February 2023 DUR Board Meeting Minutes

Date: February 15, 2023

Members Present: Barnhill, Blake, Blank (logged on at 2pm), Brown, Caldwell, Jost, McGrane, Nauts, Stone, Turnsplenty

Members Absent: Anglim, Putsch

Others Present: Katie Hawkins, Shannon Sexauer, Dani Feist, (DPHHS); Artis, Bahny, Erickson, Doppler, Zody (MPQH); and representatives from the pharmaceutical industry.

Public Comment:

- Dr. Kris French, Neurologist, Billings, MT - Ocrevus®
- Steve Hall, Genentech - Ocrevus®

There was written public comment regarding criteria for migraine therapy and for Lybalvi®. The board asked to bring back these topics for discussion at a future DUR meeting.

Meeting Minute Review: The meeting minutes from the November 9, 2022, Drug Utilization Review Board Meeting were approved as written.

Department Update: No Department update.

DUR Board Member Portal Overview: The Board was presented with a high-level overview of the DUR Board Member Portal, which Board members will utilize for upcoming meeting materials, referencing past meeting minutes, and future meeting date information. This portal will not be used for Preferred Drug List (PDL) meetings, only for DUR criteria meetings.

Board Discussion

1. **Drug Criteria Review:**

   A. Ocrevus® (ocrelizumab)

   - Criteria requirements have been removed, per DUR Board discussion.

   B. Doptelet® (avatrombopag)

   Initial Coverage Criteria

   Thrombocytopenia in Adults with Chronic Liver Disease Scheduled for Procedure

   Member must meet all the following criteria:
   - Be 18 years of age or older.
   - Have an indication for treatment of thrombocytopenia in adult patients with chronic liver disease who are scheduled to undergo a procedure.

   Prescriber requirements:
   - Must be a hematologist.

Limitations:
- Approved only one time per procedure.
- Subsequent procedure requires another PA request.
- Initial approval duration: 5 days
- Maximum daily dose: 3 tablets daily for 5 days

Chronic Immune Thrombocytopenia

Member must meet all the following criteria:
- Be 18 years of age or older.
- Have an indication for treatment of thrombocytopenia in adult patients with chronic immune thrombocytopenia (ITP) who have had an insufficient response to a previous treatment (corticosteroids, immunoglobulins, splenectomy, rituximab).
- Is at increased risk for bleeding due to clinical condition.

Prescriber requirements:
- Must be a hematologist.
- Attests platelet counts will be monitored at least monthly.

Limitations:
- Initial approval duration: 6 months
- Maximum daily dose: 2 tablets daily

Renewal Coverage Criteria

Thrombocytopenia in Adults with Chronic Liver Disease Scheduled for Procedure

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

Chronic Immune Thrombocytopenia (ITP)

Member must meet all the following criteria:
- Current platelet count is greater than or equal to 50×10^9 /L, but less than $400x10^9$/L AND/OR
- Has experienced a reduction in clinically significant bleeds.
- The pharmacy staff will inform the prescriber if adherence or compliance is not being met and discuss rationale of continuing treatment.

Prescriber requirements:
- Must be a hematologist.
- Attests platelet counts will be monitored at least monthly.

Limitations:
- Renewal approval duration: 6 months
- Maximum daily dose: 2 tablets daily

C. Nucala® (mepolizumab)

Initial Coverage Criteria

Chronic Rhinosinusitis with Nasal Polyps (CRSwNP)

Member must meet all the following criteria:

- Be 18 years of age or older.
- Has clinical documentation of chronic rhinosinusitis WITH nasal polyps as evidenced by CT scan or endoscopy.
- Concurrently using an intranasal corticosteroid, unless contraindicated.
- Have had an inadequate treatment response, intolerance, or contraindication to both of the following:
    - **One** intranasal corticosteroid (must have been adherent to therapy at optimized doses for at least three months).
    - Systemic corticosteroid trial (must be within last year) **and/or** sinus surgery for nasal polyps.

Prescriber requirements:

- Must be prescribed by, or in consult with, an appropriate specialist (allergist, immunologist, otolaryngologist).
- 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 Nucala® concomitantly with other biologics.

Limitations:

- Initial approval duration: 1 year
- Maximum allowed dose: 100mg SQ every 4 weeks

Renewal Coverage Criteria

Member must meet all the following criteria:

- Has experienced a positive clinical response (reduction in polyp size, time to first nasal polypectomy, change in loss of smell, systemic steroid use).
- The pharmacy staff will inform the prescriber if adherence or compliance is not being met and discuss rationale of continuing treatment.

Prescriber requirements:

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

Limitations:

- Renewal approval duration: 1 year
- Maximum allowed dose: 100mg SQ every 4 weeks

The Board requested that the intranasal corticosteroid trial requirement for other biologics with this indication be likewise changed from two to one.

D. Xeljanz®/ Xeljanz XR® (tofacitinib)

Initial Coverage Criteria

Rheumatoid Arthritis, Psoriatic Arthritis, Ulcerative Colitis, Ankylosing Spondylitis

Member must meet all of the following criteria:
- Be 18 years of age or older.
- Have tried and had an inadequate response or intolerance to a preferred TNF blocker.

Prescriber requirements:
- Must be prescribed by, or in consult with, an appropriate specialist (rheumatologist, gastroenterologist).
- 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®/ Xeljanz XR® concomitantly with other biologics.

Limitations:
- Initial approval duration: 1 year
- Maximum daily dose:
    - RA, PsA, AS:
        - 5mg twice daily
        - XR 11mg once daily
    - UC – Induction dosing, up to 16 weeks:
        - 10mg twice daily
        - XR 22mg once daily
    - UC – Maintenance dosing:
        - 5mg twice daily or XR 11mg once daily
        - If patient loses response: 10mg twice daily or XR 22mg once daily for the shortest duration possible.

Polyarticular Course Juvenile Idiopathic Arthritis

Member must meet all of the following criteria:
- Be 2 years of age or older.
- Have tried and had an inadequate response or intolerance to a preferred TNF blocker.

Prescriber requirements:
- Must be prescribed by, or in consult with, an appropriate specialist (rheumatologist)
- 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:
- Initial approval duration: 1 year
- Maximum daily dose: 5mg twice daily or weight-based equivalent twice daily of tablets or oral solution.

<u>Renewal Coverage Criteria</u>

Member must meet all of the following criteria for all indications:
- Documentation of positive clinical response to therapy.

Prescriber requirements for all indications:
- Annual specialist consult provided if prescriber not a specialist.
- Attests that member **will not** use Xeljanz®/ Xeljanz XR® concomitantly with other biologics.

Limitations:
- Renewal approval duration: 1 year
- Maximum daily dose:
    - RA, PsA, AS:
        - 5mg twice daily
        - XR 11mg once daily
    - UC:
        - 5mg twice daily or XR 11mg once daily
        - If patient loses response: 10mg twice daily or XR 22mg once daily for the shortest duration possible.
    - pcJIA:
        - 5mg twice daily or weight-based equivalent twice daily of tablets or oral solution.

E. Hereditary Angioedema (HAE) On-Demand Therapy

BERINERT® (C1 Esterase Inhibitor-Human), **FIRAZYR®** (icatibant), icatibant, **KALBITOR®** (ecallantide), **RUCONEST®** (C1 Esterase Inhibitor-Recombinant), **SAJAZIR®** (icatibant)

Initial Coverage Criteria

Member must meet all the following criteria:
- Meet FDA approved age for individual HAE medication requested.
- Have a diagnosis of HAE-C1INH confirmed by lab testing.
- Have documented history of severe extremity, abdominal, facial, or laryngeal HAE attacks.
- Approval for a non-preferred drug requires a trial and inadequate response, or contraindication to a preferred drug with the same indication from the Montana Healthcare Programs Preferred Drug List.
- Keep attack logs detailing attack history and submit to prescriber.

Prescriber requirements:
- Must be an appropriate specialist (Allergist, Immunologist, HAE Specialist).
- Submit the following lab values: C1INH protein antigenic level, C1INH protein functional level, and C4 level.
- Submit attack logs and chart notes detailing attack history.
- Submit current weight(kg) if medication requested requires weight-based dosing.

Limitations:
- 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.

- Initial approval duration: 1 month
- Maximum quantity limitations:
    - Berinert® (C1 Esterase Inhibitor-Human): Three 20 IU/kg infusions per month
    - Firazyr® (icatibant): Three 30mg/3ml prefilled syringes per month
    - icatibant: Three 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): Three 30mg/3ml prefilled syringes per month

Renewal Coverage Criteria

Member must meet all the following criteria:
- Have documentation of positive clinical response to therapy as evidenced by reduction/resolution of HAE attack symptoms.
- Keep attack logs detailing attack history and submit logs to prescriber.

Prescriber requirements:
- Must be an appropriate specialist (Allergist, Immunologist, HAE Specialist).
- Submit attack logs and chart notes detailing attack history.

Limitations:
- 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.
- Renewal approval duration: 1 month
- Maximum quantity limitations:
    - Berinert® (C1 Esterase Inhibitor-Human): Three 20 IU/kg infusions per month
    - Firazyr® (icatibant): Three 30mg/3ml prefilled syringes per month
    - icatibant: Three 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): Three 30mg/3ml prefilled syringes per month

F. Hereditary Angioedema (HAE) Prophylactic Therapy

CINRYZE® (C1 Esterase Inhibitor-Human), **HAEGARDA**® (C1 Esterase Inhibitor-Human), **ORLADEYO**® (berotralstat), **TAKHZYRO**® (lanadelumab-flyo)

Initial Coverage Criteria

Member must meet all the following criteria:
- FDA approved age for individual HAE medication requested.
- Have a diagnosis of HAE-C1INH confirmed by lab testing.
- Have documented history of severe extremity, abdominal, facial, or laryngeal HAE attacks.

- Be experiencing more than 2-3 severe attacks per month that require treatment with on-demand HAE medication.
- Approval for a non-preferred drug requires a trial and inadequate response, or contraindication to a preferred drug with the same indication from the Montana Healthcare Programs Preferred Drug List.
- Keep attack logs detailing attack history and submit to prescriber.

Prescriber requirements:
- Must be an appropriate specialist (Allergist, Immunologist, HAE Specialist).
- Submit the following lab values: C1INH protein antigenic level, C1INH protein functional level, and C4 level.
- Submit attack logs and chart notes detailing attack history.
- Submit current weight(kg) if medication requested requires weight-based dosing.

Limitations:
- No more than one medication for prophylactic treatment of HAE attacks will be approved. Dual therapy with two prophylactic HAE medications is not permitted.
- Initial approval duration: 6 months
- Maximum quantity limitations:
    - 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

<u>Renewal Coverage Criteria</u>

Member must meet all the following criteria:
- The pharmacy staff will inform the prescriber if adherence or compliance is not being met and discuss rationale of continuing treatment.
- Has documentation of positive clinical response to therapy as evidenced by reduction in frequency of HAE attacks.
- Keep attack logs detailing attack history and submit to prescriber.

Prescriber requirements:
- Must be an appropriate specialist (Allergist, Immunologist, HAE Specialist).
- Submit attack logs and chart notes detailing attack history.

Limitations:

- No more than one medication for prophylactic treatment of HAE attacks will be approved. Dual therapy with two prophylactic HAE medications is not permitted.
- Renewal approval duration: 6 months
- Maximum quantity limitations:
    - 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

2. Case Management Projects

- Gabapentin/pregabalin dose limit project results

    - At the September 22, 2021 DUR board meeting, the Board was notified that the Montana Healthcare Programs would be enacting quantity limits for high dose gabapentin and Lyrica®. Prior to the March 2022 implementation date, Mountain Pacific Quality Health reached out to providers regarding patients whose doses exceeded the allowed quantity limits (3600mg gabapentin/600mg pregabalin). White paper documents were sent out to providers explaining the reason for the dose limitations and the impact these medications have caused on the population. Additionally, high dose attestations were sent to providers to complete, requesting a taper plan, or providing rationale as to why a taper would not be appropriate for the patient. If the provider deemed a taper was not appropriate, a provider attestation was required which stated the dose would not be escalated any higher than the patient's current dose.

    - In October 2022, CM did a review of the patients that were impacted by the new process and of the 58 patients who were affected by dose limits, but allowed to maintain on high dose therapy, 57% were decreased down to the federally recommended maximum dose (3600mg gabapentin/600mg pregabalin) or discontinued.

- 2023 Case Management Targeted Interventions:
    - Appropriate use of albuterol
        - Targeting members with high utilization of albuterol who are not concurrently using an asthma maintenance inhaler, in particular, an inhaled corticosteroid.
    - DOAC monitoring
        - Targeting members who may have had a single, provoked blood clot and the DOAC was not discontinued after the initial treatment phase.

- Report on review of movement disorders and high dose stimulant intersection
    - Additional data was presented on vesicular monoamine transporter type 2 (VMAT2) inhibitor requests, as requested by the Board at the previous November 2022 meeting, specifically on the relationship between the requests and high dose stimulant use and stimulant use disorder. Recommendations made to the Board were no further claims review or project development, as data indicated that requests were appropriate, and numbers suggested there was not a correlation between VMAT2 inhibitor requests among members with stimulant use and/or stimulant use disorder. The Board agreed with the findings but recommended that an attestation be added to the VMAT2 inhibitor PA form, asking providers to attest that stimulant use, as well as other causes of dyskinesia, have been considered as potential causation of the movement disorder.

3. **Upcoming meeting dates:**
    - 2023 PDL Meeting Dates: March 15, 2023, April 26, 2023, May 24, 2023
    - 2023 DUR Board Meeting Dates: TBD

The next meeting will be March 15, 2023, and in this same format. The meeting adjourned at 2:42pm.