

Medical Policy:

OmvoH (mirikizumab-mrkz) Intravenous infusion

POLICY NUMBER	LAST REVIEW	ORIGIN DATE
MG.MM.PH.408	March 7, 2025	March 28, 2024

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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 (Weeks 0, 4, and 8)

Approval duration – 84 days

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)

Crohn's Disease Induction dose: 900 billable units at Week 0, 4, & 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 biologic therapy or targeted synthetic therapy; **AND**
- Baseline liver enzymes and bilirubin levels have been obtained prior to initiating therapy; **AND**

Intravenous Induction Criteria:

1. Ulcerative Colitis (UC)

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; conventional therapy [aminosalicylates, corticosteroids or immunomodulators (e.g., azathioprine, 6- mercaptopurine, methotrexate, etc.)] at maximum tolerated doses **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)

2. Crohn's Disease (CD) †

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

- i. Documented failure, contraindication, or ineffective response at maximum tolerated doses to a minimum 3-month trial of corticosteroids or immunomodulators (e.g., azathioprine, 6- mercaptopurine, or methotrexate, etc.); **OR**
- ii. Documented failure, contraindication, or ineffective response at maximum tolerated doses to a minimum 3-month trial of a TNF modifier such as adalimumab, certolizumab, or infliximab; **OR**
- iii. Patient has evidence of high-risk disease for which corticosteroids or immunomodulators are inadequate and biologic therapy is necessary

Applicable Procedure Codes

Code	Description
J2267	Injection, mirikizumab-mrkz, 1 mg; 1 billable unit = 1 mg; should be billed with the JA modifier for the intravenous infusion of the drug

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
K50.00	Crohn'S Disease Of Small Intestine Without Complications
K50.011	Crohn'S Disease Of Small Intestine With Rectal Bleeding
K50.012	Crohn'S Disease Of Small Intestine With Intestinal Obstruction
K50.013	Crohn'S Disease Of Small Intestine With Fistula
K50.014	Crohn'S Disease Of Small Intestine With Abscess
K50.018	Crohn'S Disease Of Small Intestine With Other Complication
K50.019	Crohn's disease of small intestine with unspecified complications
K50.10	Crohn'S Disease Of Large Intestine Without Complications
K50.111	Crohn'S Disease Of Large Intestine With Rectal Bleeding
K50.112	Crohn'S Disease Of Large Intestine With Intestinal Obstruction
K50.113	Crohn'S Disease Of Large Intestine With Fistula
K50.114	Crohn'S Disease Of Large Intestine With Abscess
K50.118	Crohn'S Disease Of Large Intestine With Other Complication
K50.119	Crohn'S Disease Of Large Intestine With Unspecified Complications
K50.80	Crohn'S Disease Of Both Small And Large Intestine Without Complications
K50.811	Crohn'S Disease Of Both Small And Large Intestine With Rectal Bleeding
K50.812	Crohn'S Disease Of Both Small And Large Intestine With Intestinal Obstruction
K50.813	Crohn'S Disease Of Both Small And Large Intestine With Fistula
K50.814	Crohn'S Disease Of Both Small And Large Intestine With Abscess
K50.818	Crohn'S Disease Of Both Small And Large Intestine With Other Complication
K50.819	Crohn'S Disease Of Both Small And Large Intestine With Unspecified Complications
K50.90	Crohn'S Disease, Unspecified, Without Complications
K50.911	Crohn'S Disease, Unspecified, With Rectal Bleeding
K50.912	Crohn'S Disease, Unspecified, With Intestinal Obstruction
K50.913	Crohn'S Disease, Unspecified, With Fistula
K50.914	Crohn'S Disease, Unspecified, With Abscess
K50.918	Crohn's disease, unspecified, with other complication
K50.919	Crohn'S Disease, Unspecified, With Unspecified Complications
K51.00	Ulcerative (Chronic) Pancolitis Without Complications
K51.011	Ulcerative (Chronic) Pancolitis With Rectal Bleeding
K51.012	Ulcerative (Chronic) Pancolitis With Intestinal Obstruction
K51.013	Ulcerative (Chronic) Pancolitis With Fistula
K51.014	Ulcerative (Chronic) Pancolitis With Abscess
K51.018	Ulcerative (Chronic) Pancolitis With Other Complication
K51.019	Ulcerative (Chronic) Pancolitis With Unspecified Complications
K51.20	Ulcerative (Chronic) Proctitis Without Complications
K51.211	Ulcerative (Chronic) Proctitis With Rectal Bleeding
K51.212	Ulcerative (Chronic) Proctitis With Intestinal Obstruction

K51.213	Ulcerative (Chronic) Proctitis With Fistula
K51.214	Ulcerative (Chronic) Proctitis With Abscess
K51.218	Ulcerative (Chronic) Proctitis With Other Complication
K51.219	Ulcerative (Chronic) Proctitis With Unspecified Complications
K51.30	Ulcerative (Chronic) Rectosigmoiditis Without Complications
K51.311	Ulcerative (Chronic) Rectosigmoiditis With Rectal Bleeding
K51.312	Ulcerative (Chronic) Rectosigmoiditis With Intestinal Obstruction
K51.313	Ulcerative (Chronic) Rectosigmoiditis With Fistula
K51.314	Ulcerative (Chronic) Rectosigmoiditis With Abscess
K51.318	Ulcerative (Chronic) Rectosigmoiditis With Other Complication
K51.319	Ulcerative (Chronic) Rectosigmoiditis With Unspecified Complications
K51.50	Left Sided Colitis Without Complications
K51.511	Left Sided Colitis With Rectal Bleeding
K51.512	Left Sided Colitis With Intestinal Obstruction
K51.513	Left Sided Colitis With Fistula
K51.514	Left Sided Colitis With Abscess
K51.518	Left Sided Colitis With Other Complication
K51.519	Left Sided Colitis With Unspecified Complications
K51.80	Other Ulcerative Colitis Without Complications
K51.811	Other Ulcerative Colitis With Rectal Bleeding
K51.812	Other Ulcerative Colitis With Intestinal Obstruction
K51.813	Other Ulcerative Colitis With Fistula
K51.814	Other Ulcerative Colitis With Abscess
K51.818	Other Ulcerative Colitis With Other Complication
K51.819	Other Ulcerative Colitis With Unspecified Complications
K51.90	Ulcerative Colitis, Unspecified, Without Complications
K51.911	Ulcerative Colitis, Unspecified With Rectal Bleeding
K51.912	Ulcerative Colitis, Unspecified With Intestinal Obstruction
K51.913	Ulcerative Colitis, Unspecified With Fistula
K51.914	Ulcerative Colitis, Unspecified With Abscess
K51.918	Ulcerative Colitis, Unspecified With Other Complication
K51.919	Ulcerative Colitis, Unspecified With Unspecified Complications

Revision History

Company(ies)	DATE	REVISION
EmblemHealth & ConnectiCare	3/07/2025	Annual Review: Updated length of authorization to remove: "300 mg at" Added Crohn's Disease to Dosing limits. Initial Criteria: removed and reworded: "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" as the following: " Patient is not on concurrent treatment with another biologic therapy or targeted synthetic therapy; AND" Ulcerative Colitis (UC) Removed and reworded: "ONE corticosteroid or immunomodulator (e.g. azathioprine, 6-mercaptopurine, or methotrexate)" in the following statement: "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

		<p>methotrexate);” Updated to:”conventional therapy [aminosalicylates, corticosteroids or immunomodulators (e.g., azathioprine, 6- mercaptopurine, methotrexate, etc.)] at maximum tolerated doses OR”</p> <p>Added: “Crohn’s Disease (CD) † Documented moderate to severe active disease; AND Documented failure, contraindication, or ineffective response at maximum tolerated doses to a minimum 3-month trial of corticosteroids or immunomodulators (e.g., azathioprine, 6-mercaptopurine, or methotrexate, etc.); OR Documented failure, contraindication, or ineffective response at maximum tolerated doses to a minimum 3-month trial of a TNF modifier such as adalimumab, certolizumab, or infliximab; OR Patient has evidence of high-risk disease for which corticosteroids or immunomodulators are inadequate and biologic therapy is necessary”</p> <p>Updated ICD-10 Codes</p>
EmblemHealth & ConnectiCare	3/28/2024	New Policy
EmblemHealth & ConnectiCare	6/3/2024	Addition of Approval duration – 84 days Corrected length of authorization units from 600mg to 300mg as FDA approved

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 Apr;158(5):1450-1461.