June 2025 DUR Board Meeting Minutes

Date: June 18, 2025

Members Present: Barnhill, Anglim, Blake, Blank, Caldwell, McGrane, Nauts, Oley

Members Absent: Brown, Jost, Putsch

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

Public Comment:
1. Michele Rayes, HypoPARAthyroidism Association – Yorvipath®
2. Kaysen Bala, Ascendis Pharma – Yorvipath®
3. Chad Duncan, Vertex Pharmaceuticals – Journavx™
4. Robert Twillman, American Chronic Pain Association – Journavx™
5. Michelle Manzo, UCB, Inc. – Nayzilam®

Written public comment was submitted to the Board prior to the meeting. It consisted of three manufacturer letters (Journavx™, Mounjaro®, and Yorvipath®), one patient letter (Journavx™), and one provider letter (duplicate CGRP criteria). Journavx™, Yorvipath®, and Mounjaro® are on the agenda and reviewed below. The Board requested that the CGRP criteria be revisited at a future meeting for discussion.

Meeting Minute Review: The May 21, 2025, PDL meeting minutes were approved as written.

Department Update: No Department update.

Board Discussion

1. Criteria changes/dosing & age updates:

A. Odactra™ (Dermatophagoides farinae and Dermatophagoides pteronyssinus)

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 5 years of age.

Initial Coverage Criteria

Member must meet all of the following criteria:
- Be 5 to 65 years of age.
- Have a diagnosis of house dust mite (HDM)- induced allergic rhinitis, with or without conjunctivitis.
- Have a trial and inadequate response, or contraindication to an oral antihistamine AND nasal steroid.

Prescriber requirements:
- Must be prescribed by, or in consult with, an allergy specialist.

- If not prescribed by an appropriate specialist, a copy of the specialty consult is required. Annual consult required for yearly reauthorization.
- Must confirm specific allergy (by positive skin-prick test specific for IgE antibodies to Dermatophagoides farinae and Dermatophagoides pteronyssinus house dust mites, or by positive skin testing to licensed house dust mite allergen extracts).
- Attests to the following:
    - Odactra **will not** be used concomitantly with other allergen immunotherapy.

Limitations:
Dosed per package labeling

Renewal Coverage Criteria

Member must meet all of the following criteria:
- Has documentation of positive clinical response to therapy (reduction in the frequency and/or severity of symptoms and exacerbations).

Prescriber requirements:
- Annual specialist consult provided if prescriber not a specialist.
- Attests that member **will not** use Odactra concomitantly with other allergen immunotherapy.

Quantity Limits
Maximum Daily Dose = 1.0 tablet

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

B. Spravato® (esketamine)
Criteria Updates – the criteria documented below is the updated and current criteria approved by the Board. The updates are as follows:
1. *Indication change to allow for new FDA approval as monotherapy for treatment-resistant depression (previously adjunctive only). The criteria will continue to require the use of an oral antidepressant for MDD with acute suicidal ideation or behavior.*

Initial Coverage Criteria

Treatment-resistant depression:

Member must meet all of the following criteria:
- Be 18 years of age or older.
- Have a diagnosis of major depressive disorder (MDD) as defined by the Diagnostic and Statistical Manual of Mental Disorders (DSM-5).
- Have a baseline depression assessment using a validated depression rating scale (e.g., MADRS, PHQ-9, HAM-D, etc.) within the last 2 weeks.

- Have insufficient treatment response after at least 6 weeks duration at an adequate dose to at least 2 antidepressant trials with different mechanisms of action in the last 12 months (see Table A below for allowed medications and dosages).
- Have insufficient treatment response after at least 6 weeks duration at an adequate dose to augmented antidepressant therapy with an atypical antipsychotic that is FDA approved for MDD OR lithium in the last 12 months (see Table B below for allowed medications and dosages).
- Is actively involved in weekly psychotherapy.
- Does not have aneurysmal vascular disease (including thoracic and abdominal aorta, intracranial and peripheral arterial vessels), arteriovenous malformation or history of intracerebral hemorrhage.

Prescriber requirements:

- Must be prescribed by a psychiatric specialist.
- Attests to the following:
    - Member and facility are enrolled in the Spravato® REMS program.
    - Treatment sessions will include post-treatment observation until clinically stable for a minimum of 2 hours to monitor sedation, dissociation, perceptual changes and any other adverse events.
    - Prior to initiating treatment, member will be assessed for risk of abuse or misuse AND will be assessed periodically while on Spravato® therapy.

Depressive symptoms in adults with major depressive disorder (MDD) with acute suicidal ideation or behavior:

Member must meet all of the following criteria:

- Be 18 years of age or older.
- Have a diagnosis of major depressive disorder (MDD) as defined by the Diagnostic and Statistical Manual of Mental Disorders (DSM-5).
- Have a baseline depression assessment using a validated depression rating scale (e.g., MADRS, PHQ-9, HAM-D, etc.) within the last 2 weeks.
- Is currently taking an FDA approved antidepressant AND will continue an antidepressant in conjunction with Spravato®.
- Must receive initial doses of Spravato® inpatient (Subsequent doses will be allowed outpatient).
- Must provide documentation of inpatient psychiatric assessment of suicidal ideation or behavior.
- Does not have aneurysmal vascular disease (including thoracic and abdominal aorta, intracranial and peripheral arterial vessels), arteriovenous malformation or history of intracerebral hemorrhage.

Prescriber requirements:

- Must be prescribed by a psychiatric specialist.
- Must receive initial doses of Spravato® inpatient (Subsequent doses will be allowed outpatient).
- Attests to the following:

- Member and facility are enrolled in the Spravato® REMS program.
- Treatment sessions will include post-treatment observation until clinically stable for a minimum of 2 hours to monitor sedation, dissociation, perceptual changes and any other adverse events.
- Prior to initiating treatment, member will be assessed for risk of abuse or misuse AND will be assessed periodically while on Spravato® therapy.

Limitations:

- The effectiveness of Spravato® in preventing suicide or in reducing suicidal ideation or behavior has not been demonstrated. Use of Spravato® does not preclude the need for hospitalization if clinically warranted, even if patients experience improvement after an initial dose of Spravato®.
- Spravato® is not approved as an anesthetic agent. The safety and effectiveness of Spravato® as an anesthetic agent have not been established.

Dosed per package labeling

Renewal Coverage Criteria

Treatment-resistant depression:

Member must meet all of the following criteria:

- Has positive clinical response to therapy as demonstrated by a reduction in symptom severity compared to the baseline depression assessment utilizing the same rating scale.
- Remains actively involved in weekly psychotherapy.

Prescriber requirements:

- Must be prescribed by a psychiatric specialist.
- Attests that member and facility are enrolled in the Spravato® REMS program.
- Has documentation of positive clinical response to therapy as demonstrated by a reduction in symptom severity compared to the baseline depression assessment utilizing the same rating scale.

MDD in adults with acute suicidal ideation or behavior:
No renewal available. Authorized for 4 weeks ONLY.

Quantity Limits

Treatment-resistant depression:
• Weeks 1 to 4: 2 kits/week
• Weeks 5 and after: 1 kit/week

MDD in adults with acute suicidal ideation or behavior:
• Weeks 1 to 4: 2 kits/week

Coverage Duration

Treatment-resistant depression:

Initial approval: 4 weeks
Renewal approval duration: 6 months

MDD in adults with acute suicidal ideation or behavior:
Authorized for 4 weeks ONLY.

C. Sublocade® (buprenorphine extended release)

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

1. *FDA labeling change – no longer requires 7 days of SL buprenorphine and only requires a trial dose of 4mg prior to injection.*
2. *New quick start protocol, which allows for initial injection of 300mg and repeat injection of 300mg one week later.*
3. *Expansion of appropriate injection site locations.*

Initial Coverage Criteria

Member must meet all of the following criteria:

- Be 18 years of age or older.
- Assessment/screening supports a diagnosis of Opioid Use Disorder (DSM-V).
- Has received an initial dose (i.e., 4 mg) of transmucosal buprenorphine before administering the first injection of Sublocade® if member is not currently taking buprenorphine.

Prescriber requirements:

- Must be an enrolled Montana Healthcare Programs provider.
- Must provide clinical rationale documenting necessity to switch to injectable product.
- Must perform an overdose risk assessment and recommend naloxone if appropriate.

Limitations:

- 300mg monthly for 2 doses, then 100mg monthly.
    - The second 300 mg dose of Sublocade® may be administered as early as one week after the first injection.
    - Sublocade® maintenance doses will be administered with a minimum of 26 days between doses.
- Dose by subcutaneous injection in the abdomen, thigh, buttock, or back of the upper arm.
- Prior authorization based on clinical information will be required for any change to this dosing schedule.
- If member is pregnant, please provide:
    - Estimated Due Date.
    - Attestation that OB provider has been contacted by buprenorphine provider to establish post-delivery plan (for treatment of neonatal withdrawal syndrome).
    - Provide name of OB provider, phone number, and date contacted.
    - Attestation that risk/benefit of Sublocade® treatment has been discussed with patient.

Renewal Coverage Criteria

Prescriber requirements:

- Must be enrolled as a Montana Healthcare Programs provider.
- Has documentation of positive clinical response to therapy.

Quantity Limits

- 300 mg SQ monthly for 2 doses, then 100 mg SQ monthly.
- Prior authorization based on clinical information will be required for any change to this dosing schedule.

Coverage Duration

- Initial approval: 6 doses
- Renewal approval duration: 12 months

D. Valtoco® (diazepam) Nasal Spray

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 5 years of age down to 2 years of age

Initial Coverage Criteria

Member must meet all of the following criteria:

- Be 2 years of age or older.
- Have a diagnosis of epilepsy.
- Is taking baseline antiepileptic medication.
- If medication is non-preferred, must 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 (mt.gov).

Prescriber requirements:

- Member is being prescribed baseline antiepileptic medication.
- Any request for Valtoco®, without the use of concurrent antiepileptic therapies, will require prior authorization based on clinical information.

Limitations:
Dosed per package labeling

Renewal Coverage Criteria

Member must meet all of the following criteria:

- Verification of baseline antiepileptic medication 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.
- Has positive clinical response to therapy.

Provider requirements:

- Verification of baseline antiepileptic medication 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.
- Has documentation of positive clinical response to therapy.

Quantity Limits

- Maximum Dose = 10 units each month

Coverage Duration

- Initial approval: 12 months
- Renewal approval duration: 12 months

E. Yorvipath® (palopegteriparatide) Injection

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

1. *Removed Forteo® (teriparatide) step-through requirement after review of clinical data submitted by the HypoParathyroid Association at the last DURB meeting.*

Initial Coverage Criteria

Member must meet all of the following criteria:

- Be 18 years of age or older.
- Has a diagnosis of hypoparathyroidism.
    - Not indicated for acute post-surgical hypoparathyroidism.
- Has tried and been unable to meet albumin-corrected serum calcium taking calcium and active Vitamin D at recommended doses.
- Must have achieved an albumin-corrected serum calcium of at least 7.8mg/dL prior to trial on Yorvipath®.

Prescriber requirements:

- Must be prescribed by, or in consult with, an endocrinology specialist.
- If not prescribed by an appropriate specialist, a copy of the specialty consult is required. Annual consult required for yearly reauthorization.
- Attests patient will be monitored for signs and symptoms of hypocalcemia or hypercalcemia and once stable, they will continue to have serum calcium levels done at least every 4 to 6 weeks.

Limitations:
Titrated and adjusted per package labeling

Renewal Coverage Criteria

Prescriber requirements:

- Annual specialist consult provided if prescriber not a specialist.
- Has clinical documentation that member has responded to Yorvipath therapy (achieving and maintaining serum calcium levels of 8.3 to 10.6 mg/dL).
- Attests continued serum calcium monitoring will be done every 4 to 6 weeks.

Quantity Limits

- Maximum Daily Dose = 30mcg SQ once daily

Coverage Duration

- Initial approval: 6 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 Chronic Spontaneous Urticaria (CSU) for patients 12 years of age and older.*
2. *Added PDL language.*
3. *Updated criteria language on the Chronic Rhinosinusitis with Nasal Polyps section to clarify intent.*
    - ***Original language**: member must have had an inadequate treatment response, intolerance or contraindication to both of the following:*
        - *One different intranasal corticosteroid for at least 3 months*
        - *Trial of one systemic corticosteroid (within the past year)*
        - ***And/or** sino-nasal surgery.*
    - ***Updated language**: member must have had an inadequate treatment response, intolerance or contraindication to both of the following:*
        - *One intranasal corticosteroid for at least 3 months, **AND***
        - *Trial of one systemic corticosteroid (within the past year) **OR** Sino-nasal surgery for nasal polyps.*

Chronic Spontaneous Urticaria (CSU)

Initial Coverage Criteria

Member must meet all of the following criteria:

- Be 12 years of age or older.
- Have a diagnosis of chronic spontaneous urticaria.
- Have had an inadequate response to two (2) different H1 antihistamine trials of 4 weeks each.
- If medication is non-preferred, must 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 (mt.gov) (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 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:
- Have positive clinical response to therapy (i.e., reduction in the frequency and/or severity of symptoms and exacerbations of itch and/or hives).

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 and/or hives).
- Attests that member **will not** use Dupixent® concomitantly with other biologics.

Quantity Limits
Loading dose 400mg to 600mg; maintenance dose 200mg to 300mg every other week.

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

B. Fasenra® (benralizumab)
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 eosinophilic granulomatosis with polyangiitis (EGPA) in adults.*
2. *Added PDL language.*

Initial Coverage Criteria

Treatment of adult patients with eosinophilic granulomatosis with polyangiitis (EGPA).

Member must meet all of the following criteria:
- Be 18 years of age or older.
- Has a diagnosis of EGPA and
    - Is experiencing exacerbations while on a stable dose of oral corticosteroid or during steroid taper.
    - Immunosuppressive therapy has been ineffective, contraindicated, or not tolerated.
- If medication is non-preferred, must 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 (mt.gov). (unless preferred product(s) do not have the appropriate indication).

Prescriber requirements:

- Must be prescribed by, or in consult with, a pulmonology, allergy, rheumatology or immunology specialist.
- 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 Fasenra® concomitantly with other biologics.

Limitations:

- Fasenra® is not indicated for treatment of other eosinophilic conditions or for the relief of acute bronchospasm or status asthmaticus.
- Dosed per package labeling.

Renewal Coverage Criteria

Treatment of adult patients with eosinophilic granulomatosis with polyangiitis (EGPA).

Member must meet all of the following criteria:

- Have positive clinical response to therapy such as a reduction in frequency and/or severity of symptoms and exacerbations or corticosteroid dose reduction.

Prescriber requirements:

- Annual specialist consult provided if prescriber not a specialist.
- Have documentation of positive clinical response to therapy such as a reduction in frequency and/or severity of symptoms and exacerbations or corticosteroid dose reduction.
- Attests that member **will not** use Fasenra® concomitantly with other biologics.

Quantity Limits
Maximum Dose:

Treatment of adult patients with eosinophilic granulomatosis with polyangiitis (EGPA).

- Adults 18 years of age and older: 30mg SQ every 4 weeks.

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

C. Omvoh® (mirikizumab-mrkz)

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 moderately to severely active Crohn's disease in adults added to the previous indication for moderately to severely active ulcerative colitis, as the clinical criteria for each indication is the same, but with different dosing.*

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 (UC) in adults.
    - Moderately to severely active Crohn's disease (CD) in adults.
- If medication is non-preferred, must 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 (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.
- Attests to the following:
    - Evaluate liver enzymes and bilirubin at baseline and for at least 24 weeks of treatment.
- Attests that member **will not** use Omvoh® concomitantly with other biologics.

Limitations:
Dosed per package labeling.

- Ulcerative Colitis
    - Induction
        - Intravenous infusion (IV) of 300 mg at Week 0, Week 4, and Week 8.
    - Maintenance
        - Subcutaneous injections (SQ) of 200 mg starting at Week 12 and every 4 weeks thereafter.

- Crohn's Disease
    - Induction
        - Intravenous infusion (IV) of 900 mg at Week 0, Week 4, and Week 8.
    - Maintenance
        - Subcutaneous injections (SQ) of 300 mg starting at Week 12 and every 4 weeks thereafter.

Renewal Coverage Criteria

Member must meet all of the following criteria:
- Have completed the induction phase of three IV infusions of Omvoh® (Physician Administered Drug Program).
- Has documentation of positive clinical response to therapy (i.e., reduction in the frequency and/or severity of symptoms and exacerbations) before moving to maintenance treatment at week 12.

Prescriber requirements:
- Annual specialist consult provided if prescriber not a specialist.
- Attests that member **will not** use Omvoh® concomitantly with other biologics.

Quantity Limits

Maximum Dose:
- Ulcerative Colitis

- Induction: 300 mg per IV infusion at weeks 0, 4, and 8.
- Maintenance: 200 mg per SC dose (two-100mg injections) starting at week 12 and 4 weeks thereafter.

- Crohn's Disease:
  - Induction: 900 mg per IV infusion at weeks 0, 4, and 8.
  - Maintenance: 300 mg per SC dose (one-200 mg dose and one-100 mg dose) starting at week 12 and every 4 weeks thereafter.

Coverage Duration

Initial approval duration: Three IV infusions (week 0, 4, and 8). Positive clinical response required to enter maintenance treatment at week 12 with subcutaneous dosing.

Renewal approval duration: 12 months

D. Palforzia® (Arachis hypogaea) Allergen Powder-dnfp

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. *Age expansion - new indication for patients 1 to 17 years of age with confirmed peanut allergy. Was previously approved for patients 4 to 17 years of age.*
2. *Added up-dosing language to match labeling.*
3. *Added boxed warning acknowledgement from prescriber.*

Initial Coverage Criteria

Member must meet all of the following criteria:

- Be between 1 and 17 years of age for initiation of therapy.
  - If member was established on therapy prior to the age of 18, approval will continue.
- Has a confirmed clinical history of systemic allergic reactions to peanuts.
  - Documented positive skin prick test (wheal diameter ≥ 3mm) OR
  - Peanut specific IgE (≥ 0.35kUA/L)
- Does not have:
  - Uncontrolled asthma
  - History of eosinophilic esophagitis OR other eosinophilic gastrointestinal disease.

Prescriber requirements:

- Must be prescribed by, or in consult with, an allergy or immunology 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:
  - Medication is used in conjunction with a peanut-avoidance diet.
  - Prescription for injectable epinephrine and instructions on use have been provided.
  - Monitoring for at least 60 minutes will occur after initial dose escalation and first dose of each new Up-Dosing level.

    - Prescriber is aware of black box warning of anaphylaxis which can occur at any time during treatment.
- Attests that member **will not** use Palforzia® concomitantly with biologic treatment for peanut allergy.

Limitations:
Dosed in 3 phases per package labeling

Renewal Coverage Criteria

Member must meet all of the following criteria:
- Has documentation of positive clinical response to therapy (i.e., reduction in the frequency and/or severity of symptoms and exacerbations).

Prescriber requirements:
- Annual specialist consult provided if prescriber not a specialist.
- Attests that member **will not** use Palforzia® concomitantly with biologic treatment for peanut allergy.

Quantity Limits
Maximum Dose: Dosed in 3 sequential phases to 300 mg.
Phases are: Initial dose escalation, Up-Dosing, and Maintenance.

Coverage Duration
Initial approval: 6 months if titration to 300 mg maintenance has not occurred.
Renewal approval duration: 12 months once maintenance of 300 mg has occurred.

E. Rinvoq® (upadacitinib)
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 Giant Cell Arteritis.*
2. *Added PDL language.*

Giant Cell Arteritis

Initial Coverage Criteria

Member must meet all the following criteria:
- Be 18 years of age or older.
- Have a diagnosis of giant cell arteritis.
- If medication is non-preferred, 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 (mt.gov) (unless preferred product(s) do not have the appropriate indication).

Prescriber requirements:
- Must be prescribed by, or in consult with a rheumatology specialty clinic.

- Attests that member **will not** use Rinvoq® concomitantly with other JAK inhibitors, biologic therapies, or potent immunosuppressants.
- Attests Boxed warnings have been reviewed.

Limitations:
Dosed per package labeling.

Renewal Coverage Criteria

Giant Cell Arteritis

Member must meet all the following criteria:
- Has a positive clinical response to therapy.

Prescriber requirements:
- Annual specialist consult provided if prescriber not a specialist.
- Has documentation of positive clinical response to therapy (i.e., reduction in corticosteroid dose, improvement in markers of inflammation such as ESR or CRP).
- Attests that member **will not** use Rinvoq® concomitantly with other JAK inhibitors, biologic therapies, or potent immunosuppressants.

Quantity Limits
Maximum Daily Dose:
Rinvoq® tablets maximum daily dose = 1 tablet daily

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

F. Tremfya® (guselkumab)
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 moderately to severely active Crohn's Disease.*
2. *Updated PDL language.*

Initial Coverage Criteria

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 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

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
Maximum Dose:
- Induction dosage:
  - 200 mg by intravenous infusion at Week 0, Week 4, and Week 8, **OR**
  - 400 mg by subcutaneous injection 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 200mg subcutaneous injection at Week 12, and every 4 weeks thereafter requires clinical justification and prior authorization.

Coverage Duration
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.

3. New Drug Criteria:

A. Alyftrek® (vanzacaftor, tezacaftor, and deutivacaftor tablets)

Initial Coverage Criteria

Member must meet all of the following criteria:
- Be 6 years of age or older.
- Have a diagnosis of cystic fibrosis **AND**
  - Is homozygous for the F508del mutation in the cystic fibrosis transmembrane regulator (CFTR) gene **OR**
  - Has a mutation that is responsive based on in vitro data

Prescriber requirements:
- Must be prescribed by a pulmonologist specializing in the treatment of cystic fibrosis.

- Must provide baseline percent predicted expiratory volume ($ppFEV_1$) and date measured.
- Must provide history of pulmonary exacerbations within the past 12 months.
- Attests to the following:
    - The member has been optimized on the other current standard of care cystic fibrosis therapies.
- Attests that member **will not** use Alyftrek® with other CFTR potentiators.

Limitations:
Dosed per package labeling

Renewal Coverage Criteria

Member must meet all of the following criteria:
- Has demonstrated positive clinical response to therapy.
- Has been adherent to Alyftrek® and other CF maintenance medications. Verification of compliance will be made via Medicaid paid claims data. If non-compliance is determined, the reauthorization timeframe may be reduced to allow time for the provider to address member compliance.

Prescriber requirements:
- Prescriber is a pulmonologist specializing in the treatment of cystic fibrosis.
- Attests that member **will not** use Alyftrek® with other CFTR potentiators.
- Attests that in comparison to baseline, the member has achieved a clinically meaningful response while on Alyftrek® therapy to one or more of the following:
    - Lung function improvement as demonstrated by improvement or stability in $ppFEV_1$ (Provide current $ppFEV_1$ and date)
    - Decline in pulmonary exacerbations.
    - Stability or increase in body mass index (BMI)

Quantity Limits
Maximum Daily Dose: based on age, weight

Coverage Duration
- Initial approval: 12 months
- Renewal approval duration: 12 months (this applies to the whole class. Previously, renewals were only authorized for 6 months.)

B. Journavx™ (suzetrigine)

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 acute pain.
- Has had a trial and inadequate response, or contraindication to one (1) non-steroidal anti-inflammatory.
- If medication is non-preferred, must 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 (mt.gov) (unless preferred product(s) do not have the appropriate indication).

Prescriber requirements:

- Prescriber has reviewed and discussed with member prior pain management history.
- Attests to the following:
  - The member has acute, not chronic pain.
  - The prescriber has reviewed prior pain management history and discussed with member.
  - The member does not have severe hepatic impairment.
  - The use of Journavx™ for treatment of moderate-to-severe pain has not been studied beyond 14 days.

Limitations:
Dosed per package labeling on an empty stomach.

Renewal Coverage Criteria

- Journavx™ has not been studied beyond 14 days. No renewal will be approved.

Quantity Limits
Initial dose of two (2) 50 mg tablets, then one (1) 50 mg tablet every twelve hours
Maximum daily dose after loading dose = two (2) tablets daily.

Coverage Duration
Initial approval: One (1) time authorization of 30 tablets

C. Spevigo® (spesolimab-sbzo) 150 mg/ml Subcutaneous Syringe

Initial Coverage Criteria

Member must meet all of the following criteria:

- Be 12 years of age or older **AND** weigh at least 40 kg.
- Have a diagnosis of generalized pustular psoriasis (GPP) which includes macroscopically visible sterile pustules on erythematous base and not restricted to the acral region or within psoriatic plaques.
- Is NOT experiencing a flare of generalized pustular psoriasis.

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.
- Attests to the following:
  - Subcutaneous use of Spevigo® is being used for the treatment of GPP when **NOT** experiencing a flare.
  - Intravenous use of Spevigo® is for treatment of GPP flares.
- Attests that member **will not** use Spevigo® concomitantly with other biologics.

Limitations:

- Treatment of GPP when not experiencing a flare: Loading dose of 600 mg (four 150 mg injections) administered subcutaneously at week 0 (by a healthcare professional)

followed by 300 mg (two 150 mg injections) administered subcutaneously every 4 weeks.

- Initiating or Reinitiating Subcutaneous Spevigo® After Treatment of a GPP Flare with Intravenous Spevigo®: A loading dose is not required following treatment of a GPP flare with Spevigo®, so dose is 300 mg (two 150 mg injections) subcutaneously administered every 4 weeks.

Renewal Coverage Criteria

Member must meet all of the following criteria:
- Has a positive clinical response to therapy (i.e., reduction in the frequency and/or severity of symptoms and exacerbations).

Prescriber requirements:
- Annual specialist consult provided if prescriber not a specialist.
- Has documentation of positive clinical response to therapy over baseline (i.e., reduction in the frequency and/or severity of symptoms and exacerbations based on the Dermatology Quality of Life Index or the Psoriasis Symptom Scale).
- Attests that member **will not** use Spevigo® concomitantly with other biologics.

Quantity Limits
Maximum Dose:
- 600 mg loading dose, given by a healthcare provider
- 300 mg every 4 weeks

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

4. PA Criteria Removal or Changes

Xarelto® (rivaroxaban) 2.5mg criteria removal Discussion:
Removal of the criteria was recommended. The Board agreed with this recommendation, therefore criteria will be removed.

5. Mounjaro® (tirzepatide) Discussion
At a previous DUR meeting, the Board requested that the criteria for Mounjaro® be brought back for discussion.

Jennifer Miranda, Pharmacy Case Management Supervisor, presented criteria recommendations to the Board regarding the use of Mounjaro®. The updated criteria recommendation was to require a trial and failure of two different preferred GLP-1/GIP agonists for at least six months each before approving Mounjaro®, or any other non-preferred GLP-1. This is because, according to the 2025 ADA Guidelines, Mounjaro® does not show superior efficacy in glycemic control compared to currently preferred GLP-1 options.

Slow titration of GLP-1 agonists to minimize gastrointestinal side effects (like nausea and diarrhea) is important and optimal glycemic control may take several months as doses are adjusted and other

diabetes medications are cross-titrated. Temporary rises in blood glucose during this period are not considered treatment failures.

Rapid A1C reduction can lead to hypoglycemic symptoms and treatment discontinuation, especially in patients with very high initial A1C levels. Lastly, no fixed A1C target was recommended, as goals should be individualized based on a patient's health status and risk of hypoglycemia.

With this information, the Board approved the recommendation to require 2 preferred drugs in the GLP-1/GIP category, each for a minimum of 6 months of therapy, before a non-preferred GLP-1/GIP will be approved.

The next DUR board meeting will be on September 17, 2025, in this same format. The meeting was adjourned at 2:55 p.m.