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Partnering within our communities to provide solutions to better health

Montana Healthcare Programs
Drug Prior Authorization (PA) Criteria

Omvoh™ (mirikizumab-mrkz)

I. Medication Description

Omvoh™ is an interleukin-23 antagonist indicated for the treatment of moderately to severely active ulcerative colitis in adults.

II. Position Statement

Coverage is determined through a prior authorization process **that must include** supporting clinical documentation for each request.

III. 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).
- 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:
  - Member has been screened for tuberculosis (TB) prior to initiating treatment.
  - All age-appropriate vaccines and lab work have been completed prior to Omvoh™ initiation.
  - Member or caregiver has been trained in subcutaneous injection technique prior to maintenance phase of treatment AND
  - Member or caregiver has been made aware that maintenance dose is two consecutive injections administered at different anatomic locations.
- Attests that member **will not** use Omvoh™ concomitantly with other biologics.

Limitations:

Dosed per package labeling.

- Induction
  - Intravenous infusion (IV) at Week 0, Week 4, and Week 8.

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- Maintenance
  - Subcutaneous injections (SQ) starting at Week 12 and every 4 weeks thereafter.

IV. Renewal Coverage Criteria (only for maintenance treatment)

Member must meet the following criteria:

- Have completed the induction phase of three IV infusions of Omvoh™
- Has documentation of positive clinical response to therapy (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.

V. Quantity Limits

- Maximum Daily Dose:
- Induction: 300 mg per IV infusion -Physician Administered Drug Program at weeks 0, 4, and 8.
- Maintenance: 200 mg per SQ dose (Two-100 mg injections)-Outpatient Drug Prior Authorization

VI. Coverage Duration

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

Renewal approval duration: 12 months

References:

https://uspl.lilly.com/omvoh/omvoh.html#pi

Mirikizumab as Induction and Maintenance Therapy for Ulcerative Colitis, N Engl J Med. 2023 Jun29;388 (26):2444-2455 https://www.ncbi.nlm.nih.gov/pmc/articles/PMC9671059/

Efficacy and Safety of Mirikizumab as Maintenance Therapy in Patients with Moderately to Severely Active Ulcerative Colitis: Results from the Phase 3 LUCENT-2 Study, Gastroenterol Hepatol, 2022 Jul:18(7 Suppl 2):3-4 https://www.ncbi.nlm.nih.gov/pmc/articles/PMC9671059/