September 2025 DUR Board Meeting Minutes

Date: September 17, 2025

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

Members Absent: Blank, Nauts, Putsch

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

Public Comment:
1. Erin Nowak, AbbVie – Qulipta® and Ubrelvy®
2. Tyler Lincoln, Arcutis Biotherapeutics - Zoryve® Foam
3. Shannon DiBartolo, Amgen - Otezla®
4. Jeff Martin, BioCryst - Orladeyo®
5. Mae Kwong, Soleno Therapeutics - VYKAT™ XR
6. Sara Bellefeuille, Novo Nordisk - Wegovy®
7. Wendy Bibeau, Bayer - Kerendia®
8. Lori Blackner, Pfizer US Medical - Nurtec® ODT

Written public comment was submitted to the Board prior to the meeting. It consisted of five manufacturer letters (Orladeyo™, Ekterly®, Zoryve®, Vykat™ XR, and Kerendia®), one patient advocate association (Vykat™ XR), and one provider letter (duplicate CGRP criteria). Vykat™ XR, Kerendia®, Ekterly®, Zoryve®, and duplicate CGRP criteria are on the agenda and reviewed below.

Meeting Minute Review: The June 18, 2025, DUR meeting minutes were approved as written.

Department Update: Shannon reported that Bausch has terminated several of its rebate agreements with Medicaid. While most of these changes are not expected to significantly impact our program, she wanted to inform the Board that, effective October 1, 2025, **Xifaxan®** will no longer be covered under the Medicaid program. The manufacturer has indicated that patient assistance programs will be available to support Medicaid members affected by this change.
A board member, who specializes in infectious disease, voiced concern and requested that hospital pharmacies have direct notification from the State. Shannon agreed and will provide outreach to the hospitals.

Board Discussion

1. Criteria Changes/Dosing and Age Updates:

A. Doptelet® (avatrombopag)

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 18 years of age down to 1 year of age for pediatric patients with persistent or chronic immune thrombocytopenia who have had an insufficient response to a previous treatment.*

Initial Coverage Criteria

Treatment of thrombocytopenia in patients with chronic immune thrombocytopenia (ITP).

Member must meet all of the following criteria:

- Be 18 years of age or older.
- Have a diagnosis of chronic ITP.
- 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 splenectomy, OR rituximab.

Prescriber requirements:

- Must be prescribed by a hematologist.
- Attests to the following:
    - 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.
    - Member **will not** use Doptelet® concomitantly with other thrombopoietin receptor agonists (e.g., Nplate®, Promacta®, Mulpleta®, Alvaiz®) or with spleen tyrosine kinase inhibitors (e.g., Tavalisse®).

Treatment of thrombocytopenia in adult patients with chronic liver disease who are scheduled to undergo a procedure.

Member must meet all of the following criteria:

- Be 18 years of age or older.
- Have a diagnosis of thrombocytopenia in adult patients with chronic liver disease who are scheduled to undergo a procedure.

Prescriber requirements:

- Must be prescribed by a hematologist.
- Have a platelet count of $<50x10^9$/L. Current labs from within the last 30 days will be attached to prior authorization forms.
- Attests to the following:
    - Platelet count will be measured on the day prior to initiation of treatment to determine Doptelet® dose.
    - Member **will not** use Doptelet® concomitantly with other thrombopoietin receptor agonists (e.g., Nplate®, Promacta®, Mulpleta®, Alvaiz®) or with spleen tyrosine kinase inhibitors (e.g., Tavalisse®).

Thrombocytopenia in pediatric patients 1 year and older with persistent or chronic immune thrombocytopenia who have had an insufficient response to a previous treatment

Member must meet all of the following criteria:

- Be 1 year of age or older

- Have a diagnosis of chronic or persistent ITP.
- 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 splenectomy (splenectomy is not a first-line option per guidelines in children).

Prescriber requirements:
- Must be prescribed by a hematologist.
- Attests to the following:
    - 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.
    - Member **will not** use Doptelet® concomitantly with other thrombopoietin receptor agonists (e.g., Nplate®, Promacta®, Mulpleta®, Alvaiz®) or with spleen tyrosine kinase inhibitors (e.g., Tavalisse®).

Limitations:
Dosed per package labeling according to diagnosis. Doptelet® and Doptelet® Sprinkle are not substitutable on a mg-to-mg basis.

Renewal Coverage Criteria

Treatment of thrombocytopenia in patients with chronic immune thrombocytopenia (ITP).

Member must meet all of the following criteria:
- 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.

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.
- 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 Doptelet® concomitantly with other thrombopoietin receptor agonists (e.g., Nplate®, Promacta®, Mulpleta®, Alvaiz®) or with spleen tyrosine kinase inhibitors (e.g., Tavalisse®).

Treatment of thrombocytopenia in adult patients with chronic liver disease who are scheduled to undergo a procedure.

No renewal of Doptelet® is allowed for this diagnosis. Prior authorization is required for each scheduled procedure.

Thrombocytopenia in pediatric patients 1 year and older with persistent or chronic immune thrombocytopenia who have had an insufficient response to a previous treatment

Member must meet all of the following criteria:

- 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.

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.
- 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.

Quantity Limits

Maximum Daily Dose: dose optimization is required

- ITP:40 mg daily in patients 6 years of age or older
- ITP: 20 mg Doptelet sprinkles daily in patients 1 to under 6 years of age.
- Thrombocytopenia in Chronic Liver Disease Patient Undergoing Scheduled Procedure: 60 mg daily for 5 days ONLY.

Coverage Duration

Treatment of thrombocytopenia in adult patients with chronic immune thrombocytopenia (ITP) AND children 1 year old or older with chronic or persistent immune thrombocytopenia.

Initial approval: 6 months
Renewal approval duration: 6 months

Treatment of thrombocytopenia in adult patients with chronic liver disease who are scheduled to undergo a procedure.

Initial approval: 5 days
Renewal approval duration: A new prior authorization request is required for each scheduled procedure.

B. Otezla® (apremilast)

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 18 years of age down to 6 years of age, and weighing at least 20 kg, for treatment of active psoriatic arthritis or moderate to severe plaque psoriasis.*
2. *Added PDL language.*
3. *Added dosing for Otezla XR®*

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 20 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 (unless preferred product(s) do not have the appropriate indication).

Prescriber requirements:

- Must be prescribed by, or in consult with, a dermatology or rheumatology specialist. If not prescribed by an appropriate specialist, a copy of the specialty consult is required. Annual consult required for yearly reauthorization.
- Must provide pediatric member's current weight for dosing.

Plaque Psoriasis

Member must meet all of the following criteria:

- Be 6 years of age or older AND weigh at least 20 kg.
- Have a diagnosis of:
    - Pediatric patients with moderate to severe plaque psoriasis who are candidates for phototherapy or systemic therapy.
    - Adult patients with plaque psoriasis who are candidates for phototherapy or systemic therapy.
- 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 dermatology specialist.
- If not prescribed by an appropriate specialist, a copy of the specialty consult is required. Annual consult required for yearly reauthorization.
- Must provide pediatric member's current weight for dosing.

Oral Ulcers Associated with Behcet's Disease

Member must meet all of the following criteria.

- Be 18 years of age or older.
- Have a diagnosis of oral ulcers associated with Behcet's Disease.
- Have 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 rheumatology specialist.
- If not prescribed by an appropriate specialist, a copy of the specialty consult is required. Annual consult required for yearly reauthorization.

Limitations:
Dosed per package labeling. Must weigh 50 kg for Otezla XR.

Renewal Coverage Criteria

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.

Quantity Limits
Otezla ® Maximum Daily Dose = Two (2) tablets daily
Otezla XR ® Maximum Daily Dose=One (1) tablet daily

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

2. New Indication/Formulation:

A. Dupixent® (dupilumab)
Criteria Updates – the criteria documented below is the updated and current criteria approved by the Board specific to the listed indication below. For all other previously reviewed indications, the criteria remain the same:
1. New indication for Bullous Pemphigoid in the treatment of adults.

Bullous Pemphigoid (BP)

Initial Coverage Criteria

Member must meet all of the following criteria:
- Be 18 years of age or older.
- Have a diagnosis of bullous pemphigoid confirmed by histopathology, immunopathology, or serology (i.e., Direct immunofluorescence, Indirect immunofluorescence., Immunoblotting, ELISA, etc.).
- Have had an adequate trial of oral and topical corticosteroids and not achieved or maintained remission with taper.
- 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 consultation 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.
- Must have ruled out drug-induced bullous pemphigoid (from DPP-IV inhibitors, penicillins, sulfonylureas, loop diuretics, etanercept, ibuprofen, etc.)
- Have a baseline score of the peak pruritic numeric rating scale (PP-NRS) or worst itch numerical rating scale (WI-NRS).
- Attests that member **will not** use Dupixent® concomitantly with other biologics.

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

Renewal Coverage Criteria

Member must meet all of the following criteria:

- Verification of adherence will be made via Medicaid paid claims data. If member has not shown benefit and non-compliance is determined, the reauthorization time frame may be reduced to allow time for the provider to address member compliance.

Prescriber requirements:

- Annual specialist consult provided if prescriber not a specialist.
- Has documentation of positive clinical response to therapy (i.e., reduction in body surface area involvement, reduction in number and severity of nodules)
- Has documentation of:
  - reduction in itching compared to baseline WI-NRS or PP-NRS score. **OR**
  - reduction of oral corticosteroid dose.
- Attests that member will not use Dupixent® concomitantly with other biologics.

Quantity Limits
Loading dose: 600 mg; maintenance dose 300 mg every other week.

Coverage Duration
Initial approval: 6 months
Renewal approval duration: 12 months

B. Kerendia® (finerenone)

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 reducing the risk of cardiovascular death, hospitalization for heart failure, and urgent heart failure visits in adult patients with heart failure with left ventricular ejection fraction (LVEF) $\geq$ 40%.*
2. *Added PDL language.*

Initial Coverage Criteria

Heart failure in adults with chronic kidney disease associated with type 2 diabetes

Member must meet all of the following criteria:

- Be 18 years of age or older.
- Have a diagnosis of chronic kidney disease (CKD) associated with type 2 diabetes (T2D).
- Have an A_1C of less than 10% and potassium level less than 5.0mEq/L.
- Has undergone a recent trial (within the past 90 days) of an SGLT2 preferred drug from the Montana Healthcare Programs Preferred Drug List 19
- Have a urine albumin-to-creatinine of 30 to 300 mg/g creatinine and eGFR greater than or equal to 25 ml/min/1.73m^2. [1]
- Is currently receiving a maximally tolerated ACE or ARB, unless contraindicated.
- 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 to the following:
    - Member does not have severe hepatic impairment (Child Pugh C).

Heart failure in adults with left ventricular ejection fraction ≥ 40%

Member must meet all of the following criteria:

- Be 18 years of age or older.
- Have a diagnosis of NYHA class II-IV heart failure with left ventricular ejection fraction ≥ 40% measured by any modality within the last 12 months.
- Have undergone a recent trial (within the past 90 days) of an SGLT2 preferred drug from the Montana Healthcare Programs Preferred Drug List 19
- Have been on loop diuretic treatment for at least 30 days.
- Have undergone a recent trial on spironolactone without adequate response.
- Have a potassium level less than 5.0mEq/L.
- Have an eGFR > 25 mL/min/1.73m2.
- 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 cardiology 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:
    - Member does not have severe hepatic impairment (Child Pugh C).
    - Serum potassium and renal function will be monitored while member is taking Kerendia®

Limitations:

Dosed per package labeling.

Renewal Coverage Criteria

Heart failure in adults with chronic kidney disease associated with type 2 diabetes

Prescriber requirements:

- Has documentation of member positive clinical response to therapy (i.e., slowing of the decline of eGFR and/or other measures of CKD, and/or reduction in ASCVD events such as non-fatal heart attack, non-fatal stroke, or heart failure hospitalization).
- Annual specialist consult provided if prescriber not a specialist.

Heart failure in adults with left ventricular ejection fraction ≥ 40%

Prescriber requirements:

- Has documentation of member positive clinical response to therapy (i.e., reduction of non-fatal heart attack, reduction of heart failure urgent visits, or hospitalizations).
- Annual specialist consult provided if prescriber not a specialist.

Quantity Limits
Maximum Daily Dose = One (1) tablet daily

- Up to 20mg daily for HF in CKD in patients with T2D
- Up to 40mg daily for HF with LEVF ≥ 40%

Coverage Duration
Initial approval: 6 months
Renewal approval duration: 12 months

C. Motpoly® XR (lacosamide)

Criteria Updates – the criteria documented below is the updated and current criteria approved by the Board specific to the listed indication below. For all other previously reviewed indications, the criteria remain the same:

1. *New indication for adjunctive therapy in the treatment of primary generalized tonic-clonic seizures in adults and pediatric patients weighing at least 50 kg.*

Initial Coverage Criteria

Partial onset seizures

Member must meet all of the following criteria:

- Have a weight of 50 kg or greater
- Have tried lacosamide immediate release and have a clinically compelling reason the extended-release product is necessary. Baseline seizure active is documented to show improvement upon transition from IR to XR lacosamide.
- 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:

- If discontinuation of Motpoly® XR is appropriate, there will be a gradual dose reduction over at least one week.

Primary generalized tonic-clonic seizures currently taking at least one additional anti-epilepsy drug

Member must meet all of the following criteria:

- Have a weight of 50 kg or greater
- Currently taking, and will continue taking, at least one additional anti-epileptic medication.
- Have tried lacosamide immediate release and have a clinically compelling reason the extended-release product is necessary. Baseline seizure active is documented to show improvement upon transition from IR to XR lacosamide.
- 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:

- If discontinuation of Motpoly® XR is appropriate, there will be a gradual dose reduction over at least one week.

Limitations:
Dosed per package labeling. Doses exceeding 400mg daily did not demonstrate benefit.

Renewal Coverage Criteria

Prescriber requirements:

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

Quantity Limits
Maximum Daily Dose = 400 mg

Coverage Duration
Initial approval: 6 months
Renewal approval duration: 12 months

D. **Nucala® (mepolizumab)**
Criteria Updates – the criteria documented below is the updated and current criteria approved by the Board specific to the listed indication below. For all other previously reviewed indications, the criteria remain the same:

1. *New indication for add-on maintenance treatment of adult patients with inadequately controlled chronic obstructive pulmonary disease (COPD) and an eosinophilic phenotype.*

Initial Coverage Criteria

Chronic Obstructive Pulmonary Disease (COPD)

Member must meet all of the following criteria:

- Be 18 years of age or older.
- Have a diagnosis of chronic obstructive pulmonary disease (COPD) with 2 or more exacerbations OR one exacerbation requiring hospitalization within the past twelve months.
- Have a blood eosinophil count ≥300 cells/mcL
- Be currently receiving standard treatment with triple inhalation therapy (LABA/LAMA/ICS) unless intolerance, or contraindication. Exacerbations indicating uncontrolled disease must have occurred while member was adherent to LABA/LAMA/ICS. Claims history will be used to verify adherence at time of exacerbation.
- 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 pulmonology specialist.
- If not prescribed by an appropriate specialist, a copy of the specialty consult is required. Annual consult required for yearly reauthorization.
- If member is an active smoker, prescriber attests that member has been offered nicotine cessation support.
- Attests that member **will not** use Nucala® concomitantly with other biologics (e.g., Fasenra®, Dupixent®, Cinqair®, Xolair®).

Limitations:
Dosed per package labeling

Renewal Coverage Criteria

Chronic Obstructive Pulmonary Disease (COPD)

Member must meet all of the following criteria:

- Must currently be receiving standard treatment with triple inhalation therapy (LABA/LAMA/ICS) unless intolerance, or contraindication.
- Verification of adherence 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.

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 and/or improved FEV_1).
- Attests that member will not use Nucala® concomitantly with other biologics (e.g., Fasenra®, Dupixent®, Cinqair®, Xolair®).

Quantity Limits
Maximum Daily Dose:
COPD**:** Max 100mg SQ every 4 weeks

Coverage Duration
Initial approval: 6 months
Renewal approval duration: 12 months

E. Zoryve® Foam (roflumilast 0.3%)
Criteria Updates – the criteria documented below is the updated and current criteria approved by the Board specific to the listed indication below. For all other previously reviewed indications, the criteria remain the same:

1. *New indication for plaque psoriasis of the scalp and body in adults and pediatric patients 12 years of age and older.*

Initial Coverage Criteria

Plaque Psoriasis

Member must meet all of the following criteria:

- Be 12 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:

- Has clinical documentation of functional impairment due to plaque psoriasis, which may include, but is not limited to, limitations to activities of daily living (ADLs), such as skin infections or sleep disturbances and a baseline assessment has been made to allow for documentation of positive clinical response.
- 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.

Seborrheic Dermatitis

Member must meet all of the following criteria:

- Be 9 years of age or older.
- Have a diagnosis of seborrheic dermatitis.
- Have a trial and inadequate response or contraindication to:
    - a topical antifungal agent.
    - a preferred high potency topical steroid.
    - a preferred calcineurin inhibitor

- 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:

- Has clinical documentation of functional impairment due to seborrheic dermatitis, which may include, but is not limited to, limitations to activities of daily living (ADLs), such as skin infections or sleep disturbances and a baseline assessment has been made to allow for documentation of positive clinical response.
- 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

Member must meet all 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 canister every 28 days)

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

F. Zoryve® Cream (roflumilast 0.15% and 0.3%)
Criteria Updates – the criteria documented below is the updated and current criteria approved by the Board specific to the listed indication below. For all other previously reviewed indications, the criteria remain the same:
1. *Updated PDL language and allowed for calcineurin inhibitor in place of a steroid for plaque psoriasis in sensitive areas.*

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.

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 **(both 0.3% and 0.15%):**

- 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 (both 0.3% and 0.15%)

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: 2 months
Renewal approval duration: 12 months

3. **New Drug Criteria:**

A. **Anzupgo® (delgocitinib)**

Initial Coverage Criteria

Member must meet all of the following criteria:
- Be 18 years of age or older.
- Have a diagnosis of moderate to severe chronic hand eczema (CHE) defined as hand eczema that has persisted for more than 3 months or returned twice or more within the last 12 months.
- 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 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:
  - Baseline assessment has been made to allow for documentation of positive clinical response.
- Attests that member **will not** use Anzupgo® concomitantly with other biologics, JAK inhibitors, or potent immunosuppressants.

Limitations:
Dosed per package labeling. Limited to use on hands and wrists only.

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 Anzupgo® concomitantly with other biologics, JAK inhibitors, or potent immunosuppressants.

Quantity Limits
Maximum Quantity = 60gm (2x30gm tubes every 28 days).

Coverage Duration
- Initial approval: 4 months
- Renewal approval duration: 12 months

B. EKTERLY® (sebetralstat)

Note: the criteria below also applies to BERINERT® (C1 Esterase Inhibitor-Human), FIRAZYR® (icatibant), icatibant, KALBITOR® (ecallantide), RUCONEST® (C1 Esterase Inhibitor-Recombinant), and SAJAZIR® (icatibant).

Initial Coverage Criteria

Member must meet all the following criteria:

- FDA approved age for individual HAE medication requested.
- Is not taking medication known to exacerbate angioedema (i.e., ACE inhibitors, estrogen, etc.)
- Have a diagnosis of HAE I, II, or HAE with normal C1 Inhibitor (nl-C1INH) and the following:
    - HAE I
        - Low C4 compliment level AND
        - Low C1 esterase inhibitor (C1-INH) antigenic level AND
        - Low C1-INH functional level
    - HAE II
        - Low C4 compliment level AND
        - Normal or elevated C1-INH antigenic level AND
        - Low C1-INH functional level
    - HAE nl-C1INH (formerly HAE III)
        - Normal C4 compliment level AND
        - Normal C1-INH antigenic level AND
        - Normal C1-INH functional level AND
        - Has one of the following:
            - Has a history of recurrent angioedema without urticaria which is not responsive to antihistamines or corticosteroids OR
            - Has a hereditary angioedema-causing genetic mutation OR
            - Documented family history
- Have documented history of extremity, abdominal, facial, or laryngeal HAE attacks.
- 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).
- Track and record attack date, number of on-demand doses used, and medical intervention if needed.

Prescriber requirements:

- Must be prescribed by, or in consult with, an allergy, immunology or HAE specialist.
- Submit the following lab values: C1-INH protein antigenic level, C1-INH protein functional level, and C4 level.
- Have documentation of attack history.
- Submit current weight(kg) if medication requested requires weight-based dosing.
- No more than one medication for on-demand treatment of acute HAE attacks will be approved. Dual therapy with two acute HAE medications is not permitted.

Limitations: dosed per package labeling.

Renewal Coverage Criteria

Member must meet all the following criteria:

- Track and record attack date, number of on-demand doses used, and medical intervention if needed.

Prescriber requirements:

- If not prescribed by an appropriate specialist, a copy of the specialty consult is required. Annual consult required for yearly reauthorization.
- Has documentation of positive clinical response to therapy as evidenced by reduction in frequency or severity of HAE attacks.

Quantity Limits

- Berinert® (C1 Esterase Inhibitor-Human): Three 20 IU/kg infusions per month
- Firazyr®(icatibant): Six 30mg/3ml prefilled syringes per month
- icatibant: Six 30mg/3ml prefilled syringes per month
- Kalbitor® (ecallantide): Nine 10mg/ml vials per month
- Ruconest® (C1 Esterase Inhibitor-Recombinant):
  - <84 kg: Three 50 U/kg infusions per month
  - ≥84 kg: Three 4,200 U infusions per month (Six 2100U vials)
- Sajazir® (icatibant): Six 30mg/3ml prefilled syringes per month
- Ekterly® (sebetralstat) tablets: 2 packages per month (each pack contains 4x300mg tablets which is the maximum dose for 24 hours)

Coverage Duration
Initial approval: 1 month until stable
Renewal approval duration: 6 months if stable

C. ANDEMBRY® (garadacimab-gxii) and DAWNZERA™ (donidalorsen)
Note: the criteria below also applies to CINRYZE® (C1 Esterase Inhibitor-Human), HAEGARDA® (C1 Esterase Inhibitor-Human), ORLADEYO® (berotralstat), and TAKHZYRO® (lanadelumab-flyo.

Initial Coverage Criteria

Member must meet all the following criteria:

- FDA approved age for individual HAE medication requested.
- Is not taking medication known to exacerbate angioedema (i.e., ACE inhibitor, estrogen, etc.)
- Have a diagnosis of HAE I, II, or HAE with normal C1 Inhibitor (nl-C1INH) and the following:
  - HAE I
    - Low C4 compliment level AND
    - Low C1 esterase inhibitor (C1-INH) antigenic level AND
    - Low C1-INH functional level
  - HAE II
    - Low C4 compliment level AND
    - Normal or elevated C1-INH antigenic level AND
    - Low C1-INH functional level

    - HAE - nl-C1INH (formerly HAE III)
        - Normal C4 compliment level AND
        - Normal C1-INH antigenic level AND
        - Normal C1-INH functional level AND
        - Has one of the following:
            - Has a history of recurrent angioedema without urticaria which is not responsive to antihistamines or corticosteroids OR
            - Has a hereditary angioedema-causing genetic mutation OR
            - Documented family history
- Have documented history of extremity, abdominal, facial, or laryngeal HAE attacks.
- Be experiencing more than 2 attacks per month that require treatment with on-demand HAE medication OR has one or more emergency room visits or hospitalization.
- 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, immunology or HAE specialist.
- Submit the following lab values: C1-INH protein antigenic level, C1-INH protein functional level, and C4 level.
- Have documentation of attack history.
- Submit current weight(kg) if medication requested requires weight-based dosing.
- No more than one medication for prophylactic treatment of HAE attacks will be approved. Dual therapy with two prophylactic HAE medications is not permitted.

Limitations:
Dosed per package labeling.

Renewal Coverage Criteria

Member must meet all the following criteria:
- Track and record attack date, number of on-demand doses used, and medical intervention if needed.

Prescriber requirements:
- If not prescribed by an appropriate specialist, a copy of the specialty consult is required. Annual consult required for yearly reauthorization.
- Has documentation of positive clinical response to therapy as evidenced by reduction in frequency or severity of HAE attacks.
- 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.

Quantity Limits
- Cinryze® (C1 Esterase Inhibitor-Human):
    - ≥12 y/o: 1,000 Units IV every 3 to 4 days. (1,000 Units twice per week: 8,000 Units/28 days-16 vials/month) *Doses up to 2,500 U (not to exceed 100 U/kg) every 3 or 4 days may be considered based on individual patient response*

- 6-11 y/o: 500 Units IV every 3 to 4 days (500 Units twice per week: 4,000 Units/28 days-8 vials per month) *Doses up to 1,000 U every 3 to 4 days may be considered based on individual patient response*
- Haegarda® (C1 Esterase Inhibitor-Human): 60 IU/kg SC twice weekly (every 3 to 4 days)
- Orladeyo® (berotralstat): 150 mg PO daily
- Takhzyro® (lanadelumab-flyo): 300 mg SC every 2 weeks
- Andembry® (garadacimab-gxii): 400 mg SC initial dose, then 200 mg monthly
- Dawnzera™ (donidalorsen): 80 mg SC every 4 to 8 weeks

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

D. Vykat™ XR (diazoxide choline)

Initial Coverage Criteria

Member must meet all of the following criteria:
- Be 4 years of age or older.
- Have a diagnosis of hyperphagia with Prader-Willi syndrome (PWS).
- 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 endocrinology or gastroenterology 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 prescriber has tested fasting plasma glucose (FPG) and HbA1c and optimized blood glucose for members who have hyperglycemia.
  - The prescriber will monitor:
    - FPG and HbA1c during treatment with Vykat™ XR and with dosage modifications as clinically indicated.
    - for risk of fluid overload while taking Vykat™ XR.
  - Aware of contraindication if known hypersensitivity to diazoxide, other components of VYKAT™ XR, or to thiazides.
- Attests that member **will not** use Vykat™ XR concomitantly with other diazoxide products.

Limitations:

Dosed per package labeling based on weight and titration schedule. Do not substitute VYKAT™ XR with diazoxide oral suspension because the pharmacokinetic profiles are different.

Renewal Coverage Criteria

Prescriber requirements:

- Has documentation of reduction of hyperphagic behavior (i.e., reduction in weight, pathologic food consumption, constant hunger and/or dangerous food seeking behavior).
- Annual specialist consult provided if prescriber not a specialist.
- Attests that member will not use Vykat™ concomitantly with other diazoxide products.

Quantity Limits
Maximum Daily Dose = 525 mg daily

Coverage Duration
Initial approval: 6 months
Renewal approval duration: 12 months

E. Yutrepia™ (treprostinil)

Initial Coverage Criteria

Member must meet all of the following criteria:

- Be 18 years of age or older.
- Have a diagnosis of:
  - Pulmonary arterial hypertension (WHO Group 1) **OR**
  - Pulmonary hypertension associated with interstitial lung disease (WHO Group 3)
- 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 specialist for pulmonary arterial hypertension (i.e., cardiology, pulmonology, primary care center at a large hospital, etc.).
- If not prescribed by an appropriate specialist, a copy of the specialty consult is required. Annual consult required for yearly reauthorization.
- Attests that member **will not** use Yutrepia™ concomitantly with other prostacyclin mimetics.

Limitations: Dosed per package labeling. Capsules are for inhalation, not oral use.

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 OR slowed decline of functional impairment).
- Annual specialist consult provided if prescriber not a specialist.
- Attests that member **will not** use Yutrepia™ concomitantly with other prostacyclin mimetics.

Quantity Limits
Maximum Daily Dose = Eight (8) 106 mcg capsules inhaled daily divided into 3 to 5 times a day dosing. Each capsule should be inhaled two times to ensure a full dose (848 mcg total daily dose).

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

4. **CGRP Criteria Review**
   A discussion was held about the current criteria that prevent CGRPs from being approved for both acute and prophylactic use at the same time. After a risk/benefit discussion, the Board agreed to remove the duplication restriction and allow members to use concurrent CGRP therapy for both acute and prophylactic needs.

5. **PA Criteria Removal or Changes**

   Clobazam Removal Discussion:
   Mountain Pacific requested that the existing clobazam criteria be removed based on high approval rate and low risk of concern with inappropriate use. The Board agreed to this request.

6. A board member expressed concerns about a provider prescribing Aristada 1064 mg every month instead of according to FDA labeling of 1064 mg every 2 months. Mountain Pacific and the State will look into this.

The next DUR board meeting will be on November 19, 2025, in this same format. The meeting was adjourned at 2:52 p.m.