November 2025 DUR Board Meeting Minutes

Date: November 19, 2025

Members Present: Barnhill, Anglim, Blank, Blake, Brown, Caldwell, Forster, Jost, McGrane, Oley

Members Absent: Nauts. Public member position currently vacant.

Others Present: Shannon Sexauer, Dani Feist, Josh Surginer (DPHHS); Bahny, Miranda, and Zody (Mountain Pacific); and representatives from the pharmaceutical industry.

Public Comment:
1. Kat Khachatourian, Novo Nordisk – Wegovy®
2. Krystal Ngo, Arcutis Biotherapeutics, Inc. – Zoryve® 0.05% Cream
3. Shirley Quach, Novartis - Rhapsido®
4. Lauren Warn, PTC Therapeutics - Sephience®
5. Jeffrey Baldwin, Amgen, Inc. - Repatha® and Tezspire®

Written public comment was submitted to the Board prior to the meeting. It consisted of five manufacturer letters on behalf of Repatha®, Tezspire®, Wayrilz™, Wegovy®, and Zoryve®, all of which are on the agenda and discussed later in the meeting.

Meeting Minute Review: The September 17, 2025 DUR meeting minutes were approved as written.

Department Update: None

Board Discussion

1. Criteria Changes/Dosing and Age Updates:

A. Ajovy® (fremanezumab-vfrm)

Criteria Updates – the criteria documented below is the updated and current criteria approved by the Board. For all other previously reviewed indications, the criteria remain the same. The updates are as follows:

1. New indication for Preventative Treatment of Episodic Migraine in Children Ages 6-17 and weigh 45 kg or more.

Initial Coverage Criteria

Preventative Treatment of Migraine in Adults

Member must meet all of the following criteria:

- Be 18 years of age or older.
- Have a diagnosis of episodic or chronic migraine.
- Have a history of inadequate response (trial of at least 2 months duration) to two (2) prophylactic conventional therapies that are either FDA approved or supported in guidelines.
- If patient has a contraindication or intolerance to one category or prophylactic conventional therapy, another category of medications can be used:

    - Antidepressant: amitriptyline or venlafaxine
    - Beta-blocker: metoprolol, propranolol, or timolol
    - Anti-convulsant: topiramate or valproate
- If medication is non-preferred, must have had a trial and inadequate response, or contraindication to a preferred drug with the same indication from the Montana Healthcare Programs Preferred Drug List 19 (unless preferred product(s) do not have the appropriate indication).

Prescriber requirements:
- Document number of baseline headaches.
- Attests that this therapy is being used as a preventative therapy, not for the treatment of acute attack.

Limitations:
Dosed per package labeling

Preventative Treatment of Episodic Migraine in Children

Member must meet all of the following criteria:
- Be 6-17 years of age
- Weigh 45 kg or more
- Have a diagnosis of episodic migraine.
- If 12 years of age or older, have a history of inadequate response (trial of at least 2 months duration), or intolerance to one (1) prophylactic conventional therapy that is either FDA approved or supported in guidelines including:
    - Antidepressant: amitriptyline
    - Beta-blocker: propranolol
    - Anti-convulsant: topiramate

      If patient has a contraindication to one category or prophylactic conventional therapy, another category of medications can be used.

- If medication is non-preferred, must have had a trial and inadequate response, or contraindication to a preferred drug with the same indication from the Montana Healthcare Programs Preferred Drug List 19 (unless preferred product(s) do not have the appropriate indication).

Prescriber requirements:
- Document number of baseline headaches.
- Attests that this therapy is being used as a preventative therapy, not for the treatment of acute attack.

Limitations:
Dosed per package labeling

Renewal Coverage Criteria

Prescriber requirements:

- Have documentation of member's positive clinical response to therapy as demonstrated by reduction in migraine frequency compared to number of migraine days at baseline.
- Attests that this therapy is being used as a preventative therapy, not for the treatment of acute attack.

Quantity Limits

- Adults: Maximum Daily Dose = 1 x 225mg pre-filled syringe per month or 3 x 225mg pre-filled syringes every 3 months
- Pediatric (Age 6-17 years of age) – applies to Preventative Treatment of Episodic Migraine in Children only: Maximum Daily Dose = 1 x 225mg pre-filled syringe per month

Coverage Duration

Initial approval: 12 months
Renewal approval duration: 12 months

B. Opzelura® (ruxolitinib)

Criteria Updates – the criteria documented below is the updated and current criteria approved by the Board. The updates are as follows:

1. *Change in approved age from 12 years of age down to 2 years of age.*
2. *Criteria updated to include new language/formatting and the addition of the box warnings (Black Box).*
3. *Language change for topical steroids. Previously, it was broken down by age, but now it offers the mid-potency option.*

Initial Coverage Criteria

Mild to Moderate Atopic Dermatitis

Member must meet all of the following criteria:

- Be 2 years of age or older.
- Have a diagnosis of mild to moderate atopic dermatitis **AND** is non-immunocompromised.
- If medication is non-preferred, must have had a trial and inadequate response, or contraindication to a preferred drug with the same indication from the Montana Healthcare Programs Preferred Drug List 19 (unless preferred product(s) do not have the appropriate indication)
- Have a trial and inadequate response or contraindication to all of the following:
    - a preferred high potency topical steroid
        - if high potency topical steroid is not appropriate, please give rationale and name of mid-potency topical steroid and date used **AND**
    - a preferred calcineurin inhibitor **AND**
    - Eucrisa® (crisaborole).

Prescriber requirements:

- Baseline assessment has been made to allow for documentation of positive clinical response.
- Attests to the following:
    - The prescriber is aware of the boxed warnings for serious infections, mortality, malignancy, major adverse cardiovascular events and thrombosis including pulmonary embolism.
    - Will monitor for cytopenia and change in lipid parameters.
- Attests that member **will not** use Opzelura® concomitantly with other biologics, JAK inhibitors, or potent immunosuppressants.

Limitations:
Dosed per package labeling. Apply to no more than 20% of body surface area and do not use with occlusive dressing.

Renewal Coverage Criteria

Prescriber requirements:
- Has documentation of a positive clinical response to therapy (i.e., reduction of symptoms and/or severity of symptoms or frequence of exacerbations) over baseline.
- Attests that member **will not** use Opzelura® concomitantly with other biologics, JAK inhibitors, or potent immunosuppressants.

Quantity Limits
Maximum Quantity:
- Adult and pediatric patients 12 years of age and older:
    - One (1) 60-gram tube per week **OR** One (1) 100-gram tube every two weeks
- Pediatric patients 2 to 11 years of age:
    - One (1) 60-gram tube per 2 weeks

Coverage Duration
Initial approval: 2 months
Renewal approval duration: 6 months

C. Tremfya® (guselkumab)
Criteria Updates – the criteria documented below is the updated and current criteria approved by the Board. The updates are as follows:
1. *Change in approved age down to 6 years of age for Active Psoriatic Arthritis and Moderate to Severe Plaque Psoriasis in patients who weigh at least 40 kg.*
2. *Dosing for Ulcerative Colitis (UC) in adults has been updated to match the dosing in Crohn's Disease (CD) in adults.*
3. *For UC and CD, initiation of therapy can be done via infusion or subcutaneous injection (previously, infusion was the only approved option of initiation of therapy).*

Initial Coverage Criteria

Active psoriatic arthritis

Member must meet all of the following criteria:

- Be 6 years of age or older and weigh at least 40 kg.
- Have a diagnosis of active psoriatic arthritis.
- If medication is non-preferred, must have had a trial and inadequate response, or contraindication to a preferred drug with the same indication from the Montana Healthcare Programs Preferred Drug List 19 (mt.gov) (unless preferred product(s) do not have the appropriate indication).

Prescriber requirements:

- Must be prescribed by, or in consult with, a rheumatology specialist.
- If not prescribed by an appropriate specialist, a copy of the specialty consult is required. Annual consult required for yearly reauthorization.
- Provider attests member **will not** use Tremfya® concomitantly with other biologics.

Moderate-to-severe plaque psoriasis

Member must meet all of the following criteria:

- Be 6 years of age or older and weigh at least 40 kg.
- Have a diagnosis of moderate-to-severe plaque psoriasis.
- If medication is non-preferred, must have had a trial and inadequate response, or contraindication to a preferred drug with the same indication from the Montana Healthcare Programs Preferred Drug List 19 (mt.gov) (unless preferred product(s) do not have the appropriate indication).

Prescriber requirements:

- Must be prescribed by, or in consult with, a rheumatology or dermatology specialist.
- If not prescribed by an appropriate specialist, a copy of the specialty consult is required. Annual consult required for yearly reauthorization.
- Provider attests member **will not** use Tremfya® concomitantly with other biologics.

Moderately to severely active ulcerative colitis

Member must meet all of the following criteria:

- Be 18 years of age or older.
- Have a diagnosis of moderate to severely active ulcerative colitis.
- If medication is non-preferred, must have had a trial and inadequate response, or contraindication to a preferred drug with the same indication from the Montana Healthcare Programs Preferred Drug List 19 (mt.gov) (unless preferred product(s) do not have the appropriate indication).

Prescriber requirements:

- Must be prescribed by, or in consult with, a gastroenterology specialist.
- If not prescribed by an appropriate specialist, a copy of the specialty consult is required. Annual consult required for yearly reauthorization.
- Provider attests member **will not** use Tremfya® concomitantly with other biologics.

Moderately to severely active Crohn's disease

Member must meet all of the following criteria:

- Be 18 years of age or older.
- Have a diagnosis of moderately to severely active Crohn's disease.
- If medication is non-preferred, must have had a trial and inadequate response, or contraindication to a preferred drug with the same indication from the Montana Healthcare Programs Preferred Drug List 19 (mt.gov) (unless preferred product(s) do not have the appropriate indication).

Prescriber requirements:

- Must be prescribed by, or in consult with, a gastroenterology specialist.
- If not prescribed by an appropriate specialist, a copy of the specialty consult is required. Annual consult required for yearly reauthorization.
- Provider attests member **will not** use Tremfya® concomitantly with other biologics.

Limitations:
Dosed per package labeling

Renewal Coverage Criteria (applies to all indications)

Member must meet all of the following criteria:

- Has positive clinical response to therapy (i.e., reduction in the frequency and/or severity of symptoms and exacerbations).

Prescriber requirements:

- Has documentation of positive clinical response to therapy (i.e., reduction in the frequency and/or severity of symptoms and exacerbations).
- Annual specialist consult provided if prescriber not a specialist.
- Attests that member **will not** use Tremfya® concomitantly with other biologics.

Quantity Limits

Moderate to severe plaque psoriasis AND active psoriatic arthritis:
Maximum Dose =100 mg subcutaneous injection at Week 0, Week 4, and every 8 weeks thereafter.

Moderate to severely active ulcerative colitis and moderate to severely active Crohn's disease:
Maximum Dose:

- Induction dosage:
  - 200 mg by intravenous infusion at Week 0, Week 4, and Week 8 **OR**
  - **400 mg subcutaneous injection (two 200 mg syringes) at Week 0, Week 4 and Week 8.**
- Maintenance:
  - 100 mg subcutaneous injection at Week 16, and every 8 weeks thereafter **OR**

- Alternative dosing of 200 mg subcutaneous injection at Week 12, and every 4 weeks thereafter requires clinical justification and prior authorization.

Coverage Duration

Moderate to severe plaque psoriasis and active psoriatic arthritis:
Initial approval: 28 weeks (required update from provider prior to dose at 28 weeks)

Renewal approval duration: 12 months

Moderate to severely active ulcerative colitis and moderate to severely active Crohn's disease:
Initial approval: 24 weeks (requires update from provider prior to dose at 24 weeks)

Renewal approval duration: 12 months through Drug Prior Authorization

- Requests to change dosing regimen will require Prior Authorization.

2. New Indication/Formulation:

A. Leqembi® (lecanemab-irmb)

Criteria Updates – the criteria documented below is the updated and current criteria approved by the Board. The updates are as follows:

1. *Requirement for an additional MRI before the 3rd infusion will be approved.*
2. *Requirement that all monitoring during treatment will be done within the week prior to infusion.*
3. *Previous doses were only available via infusion and administered every 2 weeks. There is now a maintenance protocol that is approved after 18 months. Members can continue with IV every 2 weeks, change to infusion every 4 weeks, or use the new subcutaneous, at-home dosing weekly.*

Initial Coverage Criteria

Member must meet all of the following criteria:

- Be 50 years of age or older.
- Have a diagnosis of mild cognitive impairment due to Alzheimer's disease or has mild Alzheimer's dementia stage of disease as evidenced by all of the following:
  - Clinical Dementia Rating (CDR)-Global Score of 0.5
  - Mini-Mental Status Exam (MMSE) score between 22 and 30 and a Memory Box score of 0.5
  - Objective evidence of cognitive impairment at screening as indicated by at least 1 standard deviation below age-adjusted mean in the Wechsler-Memory Scale-IV Logical Memory II.
- Have a positive amyloid Positron Emission Tomography (PET) scan confirming presence of amyloid beta pathology.
- Have an adequate trial of at least 3 months with a Montana Healthcare Programs preferred Alzheimer's therapy (cholinesterase inhibitor) and the preferred drug was ineffective or caused intolerable side effects. 19 (mt.gov)
  - If taking medications to treat symptoms related to Alzheimer's Disease, dosages must be stable for at least 12 weeks prior to starting Leqembi® and dosages will

not be adjusted during Leqembi® therapy. Additional therapies may not be initiated during Leqembi® treatment.

- Have a recent baseline brain magnetic resonance imaging (MRI) within 3-6 months prior to initiating treatment with Leqembi®
    - Obtain an MRI within one week prior to the 3rd, 5th, 7th, and 14th infusions.
    - If a patient experiences symptoms suggestive of ARIA, clinical evaluation should be performed, including an MRI if indicated.

Prescriber requirements:

- Must be a neurology specialist.
- Must discuss genetic testing for ApoE ε4 status prior to treatment.
- Have ruled out any other medical or neurological conditions (other than Alzheimer's Disease) that may be contributing to member's cognitive impairment, including any medications that can substantially contribute to cognitive impairment (see Beer's List).
- Agree to obtain an MRI within one week prior to the 3rd, 5th, 7th, and 14th infusions. If a patient experiences symptoms suggestive of ARIA, clinical evaluation will be performed, including an MRI if indicated.
    - For patients with radiographic findings of ARIA, enhanced clinical vigilance is recommended.
    - Additional MRIs may be considered if clinically indicated.
    - Interruption of treatment may be indicated per labeling based on severity of results.
- Prescriber attests to the following:
    - The prescriber is aware of the boxed warning (black box) of amyloid related imaging abnormalities (ARIA).
    - The prescriber is aware of the boxed warning of increased risk to patients who are apolipoprotein E ε4 homozygotes and has discussed this with patients at risk.
    - The prescriber has considered the risk of concomitant use of Leqembi® with any medication with platelet anti-aggregate or anti-coagulant properties (unless aspirin ≤ 325 mg daily.
    - Dose adjustments to medications currently being used to treat symptoms related to Alzheimer's Disease will not be allowed during Leqembi® treatment.
    - Additional Alzheimer's Disease therapies will not be initiated during Leqembi® treatment.

Limitations:
Dosed per package labeling.

Renewal Coverage Criteria

Member must meet all of the following criteria:

- Will discontinue treatment when reduction of amyloid plaques are reduced to minimal levels on amyloid PET imaging, defined as either of the following:
    - Level is < 11 Centiloids on a single PET scan **OR**
    - Level is 11 to < 25 Centiloids on 2 consecutive PET scans.
- Has not progressed to moderate or severe AD.

Prescriber requirements:

- Be a neurology specialist.
- Obtain follow-up MRI one week prior to the 3rd, 5th, 7th, and 14th infusions.
- Monitor appropriately for ARIA. If imaging shows ARIA, manage treatment per labeling.

Quantity Limits

Starting Dose: 10 mg/kg administered intravenously over approximately one hour every 2 weeks.

After eighteen months (18) the starting dose may be continued **OR** a transition to a maintenance dosage regimen may be considered.

Maintenance Dose:

- 10 mg/kg administered intravenously once every four (4) weeks **OR**
- 360 mg administered subcutaneously once every week

Coverage Duration
Initial approval: 6 months
Renewal approval duration: 6 months

B. Repatha® (evolocumab)

Criteria Updates – the criteria documented below is the updated and current criteria approved by the Board. The updates are as follows:

1. *New indication for reduced risk of major adverse cardiovascular events (CV death, myocardial infarction, stroke, unstable angina requiring hospitalization, or coronary revascularization) in adults at increased **risk** for these events.*

Initial Coverage Criteria

Member must meet all of the following criteria:

- Be 18 years of age or older and have a diagnosis of:
  - primary lipidemia **OR**
  - risk of major adverse cardiovascular events evidenced by **one (1)** of the following:
    - Significant coronary artery disease
    - Significant atherosclerotic cerebrovascular disease
    - Significant peripheral arterial disease
    - Diabetes mellitus
- Be 10 years of age or older and have a diagnosis of:
  - heterozygous familial hypercholesterolemia (HeFH) **OR**
  - homozygous familial hypercholesterolemia (HoFH).
- Have a trial and inadequate response or contraindication to at least two (2) high intensity statins (i.e., atorvastatin/rosuvastatin) at maximum tolerated dose in combination with ezetimibe.

- If medication is non-preferred, must have had a trial and inadequate response, or contraindication to a preferred drug with the same indication from the Montana Healthcare Programs Preferred Drug List 19 (unless preferred product(s) do not have the appropriate indication)

Prescriber requirements:
- Attests that member **will not** use Repatha® concomitantly with other PSCK-9 medications.

Limitations:
Dosed per package labeling

Renewal Coverage Criteria

Prescriber requirements:
- Has documentation of positive clinical response to therapy (i.e., reduction in LDL-C levels).
- Attests that member **will not** use Repatha® concomitantly with other PCSK-9 medications.

Quantity Limits
Maximum Dose
- Hypercholesterolemia OR Risk of MACE: 140 mg every 2 weeks OR 420mg once each month.
- HeFH: 140 mg every 2 weeks OR 420mg once each month.
- HoFH: 420 mg once each month.

Coverage Duration
Initial approval: 3 months
Renewal approval duration: 12 months

C. Tezspire® (tezepelumab)

Criteria Updates – the criteria documented below is the updated and current criteria approved by the Board. The updates are as follows:

1. *New indication for add-on maintenance treatment of inadequately controlled chronic rhinosinusitis with nasal polyps (CRSwNP) in adults and pediatric patients aged 12 years and older.*

Initial Coverage Criteria

Severe Asthma

Member must meet all the following criteria:
- Be 12 years of age or older.
- Have a diagnosis of severe asthma.

- Have a history of severe asthma attacks despite treatment with inhaled corticosteroid (ICS) in combination with long-acting beta2-agonist (LABA) inhaler at optimized doses for three consecutive months.
- Continue to use ICS in combination with LABA inhaler at optimized dose.
- If medication is non-preferred, must have had a trial and inadequate response, or contraindication to a preferred drug with the same indication from the Montana Healthcare Programs Preferred Drug List 19 (mt.gov (unless preferred product(s) do not have the appropriate indication).

Prescriber requirements:

- Must be prescribed by, or in consult with, an allergy, pulmonology or immunology specialist.
- If not prescribed by an appropriate specialist, a copy of the specialty consult is required. Annual consult required for yearly authorization.
- Provider attests that member **will not** use Tezspire® concomitantly with other biologics.

Chronic Rhinosinusitis With Nasal Polyps

Member must meet all the following criteria:

- Be 12 years of age or older.
- Have a diagnosis of inadequately controlled chronic rhinosinusitis with nasal polyps (CRSwNP) as evidenced by CT scan or endoscopy.
- If medication is non-preferred, must have had a trial and inadequate response, or contraindication to a preferred drug with the same indication from the Montana Healthcare Programs Preferred Drug List 19 (mt.gov) (unless preferred product(s) do not have the appropriate indication).
- Have had an inadequate treatment response, intolerance, or contraindication to both of the following:
    - **One (1)** intranasal corticosteroid (must have been adherent to therapy at optimized doses for at least three months) **AND**
    - Systemic corticosteroid trial (must be within last year) **OR** Sinus surgery for nasal polyps.

Prescriber Requirements:

- Must be prescribed by, or in consult with, an allergy, pulmonology, or otolaryngology specialist.
- If not prescribed by an appropriate specialist, a copy of the specialty consult is required. Annual consult required for yearly reauthorization.
- Attests that:
    - Unless contraindicated, member will continue treatment with a nasal corticosteroid.
    - Member **will not** use Tezspire® concomitantly with other biologics.

Renewal Coverage Criteria

Severe Asthma

Member must meet all the following criteria:

- Has been adherent to Tezspire® and ICS/LABA therapy.
- Has experienced a positive clinical response (reduction in frequency and/or severity of symptoms and exacerbations or medication dose reduction).

Provider requirements:

- Annual specialist consult provided if prescriber is not a specialist.
- Has documentation of positive clinical response to therapy (i.e., reduction in the frequency and/or severity of symptoms and exacerbations).
- Provider attests that member **will not** use Tezspire® concomitantly with other biologics.

Chronic Rhinosinusitis with Nasal Polyps

Member must meet all of the following criteria:

- Unless contraindicated, must currently be using a nasal corticosteroid.
- Verification of adherence will be made via Medicaid paid claims data.

Prescriber requirements:

- Annual specialist consult provided if prescriber not a specialist.
- Documentation is provided supporting positive response to therapy as demonstrated by a reduction in severity of sino-nasal symptoms or systemic steroid reduction (if using).
- Attests that member **will not** use Tezspire® concomitantly with other biologics.

Quantity Limits
Maximum dose = 210 mg SQ every four weeks

Coverage Duration

Severe Asthma
Initial approval duration: 12 months
Renewal approval duration: 12 months

Chronic Rhinosinusitis with Nasal Polyps
Initial approval duration: 6 months
Renewal approval duration: 12 months

D. Wegovy® (semaglutide injection)

Criteria Updates – the criteria documented below is the updated and current criteria approved by the Board. The updates are as follows:

1. *New indication for the treatment of noncirrhotic metabolic dysfunction-associated steatohepatitis (MASH), formerly known as nonalcoholic steatohepatitis (NASH), with moderate to advanced liver fibrosis (consistent with stages F2 to F3 fibrosis) in adults.*

Initial Coverage Criteria

Reduction of risk of MACE in adults with established CVD and obesity or overweight

Member must meet all of the following criteria:

- Be 18 years of age or older.
- Have established cardiovascular disease with a history of prior myocardial infarction, prior stroke, or peripheral arterial disease.
- A BMI of greater than 27 kg/m^2.
- Does not have Type 2 diabetes. Members with type 2 diabetes must be managed with a GLP-1 agonist U.S. Food and Drug Administration (FDA)-approved for that indication from the Montana Healthcare Programs preferred drug list.
- Agreed to adhere to a reduced calorie diet and increased physical activity plan.
- If medication is non-preferred, must have had a trial and inadequate response, or contraindication to a preferred drug with the same indication from the Montana Healthcare Programs Preferred Drug List 19 (unless preferred product(s) do not have the appropriate indication)

Prescriber requirements:

- Must be prescribed by, or in consult with, an appropriate cardiac specialist.
- If not prescribed by an appropriate specialist, a copy of the specialty consult is required. Annual consult required for yearly reauthorization.
- Attests to the following:
    - The provider is aware Wegovy® is contraindicated in members with a personal or family history of medullary thyroid cancer or multiple endocrine neoplasia 2.
    - The provider is aware of boxed warning about the risk of thyroid C-cell tumors.
    - The provider is aware of the risk of pancreatitis, gallbladder disease, hypoglycemia, acute kidney injury and diabetic retinopathy complications.
    - The provider is aware Wegovy® may increase the risk of suicidal behavior and ideation.
- Attests that member will be placed on a reduced calorie diet and increased physical activity plan.

MASH in Adults with moderate to advanced liver fibrosis

Member must meet all of the following criteria:

- Be 18 years of age or older.
- Have a diagnosis of noncirrhotic metabolic dysfunction associated steatohepatitis (MASH) with moderate to advanced liver fibrosis (consistent with stages F2 to F3 fibrosis) diagnosed by one of the following:
    - Specialized ultrasound (such as FibroScan®) measuring fat, inflammation, and scarring in the liver.
    - Liver biopsy.
- Does not have Type 2 diabetes. Members with type 2 diabetes must be managed with a GLP-1 agonist U.S. Food and Drug Administration (FDA)-approved for that indication from the Montana Healthcare Programs preferred drug list.
- Have had a trial of diet, exercise, and lifestyle modification.
- Continue with diet, exercise, and lifestyle modifications.

- If medication is non-preferred, must have had a trial and inadequate response, or contraindication to a preferred drug with the same indication from the Montana Healthcare Programs Preferred Drug List 19 (unless preferred product(s) do not have the appropriate indication)

Prescriber requirements:
- Must be prescribed by, or in consult with, a gastroenterology or hepatology specialist.
- If not prescribed by an appropriate specialist, a copy of the specialty consult is required. Annual consult required for yearly reauthorization.
- Comorbid conditions (including, but not limited to, those listed below) are being managed with maximumly tolerated medications:
  - Hypertension
  - Dyslipidemia
  - Type 2 Diabetes
- Attests to the following:
  - The provider is aware Wegovy® is contraindicated in members with a personal or family history of medullary thyroid cancer or multiple endocrine neoplasia 2.
  - The provider is aware of boxed warning about the risk of thyroid C-cell tumors.
  - The provider is aware of the risk of pancreatitis, gallbladder disease, hypoglycemia, acute kidney injury and diabetic retinopathy complications.
  - The provider is aware Wegovy® may increase the risk of suicidal behavior and ideation.
- Attests that member will continue on a reduced calorie diet and increased physical activity plan.

Limitations:
Dosed per package labeling

Renewal Coverage Criteria

Reduction of risk of MACE in adults with established CVD and obesity or overweight

Prescriber requirements:
- Annual specialist consult provided if prescriber not a specialist.
- Has documentation of positive clinical measures of cardiovascular disease risk reduction (weight reduction, reduced waist circumference, blood pressure improvement, improved cholesterol profile).
- Attests member has maintained a reduced calorie diet and increased physical activity plan.

MASH in Adults with moderate to advanced liver fibrosis

Prescriber requirements:
- Annual specialist consult provided if prescriber not a specialist.
- At initial 12-month review, and every 4 years thereafter at minimum, provide documentation of improvement in MASH with no worsening of fibrosis OR

improvement of fibrosis with no worsening of MASH documented by one (1) of the following:
    - Specialized ultrasound (such as FibroScan®) measuring fat, inflammation, and scarring in the liver.
    - Liver biopsy.
      ***Date and score of last measurement will be required at annual renewal*
- Attests member has maintained a reduced calorie diet and increased physical activity plan.
- Continued maximumly tolerated medications for hypertension, dyslipidemia, and Type 2 diabetes if appropriate.

Quantity Limits
Maximum dose = 2.4 mg weekly

Coverage Duration
Initial approval duration: 12 months
Renewal approval duration: 12 months

E. Zoryve® Cream (roflumilast) 0.05%, 0.15%, and 0.3%
Criteria Updates – the criteria documented below is the updated and current criteria approved by the Board. The updates are as follows:
1. *New 0.05% strength approved for mild to moderate atopic dermatitis in pediatric patients 2 to 5 years of age.*

Initial Coverage Criteria

Zoryve Cream 0.3%
Member must meet all of the following criteria:
- Be 6 years of age or older.
- Have a diagnosis of plaque psoriasis.
- If medication is non-preferred, must have had a trial and inadequate response, or contraindication to a preferred drug with the same indication from the Montana Healthcare Programs Preferred Drug List 19 (mt.gov) (unless preferred product(s) do not have the appropriate indication).
- Have a trial and inadequate response or contraindication to a preferred high potency topical steroid OR a preferred calcineurin inhibitor for plaques on facial, intertriginous, or genital areas.
- Have a trial and inadequate response or contraindication to a preferred calcipotriene agent.

Prescriber requirements:
- Attests to the following:
    - The member does not have moderate to severe liver impairment (Child-Pugh B or C).
    - Baseline assessment has been made to allow for documentation of positive clinical response.

Zoryve Cream 0.15%

Member must meet all of the following criteria:

- Be 6 years of age or older.
- Have a diagnosis of mild to moderate atopic dermatitis.
- If medication is non-preferred, must have had a trial and inadequate response, or contraindication to a preferred drug with the same indication from the Montana Healthcare Programs Preferred Drug List 19 (mt.gov) (unless preferred product(s) do not have the appropriate indication).
- Have a trial and inadequate response or contraindication to a preferred high potency topical steroid.
- Have a trial and inadequate response or contraindication to a preferred calcineurin inhibitor.

Prescriber requirements:

- Attests to the following:
    - The member does not have moderate to severe liver impairment (Child-Pugh B or C).
    - Baseline assessment has been made to allow for documentation of positive clinical response.

Zoryve Cream 0.05%

Member must meet all of the following criteria:

- Be 2 to 5 years of age.
- Have a diagnosis of mild to moderate atopic dermatitis.
- If medication is non-preferred, must have had a trial and inadequate response, or contraindication to a preferred drug with the same indication from the Montana Healthcare Programs Preferred Drug List 19 (mt.gov) (unless preferred product(s) do not have the appropriate indication).
- Have a trial and inadequate response or contraindication to a preferred high potency topical steroid.
    - If high potency topical steroid is not appropriate, please give rationale and name of mid-potency topical steroid and date used.
- Have a trial and inadequate response or contraindication to a preferred calcineurin inhibitor.

Prescriber requirements:

- Attests to the following:
    - The member does not have moderate to severe liver impairment (Child-Pugh B or C).
    - Baseline assessment has been made to allow for documentation of positive clinical response.

Limitations:
Dosed per package labeling

Renewal Coverage Criteria (applies to all cream strengths)

Member must meet all of the following criteria:

- Has a positive clinical response to therapy (i.e., reduction of symptoms and/or severity of symptoms or exacerbations) over baseline.

Prescriber requirements:

- Has documentation of a positive clinical response to therapy (i.e., reduction of symptoms and/or severity of symptoms or exacerbations) over baseline).

Quantity Limits
Maximum quantity = 60gm (1 tube every 28 days)

Coverage Duration
Initial approval duration: 2 months
Renewal approval duration: 12 months

3. **New Drug Criteria:**

A. Jascayd® (nerandomilast)
***Ofev® and Esbriet® criteria were both updated to match the current language. Those criteria are listed below.**

Initial Coverage Criteria

Member must meet all of the following criteria:

- Be 18 years of age or older.
- Have a diagnosis of idiopathic pulmonary fibrosis (IPF).
- If medication is non-preferred, must have had a trial and inadequate response, or contraindication to a preferred drug with the same indication from the Montana Healthcare Programs Preferred Drug List 19 (unless preferred product(s) do not have the appropriate indication)

Prescriber requirements:

- Must be prescribed by, or in consult with, a pulmonology specialist.
- If not prescribed by an appropriate specialist, a copy of the specialty consult is required. Annual consult required for yearly reauthorization.
- Attests to the following:
    - If member is an active smoker, provider attests that member has been offered nicotine cessation support.
    - The prescriber has documented baseline Forced Expiratory Volume (FEV1) and Forced Vital Capacity (FVC) when Jascayd® is initiated.

Limitations:
Dosed per package labeling

Renewal Coverage Criteria

Prescriber requirements:

- Has documentation of positive clinical response to therapy (i.e., reduction in the severity of symptoms and exacerbations, slowed decline of forced vital capacity, etc.).
- Annual specialist consult provided if prescriber not a specialist.

Quantity Limits
Maximum Daily Dose = 18 mg (one capsule) twice daily

Coverage Duration

Initial approval: 6 months
Renewal approval duration: 12 months

B. Ofev® (nintedanib)
Criteria Updates – the criteria documented below is the updated and current criteria approved by the Board. The updates are as follows:
1. *Smoking language update*
2. *Preferred drug list language update*
3. *Two new FDA approved indications for chronic fibrosing interstitial lung disease with a progressive phenotype and systemic sclerosis-associated interstitial lung disease.*

Initial Coverage Criteria

Member must meet all of the following criteria:
- Be 18 years of age or older.
- Have a diagnosis of one (1) of the following:
  - idiopathic pulmonary fibrosis (IPF)
  - chronic fibrosing interstitial lung diseases with a progressive phenotype
  - systemic sclerosis-associated interstitial lung disease
- If medication is non-preferred, must have had a trial and inadequate response, or contraindication to a preferred drug with the same indication from the Montana Healthcare Programs Preferred Drug List 19 (unless preferred product(s) do not have the appropriate indication)

Prescriber requirements:
- Must be prescribed by, or in consult with, a pulmonology specialist.
- If not prescribed by an appropriate specialist, a copy of the specialty consult is required. Annual consult required for yearly reauthorization.
- Attests to the following:
  - If member is an active smoker, provider attests that member has been offered nicotine cessation support.
  - The prescriber has documented baseline Forced Expiratory Volume (FEV1) and Forced Vital Capacity (FVC) when Ofev® is initiated.

Limitations:
Dosed per package labeling

Renewal Coverage Criteria

Prescriber requirements:

- Has documentation of positive clinical response to therapy (i.e., reduction in the severity of symptoms and exacerbations, slowed decline of forced vital capacity, etc.).
- Annual specialist consult provided if prescriber not a specialist.

Quantity Limits
Maximum Daily Dose = 150 mg (one capsule) twice daily

Coverage Duration

Initial approval: 6 months
Renewal approval duration: 12 months

C. Esbriet® (pirfenidone)
Criteria Updates – the criteria documented below is the updated and current criteria approved by the Board. The updates are as follows:
1. *Smoking language update*
2. *Preferred drug list language update*

Initial Coverage Criteria

Member must meet all of the following criteria:
- Be 18 years of age or older.
- Have a diagnosis of idiopathic pulmonary fibrosis (IPF)
- If medication is non-preferred, must have had a trial and inadequate response, or contraindication to a preferred drug with the same indication from the Montana Healthcare Programs Preferred Drug List 19 (unless preferred product(s) do not have the appropriate indication)

Prescriber requirements:
- Must be prescribed by, or in consult with, a pulmonology specialist.
- If not prescribed by an appropriate specialist, a copy of the specialty consult is required. Annual consult required for yearly reauthorization.
- Attests to the following:
  - If member is an active smoker, provider attests that member has been offered nicotine cessation support.
  - The prescriber has documented baseline Forced Expiratory Volume (FEV1) and Forced Vital Capacity (FVC) when Esbriet® is initiated.

Limitations:
Dosed per package labeling

Renewal Coverage Criteria

Prescriber requirements:
- Has documentation of positive clinical response to therapy (i.e., reduction in the severity of symptoms and exacerbations, slowed decline of forced vital capacity, etc.).
- Annual specialist consult provided if prescriber not a specialist.

Quantity Limits
Maximum Daily Dose = 801 mg (one tablet) three times daily after titration

Coverage Duration

Initial approval: 6 months
Renewal approval duration: 12 months

D. Rhapsido® (remibrutinib)

Initial Coverage Criteria

Member must meet all of the following criteria:

- Be 18 years of age or older.
- Have a diagnosis of chronic spontaneous urticaria (CSU).
- Have had an inadequate response to two (2) different H1 antihistamine trials of 4 weeks each.
- Does not have mild, moderate or severe hepatic impairment.
- If medication is non-preferred, must have had a trial and inadequate response, or contraindication to a preferred drug with the same indication from the Montana Healthcare Programs Preferred Drug List 19 (unless preferred product(s) do not have the appropriate indication).

Prescriber requirements:

- Must be prescribed by, or in consult with, an allergy, dermatology, or immunology specialty clinic.
- If not prescribed by an appropriate specialist, a copy of the specialty consult is required. Annual consult required for yearly reauthorization.
- Attests to the following:
  - The member will be monitored for signs and symptoms of bleeding.
  - The prescriber will review potential risk of drug interactions.
- Attests that member **will not** use Rhapsido® concomitantly with other biologics.

Limitations:
Dosed per package labeling. Rhapsido® is not indicated for any form of urticaria other than CSU.

Renewal Coverage Criteria

Prescriber requirements:

- Annual specialist consult provided if prescriber not a specialist.
- Has documentation of positive clinical response to therapy (i.e., reduction in the frequency and/or severity of symptoms and exacerbations of itch or hives).
- Attests that member **will not** use Rhapsido® concomitantly with other biologics.

Quantity Limits
Maximum Daily Dose = Two (2) tablets daily (50mg total daily dose)

Coverage Duration
Initial approval: 3 months
Renewal approval duration: 12 months

E. Sephience™ (sepiapterin)

Initial Coverage Criteria

Member must meet all the following criteria:

- Be 1 month of age or older.
- Have a diagnosis of phenylketonuria (PKU) that leads to hyperphenylalaninemia (HPA) documented by elevated baseline blood Phe concentrations obtained 0-4 weeks prior to initiation.
- Is on a Phe restricted and protein rich diet.

Prescriber requirements:

- Must be prescribed by, or in consult with, a geneticist, an endocrinology, neurology or biochemical/metabolic specialist.
- If not prescribed by an appropriate specialist, a copy of the specialty consult is required. Annual consult required for yearly reauthorization.
- Attests to the following:
    - Regular dietary assessment of protein and Phe intake will be performed.
    - Will closely monitor Phe levels and member's response to therapy.

Limitations: Dosed per package labeling depending on age and weight.

Renewal Coverage Criteria

- Member must have a positive clinical response and decreased Phe level.
- Specialist consult provided if prescriber is not a specialist.

Quantity Limits

- Starting dosage:
    - < 6 months of age: 7.5 mg/kg/day
    - 6 months to less than 1 year of age: 15mg/kg
    - 1 to less than 2 years of age: 30 mg/kg
    - 2 years of age and older: 60 mg/kg
- Titration:
    - Dose adjusted based on Phe level.
- Maximum: 60 mg/kg/day

Coverage Duration

Initial approval: 6 months
Renewal approval duration: 12 months

F. Wayrilz® (rilzabrutinib)

Initial Coverage Criteria

Member must meet all of the following criteria:

- Be 18 years of age or older.
- Have a diagnosis of persistent or chronic immune thrombocytopenia (ITP).
- If medication is non-preferred, must have had a trial and inadequate response, or contraindication to a preferred drug with the same indication from the Montana

Healthcare Programs Preferred Drug List 19 (unless preferred product(s) do not have the appropriate indication)
- Have a platelet count of <$30x10^9$/L OR a platelet count of $30x10^9$/L to $50x10^9$/L with symptomatic bleeding or risk factors for bleeding.
- Have a trial and inadequate response to
    - corticosteroids, OR immunoglobulins, OR rituximab, OR an inadequate response to splenectomy **AND**
    - a thrombopoietin (TPO) receptor agonist

Prescriber requirements:
- Must be prescribed by a hematologist.
- Platelet count will be measured at least monthly throughout course of treatment. Current labs from within the last 30 days will be attached to prior authorization forms.
- Attests to the following:
    - The member, if a female of childbearing age, has confirmation of a negative pregnancy test and has been counseled on risk to embryo if used during pregnancy and risk of lactation post-partum.
    - The prescriber is aware of :
        - Risk of liver injury and will monitor member
        - Wayrilz® should be avoided in severe hepatic and renal impairment.
        - Numerous drug and food interactions, including proton pump inhibitors and H2 antagonists, with Wayrilz®
        - Attests that member **will not** use Wayrilz® concomitantly with thrombopoietin receptor agonists (e.g., Nplate®, Promacta®, Mulpleta®, Alvaiz®) or with spleen tyrosine kinase inhibitors (e.g., Tavalisse®) or other biologics and immunosuppressants.

Limitations:
Dosed per package labeling

Renewal Coverage Criteria
Prescriber requirements:
- Must be prescribed by a hematologist.
- Platelet count is greater than or equal to 50 x 10^9 /L, but less than 400 x 10^9/L **OR** number of clinically significant bleeding events has declined.
- Verification of compliance will be made via Medicaid paid claims data. If non-compliance is determined, the reauthorization time frame may be reduced to allow time for the provider to address member compliance.
- Attests that member **will not** use Wayrilz® concomitantly with thrombopoietin receptor agonists (e.g., Nplate®, Promacta®, Mulpleta®, Alvaiz®) or with spleen tyrosine kinase inhibitors (e.g., Tavalisse®) or other biologics and immunosuppressants.

Quantity Limits
Maximum Daily Dose = Two (2) 400mg tablets (one tablet twice daily)

Coverage Duration
Initial approval: 12 months
Renewal approval duration: 12 months

G. Zymfentra® (infliximab-dyyb)

Initial Coverage Criteria

Member must meet all of the following criteria:

- Be 18 years of age or older.
- Have a diagnosis of:
  - Moderately to severely active ulcerative colitis
  - Moderately to severely active Crohn's disease
- Have completed initial doses of intravenous infliximab at week 0, 2, and 6, then may begin subcutaneous injection at week 10.
- If medication is non-preferred, member has had a trial and inadequate response, or contraindication to a preferred drug with the same indication from the Montana Healthcare Programs Preferred Drug List 19 (unless preferred product(s) do not have the appropriate indication)

Prescriber requirements:

- Must be prescribed by, or in consult with, a gastroenterology specialist.
- If not prescribed by an appropriate specialist, a copy of the specialty consult is required. Annual consult required for yearly reauthorization.
- Attests they have reviewed all boxed warnings for serious infection and malignancy.
- Attests that member **will not** use Zymfentra® concomitantly with other biologics.

Limitations:
Dosed per package labeling for subcutaneous use only. **Only approved for maintenance treatment** beginning at week 10 after infliximab intravenous infusions.

Renewal Coverage Criteria

Prescriber requirements:

- Has documentation of positive clinical response to therapy (i.e., reduction in the frequency and/or severity of symptoms and exacerbations).
- Annual specialist consult provided if prescriber not a specialist.
- Attests that member **will not** use Zymfentra® concomitantly with other biologics.

Quantity Limits
Maximum Dose = 120 mg subcutaneously every two (2) weeks.

Coverage Duration
Initial approval: 12 months
Renewal approval duration: 12 months

4. Board Discussion:

Tamara Jost, Board Member, informed the Board that because gabapentin is classified as a controlled substance at the state level but not at the federal level, Veterans Affairs pharmacies are not required to report gabapentin dispensing to the Montana Prescription Drug Registry or any other state drug monitoring program. She requested that the Montana Department of Public Health and Human Services (DPHHS) assist in disseminating this information to Montana providers. The

Montana Pharmacy Association and the Montana Primary Care Association will receive this information for distribution to their respective members.

The next DUR board meeting will be in January 2026 (exact date TBD), in this same format. The meeting was adjourned at 3:05 p.m.