**
- Medical record documentation of therapeutic failure on, intolerance to, or contraindication to amantadine

MEDISPAN AUTHORIZATION LEVEL: ~~GPI-12~~ GPI 10

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

- QL FOR LETTER ONLY:
    - Austedo 6 mg tablet: 2 tablets per day, 30 day supply per fill
    - Austedo 9 mg tablet: 4 tablets per day, 30 day supply per fill
    - Austedo 12 mg tablet: 4 tablets per day, 30 day supply per fill
    - Austedo XR 6 mg tablet: 1 tablet per day, 30 day supply per fill
    - Austedo XR 12 mg tablet: 2 tablets per day, 30 day supply per fill
    - Austedo XR 18 mg tablet: 2 tablets per day, 30 day supply per fill
    - Austedo XR 24 mg tablet: 2 tablets per day, 30 day supply per fill
    - Austedo XR 30 mg tablet: 1 tablet per day, 30 day supply per fill

AUTHORIZATION DURATION: Initial approval will be for a period of one (1) year. Reevaluation of coverage will be every one (1) year and will require documentation of:

- For patients with Huntington's disease: Medical record documentation of an improvement in chorea associated with Huntington's Disease as evidenced by a reduction in the Total Maximal Chorea Score from baseline.
- For patients with Tardive Dyskinesia: Medical record documentation of an improvement in tardive dyskinesia (TD) as evidenced by a reduction from baseline in the patient's AIMS score

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

HERNEXEOS (zongertinib)

Clinical Summary: Hernexeos is now indicated for the treatment of adult patients with unresectable or metastatic non-squamous non-small cell lung cancer (NSCLC) whose tumors have HER2 (ERBB2)

tyrosine kinase domain activating mutations, as detected by an FDA-authorized test. Previously Hernexeos was indicated for second-line treatment in patients who had received prior systemic therapy.

There is no change to the recommended dosage of Hernexeos for the changed indication.

Approval for Hernexeos comes from a second cohort of the Beamion LUNG-1 trial, a single-arm, open-label, multi-cohort trial in patients with unresectable or metastatic NSCLC with HER-2 mutations. This cohort included 72 patients who had not received prior therapy for advanced disease. Patients were treated with Hernexeos orally once daily until disease progression or unacceptable toxicity. The efficacy endpoints were objective response rate (ORR) and duration of response (DOR) by RECIST v1.1. as assessed by blinded independent central review (BICR). Results are shown in Table 1.

Table 1. Efficacy Results for Beamion LUNG-1 in Previously Untreated Non-Squamous NSCLC[1]

Efficacy Parameter	**HERNEXEOS N = 72**
Objective Response Rate (ORR), % (95% CI)[1]	76 (65, 85)
Complete response, %	11
Partial response, %	65
Duration of Response (DOR)	**N = 55**
Range, months	1.4, 18+
DOR ≥ 6 months,[2] %	64
DOR ≥ 12 months,[2] %	44

Abbreviation: CI = Confidence Interval, +: Ongoing response.
[1]Based on Wilson confidence interval.
[2]Based on observed duration of response.

Current Formulary Status: Brand NP tier (Oral Oncology, $0 Copay), requires a PA for NSO, Reviewed with the standard oral oncology policy

Recommendation: No changes are recommended to the formulary placement, quantity limits, or authorization duration at this time.

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

LINZESS (linaclotide)

Clinical Summary: Linzess has recently been approved for functional constipation (FC) in pediatric patients 6 years of age and older. Previous approvals include chronic idiopathic constipation (CIC) in adults and irritable bowel syndrome with constipation (IBS-C) in adults and pediatric patients 7 years of age and older.

Updated dosing:

Functional constipation dose for ages 6 and above: 72 mcg daily
IBS-C adult dose: 290 mcg once daily
IBS-C dose for 7 years of age and older: 145 mcg once daily
CIC adult dose: 145 mcg once daily; 72 mcg once daily may be used based on presentation and tolerability

Summary of Updated Clinical Studies: The safety and effectiveness of Linzess for the treatment of functional constipation in pediatric patients ages 6 to 17 was established in a 12-week double blind, placebo-controlled, randomized, multicenter, clinical trial (trial 7; NCT04026113). A total of 328 patients received Linzess 72 mcg or placebo once daily and were evaluated for efficacy.

Patients in the trial had a mean age of 11 years (rang 6 to 17 years); 55% were female; 45% identified as Hispanic or Latino; 70% identified as White, 26% as Black or African American, 2% as Asian, and 2% identified as another racial group.

For trial enrollment, Rome III criteria for child/adolescent functional constipation were modified to require that patients have less than 3 Spontaneous Bowel Movements (SBMs) per week (defined as a bowel movement that occurred in the absence of laxative, enema, or suppository use on the calendar day of or before the bowel movement) and 1 or more of the following criteria at least once per week for at least 2 months before the screening visit:

- History of stool withholding or excessive voluntary stool retention
- History of painful or hard bowel movements (BMs)
- History of large diameter stools that may obstruct the toilet
- Presence of a large fecal mass in the rectum
- At least 1 episode of fecal incontinence per week

Patients were also required to have an average of less than 3 SBMs per week during the 2- week baseline period. Patients were excluded if they met criteria for pediatric IBS-C or had fecal impaction. Patients were allowed to continue previously stable doses of bulk laxatives, fiber, stool softeners, or probiotics. During the trial, patients could use bisacodyl or senna as needed, but were not allowed to take other laxatives, bismuth, prokinetic agents, or other drugs to treat functional constipation.

The efficacy of LINZESS in the treatment of FC in pediatric patients 6 to 17 years of age was assessed using change-from-baseline endpoints. The primary efficacy endpoint was the 12- week change from baseline in SBM frequency rate. The results demonstrated that patients who received LINZESS had statistically significant improvements compared with placebo as shown in Table 8. SBM frequency improved during week 1 and was maintained throughout the remainder of the 12-week treatment program.

Table 8: Efficacy Endpoint in Placebo-Controlled Trial of Pediatric Patients 6 to 17 Years of Age with FC (Trial 7): 12-week Change from Baseline in SBM Frequency Rate (SBMs/week)

	Trial 7		
	LINZESS 72 mcg Once Daily (N=164)	**Placebo (N=164)**	**Treatment Difference [95% CI]**
Baseline SBM Frequency Rate	1.2	1.3	
Least Squares 12-week Mean Change from Baseline in SBM Frequency Rate*	2.6	1.3	1.3 [0.7, 1.8]
* Primary Endpoint CI = Confidence Interval			

Summary of Safety Considerations

- Adverse reactions: diarrhea was most common for this age and diagnosis
- Contraindicated in patients less than 2 years of age

Current Formulary Status: formulary, quantity limit, no prior authorization required

Recommendation: No changes recommended to formulary status at this time.

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

RECARBRIO (imipenem/cilastatin/relebactam)

Clinical Summary: Recarbrio is now indicated for adults and pediatric patients weighing at least 2 kg for the treatment of the following infections caused by susceptible gram-negative microorganisms: hospital-acquired bacterial pneumonia and ventilator-associated bacterial pneumonia (HABP/VABP), complicated urinary tract infections, including pyelonephritis (cUTI) in patients who have limited or no alternative treatment options, and complicated intra-abdominal infections (cIAI) in patients who have limited or no alternative treatment options. Previously Recarbrio was only indicated for the treatment of adult patients. Recarbrio is not recommended in pediatric patients less than 37 weeks post-menstrual age (gestational age at birth plus post-natal age) or in pediatric patients weighing less than 30 kg with renal impairment.

The recommended dosage of Recarbrio for pediatric patients is an intravenous infusion administered at a dosage based on age and weight (shown in the table below). The treatment duration for Recarbrio is 4 to 14 days duration based on severity, location of infection, and clinical response.

Recommended Dosage of RECARBRIO In Pediatric Patients Weighing at Least 2 kg

Age Range	Body Weight	Dose	Dosing Frequency	Infusion Duration
Birth[a] to less than 3 months	2 kg or greater	RECARBRIO 37.5[b] mg/kg	Every 8 hours	60 minutes
3 months to less than 18 years	less than 30 kg	RECARBRIO 37.5[b] mg/kg	Every 6 hours	60 minutes
3 months to less than 18 years	30 kg or greater	RECARBRIO 1.25[c] grams	Every 6 hours	30 minutes

[a] Pediatric patients from birth (includes pediatric patients at least 37 weeks post-menstrual age)
[b] Provides 15 mg/kg imipenem, 15 mg/kg cilastatin, and 7.5 mg/kg relebactam
[c] Provides 500 mg imipenem, 500 mg cilastatin, and 250 mg, relebactam

The efficacy of Recarbrio in the pediatric population is based on results of a randomized, active-controlled, open-label trial in hospitalized patients from birth to less than 18 years of age with HABP/VABP, cUTI, or cIAI. Patients were randomized 3:1 to receive IV Recarbrio or active control (defined as investigator's choice of specified comparators). Patients with HABP/VABP received IV therapy for 7 to 14 days. Patients with cUTI or cIAI received IV therapy for a minimum of 3 days before an optional switch to oral step down therapy (to complete a total of 5 to 14 days of antibacterial therapy).

The modified intent-to-treat population included 113 patients who were randomized to at least one dose of trail treatment (Recarbrio, n=85; active control, n=28). The MITT population included 54 patients with cUTI, 53 patients with cIAI, and 6 patients with HABP/VABP.

The primary objective was to evaluated safety and tolerability of Recarbrio in pediatric patients. Efficacy assessments were not powered for formal hypothesis testing between treatment groups. For HABP/VABP and cIAI, Table 1 shows the clinical cure rates at early follow-up (EFU, 7-14 days after the end of therapy). For cUTI, Table 2 shows the clinical cure and microbiologic response rates at EFU in the MITT population. No patient died in either intervention group in the study through Day 28.

Table 1: Clinical Cure Rates at the EFU Visit (7 to 14 Days after End of Therapy) in Pediatric Patients with HABP/VABP or cIAI in Trial 4 (MITT Population)[1]

	RECARBRIO n/N (%)	Active Control n/N (%)
HABP/VABP	5/5 (100.0)	1/1 (100.0)
cIAI	34/39 (87.2)	13/14 (92.9)

Table 2: Clinical Cure and Microbiologic Response Rates at the EFU Visit (7 to 14 Days after End of Therapy) in Pediatric Patients with cUTI in Trial 4 (mMITT Population)[1]

	RECARBRIO n/N (%)	ACTIVE Control n/N (%)
Clinical Cure	20/30 (66.7)	7/10 (70.0)
Microbiologic Response	20/30 (66.7)	8/10 (80.0)

The safety and efficacy of Recarbrio has been established in pediatric patients weighing at least 2 kg for the treatment of HABP/VABP, and for the treatment of cUTI and CIAI in patients who have limited or no alternative treatment options. Use of Recarbrio in pediatric patients is supported by evidence from the clinical trial as well as well-controlled clinical trials in adults with HABP/VABP, cUTI or CIAI, as well as additional pharmacokinetic, safety, and efficacy data from pediatric trials.

The safety profile of Recarbrio in pediatric patients was consistent to that of adult patients treated with Recarbrio. The most common reactions occurring in pediatric patients were vomiting, diarrhea, nausea, headache, and phlebitis/infusion site reactions, and rash.

Current Formulary Status: Medical Benefit, requiring PA

Recommendation: No changes are needed to the formulary placement, authorization duration, or quantity limits for Recarbrio. It is recommended that the Medical Benefit Policy be updated as follows:

Medical Benefit Policy 215.0

- Prescription is written by or in consultation with Infectious Disease **AND**
- ~~Medical record documentation that the member is greater than or equal to 18 years of age **AND**~~
- Medical record documentation of one of the following:
    - Diagnosis of Complicated Urinary Tract Infection (including Pyelonephritis) (cUTI) caused by the following susceptible gram-negative microorganisms: *Enterobacter cloacae, Escherichia coli, Klebsiella aerogenes, Klebsiella pneumoniae, or Pseudomonas aeruginosa* **OR**
    - Diagnosis of Complicated Intra-abdominal Infection (cIAI) caused by the following susceptible gram-negative microorganisms*: Bacteroides caccae, Bacteroides fragilis, Bacteroides ovatus, Bacteroides stercoris, Bacteroides thetaiotaomicron, Bacteroides uniformis, Bacteroides vulgatus, Citrobacter freundii, Enterobacter cloacae, Escherichia coli, Fusobacterium nucleatum, Klebsiella aerogenes, Klebsiella oxytoca, Klebsiella pneumoniae, Parabacteroides distasonis, or Pseudomonas aeruginosa* **OR**
    - Diagnosis of hospital-acquired bacterial pneumonia and ventilator-associated bacterial pneumonia, caused by the following susceptible gram-negative microorganisms: *Acinetobacter calcoaceticus-baumannii complex, Enterobacter cloacae, Escherichia coli, Haemophilus influenzae, Klebsiella aerogenes, Klebsiella oxytoca, Klebsiella pneumoniae, Pseudomonas aeruginosa, or Serratia marcescens*

  AND
- Medical record documentation of a culture and sensitivity showing the patient's infection is not susceptible to preferred alternative antibiotic treatments OR a documented history of previous

intolerance to or contraindication to three (3) preferred alternative antibiotics shown to be susceptible on the culture and sensitivity **AND**

- Medical record documentation of a therapeutic failure on imipenem/cilastatin OR medical rationale of why imipenem/cilastatin cannot be used.

AUTHORIZATION DURATION: If approved, Recarbrio will be authorized for up to 14 days.

QUANTITY LIMITS: 4 vials per day (Facets RX Count of 7000 units)

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

SUSVIMO (ranibizumab)

Clinical Summary: Susvimo is a vascular endothelial growth factor (VEGF) inhibitor now indicated for the treatment of patients with Diabetic Macular Edema (DME) and Diabetic Retinopathy (DR) who have previously responded to at least two intravitreal injections of a Vascular Endothelial Growth Factor (VEGF) inhibitor medication. Previously, Susvimo was only indicated for the treatment of patients with Neovascular (wet) Age-related Macular Degeneration (AMD) who have previously responded to at least two intravitreal injections of a Vascular Endothelial Growth Factor (VEGF) inhibitor medication.

The dosing of Susvimo has been updated to include recommendations for DME and DR. For DME, the recommended dose is 2mg delivered via ocular implant with refills every 24 weeks (approximately 6 months). This is the same dose that is recommended for the indication of wet AMD. For DR, the recommended dose is 2mg delivered via ocular implant with refills every 36 weeks (approximately 9 months). Supplemental treatment with intravitreal injection of ranibizumab 0.5mg is allowed while the Susvimo implant is in place if clinically necessary.

The efficacy of Susvimo in adult patients with DME was evaluated in a randomized, visual assessor-masked, active treatment-controlled study (Pagoda [GR40550], NCT04108156), which included 634 patients. Patient ages ranged from 29 to 89 years old (mean 60.7 years), overall mean visual acuity was 65.3 letters (range 25-89 letters), and 21% of patients were previously treated for DME. Patients were randomized 3:2 to receive 2mg Susvimo via implant every 24 weeks or 0.5mg ranibizumab via intravitreal injection every 4 weeks.

The primary efficacy outcome was change from baseline in Best Corrected Visual Acuity (BCVA) score averaged over Week 60 and Week 64. The study showed that Susvimo was non-inferior to intravitreal ranibizumab injections administered every 4 weeks. Results are summarized in Table 1 and Figure 1. Consistent results across subgroups for mean change in baseline BCVA were observed.

Table 1. Key efficacy outcomes at Week 60 and Week 64 in the Pagoda (GR40550) Study

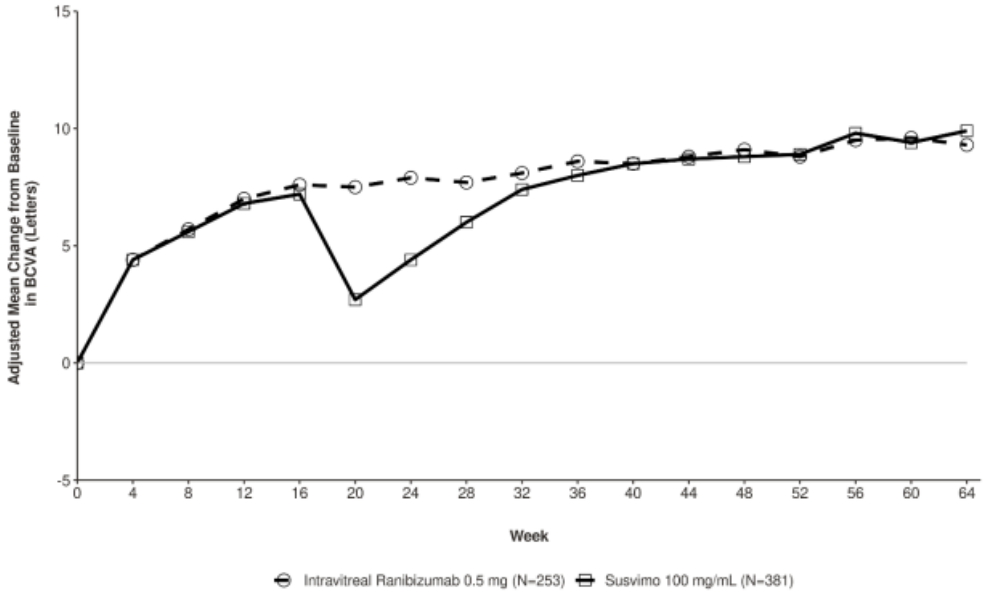
Outcome Measure*	SUSVIMO 100 mg/mL n=381	Intravitreal ranibizumab 0.5 mg (10 mg/mL) n=253	Difference (95% CI)**
Change in BCVA scores from baseline averaged over Week 60 and Week 64 Adjusted Mean	9.6	9.4	0.2 (-1.2, 1.6)

BCVA = Best corrected visual acuity

*BCVA measured using the Early Treatment Diabetic Retinopathy Study (ETDRS) visual acuity chart at a starting distance of 4 meters.

**All estimates are adjusted estimates based on a mixed-effect model with repeated measures. 95% is a rounding of 95.05% CI; The type 1 error was adjusted for interim safety monitoring.

Figure 1. Adjusted Mean change from Baseline in Best Corrected Visual Acuity in study eye through Week 64 in the Pagoda (GR40550) study



The efficacy of Susvimo in adult patients with moderate to severe non-proliferative DR was evaluated in randomized, visual assessor and reading center-masked study (Pavilion [GR41675], NCT04503551), which included 174 patients. Patients has not received prior treatment in the study eye for DR. Patients ages ranged from 24 to 83 years (mean 53.9 years) and overall baseline visual acuity was 82.4 letters (range: 69 to 97 letters). Patients were randomized 5:3 to receive either Susvimo eye implant every 36 weeks or to clinical observation. Patients receiving Susvimo had two loading doses of injectable intravitreal ranibizumab 0.5mg to the study eye, while the observational arm did not. Supplemental intravitreal ranibizumab was allowed for patients in either arm who developed center-involved DME or proliferative DR/anterior segment neovascularization.

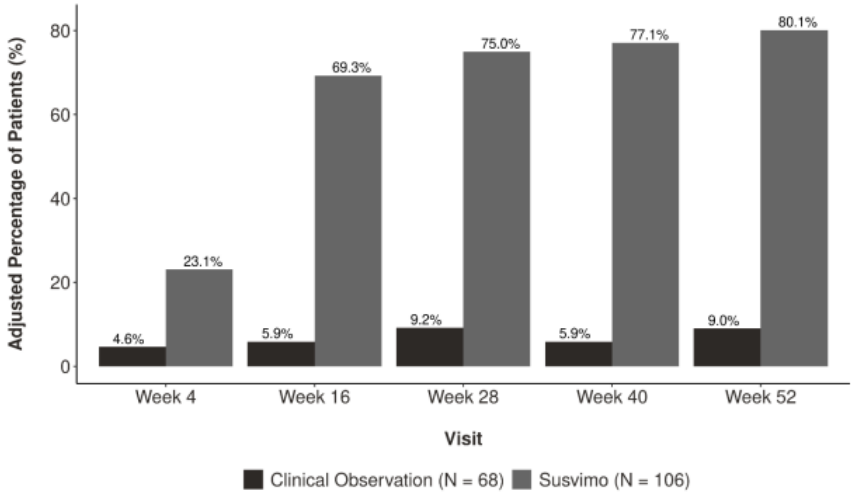
The primary endpoint was the proportion of patients with a ≥ 2-step improvement on the Early Treatment Diabetic Retinopathy Study Diabetic Retinopathy Severity Scale (ETDRS-DRSS) from baseline at Week 52 versus clinical observation. Susvimo was found to be superior to clinical observation at week 52. Results are summarized in Table 2 and Figure 2. No patients in the Susvimo arm required supplemental treatment while 40% of patients in the observational arm received 1 or more supplemental treatments through week 52. Consistent results across subgroups were observed in the ETDRS-DRSS score.

Table 2. Efficacy Outcomes through Week 52 in the Pavilion (GR41675) Study

Outcome Measure	SUSVIMO 100 mg/mL (n=106)	Clinical Observation (n=68)	Difference 95% CI *
Adjusted proportion of patients with ≥ 2-step improvement from baseline on the ETDRS-DRSS at Week 52	80%	9%	71% (61%, 81%)

ETDRS-DRSS = Early Treatment Diabetic Retinopathy Study Diabetic Retinopathy Severity Scores
CMH = Cochran-Mantel-Haenszel test
*All estimates are adjusted estimates based on the CMH method. 95% is a rounding of 95.04% CI; the type 1 error was adjusted for interim safety monitoring. p<0.01 compared with clinical observation.

Figure 2. Adjusted Proportion of Patients with a ≥ 2-Step Improvement from Baseline on ETDRS-DRSS in Study Eye over Time through Week 52 in the Pavilion (GR41675) Study



No new contraindications were added to the prescribing information with the new indications. A warning and precaution for postoperative intraocular inflammation was added with the new indications. The most common adverse reactions in DME patients were: conjunctival hemorrhage (62%), conjunctival hyperemia (15%), iritis (14%), eye pain (13%), cataract (11%), conjunctival disorder (10%) and vitreous hemorrhage (10%). The most common adverse reactions in DR patients were: conjunctival hemorrhage (73%), conjunctival disorder (14%), iritis (12%) and conjunctival hyperemia (11%). No changes were made to the pediatric and geriatric sections of the prescribing information with the new indication.

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

Recommendation: There are no changes recommended to the formulary placement of Susvimo. It is recommended to change the prior authorization criteria, authorization duration and quantity limit of MBP 252.0 Susvimo (ranibizumab implant).

MBP 252.0 Susvimo (ranibizumab implant) – Commercial/Exchange/CHIP

- Medical record documentation of a diagnosis of neovascular age-related macular degeneration (nAMD) OR diabetic retinopathy (DR) with or without macular edema (DME) **AND**
- Medical record documentation patient has previously responded to at least two (2) intravitreal doses of a Vascular Endothelial Growth Factor (VEGF) inhibitor medication **AND**
- Medical record documentation of therapeutic failure on, intolerance to, or contraindication to an adequate trial of intravitreal bevacizumab (Avastin) given at every four (4) week dosing intervals **AND**
- Medical record documentation of therapeutic failure on, intolerance to, or contraindication to two (2) additional intravitreal VEGF inhibitors (e.g. a preferred aflibercept product, Beovu [indicated for nAMD and DME only], or a preferred ranibizumab product)

AND

- Medical record documentation that Susvimo (ranibizumab) will not be given in combination with an intravitreal Vascular Endothelial Growth Factor (VGEF) inhibitor administration to the same eye **OR**
- If the request is for use in combination with an intravitreal VEGF inhibitor administration to the same eye, all of the following must be met:
    - Medical record documentation Susvimo (ranibizumab) will be given in combination with intravitreal ranibizumab injection (Lucentis) **AND**

- Medical record documentation intravitreal ranibizumab injection will be administered on an as needed basis, as determined by the prescriber

AUTHORIZATION DURATION: Approval will be given for an initial duration of two (2) years or less if the reviewing provider feels it is medically appropriate. After the initial two (2) year approval, subsequent approvals will be for a ~~lifetime~~ 12 month duration or less if the reviewing provider feels it is medically appropriate, and will require:

- Medical record documentation that Susvimo (ranibizumab) will not be given in combination with an intravitreal Vascular Endothelial Growth (VEGF) inhibitor

QUANTITY LIMIT:
Neovascular (Wet) Age-Related Macular Degeneration (AMD) or Diabetic Macular Edema (DME):
0.2mL (2 vials) per 24 weeks (to allow 2mg per 24 weeks per treated eye)

Diabetic Retinopathy (DR) without DME:
0.2mL (2 vials) per 36 weeks (to allow 2mg per 24 weeks per treated eye)

LIMITATION: Susvimo (ranibizumab) to be given in combination with intravitreal ranibizumab (Lucentis) injections after 92 weeks from the start of Susvimo therapy has not been studied in clinical trials and will require prior authorization.

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

TECVAYLI (teclistmab-cqyv)

Clinical Summary: Tecvayli is now indicated for the treatment of adult patients with relapsed or refractory multiple myeloma in combination with daratumumab hyaluronidase-fihj in patients who have received at least one prior line of therapy, including a proteasome inhibitor and an immunomodulatory agent. The previous indication is Tecvayli as monotherapy for fifth-line treatment of R/R MM.

The recommended dosage of Tecvayli for the new indication is shown in Table 1. Tecvayli treatment is continued until disease progression or unacceptable toxicity.

Table 1: TECVAYLI Dosage Schedule in Combination with Daratumumab Hyaluronidase-fihj

Dosing schedule	Week/Day	TECVAYLI Dosage[a]	Concomitant Therapy
	Day 0	N/A	Daratumumab hyaluronidase-fihj
Step-up dosing schedule[b]	Day 1	Step-up dose 1 (0.06 mg/kg) [c]	N/A
	Day 3	Step-up dose 2 (0.3 mg/kg) [d]	N/A
	Day 7	First treatment dose (1.5 mg/kg) [e,f]	Daratumumab hyaluronidase-fihj
Weekly dosing schedule	Weeks 2 to 8	1.5 mg/kg once weekly[f,g]	Daratumumab hyaluronidase-fihj once weekly
Biweekly (every two weeks) dosing schedule	Weeks 9 to 24	3 mg/kg every two weeks[f,h]	Daratumumab hyaluronidase-fihj every two weeks
Every four weeks dosing schedule	Week 25 onwards	3 mg/kg every four weeks[f,i]	Daratumumab hyaluronidase-fihj every four weeks

b. The Step-up dosing schedule is a component of the recommended TECVAYLI dosage but is not applicable for the daratumumab hyaluronidase-fihj dosing.
c Step-up dose 1 must be administered 20 hours or more after the daratumumab hyaluronidase-fihj dose.
d Step-up dose 2 may be given between 2 to 4 days after step-up dose 1 and if adverse reactions occur, step-up dose 2 may be given up to 7 days after step-up dose 1 to allow for resolution of adverse reactions.
e First treatment dose (1.5 mg/kg) may be given between 2 to 4 days after step-up dose 2 and if adverse reactions occur, first full treatment dose may be given up to 7 days after step-up dose 2 to allow for resolution of adverse reactions.

f Administer TECVAYLI at least 3 hours after the daratumumab hyaluronidase-fihj dose for the first treatment dose. For subsequent doses, administer TECVAYLI at least 15 minutes after the daratumumab hyaluronidase-fihj dose.
g Maintain a minimum of 5 days between 1.5 mg/kg once weekly doses.
h Maintain a minimum of 12 days between 3 mg/kg every two weeks doses.
i Maintain a minimum of 25 days between 3 mg/kg every four weeks doses.

The efficacy of Tecvayli in combination with Darzalex Faspro was evaluated in MajesTEC-3, a randomized open-label study comparing Tecvayli + Darzalex Faspro to investigator's choice of either daratumumab hyaluronidase-fihj, pomalidomide and dexamethasone (DPd) or daratumumab hyaluronidase-fihj, bortezomib and dexamethasone (DVd) in adult patients with R/R MM. Patients included in the trial had received one to three prior lines of therapy including a proteasome inhibitor and lenalidomide.

The major efficacy outcome was progression-free survival (PFS) by Independent Review Committee (IRC) assessment based on International Myeloma Working Group (IMWG) 2016 criteria. The trial demonstrated statistically significant improvement in Tecvayli in combination with Darzalex Faspro compared to the control group in both PFS and overall survival (OS). Results are shown in Table 2.

Table 2. Efficacy Results (MajesTEC-3)[1]

	TECVAYLI with daratumumab hyaluronidase-fihj (N=291)	**DPd or DVd (N=296)**
Progression-free survival (PFS)[a,1]		
Number of events, n (%)	44 (15)	187 (63)
Median, months (95% CI)	NR (NE, NE)	18.1 (14.6, 22.8)
Hazard ratio (95% CI)[b] ; p-value[c]	0.17 (0.12, 0.23); <0.0001	
Overall survival (OS)[a,1]		
Number of events, n (%)	46 (16)	98 (33)
Median, months (95% CI)	NR (NE, NE)	NR (41.4, NE)
Hazard ratio (95% CI)[b]; p-value[c]	0.46 (0.32, 0.65); <0.0001	
Overall response (sCR+CR+VGPR+PR)[a], n (%)	259 (89.0)	223 (75.3)
95% CI (%)	(84.8, 92.4)	(70.0, 80.1)
p-value[d]	<0.0001	
Stringent complete response (sCR), n (%)	225 (77.3)	69 (23.3)
Complete response (CR), n (%)	13 (4.5)	26 (8.8)
Very good partial response (VGPR), n (%)	14 (4.8)	74 (25.0)
Partial response (PR), n (%)	7 (2.4)	54 (18.2)
Complete response or better (sCR+CR)[a], n (%)	238 (81.8)	95 (32.1)
95% CI (%)	(76.9, 86.0)	(26.8, 37.7)
p-value[d]	<0.0001	
MRD negativity rate[e,f], N	262	269
n (%)	153 (58.4)	46 (17.1)
95% CI (%)	(52.2, 64.4)	(12.8, 22.1)
p-value[g]	<0.0001	
MRD negativity rate in patients with CR or better[f]		
Number of patients with CR or better, n	216	86
MRD negativity rate, n (%)	153 (70.8)	46 (53.5)
95% CI (%)	(64.3, 76.8)	(42.4, 64.3)

DPd = daratumumab hyaluronidase-fihj, pomalidomide, dexamethasone; DVd = daratumumab hyaluronidase-fihj, bortezomib, dexamethasone; CI=confidence interval; NE=not estimable; NR=not reached; MRD = minimal residual disease. 1 Median duration of follow-up = 34.5 months a Based on intent-to-treat analysis set b Stratified Cox proportional hazard model. For all stratified analyses, stratification was based on ISS staging (I vs. II or III) and number of prior lines of therapy (1 vs. 2 or 3), as randomized c Stratified log-rank test d Stratified Cochran Mantel-Haenszel Chi-Squared test e Based on MRD next-generation sequencing (NGS) primary analysis set, defined as all randomized patients enrolled at sites where next generation sequencing assay was available. f Based on a threshold of 10-5 using a next generation sequencing assay (clonoSEQ). g Fisher's exact test

In MajesTEC-3, serious adverse reactions were reported in 71% of patients, including pneumonia, upper respiratory tract infection, cytokine release syndrome, COVID-19, sepsis, second primary malignancy, pyrexia, febrile neutropenia, and gastroenteritis. Fatal adverse reactions occurred in 2.5% of patients including sepsis, pneumonia, sudden death, myocardial infarction, enterovirus myocarditis, and

hemophagocytic lymphohystiocytosis. Permanent discontinuation occurred in 6% of patients. Dose interruptions occurred in 94% of patients. The most common adverse reactions were hypogammaglobulinemia, upper respiratory tract infection, cytokine release syndrome, cough, diarrhea, musculoskeletal pain, COVID-19, pneumonia, injection site reaction, fatigue, pyrexia, headache, nausea, gastroenteritis, and weight loss.

In MajesTEC-3, 51% of patients were younger than 65 years of age, 39% were 65 to 74 years of age, and 11% were 75 years of age or older. No overall differences in effectiveness were observed between patients 65 to 74 years of age compared to younger patients. The study did not include a sufficient number of patients 75 years of age or older to assess whether there are differences in effectiveness compared to younger patients. There was a higher incidence of serious adverse reactions in patients 75 years of age or older (83%) and in patients 65 to 74 years of age (77%) as compared to patients younger than 65 years of age (63%).

Current Formulary Status: Medical Benefit, requiring a PA

Recommendation: There are no changes recommended to the formulary placement or authorization duration. The following changes are recommended for Medical Benefit Policy 273.0 to incorporate the new indication:

Medical Benefit Policy 273.0

- Medical record documentation that Tecvayli is prescribed by a hematologist or oncologist **AND**
- Medical record documentation of age greater than or equal to 18 years old **AND**
- Medical record documentation of a diagnosis of relapsed or refractory multiple myeloma **AND**
- Medical Record documentation of one of the following:
    - Medical record documentation that Tecvayli is being used as monotherapy AND 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 OR
    - Medical record documentation that Tecvayli is being used in combination with daratumumab hyaluronidase-fihj (Darzalex Faspro) AND documentation of treatment with at least one prior line of therapy, including a proteasome inhibitor and an immunomodulatory agent

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.

TEZSPIRE (Tezepelumab-ekko)

Clinical Summary: Tezspire is a thymic stromal lymphopoietin (TSLP) blocker, human monoclonal antibody (IgG2λ), indicated for the add-on maintenance treatment of adult and pediatric patients aged 12 years and older with inadequately controlled chronic rhinosinusitis with nasal polyps (CRSwNP). It was previously indicated for the add-on maintenance treatment of adult and pediatric patients aged 12 years and older with severe asthma.

Updated Dosing: The recommended dosage is 210 mg administered subcutaneously once every 4 weeks.

Summary of Updated Clinical Studies: The efficacy of Tezspire for add-on maintenance treatment of inadequately controlled CRSwNP was evaluated in a randomized, double-blind, parallel group, multicenter, placebo-controlled trial (WAYPOINT [NCT04851964]) of 52 weeks treatment duration conducted in 408 patients aged 18 years and older on standard of care treatment for CRSwNP. This study included patients with symptomatic CRSwNP despite treatment with nasal corticosteroids, and who had systemic corticosteroids within the past 12 months and/or any history of sino-nasal surgery, or with contraindications and/or intolerance to either. Patients received Tezspire 210 mg or placebo subcutaneously every 4 weeks for 52 weeks in addition to nasal corticosteroid treatment for CRSwNP. Statistically significant efficacy was observed in WAYPOINT for the co-primary endpoints of improvement in total NPS and in bi-weekly mean NCS at Week 52.

Table 7 Results of Change from Baseline in Total Nasal Polyp Score and Bi-weekly Mean Nasal Congestion Score at Week 52 in Adults with CRSwNP (WAYPOINT)

	TEZSPIRE 210 mg Q4W (N=203)		Placebo (N=205)		LS mean difference vs. placebo (95% CI)
Scores	Baseline mean	LS mean change	Baseline mean	LS mean change	
NPS	6.1	-2.47	6.1	-0.47	-2.01 (-2.33, -1.68)
NCS	2.59	-1.76	2.55	-0.81	-0.95 (-1.12, -0.78)

LS mean change, Least squared mean change from baseline; reduction in score indicates improvement; NCS, Nasal congestion score; NPS, Nasal polyp score

Key secondary endpoints at Week 52 included time to surgery decision and/or systemic corticosteroid use for nasal polyps, change from baseline in loss of smell, and change from baseline in Lund-Mackay (LMK) sinus CT scan score. Tezspire significantly reduced the proportion of patients with need for sino-nasal surgery or systemic corticosteroids by 92% compared to placebo over 52 weeks (Hazard Ratio: 0.08; 95% CI: 0.03, 0.17).

Current Formulary Status: Specialty tier or Brand non preferred tier requiring a prior auth

Recommendation: There are no changes to formulary status, quantity limits, or authorization duration at this time. It is recommended to update the following policies to include the new FDA approved indication. These recommendations for Commercial and Medical policies below currently align with current Nucala policies. Of note, still waiting to hear from vendor regarding rebates so will address at later time if needed.

Commercial Policy 754.0 Tezspire

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

Asthma

- Medical record documentation that Tezspire is prescriber by or in consultation with an allergist, immunologist, or pulmonologist **AND**
- Medical record documentation of age greater than or equal to 12 years **AND**
- Medical record documentation of severe asthma **AND**
- Medical record documentation that Tezspire will be used as an add-on maintenance treatment **AND**

- Medical record documentation that Tezspire will not be used in combination with another biologic medication indicated for asthma treatment (e.g. Xolair, Nucala, Fasenra, Dupixent, Cinqair) **AND**
- Medical record documentation of one of the following:
    - Poor control or intolerance, despite a 3 month trial of: medium –high dose inhaled corticosteroids and another controller medication (long-acting beta agonists, long-acting muscarinic antagonist, or leukotriene receptor antagonists) with or without oral corticosteroids **OR**
    - Two or more asthma exacerbations requiring systemic corticosteroid treatment or one asthma exacerbation resulting in hospitalization in the past 12 months despite current therapy to medium- high inhaled corticosteroids and another controller medication (long-acting beta agonists, long-acting muscarinic antagonist, or leukotriene receptor antagonists)

Chronic Rinosinusitis with nasal polyps (CRSwNP)

- Medical record documentation that Tezspire is prescribed by or in consultation with an allergist, pulmonologist, immunologist or otolaryngologist (ENT provider) **AND**
- Medical record documentation of age greater than or equal to 12 years **AND**
- Medical record documentation of a diagnosis of chronic rhinosinusitis with nasal polyps (CRSwNP) **AND**
- Medical record documentation that Tezspire will be used as add-on maintenance treatment **AND**
- Medical record documentation of a therapeutic failure on intolerance to, or contraindication to three (3) intranasal corticosteroids

MEDISPAN AUTHORIZATION LEVEL: GPI-12

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

- QL FOR LETTER ONLY:
    - 1.91 mL (210 mg) per 28 days

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 the member experiences toxicity or worsening of disease.

Medical benefit Policy MBP 259.0

Tezspire (tezepelumab-ekko) will be considered medically necessary for the commercial, exchange, CHIP, and Medicare lines of business when all of the following criteria are met:

Asthma

- Prescription written by or in consultation with an allergist, immunologist, or pulmonologist **AND**
- Medical record documentation of age greater than or equal to 12 years **AND**
- Medical record documentation of severe asthma **AND**
- Medical record documentation that Tezspire will be used as an add-on maintenance treatment **AND**
- Medical record documentation of one of the following:
    - Poor control or intolerance, despite a 3 month trial of: medium–high dose inhaled corticosteroids and another controller medication (long-acting beta agonists, long-acting muscarinic antagonist, or leukotriene receptor antagonists) with or without oral corticosteroids **OR**
    - Two or more asthma exacerbations requiring systemic corticosteroid treatment or one asthma exacerbation resulting in hospitalization in the past 12 months despite current therapy to medium- high inhaled corticosteroids and another controller medication (long-

acting beta agonists, long-acting muscarinic antagonist, or leukotriene receptor antagonists)

AND

- Medical record documentation that Tezspire will not be used in combination with another biologic medication indicated for asthma treatment (e.g. Xolair, Nucala, Fasenra, Dupixent, Cinqair)

Chronic Rhinosinusitis with Nasal Polyps (CRSwNP)

- Medical record documentation that Tezspire is prescribed by or in consultation with an allergist, pulmonologist, immunologist, or otolaryngologist (ENT provider) **AND**
- Medical record documentation of age greater than or equal to 12 years **AND**
- Medical record documentation of a diagnosis of chronic rhinosinusitis with nasal polyps (CRSwNP) **AND**
- Medical record documentation that Tezspire will be used as add-on maintenance treatment **AND**
- Medical record documentation of a therapeutic failure on, intolerance to, or contraindication to three (3) intranasal corticosteroids **AND**
- Medical record documentation that the medication will not be used in combination with Fasenra (benralizumab), Cinqair (reslizumab), Dupixent (dupilumab), Xolair (omalizumab), or Tezspire (tezepelumab)

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 LIMITS: 1.91 mL (210 mg) every 28 days

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

UPLIZNA (inebilizumab-cdon)

Clinical Summary: Uplizna has recently been approved for two additional indications in addition to neuromyelitis optica spectrum disorder (NMOSD). The new indications are:

- Immunoglobulin G4-related disease (IgG4-RD) in adult patients
- Generalized myasthenia gravis (gMG) in adult patients who are anti-acetylcholine receptor (AChR) or anti-muscle specific tyrosine kinase (MuSK) antibody positive

Immunoglobulin G4-related disease (IgG4-RD)

Uplizna is the first FDA-approved treatment for IgG4-RD and was previously granted Breakthrough Therapy designation. All patients with IgG4-RD require treatment. Corticosteroids are the primary treatment for IgG4-RD and often yield a response within 4 weeks. Response markers include symptomatic improvement, mass size reduction, improved organ function, and lower serum IgG4. Off-label immunosuppressants (e.g., mycophenolate, azathioprine) and rituximab are also used in patients who have an inadequate response or intolerability to steroids or in patients with relapsing disease, however there have been no significant clinical trials completed that support the use of either. The dosing remains consistent with the previously approved indication of NMOSD: 300 mg IV followed by 300 mg IV two weeks later. Subsequent doses are 300 mg IV every 6 months (starting 6 months from the first infusion).

IgG4-RD is a multi-organ, fibro-inflammatory condition characterized by elevated serum levels of IgG4 and tumor-like lesions. Though IgG4-RD can affect any organ, the disease is most commonly identified in the pancreas, kidneys, orbital structures, salivary glands, and retroperitoneum. Diagnosis of IgG4-RD is reached through clinical, histopathologic, and serologic evaluations. The prevalence of IgG4-RD is

estimated to be 5.3 per 100,000 people in the United States. Amgen estimates approximately 20,000 people in the United States have IgG4-RD. A diagnosis of IgG4-RD can be made by using the American College of Rheumatology/European League Against Rheumatism (ACR/EULAR) classification criteria, a complex set of criteria including radiologic involvement, histological findings, absence if exclusion criteria, and scoring ≥ 20 in eight weighted domains.

The safety and efficacy of Uplizna for treatment of IgG4-RD was studied in the MITIGATE Trial (NCT04540497). A total of 127 patients (94.1%) completed the 52-week treatment period. Patients were randomized (1:1) to receive Uplizna 300 mg IV on Day 1, Day 15, and Week 26 (n=68) or placebo IV on Day 1, Day 15, and Week 26 (n=67). All patients received glucocorticoid treatment for 3-8 weeks before undergoing randomization. The primary endpoint was the first-treated disease flare positively adjudicated by the adjudication committee during the treatment period, assessed in a time-to-event analysis. Key secondary endpoints were annualized flare rate for treated and adjudicated IgG4-RD flares during the treatment period, flare-free, treatment-free complete remission at Week 52, and flare-free, glucocorticoid-free complete remission at Week 52. The results are summarized in Table 1 below.

Table 1: Efficacy Outcomes from the MITIGATE Trial

	Uplizna (n = 68)	Placebo (n = 67)	Treatment Effect (95% CI)
Efficacy Outcomes			
IgG4-RD Flare	10.3%	59.7%	0.13 (0.06–0.28)
Annualized Flare Rate, no. (95% CI)	0.10 (0.05–0.21)	0.71 (0.53–0.94)	0.14 (0.06–0.31)
Flare-Free Treatment-Free CR at Week 52[a]	57.4%	22.4%	4.68 (2.21–9.91)
Flare-Free Steroid-Free CR at Week 52[b]	58.8%	22.4%	4.96 (2.34–10.52)
Mean Steroid Dose per Patient During the Treatment Period (Excluding 8-Week Taper)	118.3 mg	1384.5 mg	–
Patients Discontinuing Steroid Treatment Entirely	90%	37%	–
Safety Outcomes			
≥1 AE[c]	97%	98%	–
Grade ≥3 AEs	18%	12%	–
Serious AEs	18%	9%	–
AEs Leading to Study Withdrawal	9%	4%	–
Infusion-Related AEs	4%	7%	–

Source: *N Engl J Med*, 2024.

Abbreviations: AE, adverse event; CR, complete remission; IgG4-RD, immunoglobulin G4-related disease.

[a] Flare-free, treatment-free CR was defined as the lack of evident disease activity at Week 52, no flare during the treatment period, and no treatment for flare or disease control except the required 8-week glucocorticoid taper; patients who did not complete the treatment period or who missed the IgG4-RD activity assessment at Week 52 were considered to have not had CR at Week 52.

[b] Flare-free, steroid-free CR was defined as the lack of evident disease activity at Week 52, no flare during the treatment period, and no steroid treatment for flare or disease control except the required 8-week steroid taper.

[c] AEs occurring in >10% of the Uplizna group included coronavirus disease 2019 (24%), lymphopenia (16%), and urinary tract infection (12%).

Generalized myasthenia gravis (gMG)

Uplizna is now approved for the treatment of generalized myasthenia gravis (gMG) in adults who are anti-acetylcholine receptor (AChR) or anti-muscle specific tyrosine kinase (MuSK) antibody positive (Ab+). Uplizna is the first gMG treatment that can be administered every 6 months. It will compete with Imaavy and Rystiggo for patients who are anti-MuSK Ab+ and with all other treatment options for patients who are anti-AChR Ab+. The dosing remains consistent with the previously approved indication of NMOSD:

300 mg IV followed by 300 mg IV two weeks later. Subsequent doses are 300 mg IV every 6 months (starting 6 months from the first infusion).

Myasthenia gravis (MG) is the most common primary disorder of neuromuscular transmission and is characterized by weakness in ocular, bulbar, limb, and respiratory muscles. In the United States, approximately 126,725 people (37 per 100,000) have MG. The cause of MG us unknown, but it is usually diagnosed in young women 20-30 years of age or men ≥ 50 years of age. The initial therapy for most patients with mild to moderate MG is an oral acetylcholinesterase inhibitor, usually pyridostigmine. Patients with severe disease, or rapidly worsening disease, should be treated much like those in a myasthenic crisis using rapid therapies (e.g., plasma exchange or IVIG followed by glucocorticoids and other immunotherapies). Immunotherapy is indicated for patients who remain significantly symptomatic on pyridostigmine, or who become symptomatic again after a temporary response to pyridostigmine. Glucocorticoids are typically used initially, and many patients with gMG require the addition of a nonsteroidal immunotherapeutic agent such as azathioprine or mycophenolate for maintenance and to spare long-term glucocorticoid toxicities. Immunotherapy used to treat gMG include Vyvgart, Vyvgart Hytrulo, Rystiggo, Imaavy, Soliris, Ultomiris, Zilbrysq, and now Uplizna.

Uplizna was studied in the Phase 3 MINT trial (NCT04524273) [n=238], which included adult patients with gMG who were anti-AChR Ab+ (n=190) or anti-MuSK Ab+ (n=48). Eligibility criteria included Myasthenia Gravis Foundation of America (MGFA) Clinical Classification Class II to IV, Myasthenia gravis-Activities of Daily Living (MG-ADL) score between 6 and 10, and Quantitative Myasthenia Gravis (QMG) score of ≥ 11. Patients were randomized 1:1 to receive Uplizna at the standard dose or placebo. Participants must have been receiving a stable dose of steroids and/or nonsteroidal immunosuppressive therapy (or both) at the time of randomization. The randomized, controlled period was 52 weeks for the anti-AChR Ab+ population and 26 weeks for the anti-MuSK Ab+ population. The primary analysis was conducted after week 26 in both populations. The primary efficacy endpoint was the change in the MG-ADL score at week 26, in the overall population. A statistically significant difference favoring Uplizna was observed in the mean change from baseline in MG-ADL total score (-4.2 points in the Uplizna-treated group compared to -2.2 points for placebo). The secondary endpoint was the change from baseline in the QMG score at week 26 in the overall population. A statistically significant difference favoring Uplizna was observed in the mean change from baseline in QMG total score in the total population (-4.8 points in the Uplizna-treated group compared to -2.3 for placebo). The results are summarized in Table 2.

Table 2: Change from Baseline in MG-ADL and QMG Total Score at Week 26 in Adult gMG Patients who are Anti-AChR Ab+ or Anti-MuSK Ab+ (MINT Trial)

	Overall Population (Primary)		Anti-AChR-Ab+ Population		Anti-MuSK-Ab+ Population	
	UPLIZNA N = 119	Placebo N = 117	UPLIZNA N = 95	Placebo N = 93	UPLIZNA N = 24	Placebo N = 24
MG-ADL Score						
LS Mean	-4.2	-2.2	-4.2	-2.4	-3.9	-1.7
Difference	-1.9		-1.8		-2.2	
95% CI	(-2.9, -1.0)		(-2.9, -0.7)		(-4.2, -0.2)	
p-value	<0.0001		0.0015		0.0297	
QMG Score						
LS Mean	-4.8	-2.3	-4.4	-2.0	-5.2	-3.0
Difference	-2.5		-2.5		-2.3	
95% CI	(-3.8, -1.2)		(-3.9, -1.0)		(-5.3, 0.7)	
p-value	0.0002		0.0011		NS	

Ab+ = antibody positive; CI = confidence interval; LS = least square; NS = not significant

Current Formulary Status: Medical benefit requiring prior authorization

Recommendation: Prior authorization criteria for Immunoglobulin G4-related disease and generalized myasthenia gravis will be added to MBP 225 Uplizna. The new criteria are listed below.

For Immunoglobulin G4-Related Disease (IgG4-RD)

- Medical record documentation of age 18 years or older AND
- Medical record documentation that Uplizna is prescribed by or in consultation with a rheumatologist, hepatologist, immunologist, endocrinologist, nephrologist, or other provider with experience in treating IgG4-RD AND
- Medical record documentation of a confirmed diagnosis of IgG4-RD based on the American College of Rheumatology/European League Against Rheumatism (ACR/EULAR) classification criteria AND
- Medical record documentation of involvement of at least 1 or more organ (e.g., pancreas, kidneys, orbital structures, salivary glands, and retroperitoneum) in a manner consistent with IgG4-RD AND
- Medical record documentation that the patient is refractory to or has a contraindication for the use of glucocorticoids AND
- Medical record documentation that Uplizna will not be used in combination with a disease modifying therapy for the treatment of IgG4-RD (e.g., rituximab)

For Generalized Myasthenia Gravis (Commercial/Exchange/CHIP/Medicaid)

- Medical record documentation of age 18 years or older AND
- Medical record documentation that Uplizna is prescribed by or in consultation with a neurologist **AND**
- Medical record documentation of a diagnosis of generalized myasthenia gravis (gMG) that is anti-acetylcholine receptor (AChR) positive OR anti-muscle-specific tyrosine kinase (MuSK) antibody positive **AND**
- Medical record documentation of Myasthenia Gravis Foundation of America Clinical Classification (MGFA) Class II to IVa **AND**
- Medical record documentation of a baseline Myasthenia Gravis-Activities of Daily Living (MG-ADL) score greater than or equal to 6 **AND**
- Medical record documentation of therapeutic failure on, intolerance to, or contraindication to corticosteroids AND
- Medical record documentation of therapeutic failure on intolerance to, or contraindication to at least two (2) non-steroidal immunosuppressive therapies OR has failed at least one (1) immunosuppressive therapy and required chronic plasmapheresis or plasma exchange (PE) **AND**
- Medical record documentation of failure on, intolerance to, or contraindication to intravenous immunoglobulin (IVIG).

For Generalized Myasthenia Gravis Only:

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 and will require:

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

The medication will no longer be covered if patient experiences 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.

XELJANZ (tofacitinib)

Clinical Summary: Xeljanz received approval in 2025 expanding its indication beyond polyarticular-course juvenile idiopathic arthritis (pcJIA), which had been approved earlier (2020), to now also include juvenile psoriatic arthritis (jPsA) for children 2 years and older who have had an inadequate

response or intolerance to at least one TNF blocker. This approval was supported by data from the pcJIA-I pivotal pediatric trial completed in 2020, which included juvenile psoriatic arthritis (jPsA) patients within its enrolled population. The inclusion of jPsA patients in the pcJIA study allowed the FDA to extend the indication to pediatric PsA patients age 2 and older without requiring any additional studies.
The recommended dosing of Xeljanz in pediatric patients is weight based.

- **Weight 10 to <20 kg (oral solution [1 mg/mL])**
  - 3.2 mg twice daily
- **Weight 20 to <40 kg (oral solution [1 mg/mL])**
  - 4 mg twice daily
- **Weight ≥40 kg (oral solution [1 mg/mL] or immediate-release tablet)**
  - 5 mg twice daily

The types of adverse reactions in pediatric patients 2 years of age and older with pcJIA, were consistent with those seen in adults with RA and PsA, with the most serious adverse reactions being infections including pneumonia, cellulitis, herpes zoster, and urinary tract infection.

Safety and efficacy are supported by evidence from adequate and well-controlled studies of Xeljanz tablets in adults with RA, pharmacokinetic (PK) data from adult patients with RA, and with additional safety, efficacy, and PK data from the pcJIA clinical trial of XELJANZ in pediatric patients 2 years and older with active pcJIA.

Current Formulary Status: Pharmacy benefit requiring prior authorization; specialty tier or brand non preferred for members with a 3 tier benefit.

Recommendation: It is recommended to update the existing Xeljanz policy as follows:

For treatment of psoriatic arthritis

- Medical record documentation of a diagnosis of moderately to severely active psoriatic arthritis which must include documentation of either active psoriatic lesions or a documented history of psoriasis **AND**
- Medical record documentation that Xeljanz or Xeljanz XR is prescribed by a rheumatologist or dermatologist **AND**
- ~~Medical record documentation that Xeljanz or Xeljanz XR is being prescribed in combination with non-biologic disease modifying antirheumatic drug (DMARD) therapy (including but not limited to methotrexate, sulfasalazine, and/or leflunomide) **AND**~~
- Medical record documentation of age greater than or equal to 2 years of age **AND**
- Medical record documentation of intolerance to, contraindication to, or therapeutic failure on a minimum 3 month trial of adalimumab* **OR** Enbrel* **AND**
- Medical record documentation that Xeljanz or Xeljanz XR is not being used concurrently with a tumor necrosis factor (TNF) blocker or other biologic agent **AND**
- Medical record documentation that Xeljanz or Xeljanz XR is being dosed consistent with Food and Drug Administration (FDA)-approved labeling

MEDISPAN AUTHORIZATION LEVEL: GPI-14, number of claims authorized = 1, enter for one month duration

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

- QL FOR LETTER ONLY:
  - Xeljanz 5 mg: 2 tablets per day, 30 day supply per fill
  - Xeljanz XR 11 mg: 1 tablet per day, 30 day supply per fill
  - Xeljanz oral solution: 10 mL per day, 30 day supply per fill

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

UPDATES

DAPAGLIFLOZIN UPDATE

Background: The GHP Commercial, Exchange, and CHIP formularies currently prefer Jardiance in the sodium glucose linked transporter 2 (SGLT2) category. It is recommended to evaluate dapagliflozin (generic Farxiga) for formulary additional as it has been identified that it will be available as a multisource generic in April 2026.

Similar to Jardiance, dapagliflozin is indicated for glycemic control in type II diabetes and heart failure but also offers coverage for heart failure associated with chronic kidney disease.

Table. FDA-Approved Indications of SGLT2 Inhibitors

Indication*	Glycemic Control in T2DM	HF	HF/T2DM	CVD/T2DM	CKD/T2DM	HF/CKD	CVD/CKD
Brenzavvy	X						
Farxiga	X	X	X			X	
Invokana	X			X	X		
Jardiance	X	X		X			X
Steglatro	X						

When dapagliflozin is compared to Jardiance for shared indications, dapagliflozin offers similar efficacy as well as a comparable side effect profile.

Table. A1c Comparison of SGLT2 Inhibitors (Monotherapy)

Agent	Dose	Number of Patients in Study	Baseline Mean	Change from Baseline	Difference from Placebo	Proportion of Patients Achieving HbA1c <7%
Brenzavvy	20 mg	138	8.1	–0.5	–0.4	31%
	Placebo	69	7.9	–0.1	–	20%
Farxiga	10 mg	70	8.0	–0.9	–0.7	50.8%
	5 mg	64	7.8	–0.8	–0.5	44.2%
	Placebo	75	7.8	–0.2	–	31.6%
Invokana	300 mg	197	8.01	–1.03	–1.16	62%
	100 mg	195	8.06	–0.77	–0.91	45%
	Placebo	192	7.97	0.14	–	21%
Jardiance	25 mg	224	7.9	–0.8	–0.9	44%
	10 mg	224	7.9	–0.7	–0.7	35%
	Placebo	228	7.9	0.1	–	12%
Steglatro	15 mg	151	8.4	–0.8	–0.7	38.8%
	5 mg	155	8.2	–0.7	–0.6	30.1%
	Placebo	153	8.1	–0.2	–	16.9%

Dapagliflozin is expected to face generic competition beginning 4/5/2026 with upwards of 15 entrants into the market. The entrance of multiple generic manufacturers is anticipated to significantly reduce the acquisition cost of dapagliflozin which will offer savings to both the plan and members in the form of reduce copayments/coinsurance. There is no impact to existing Jardiance rebates as a result of generic dapagliflozin being added to the formularies.

Recommendation: Given that dapagliflozin offers a comparable efficacy and safety profile to Jardiance while offering financial savings for both members and the plan, it is recommended that dapagliflozin is added to the prescription drug formulary at the next available opportunity. Existing quantity limits will remain in place.

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

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

IPF policy updates (Ofev, pirfenidone, Jascayd)

Background: Currently, our Jascayd, Ofev, and pirfenidone commercial policies require "Medical record documentation that the patient was taught pulmonary rehabilitation techniques". Our pulmonologists believe that pulmonary rehab should be part of the treatment for an IPF patient, however if it cannot be completed, patients should still be eligible for antifibrotic treatment. For adult patients with interstitial lung disease, the American Thoracic Society recommends participation in pulmonary rehabilitation (strong recommendation, moderate-quality evidence). However, no other major insurance companies appear to require pulmonary rehabilitation as a prerequisite for approval of antifibrotic agents. Also, patient participation in pulmonary rehabilitation was not part of the inclusion criteria in the clinical trials. Therefore, it is recommended to remove the pulmonary rehab requirement from our IPF policies.

Recommendation: It is recommended to remove the following criteria from the IPF sections of policies 366.0, 365.0, and Jascayd commercial policy.

- Medical record documentation that member was taught pulmonary rehabilitation techniques

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

YESCARTA – medical benefit policy update

Background: The prescribing information for Yescarta was updated on February 2026 to remove the limitation of use for Primary Central Nervous System Lymphoma (PCNSL). An approval letter by the FDA was drafted on February 5, 2026 outlining the change. The neurologic toxicities warning and precaution was updated to include results for Study 4, a single-arm, single-center, open-label study in 13 patients with relapsed or refractory PCNSL. 11 of 13 patients (85%) had neurological toxicities, with 4 of 13 (31%) having grade 3 neurologic toxicities. The most common included confusional state (38%), headache (31%), somnolence (31%), disturbance in attention (23%), lethargy (23%), tremor (23%), gait disturbance (15%), hypersomnia (15%), insomnia (15%), and seizures (15%). Rates of neurologic toxicities from other trials of Yescarta in the prescribing information were 78%, 87% and 77%. Other common adverse reactions from Study 4 are listed within the prescribing information.

Recommendation: It is recommended to remove the note from MBP 162.0 stating that Yescarta is not indicated for treatment of patients with PCNSL.

MBP 162.0 Yescarta (axicabtagene ciloleucel)

Large B-Cell Lymphoma (second-line)

- Prescription written by a hematologist/oncologist **AND**
- Medical record documentation that patient is 18 years of age or older **AND**
- Medical record documentation of large B-cell lymphoma that is refractory to first-line chemoimmunotherapy OR that relapses within 12 months of first-line chemoimmunotherapy **AND**
- Medical record documentation that the member has not received prior treatment with CAR-T cell therapy or other genetically modified T cell therapy

Large B-Cell Lymphoma (third-line or beyond)

- Prescription written by a hematologist/oncologist **AND**
- Medical record documentation that patient is 18 years of age or older **AND**

- Medical record documentation of one of the following diagnoses:
    - Relapsed or refractory diffuse large B-cell lymphoma (DLBCL) not otherwise specified OR
    - Relapsed or refractory primary mediastinal large B-cell lymphoma OR
    - Relapsed or refractory high-grade B-cell lymphoma OR
    - Relapsed or refractory diffuse large B-cell lymphoma (DLBCL) arising from follicular lymphoma

AND

- Medical record documentation of a therapeutic failure on two or more previous lines of therapy **AND**
- Medical record documentation that the member has not received prior treatment with CAR-T cell therapy or other genetically modified T cell therapy

~~Note: Yescarta is not indicated for the treatment of patients with primary central nervous system lymphoma.~~

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

Voting responses were received from 31 of 50 members. The vote was unanimously approved.

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

Meeting will be held virtually via phone/Microsoft Teams.