

## Clinical Policy: Mirikizumab-mrkz (Omvoh)

Reference Number: CP.PHAR.662

Effective Date: 03.01.23

Last Review Date: 05.24

Line of Business: Medicaid

[Coding Implications](#)

[Revision Log](#)

See [Important Reminder](#) at the end of this policy for important regulatory and legal information.

### Description

Mirikizumab-mrkz (Omvoh<sup>™</sup>) is an interleukin-23 antagonist.

### FDA Approved Indication(s)

Omvoh is indicated for the treatment of moderately to severely active ulcerative colitis in adults.

### Policy/Criteria

*Provider must submit documentation (such as office chart notes, lab results or other clinical information) supporting that member has met all approval criteria.*

It is the policy of health plans affiliated with Centene Corporation<sup>®</sup> that Omvoh is **medically necessary** when the following criteria are met:

#### I. Initial Approval Criteria

##### A. Ulcerative Colitis (must meet all):

1. Diagnosis of UC;
2. Prescribed by or in consultation with a gastroenterologist;
3. Age  $\geq$  18 years;
4. Documentation of a Mayo Score  $\geq$  6 (*see Appendix E*);
5. Failure of an 8-week trial of systemic corticosteroids, unless contraindicated or clinically significant adverse effects are experienced;
6. Member meets ONE\* of the following, unless contraindicated or clinically significant adverse effects are experienced (a or b, *see Appendix D*):
  - a. Failure of a  $\geq$  3 consecutive month trial of one adalimumab product (e.g., *Hadlima, Yusimry, adalimumab-adaz, adalimumab-adbm, and adalimumab-fkjp are preferred*);
  - b. History of failure of two TNF blockers;  
*\*Prior authorization may be required for adalimumab products*
7. If member has had a history of failure of two TNF blockers or one adalimumab product, then failure of Zeposia<sup>®</sup>;
8. Member does not have combination use with biological disease-modifying antirheumatic drugs or Janus kinase inhibitors (*see Section III: Diagnoses/Indications for which coverage is NOT authorized*);
9. Dose does not exceed both of the following (a and b):
  - a. Initial (IV): 300 mg at Weeks 0, 4, and 8;
  - b. Maintenance (SC): 200 mg at Week 12 and every 4 weeks.

**Approval duration: 6 months**

**B. Other diagnoses/indications (must meet 1 or 2):**

1. If this drug has recently (within the last 6 months) undergone a label change (e.g., newly approved indication, age expansion, new dosing regimen) that is not yet reflected in this policy, refer to one of the following policies (a or b):
  - a. For drugs on the formulary (commercial, health insurance marketplace) or PDL (Medicaid), the no coverage criteria policy for the relevant line of business: CP.PMN.255 for Medicaid; or
  - b. For drugs NOT on the formulary (commercial, health insurance marketplace) or PDL (Medicaid), the non-formulary policy for the relevant line of business: CP.PMN.16 for Medicaid; or
2. If the requested use (e.g., diagnosis, age, dosing regimen) is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized) AND criterion 1 above does not apply, refer to the off-label use policy for the relevant line of business: CP.PMN.53 for Medicaid.

**II. Continued Therapy**

**A. Ulcerative Colitis (must meet all):**

1. Member meets one of the following (a or b):
  - a. Currently receiving medication via Centene benefit or member has previously met initial approval criteria;
  - b. Member is currently receiving medication and is enrolled in a state and product with continuity of care regulations (*refer to state specific addendums for CC.PHARM.03A and CC.PHARM.03B*);
2. Member is responding positively to therapy;
3. Member does not have combination use with biological disease-modifying antirheumatic drugs or Janus kinase inhibitors (*see Section III: Diagnoses/Indications for which coverage is NOT authorized*);
4. If request is for a dose increase, new dose does not exceed 200 mg every 4 weeks.

**Approval duration: 12 months**

**B. Other diagnoses/indications (must meet 1 or 2):**

1. If this drug has recently (within the last 6 months) undergone a label change (e.g., newly approved indication, age expansion, new dosing regimen) that is not yet reflected in this policy, refer to one of the following policies (a or b):
  - a. For drugs on the formulary (commercial, health insurance marketplace) or PDL (Medicaid), the no coverage criteria policy for the relevant line of business: CP.PMN.255 for Medicaid; or
  - b. For drugs NOT on the formulary (commercial, health insurance marketplace) or PDL (Medicaid), the non-formulary policy for the relevant line of business: CP.PMN.16 for Medicaid; or
2. If the requested use (e.g., diagnosis, age, dosing regimen) is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized) AND criterion 1 above does not apply, refer to the off-label use policy for the relevant line of business: CP.PMN.53 for Medicaid.

**III. Diagnoses/Indications for which coverage is NOT authorized:**

- A. Non-FDA approved indications, which are not addressed in this policy, unless there is sufficient documentation of efficacy and safety according to the off label use policies – CP.PMN.53 for Medicaid or evidence of coverage documents;
- B. Combination use with biological disease-modifying antirheumatic drugs (bDMARDs) or potent immunosuppressants, including but not limited to any tumor necrosis factor (TNF) antagonists [e.g., Cimzia<sup>®</sup>, Enbrel<sup>®</sup>, Humira<sup>®</sup> and its biosimilars, Remicade<sup>®</sup> and its biosimilars (Avsola<sup>™</sup>, Inflectra<sup>™</sup>, Renflexis<sup>™</sup>, Zymfentra<sup>®</sup>), Simponi<sup>®</sup>], interleukin agents [e.g., Actemra<sup>®</sup> (IL-6RA), Arcalyst<sup>®</sup> (IL-1 blocker), Bimzelx<sup>®</sup> (IL-17A and F antagonist), Cosentyx<sup>®</sup> (IL-17A inhibitor), Ilaris<sup>®</sup> (IL-1 blocker), Ilumya<sup>™</sup> (IL-23 inhibitor), Kevzara<sup>®</sup> (IL-6RA), Kineret<sup>®</sup> (IL-1RA), Omvoh<sup>™</sup> (IL-23 antagonist), Siliq<sup>™</sup> (IL-17RA), Skyrizi<sup>™</sup> (IL-23 inhibitor), Stelara<sup>®</sup> (IL-12/23 inhibitor), Taltz<sup>®</sup> (IL-17A inhibitor), Tofidence<sup>™</sup> (IL-6), Tremfya<sup>®</sup> (IL-23 inhibitor), Wezlana<sup>™</sup> (IL-12/23 inhibitor)], Janus kinase inhibitors (JAKi) [e.g., Cibinco<sup>™</sup>, Olumiant<sup>™</sup>, Rinvoq<sup>™</sup>, Xeljanz<sup>®</sup>/Xeljanz<sup>®</sup> XR,], anti-CD20 monoclonal antibodies [Rituxan<sup>®</sup> and its biosimilars (Riabni<sup>™</sup>, Ruxience<sup>™</sup>, Truxima<sup>®</sup>), Rituxan Hycela<sup>®</sup>], selective co-stimulation modulators [Orencia<sup>®</sup>], integrin receptor antagonists [Entyvio<sup>®</sup>], tyrosine kinase 2 inhibitors [Sotyktu<sup>™</sup>], and sphingosine 1-phosphate receptor modulator [Velsipity<sup>™</sup>] because of the additive immunosuppression, increased risk of neutropenia, as well as increased risk of serious infections.

**IV. Appendices/General Information**

*Appendix A: Abbreviation/Acronym Key*

DMARD: disease-modifying antirheumatic drug

FDA: Food and Drug Administration

TNF: tumor necrosis factor

UC: ulcerative colitis

*Appendix B: Therapeutic Alternatives*

*This table provides a listing of preferred alternative therapy recommended in the approval criteria. The drugs listed here may not be a formulary agent for all relevant lines of business and may require prior authorization.*

Drug Name	Dosing Regimen	Dose Limit/ Maximum Dose
corticosteroids	Prednisone 40 mg – 60 mg PO QD, then taper dose by 5 to 10 mg/week  Budesonide (Uceris <sup>®</sup> ) 9 mg PO QAM for up to 8 weeks	Varies
Hadlima (adalimumab-bwwd), Yusimry (adalimumab-aqvh), adalimumab-adaz (Hyrimoz <sup>®</sup> ), adalimumab-fkjp (Hulio <sup>®</sup> ), adalimumab-adbm (Cyltezo <sup>®</sup> )	<u>Initial dose:</u> 160 mg SC on Day 1, then 80 mg SC on Day 15  <u>Maintenance dose:</u> 40 mg SC every other week starting on Day 29	40 mg every other week

Drug Name	Dosing Regimen	Dose Limit/ Maximum Dose
Zeposia <sup>®</sup> (ozanimod)	Days 1-4: 0.23 mg PO QD Days 5-7: 0.46 mg PO QD Day 8 and thereafter: 0.92 mg PO QD  If a dose of Zeposia is missed during the first 2 weeks of treatment, reinitiate treatment using the titration regimen. If a dose of Zeposia is missed after the first 2 weeks of treatment, continue with the treatment as planned.	0.92 mg/day

Therapeutic alternatives are listed as Brand name<sup>®</sup> (generic) when the drug is available by brand name only and generic (Brand name<sup>®</sup>) when the drug is available by both brand and generic.

*Appendix C: Contraindications/Boxed Warnings*

- Contraindication(s): history of serious hypersensitivity reaction to mirikizumab-mrkz or any of the excipients
- Boxed warning(s): none reported

*Appendix D: General Information*

- TNF blockers:
  - Etanercept (Enbrel<sup>®</sup>), adalimumab (Humira<sup>®</sup>) and its biosimilars, infliximab (Remicade<sup>®</sup>) and its biosimilars (Avsola<sup>™</sup>, Renflexis<sup>™</sup>, Inflectra<sup>®</sup>, Zymfentra<sup>®</sup>), certolizumab pegol (Cimzia<sup>®</sup>), and golimumab (Simponi<sup>®</sup>, Simponi Aria<sup>®</sup>).

*Appendix E: Mayo Score*

- Mayo Score: evaluates ulcerative colitis stage, based on four parameters: stool frequency, rectal bleeding, endoscopic evaluation and Physician's global assessment. Each parameter of the score ranges from zero (normal or inactive disease) to 3 (severe activity) with an overall score of 12.

Score	Decoding
0 – 2	Remission
3 – 5	Mild activity
6 – 10	Moderate activity
>10	Severe activity

**V. Dosage and Administration**

Indication	Dosing Regimen	Maximum Dose
Ulcerative colitis	<u>Induction dose:</u> 300 mg IV at Weeks 0, 4, and 8  <u>Maintenance dose:</u> 200 mg SC at Week 12, and every 4 weeks	200 mg/4 weeks (after loading doses)

**VI. Product Availability**

- Single-dose vial (for intravenous infusion): 300 mg/15 mL (20 mg/mL)
- Single-dose prefilled pen (for subcutaneous use): 100 mg/mL
- Single-dose prefilled syringe (for subcutaneous use): 100 mg/mL

**VII. References**

1. Omvoh Prescribing Information. Indianapolis, IN; Eli Lilly and Company; April 2024. Available at: [https://www.accessdata.fda.gov/drugsatfda\\_docs/label/2024/761279s001lbl.pdf](https://www.accessdata.fda.gov/drugsatfda_docs/label/2024/761279s001lbl.pdf). Accessed May 13, 2024.
2. Feuerstein JD, Isaacs KL, Schneider Y, et al. AGA Clinical practice guidelines on the management of moderate to severe ulcerative colitis. *Gastroenterology* 2020;158:1450–1461. <https://doi.org/10.1053/j.gastro.2020.01.006>.
3. Rubin DT, Ananthakrishnan AN, Siegel CA, Sauer BG, Long MD. ACG Clinical Guideline: Ulcerative Colitis in Adults. *Am J Gastroenterol.* 2019 March;114(3):384-413. doi: 10.14309/ajg.0000000000000152.

**Coding Implications**

Codes referenced in this clinical policy are for informational purposes only. Inclusion or exclusion of any codes does not guarantee coverage. Providers should reference the most up-to-date sources of professional coding guidance prior to the submission of claims for reimbursement of covered services.

HCPCS Codes	Description
J2267	Injection, mirikizumab-mrkz, 1 mg

Reviews, Revisions, and Approvals	Date	P&T Approval Date
Policy created	12.06.23	02.24
Added new HCPCS code [C9168] and removed HCPCS codes [C9399, J3590].	02.19.24	
2Q 2024 annual review: added Zymfentra, Wezlana, Sotyktu, and Velsipity to section III.B; references reviewed and updated.	01.22.24	05.24
RT4: added new dosage form [single-dose prefilled syringe 100 mg/mL]. Added HCPCS code [J2267].	05.13.24	

**Important Reminder**

This clinical policy has been developed by appropriately experienced and licensed health care professionals based on a review and consideration of currently available generally accepted standards of medical practice; peer-reviewed medical literature; government agency/program approval status; evidence-based guidelines and positions of leading national health professional organizations; views of physicians practicing in relevant clinical areas affected by this clinical policy; and other available clinical information. The Health Plan makes no representations and accepts no liability with respect to the content of any external information used or relied upon in developing this clinical policy. This clinical policy is consistent with standards of medical

practice current at the time that this clinical policy was approved. “Health Plan” means a health plan that has adopted this clinical policy and that is operated or administered, in whole or in part, by Centene Management Company, LLC, or any of such health plan’s affiliates, as applicable.

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**Note:**

**For Medicaid members**, when state Medicaid coverage provisions conflict with the coverage provisions in this clinical policy, state Medicaid coverage provisions take precedence. Please refer to the state Medicaid manual for any coverage provisions pertaining to this clinical policy.

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