**June 2026 DUR Board Meeting Minutes**

**Date: June 24, 2026**

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

**Members Absent:** Anglim, Harrison, Rask

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

**Public Comment**:
1. Svetlana Yakov, Billings Advanced Psychiatry PLLC – Spravato®
2. Nirmal Ghuman, Johnson & Johnson – Icotyde™ and Spravato®

Written public comments were received and distributed to the Board prior to the meeting. It consisted of two prescriber letters for Spravato® and one from the Cystic Fibrosis Foundation for Pulmozyme®. Both medications were on the agenda and reviewed later in the meeting.

**Meeting Minute Review:** The May 20, 2026, PDL meeting minutes were approved as written.

**Department Update:** There was no Department update.

**Board Discussion**

**1. Criteria Changes/Dosing, Age, and Language Updates:**

**A. Rinvoq® (upadacitinib)**

*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. *FDA indication has been modified for UC & CD to read treatment in adults who have had an inadequate response or intolerance to one or more TNF blockers. If TNF blockers are clinically inadvisable, patients should have received at least one approved systemic therapy prior to use of Rinvoq®.*

**Initial Coverage Criteria**

**Moderately-to-Severely Active Ulcerative Colitis and Moderately-to-Severely Active Crohn's Disease**

Member must meet all the following criteria:
- Be 18 years of age or older.
- Have a diagnosis of:
  - moderately-to severely active ulcerative colitis OR
  - moderately-to severely active Crohn's disease.
- Have had an inadequate response or intolerance to one or more TNF blockers.
- 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.
- Attests that member **will not** use Rinvoq® concomitantly with other JAK inhibitors, biologic therapies, or potent immunosuppressants.
- Attests Boxed warnings have been reviewed.

**Limitations for all indications:**

Dosing per package labeling

**Renewal Coverage Criteria**

**Moderately-to-Severely Active Ulcerative Colitis and Moderately-to-Severely Active Crohn's Disease**

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
- 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

**B. Stelara® (ustekinumab)**

*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. *Age expansion for Crohn's disease only – from 18 years of age and older, now down to 2 years of age and older.*
2. *Added pediatric dosing limits for Crohn's disease.*

**Initial Coverage Criteria**

**Moderately-to-severely active Crohn's disease**

Member must meet all of the following criteria:

- Be 2 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 (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 that member **will not** use Stelara (ustekinumab) concomitantly with other biologics.

**Renewal Coverage Criteria**

Prescriber requirements:

- Has documentation of positive clinical response to therapy (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 Stelara® (ustekinumab) concomitantly with other biologics.

**Quantity Limits**

- **Adults and patients 2 and older with Crohn's disease receive one initial intravenous infusion** based on body weight
  - 10 kg to 25 kg=10 mg/kg IV
  - 25 kg to 55 kg=260 mg IV
  - 55 kg to 85 kg=390 mg IV
  - >85 kg=520 mg IV
- **Adults and patients 2 and older with Crohn's disease receive maintenance subcutaneous** doses based on weight 8 weeks after the initial IV dose, then every 8 weeks thereafter
  - 10 kg to 35 kg=2.5 mg/kg
  - >35 kg=90 mg

**Coverage Duration**

**Ulcerative colitis and Crohn's disease**

- Initial approval: 2 doses (infusion week 0, and injection week 8)
- Renewal approval duration: 12 months

**C. Tzield® (teplizumab-mzwv)**

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

1. *Age expansion from 8 years of age and older, down to 1 year of age and older for the indication of delay the onset of Stage 3 type 1 diabetes mellitus in adults and pediatric patients ≥1 year of age with stage 2 type 1 diabetes mellitus*
2. *New indication - delay the decline in endogenous insulin production in pediatric patients aged 8 to 17 years recently diagnosed with Stage 3 type 1 diabetes mellitus*

**Initial Coverage Criteria**

**Delay the onset of Stage 3, type 1 diabetes mellitus in adults and pediatric patients ≥1 year of age with stage 2, type 1 diabetes mellitus**

Member must meet all of the following criteria:

- Be 1 years of age or older.
- Have confirmed Stage 2, T1D diagnosis documented by **BOTH** of the following:
  - At least two (2) of the following positive pancreatic islet cell autoantibodies:
    - Glutamic acid decarboxylase 65 (GAD) autoantibodies
    - Insulin autoantibody (IAA)
    - Insulinoma-associated antigen 2 autoantibody (IA-2A)
    - Zinc transporter 8 autoantibody (ZnT8A)
    - Islet cell autoantibody (ICA)
  - Dysglycemia without overt hypoglycemia using an oral glucose tolerance test if an oral glucose tolerance test is not available, an alternative method for diagnosing dysglycemia without overt hyperglycemia may be appropriate. Examples are:
    - Fasting plasma glucose level of 100 to 125mg/dL
    - 2-hour post-prandial glucose of 140 to 199 mg/dL

Prescriber requirements:

- Must be prescribed by, or in consult with, an endocrinologist.
- If not prescribed by an appropriate specialist, a copy of the specialty consult is required. Annual consult required for yearly reauthorization.
- Must include a current patient body surface area (BSA).
- Prescriber attests to the following:
  - The member has had a complete blood count and liver enzyme tests prior to initiation of Tzield®.
  - Member's diagnosis confirms an autoimmune origin and does not suggest type 2 diabetes or other forms of diabetes.
  - Consideration has been made for boxed warning of viral reactivation including Epstein-Barr virus and cytomegalovirus and member has been tested for active infection of both.
  - Member will be monitored for viral reactivation during Tzield® treatment and for at least 2 months following the last infusion.
  - Prescriber is aware of the risk of cytokine release syndrome, serious infection, hypersensitivity reactions, and other risks associated with Tzield® infusion.

**Delay the decline in endogenous insulin production in pediatric patients aged 8 to 17 years recently diagnosed with Stage 3, T1D**

Member must meet the following criteria:

- Be 8 to 17 years of age.
- Have been diagnosed within the last 8 weeks with Stage 3, T1D based on confirmation of:
  - At least one positive pancreatic islet cell autoantibody, AND
  - Peak C-peptide ≥ 0.2 pmol/mL on a mixed-meal tolerance test (if a mixed meal tolerance test is not available, an alternative method for measuring peak C-peptide ≥ 0.2 pmol/mL may be appropriate).

Prescriber requirements:

- Must be prescribed by, or in consult with, an endocrinologist.
- If not prescribed by an appropriate specialist, a copy of the specialty consult is required. Annual consult required for yearly reauthorization.
- Must include a current patient body surface area (BSA).
- Prescriber attests to the following:
  - The member has had a complete blood count and liver enzyme tests prior to initiation of Tzield®.
  - Member's diagnosis confirms an autoimmune origin and does not suggest type 2 diabetes or other forms of diabetes.
  - Consideration has been made for boxed warning of viral reactivation including Epstein-Barr virus and cytomegalovirus and member has been tested for active infection of both.
  - Member will be monitored for viral reactivation during Tzield® treatment and for at least 2 months following the last infusion.
  - Prescriber is aware of the risk of cytokine release syndrome, serious infection, hypersensitivity reactions, and other risks associated with Tzield® infusion.

Limitations:
Dosed per package labeling based on body surface area (BSA).

**Renewal Coverage Criteria**

- Renewal coverage is not allowed.
  - Treatment to delay the onset of Stage 3, T1D in members with Stage 2, T1D is a one-time 14-day course.
  - Treatment to delay the decline of insulin production in members 8-17 years of age recently diagnosed with Stage 3, T1D is 2 (two) 12-day courses of Tzield® six (6) months apart.

**Quantity Limits**
Dose by intravenous infusion over a minimum of:

- 30 minutes in adult and pediatric patients 8 years of age and older
- 2 hours in pediatric patients aged 1 to less than 8 years of age

**Coverage Duration**

- No renewal is available for treatment of members with Stage 2, T1D. Approval is for a one-time 14-day course.
- Treatment to delay the decline in endogenous insulin production in members with Stage 3, T1D allows for two (2) 12-day treatment courses six (6) months apart.

**D. Xeljanz®/Xeljanz XR® (tofacitinib)**

*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. *Age expansion for PsA from 18 years of age and older down to 2 years of age and older.*
2. *PsA moved to the PcJIA criteria section.*

**Initial Coverage Criteria**

**Polyarticular Course Juvenile Idiopathic Arthritis, Psoriatic Arthritis**

Member must meet all of the following criteria:

- Be 2 years of age or older.
- Have a diagnosis of:
  - Active polyarticular course juvenile idiopathic arthritis OR
  - Active psoriatic arthritis.
- Have tried and had an inadequate response or intolerance to a preferred TNF blocker.

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.
- Attests that they have reviewed the black box warning.
- Attests that member **will not** use Xeljanz® concomitantly with other biologics.

Limitations:
Dosed per package labeling.

**Renewal Coverage Criteria**

Member must meet all of the following criteria:

- Documentation of positive clinical response to therapy.

Prescriber requirements:

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

**Quantity Limits**

**PcJIA, PsA**

- Adults: 5 mg twice daily or XR 11 mg once daily
- Pediatric patients 2-18 years of age
  - 10-20 kg body weight: 3.2 mg twice daily
  - 20-40 kg body weight: 4 mg twice daily
  - Over 40 kg body weight: 5 mg twice daily

**Coverage Duration**
Initial approval duration: 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 Allergic Fungal Rhinosinusitis (AFRS) for the treatment of adult and pediatric patients aged 6 years and older with allergic fungal rhinosinusitis who have a history of sino-nasal surgery.*
2. *Age expansion for Chronic Spontaneous Urticaria (CSU) from 12 years of age and older, down to 2 years of age and older.*

**Initial Coverage Criteria**

**Chronic Spontaneous Urticaria (CSU)**

Member must meet all of the following criteria:

- Be 2 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.

**Allergic Fungal Rhinosinusitis (AFRS)**

Member must meet all of the following criteria:

- Be 6 years of age or older.
- Has a CT confirmed diagnosis of allergic fungal rhinosinusitis with a history of sino-nasal surgery with all of the following:
  - Positive fungal-specific IgE in serum or positive skin test in the previous 12 months AND
  - Presence of nasal polyps AND
  - Eosinophilic mucin/mucous identified within 5 years with or without positive fungal stain
- Unless contraindicated, must currently be using a nasal corticosteroid at optimized doses for at least 3 months (unless less than 3 months post-surgery, then must be using since surgery).
- 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, an allergy, pulmonology, or otolaryngology specialty clinic.
- If not prescribed by an appropriate specialist, a copy of the specialty consult is required. Annual consult required for yearly reauthorization.
- Has a baseline assessment of AFRS severity (i.e. Lund-McKay (LMK) score, nasal polyp size/count, nasal congestion/discharge, sense of smell, etc.).
- Attests that unless contraindicated, member will continue treatment with a nasal corticosteroid.
- Attests member **will not** use Dupixent® concomitantly with other biologics.

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

**Renewal Coverage Criteria**

**Chronic Spontaneous Urticaria (CSU):**

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.

**Allergic Fungal Rhinosinusitis (AFRS)**

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.
- Has documentation of positive clinical response to therapy (i.e. improved Lund-McKay (LMK) score, reduced nasal polyp size/count, reduced nasal congestion/discharge, improved sense of smell, etc.).
- Attests that member **will not** use Dupixent® concomitantly with other biologics.

**Quantity Limits**

**CSU:** Loading dose 400mg to 600mg; maintenance dose 200mg to 300mg every other week.
**AFRS:**

- 15-29kg: 300mg every 4 weeks
- 30-59kg: 200mg every 2 weeks
- ≥60kg: 300mg every 2 weeks

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

**B. Sotyktu® (deucravacitinib)**

*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:*

*a. New indication for the treatment of active psoriatic arthritis in adults.*
*b. Language update for PsO to match existing criteria of PsA.*

**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 plaque psoriasis and is a candidate for systemic therapy or phototherapy OR
  - 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 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.
- Has clinical documentation of baseline disease severity (e.g., body surface area or severity index using a scoring tool, etc.).
- Attests that member **will not** use Sotyktu® concomitantly with other TYK2 or JAK inhibitors, biologic therapies, or potent immunosuppressants.

Limitations:
Dosed per package labeling.

**Renewal Coverage Criteria**

Prescriber requirements:
- Has documentation of positive clinical response to therapy (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 Sotyktu® concomitantly with other TYK inhibitors, JAK inhibitors, biologics, or potent immunosuppressants.

**Quantity Limits**
Maximum Daily Dose = 1 tablet

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

**3. New Drug Criteria:**

**A. Icotyde™ (icotrokinra)**

**Initial Coverage Criteria**

**Plaque Psoriasis**

Member must meet all of the following criteria:
- Be at least 12 years of age or older. Pediatric patients must weigh at least 40kg.
- Have a diagnosis of moderate to severe plaque psoriasis.
- Must be a candidate for systemic therapy or phototherapy.
- 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 dermatology specialist.
- If not prescribed by an appropriate specialist, a copy of the specialty consult is required. Annual consult required for yearly reauthorization.
- Has clinical documentation of baseline disease severity (e.g., body surface area involvement, severity index using a scoring tool).

- Attests that member **will not** use Icotyde™ concomitantly with other biologics.

**Renewal Coverage Criteria**

Prescriber requirements:
- Annual specialist consult provided if prescriber is not a specialist.
- Documentation of positive clinical response (e.g., reduction in body surface area involvement, reduction in severity index using a scoring tool).
- Attests that member **will not** use Icotyde™ concomitantly with other biologics.

**Quantity Limits**
Maximum Daily Dose = 1 tablet (200mg) per day

**Coverage Duration**
Initial approval: 16 weeks
Renewal approval duration: 12 months

**B. Nereus® (tradipitant)**

**Initial Coverage Criteria**

Member must meet all of the following criteria:
- Be 18 years of age or older.
- Have a history of motion sickness and no history of chronic nausea caused by a disorder, condition, or medication (e.g. irritable bowel syndrome, gastroparesis, cyclic vomiting syndrome, migraine, pregnancy, chemotherapy).
- Must have had a documented trial and inadequate response, or contraindication to transdermal scopolamine, meclizine, and dimenhydrinate.
- 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:
  - The medication is being prescribed for the approved indication of vomiting induced by motion.

Limitations:
Dosed per package labeling

**Renewal Coverage Criteria**

Prescriber requirements:
- Has documentation of positive clinical response to therapy (reduction in vomiting induced by motion).
- Attests that the medication is being prescribed for the approved indication of reduction in vomiting induced by motion.

**Quantity Limits**

Maximum Daily Dose = 170 mg (2 capsules)
Maximum initial quantity: 1 bottle of 36, 85mg capsules
Maximum of 90 doses or 180 capsules in 12 months

**Coverage Duration**
Initial approval: 1 bottle of 36 capsules
Renewal approval duration: 12 months

4. **Follow up from PDL meetings:**

**A. Spravato® (esketamine)**
Requests during the PDL season were made to the Board to return Spravato® criteria for discussion and further review of the following criteria requirements:

- Weekly psychotherapy
- Hospitalization for the initial dose given for depressive symptoms with major depressive disorder with acute suicidal ideation or behavior.

The Board members discussed their rationale for the criteria that are currently in place. Some additional discussion points raised for both criteria change requests were safety, accessibility, and appropriate use.

After discussion concluded and all members were given an opportunity to raise any additional issues, a vote was taken with outcomes as follows:

- Weekly psychotherapy was expanded to "weekly psychotherapy with a licensed psychotherapy provider" and unanimously approved with the updated language.
- Hospitalization for the initial dose given for depressive symptoms with major depressive disorder with acute suicidal ideation or behavior was unanimously approved to be retained.

Table A and Table B in the Spravato® criteria were updated with current additions.

<u>The following additions were made to Table A-Antidepressant Medications:</u>
Protriptyline (Vivactil®)
Bupropion and dextromethorphan (Auvelity®)
Gepirone (Exxua®)

<u>Table B-Augmented Antidepressant Therapy Medications:</u>

Cariprazine (Vrylar®)
Lumateperone (Caplyta®)

**B. Antifungals:** *Criteria review was requested for these two medications during a previous PDL meeting, due to the Infectious Disease Specialist board member's safety concerns. Griseofulvin is new criteria, and the criteria for ketoconazole was expanded to include lab work.*

**Griseofulvin**

**Initial Coverage Criteria**

Member must meet all of the following criteria:

- Be 2 years of age or older.
- Have a diagnosis of a superficial fungal infection resistant to topical treatment.
- 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:

- Prescriber attests if therapy is continued beyond eight weeks or repeated courses of griseofulvin are given, liver function tests and a complete blood count will be obtained to evaluate for hepatic or hematologic toxicity.
- Prescriber attests:
  - Female members with reproductive potential have been counseled on the risk of therapy during pregnancy, especially in the first trimester.
  - Male members have been counseled that fathering a child should be avoided for at least 6 months after therapy.

Limitations:
Dosed per package labeling.

**Renewal Coverage Criteria**

Prescriber requirements:

- Has documentation of positive clinical response to therapy.
- Repeated courses or those lasting beyond 8 weeks require liver function tests and complete blood count to be evaluated for hepatic or hematologic toxicity.

**Quantity Limits**

- Maximum Daily Dose:
- Microsize - 1000 mg daily
- Ultramicrosize - 750 mg daily

**Coverage Duration**
Initial approval: 8 weeks
Renewal approval duration: 8 weeks

**Ketoconazole Oral**

**Initial Coverage Criteria**

Member must meet all of the following criteria:

- Have a diagnosis of life-threatening or endemic mycoses and no alternative treatment is available or tolerated.
- Does not have acute or chronic liver 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 consultation with, an infectious disease specialist.
- If not prescribed by an appropriate specialist, a copy of the specialty consult is required.
- Attests to the following:
  - The member has been informed of risk of serious hepatotoxicity.
  - The prescriber will obtain baseline liver function tests and monitor alanine transaminase (ALT) weekly for the duration of treatment.
- Attests that member **will not** use ketoconazole concomitantly with the following contraindicated drugs due to prolongation of the QT interval: dofetilide, quinidine, pimozide, lurasidone, cisapride, methadone, disopyramide, dronedarone, ranolazine. If concomitant use is necessary, provider will have an appropriate monitoring plan in place.
- Attests that member **will not** use ketoconazole with other contraindicated drugs.

Limitations:
Dosed per package labeling

**Renewal Coverage Criteria**

Prescriber requirements:

- Specialist consult provided if prescriber is not a specialist.
- Has documentation of positive clinical response to therapy.
- Attests that weekly ALT monitoring and other recommended liver function tests based on ALT results are being done.
- Attests that member **will not** use ketoconazole concomitantly with contraindicated drugs that prolong the QT interval or other contraindicated drugs.

**Quantity Limits**
Maximum Daily Dose = 400mg (2 tablets)

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

## C. Lipid lowering agents:

*It was requested by the Board during a previous PDL meeting to return and review the criteria for Repatha®. Also to update this class to be current with the 2026 ACC/AHA/AACVPR/ABC/ACPM/ADA/AGS/APhA/ASPC/NLA/PCNA Joint Guideline on the Management of Dyslipidemia.*

*Updated the statin requirement. Was previously a trial of two different statins in conjunction with ezetimibe. Accepted update is a trial of at least one high-intensity statin (atorvastatin/rosuvastatin) for at least 12 weeks **AND** will continue to receive maximally tolerated high-intensity statin therapy in combination with ezetimibe unless ineffective or contraindicated.*

### 1. Evkeeza™ (evinacumab-dgnb)

*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:*

*a. Age expansion from 12 years of age and older, down to 1 year of age and older*
*b. Changed statin requirement from two high-intensity statins to one high-intensity statin*
*c. Initial approval changed from six months to three months (response shows up by two months)*

**Initial Coverage Criteria**

Member must meet all of the following criteria:

- Be 1 year of age or older.
- Has a diagnosis of homozygous familial hypercholesterolemia.
- Has an LDL-cholesterol greater than or equal to 70 mg/dl.
- Has had an inadequate response (trial of at least 12 weeks), intolerance or contraindication to ALL of the following medications:
  - One high-intensity statin (atorvastatin/rosuvastatin)
  - Ezetimibe
  - PCSK9 inhibitor
- Continue background lipid-lowering therapies in combination with Evkeeza™
- 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, endocrinology or lipid 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:
  - Female member of childbearing age has been counseled on use of contraception while using Evkeeza™ due to potential fetal harm.
- Attests that member **will not** use Evkeeza™ concomitantly with other biologics, except PCSK9s.

Limitations:
Dosed per package labeling

**Renewal Coverage Criteria**

Member must meet all of the following criteria:

- Member has been adherent to Evkeeza™ and all additional lipid lowering agents the member was taking at initiation of Evkeeza™ therapy.

Prescriber requirements:

- Annual specialist consult required if prescriber is not a specialist.
- Has documentation of positive clinical response to therapy (i.e., reduction in LDL-C levels).
- Attests that member **will not** use Evkeeza™ concomitantly with other biologics, except PCSK9s.

**Quantity Limits**
Maximum Daily Dose = 15 mg/kg IV every 4 weeks

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

**2. Leqvio® (inclisiran)**

*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:*

*a. New indication and age expansion*
- *Adults with ASCVD changed to adults with hypercholesterolemia*
- *Changed from 18 years of age and older, down to 12 years of age and older, for heterozygous familial hypercholesterolemia (HeFH)*
- *New indication for homozygous familial hypercholesterolemia (HoFH) in pediatric patients age 12 years of age and older through 17 years of age*

*b. Changed statin requirement from two high-intensity statins to one high-intensity statin*

*c. Initial approval changed from nine months to two injections (initial and at three months) prior to injection at nine months (response shows at three months)*

***NOTE: The criteria below has not been approved by the Board and will remain interim until the next review.*

**Initial Coverage Criteria**

Member must meet all of the following criteria:
- Be 18 years of age or older and have a diagnosis of hypercholesterolemia **OR**
- Be 12 years of age or older and have a diagnosis of heterozygous familial hypercholesterolemia (HeFH) **OR**
- Be 12 to 17 years of age and have a diagnosis of homozygous familial hypercholesterolemia (HoFH).
- Has an LDL-C greater than or equal to 70 mg/dl
- Has trialed at least one high-intensity statin (atorvastatin/rosuvastatin) for at least 12 weeks **AND** will continue receiving maximally tolerated high-intensity statin therapy in combination with ezetimibe unless ineffective or 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:
- Must be prescribed by, or in consult with, a cardiology, endocrinology, or lipid 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 Leqvio® concomitantly with other PCSK9 inhibitors.

Limitations:
Dosed per package labeling

**Renewal Coverage Criteria**

Member must meet all of the following criteria:
- Member has been adherent to statin at maximally tolerated dose.
- Member has been adherent to ezetimibe.

Prescriber requirements:
- Has documentation of positive clinical response to therapy as defined by a reduction in LDL-C.
- Annual specialist consult provided if prescriber is not a specialist.
- Attests that member **will not** use Leqvio® concomitantly with other PCSK9 inhibitors.

**Quantity Limits**
284 mg SQ initially, again at 3-months, then every 6 months.

**Coverage Duration**
Initial approval: 2 doses (initial and 3 months)
Renewal approval duration: 12 months

**3. Praluent® (alirocumab)**

*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:*

*a. Age expansion and language update*
  - *Adults with ASCVD changed to adults with hypercholesterolemia*
  - *Changed from 18 years of age and older, down to 8 years of age and older, for heterozygous familial hypercholesterolemia (HeFH)*

*b. Changed statin requirement from two high-intensity statins to one high-intensity statin*

*c. Initial approval changed from nine months to two injections (initial and at three months) prior to injection at nine months (response shows at three months)*

**Initial Coverage Criteria**

Member must meet all of the following criteria:
- Be 18 years of age or older and have a diagnosis of either:
  - hypercholesterolemia
  - 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
  - homozygous familial hypercholesterolemia (HoFH)
- Be 8 years of age or older and have a diagnosis of:
  - heterozygous familial hypercholesterolemia (HeFH)
- Has an LDL-cholesterol equal to or greater than 70 mg/dl

- Has trialed at least one high-intensity statin (atorvastatin/rosuvastatin) for at least 12 weeks **AND** will combine statin with ezetimibe if needed to meet LCL-C goal unless either is ineffective or 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 that member **will not** use Praluent® concomitantly with other PCSK9 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 Praluent® concomitantly with other PCSK9 medications.

**Quantity Limits**
Maximum Dose
- Hypercholesterolemia OR Risk of MACE: 150 mg every 2 weeks OR 300 mg once each month.
- HeFH:
  - Adults: 150 mg every 2 weeks OR 300 mg once each month.
  - Pediatric: weight < 50 kg, 150 mg once each month, weight ≥ 50 kg, 300 mg once each month.
- HoFH: 150 mg every 2 weeks.

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

**4. Repatha® (evolocumab)**

*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:*

*a. Age expansion and language update*
- *Adults with ASCVD changed to adults with hypercholesterolemia*
- *Changed from 18 years of age and older, down to 10 years of age and older, for heterozygous familial hypercholesterolemia (HeFH)*
- *Changed from 18 years of age and older, down to 10 years of age and older, for homozygous familial hypercholesterolemia (HoFH)*
- *Changed statin requirement from two high-intensity statins to one high-intensity statin*

**Initial Coverage Criteria**

Member must meet all of the following criteria:

- Be 18 years of age or older and have a diagnosis of:
  - hypercholesterolemia **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).
- Has an LDL-cholesterol equal to or greater than 70 mg/dl
- Has trialed at least one high-intensity statin (atorvastatin/rosuvastatin) for at least 12 weeks **AND** will combine statin with ezetimibe if needed to meet LCL-C goal unless either is ineffective or 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 that member **will not** use Repatha® concomitantly with other PCSK9 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 PCSK9 medications.

**Quantity Limits**
Maximum Dose

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

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

**5. PA Criteria Removal**

- **Pulmozyme®** - request approved by the Board due to high approval rate and appropriate use**.**
- **Benlysta®** - request approved by the Board due to high approval rate and appropriate use**.**
- **Calcitonin-salmon (nasal)** – request approved by the Board due to high approval rate and appropriate use**.**

The next DUR board meeting is tentatively scheduled for September 9, 2026, in this same format. The meeting was adjourned at 2:46 p.m.