Medical Policy:

Omvoh (mirikizumab-mrkz) Intravenous infusion

POLICY NUMBER	LAST REVIEW	ORIGIN DATE
MG.MM.PH.408	January 18, 2024	March 28, 2024

Definitions

Omvoh intravenous, a monoclonal antibody against the p19 subunit of the interleukin (IL)-23 cytokine, is indicated for induction treatment of ulcerative colitis (UC), in adults with moderate to severe active disease.

In UC, a three-dose induction regimen (300 mg at Weeks 0, 4, and 8) is administered by IV infusion.

Following induction therapy with the IV product, the recommended maintenance is Omvoh subcutaneous injection, given as a 200 mg subcutaneous injection administered at Week 12 (4 weeks following the last induction dose), then once every 4 weeks thereafter.

Length of Authorization

Coverage will be provided for 3 induction doses (600 mg at Weeks 0, 4, and 8)

Dosing Limits [Medical Benefit]

Max Units (per dose and over time) [HCPCS Unit]

Ulcerative Colitis: Induction dose: 300 billable units (300mg at Weeks 0, 4, and 8)

Guideline

I. INITIAL APPROVAL CRITERIA

Coverage is provided in the following conditions:

- Patient is at least 18 years of age; **AND**
- Physician has assessed baseline disease severity utilizing an objective measure/tool; **AND**
- Patient is up to date with all age-appropriate vaccinations, in accordance with current vaccination guidelines, prior to initiating therapy; **AND**
- Patient has been evaluated and screened for the presence of latent tuberculosis (TB) infection prior to initiating treatment and will receive ongoing monitoring for the presence of TB during treatment; **AND**
- Patient does not have an active infection, including clinically important localized infections; **AND**
- Patient will not receive live vaccines during therapy; **AND**
- Patient is not on concurrent treatment with another IL-inhibitor, TNF-inhibitor, biologic response modifier or other non-biologic immunomodulating agent (e.g., apremilast, tofacitinib, baricitinib, upadacitinib, abrocitinib, deucravacitinib, etc.); **AND**
- Baseline liver enzymes and bilirubin levels have been obtained prior to initiating therapy; **AND**

Intravenous Induction Criteria:

1. **Ulcerative Colitis**

   A. Documented moderate to severely active disease; **AND**

      i. Documented failure, contraindication, or ineffective response at maximum tolerated doses to a minimum (3) month trial of ONE corticosteroid or immunomodulator (e.g. azathioprine, 6-mercaptopurine, or methotrexate); **OR**

      ii. Documented failure, contraindication, or ineffective response at maximum tolerated doses to a minimum (3) month trial of a TNF modifier (e.g. adalimumab, certolizumab, or infliximab)

Applicable Procedure Codes

Code	Description
C9168	Injection, mirikizumab-mrkz, 1 mg; 1 billable unit = 1 mg (Effective 04/01/2024 for IV formulation ONLY)

Applicable NDCs

Code	Description
00002-7575-01	Omvoh IV infusion, single-dose vial 300mg/15ml (20mg/mL) carton of 1

ICD-10 Diagnoses

Code	Description
K00-K95	Diseases of the digestive system
K50-K52	Noninfective enteritis and colitis
K51	Ulcerative colitis

Revision History

Company(ies)	DATE	REVISION
EmblemHealth & ConnectiCare	3/28/2024	New Policy

References

1. Omvoh injection [prescribing information]. Indianapolis, IN: Eli Lilly; October 2023.
2. Rubin DT, Ananthakrishnan AN, Siegel CA, et al. ACG clinical guideline: ulcerative colitis in adults. Am J Gastroenterol. 2019;114(3):384-413.
3. Feuerstein JD, Isaacs KL, Schneider Y, et al. AGA clinical practice guidelines on the management of moderate to severe ulcerative colitis. Gastroenterology. 2020 Apr158(5):1450-1461.