Omvoh™ (mirikizumab-mrkz)
(Subcutaneous/Intravenous)

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I. Length of Authorization

- Coverage will be provided for 9 weeks (for 3 intravenous doses) initially as induction and may be renewed annually thereafter for subcutaneous maintenance.

II. Dosing Limits

A. Quantity Limit (max daily dose) [NDC Unit]:

- Omvoh 300 mg/15 mL single-dose vial for intravenous infusion: 1 vial at Weeks 0, 4 & 8 (3 vials total)
- Omvoh 100 mg/mL solution in a single-dose prefilled pen for subcutaneous injection: 2 pens starting on week 12 and every 4 weeks thereafter
- Omvoh 100 mg/mL solution in a single-dose prefilled syringe for subcutaneous injection: 2 syringes starting on week 12 and every 4 weeks thereafter

B. **Max Units (per dose and over time) [HCPCS Unit]:**

- Induction dose: 300 billable units at Week 0, 4, & 8
- Maintenance: 200 billable units at Week 12 and every 4 weeks thereafter

III. Initial Approval Criteria [1]

Coverage is provided in the following conditions:

For Commercial Members Only
• Patients must have an inadequate response to an adequate trial of, or contraindication or intolerance to one of the preferred self-administered products including adalimumab biosimilars*, Stelara (ustekinumab), or Xeljanz (tofacitinib) AND Entyvio SC (vedolizumab SC) prior to initiating therapy; **AND**
For Medicaid Members Only
• Patients must have an inadequate response to an adequate trial of, or contraindication or intolerance to one of the preferred self-administered products including adalimumab biosimilars* prior to initiating therapy; **AND**
Note: *Preferred biosimilars are: Hadlima (adalimumab-bwwd) and adalimumab-adaz

- 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**
- Baseline liver enzymes and bilirubin levels have been obtained prior to initiating therapy; **AND**

Universal Criteria [1]

- 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**

Ulcerative Colitis † [1,8-10,13]

- Documented moderate to severe active disease; **AND**
  - Documented failure or ineffective response to a minimum 3-month trial of conventional therapy [aminosalicylates, corticosteroids or immunomodulators (e.g., azathioprine, 6-mercaptopurine, methotrexate, etc.)] at maximum tolerated doses, unless there is a contraindication or intolerance to use; **OR**
  - Documented failure, contraindication, or ineffective response at maximum tolerated doses to a minimum 3-month trial on previous therapy with of a TNF modifier such as adalimumab, golimumab, or infliximab

† FDA Approved Indication(s); ‡ Compendia Recommended Indication(s); Φ Orphan Drug

IV. Renewal Criteria [1,3-5,8]

Coverage may be renewed based upon the following criteria:

- Patient continues to meet the universal and indication-specific criteria as identified in section III; **AND**
- Absence of unacceptable toxicity from the drug. Examples of unacceptable toxicity include: serious hypersensitivity reactions (including anaphylaxis), severe infections, hepatotoxicity, drug-induced liver injury, etc.; **AND**
  - Patient is to start maintenance therapy and has received three 300 mg intravenous induction doses at weeks 0, 4 and 8.; **AND**

- Patient has shown a beneficial disease response and/or no worsening of disease with an absence of unacceptable toxicity to the intravenous doses; **OR**

- Patient requires continuation of maintenance therapy; **AND**
  - Disease response as indicated by improvement in signs and symptoms compared to baseline such as stool frequency, rectal bleeding, and/or endoscopic activity, tapering or discontinuation of corticosteroid therapy, and/or an improvement on a disease activity scoring tool [e.g., an improvement on the Ulcerative Colitis Endoscopic Index of Severity (UCEIS) score or the Mayo Score].

V. Dosage/Administration [1]

Indication	Dose
Ulcerative Colitis	**Induction:** Administer 300 mg intravenously at Week 0, Week 4, and Week 8. **Maintenance:** Administer 200mg (given as two consecutive injections of 100 mg each) subcutaneously at Week 12 and every 4 weeks thereafter. Patients may self-inject the maintenance dose after training in subcutaneous injection technique.

VI. Billing Code/Availability Information

HCPCS Code(s):

- J3590 – Unclassified biologics *(Discontinue use on 07/01/2024)*
- C9168 – Injection, mirikizumab-mrkz, 1 mg; 1 billable unit = 1 mg *(Discontinue use on 07/01/2024)*
- J2267***** – Injection, mirikizumab-mrkz, 1 mg; 1 billable unit = 1 mg *(Effective 07/01/2024)*

  *(***Note:** CMS generally creates codes for products themselves, without specifying a route of administration in the code descriptor, as there might be multiple routes of administration for the same product. Drugs that fall under this category should be billed with either the JA modifier for the intravenous infusion of the drug or billed with the JB modifier for subcutaneous injection of the drug.)*

NDC(s):

- Omvoh carton containing one 300 mg/15 mL single-dose vial for intravenous infusion: 00002-7575-xx
- Omvoh carton containing two 100 mg/mL single-dose prefilled pens for subcutaneous injection: 00002-8011-xx
- Omvoh carton containing two 100 mg/mL single-dose prefilled syringes for subcutaneous injection: 00002-8870-xx

VII. References

1. Omvoh [package insert]. Indianapolis, IN; Eli Lilly and Company; April 2024. Accessed May 2024.

2. D'Haens G, Kobayashi T, Morris N, et al. OP26 Efficacy and safety of mirikizumab as induction therapy in patients with moderately to severely active Ulcerative Colitis: Results from the Phase 3 LUCENT-1 study. Journal of Crohn's and Colitis, Volume 16, Issue Supplement_1, January 2022, Pages i028–i029, https://doi.org/10.1093/ecco-jcc/jjab232.025.
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12. Harbord M, Eliakim R, Bettenworth D, et al. Third European Evidence-based Consensus on Diagnosis and Management of Ulcerative Colitis. Part 2: Current Management. J Crohns Colitis. 2017 Jan 28. doi: 10.1093/ecco-jcc/jjx009.
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Appendix 1 – Covered Diagnosis Codes

ICD-10 Code	ICD-10 Description
K51.00	Ulcerative (chronic) pancolitis without complications

ICD-10 Code	ICD-10 Description
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

ICD-10 Code	ICD-10 Description
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
K52.1	Toxic gastroenteritis and colitis

Appendix 2 – Centers for Medicare and Medicaid Services (CMS)

The preceding information is intended for non-Medicare coverage determinations. Medicare coverage for outpatient (Part B) drugs is outlined in the Medicare Benefit Policy Manual (Pub. 100-2), Chapter 15, §50 Drugs and Biologicals. In addition, National Coverage Determinations (NCDs) and/or Local Coverage Determinations (LCDs) may exist and compliance with these policies is required where applicable. Local Coverage Articles (LCAs) may also exist for claims payment purposes or to clarify benefit eligibility under Part B for drugs which may be self-administered. The following link may be used to search for NCD, LCD, or LCA documents: https://www.cms.gov/medicare-coverage-database/search.aspx. Additional indications, including any preceding information, may be applied at the discretion of the health plan.

Medicare Part B Covered Diagnosis Codes (applicable to existing NCD/LCD/LCA): N/A

Medicare Part B Administrative Contractor (MAC) Jurisdictions		
Jurisdiction	**Applicable State/US Territory**	**Contractor**
E (1)	CA, HI, NV, AS, GU, CNMI	Noridian Healthcare Solutions, LLC
F (2 & 3)	AK, WA, OR, ID, ND, SD, MT, WY, UT, AZ	Noridian Healthcare Solutions, LLC
5	KS, NE, IA, MO	Wisconsin Physicians Service Insurance Corp (WPS)
6	MN, WI, IL	National Government Services, Inc. (NGS)
H (4 & 7)	LA, AR, MS, TX, OK, CO, NM	Novitas Solutions, Inc.
8	MI, IN	Wisconsin Physicians Service Insurance Corp (WPS)
N (9)	FL, PR, VI	First Coast Service Options, Inc.
J (10)	TN, GA, AL	Palmetto GBA
M (11)	NC, SC, WV, VA (excluding below)	Palmetto GBA
L (12)	DE, MD, PA, NJ, DC (includes Arlington & Fairfax counties and the city of Alexandria in VA)	Novitas Solutions, Inc.
K (13 & 14)	NY, CT, MA, RI, VT, ME, NH	National Government Services, Inc. (NGS)
15	KY, OH	CGS Administrators, LLC