

Clinical Policy: Mirikizumab-mrkz (Omvoh)

Reference Number: PA.CHIP.PHAR.662

Effective Date: 01/2026

Last Review Date: 10/2025

Description

Mirikizumab-mrkz (Omvoh™) is an interleukin-23 antagonist..

FDA Approved Indication(s)

Omvoh is indicated for the treatment of:

- Moderately to severely active ulcerative colitis (UC) in adults
- Moderately to severely active Crohn's disease (CD) in adults

Policy/Criteria

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

It is the policy of PA Health & Wellness® that Mirikizumab-mrkz (Omvoh) is **medically necessary** when the following criteria are met:

I. Initial Approval Criteria

A. Crohn's Disease (must meet all):

1. Diagnosis of CD;
2. Prescribed by or in consultation with a gastroenterologist;
3. Age \geq 18 years;
4. Member meets one of the following (a or b):
 - a. Failure of a \geq 3 consecutive month trial of at least ONE immunomodulator (e.g., azathioprine, 6-mercaptopurine [6-MP], methotrexate [MTX]) at up to maximally indicated doses, unless clinically significant adverse effects are experienced or all are contraindicated;
 - b. Medical justification supports inability to use immunomodulators (*see Appendix D*);
5. 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, Simlandi, Yusimry, adalimumab-aaty, adalimumab-adaz, adalimumab- abdm, and adalimumab-fkjp are preferred*);
 - b. History of failure of two TNF blockers;
**Prior authorization may be required for adalimumab products*
6. Failure of a \geq 3 consecutive month trial of one ustekinumab product (e.g. *Otulifi®, Pyzchiva® (branded), Steqeyma®, Yesintek™ are preferred*), unless clinically significant adverse effects are experienced or all are contraindicated;
**Prior authorization may be required for ustekinumab products*
7. 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*);
8. Dose does not exceed both of the following (a and b):
 - a. Initial (IV): 900 mg at Weeks 0, 4, and 8;
 - b. Maintenance (SC): 300 mg at Week 12 and every 4 weeks.

Approval duration: 6 months

B. 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 or modified Mayo Score \geq 5 (*see Appendix E*);
5. Failure of an 8-week trial of systemic corticosteroids, unless contraindicated or clinically significant adverse effects are experienced;
6. Failure of one of the following, used for \geq 3 consecutive months, unless clinically significant adverse effects are experienced or all are contraindicated (a or b):
 - a. One adalimumab product (e.g., *Hadlima*, *Simlandi*, *Yusimry*, *adalimumab-aaty*, *adalimumab-adaz*, *adalimumab-adbm*, and *adalimumab-fkjp* are preferred), unless the member has had a history of failure of two TNF blockers;
 - b. One ustekinumab product (e.g. *Otulsi*[®], *Pyzchiva*[®] (branded), *Stegeyma*[®], *Yesintek*[™] are preferred);

**Prior authorization may be required for adalimumab products and ustekinumab products*

7. 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*);
8. 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

C. 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 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 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. All Indications in Section I (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 one of the following (a or b):
 - a. CD: 300 mg every 4 weeks;
 - b. UC: 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 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 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®, Enbrel®, Humira® and its biosimilars, Remicade® and its biosimilars, Simponi®], interleukin agents [e.g., Actemra® (IL-6RA) and its biosimilars, Arcalyst® (IL-1 blocker), Bimzelx® (IL-17A and F antagonist), Cosentyx® (IL-17A inhibitor), Ilaris® (IL-1 blocker), Ilumya™ (IL-23 inhibitor), Kevzara® (IL-6RA), Kineret® (IL-1RA), Omvoh™ (IL-23 antagonist), Siliq™ (IL-17RA), Skyrizi™ (IL-23 inhibitor), Spevigo® (IL-36 antagonist), Stelara® (IL-12/23 inhibitor) and its biosimilars, Taltz® (IL-17A inhibitor), Tremfya® (IL-23 inhibitor)], Janus kinase inhibitors (JAKi) [e.g., Cibinqo™, Olumiant™, Rinvoq™, Xeljanz®/Xeljanz® XR,], anti-CD20 monoclonal antibodies [Rituxan® and its biosimilars], selective co-stimulation modulators [Orencia®], integrin receptor antagonists [Entyvio®], tyrosine kinase 2 inhibitors [Sotyktu™], and sphingosine 1-phosphate receptor modulator [Velsipity™] 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

CD: Crohn's disease

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
azathioprine (Azasan [®] , Imuran [®])	CD* 1.5 – 2.5 mg/kg/day PO	2.5 mg/kg/day
corticosteroids	CD* prednisone 40 mg – 60 mg PO QD for 1 to 2 weeks, then taper daily dose by 5 mg weekly until 20 mg PO QD, and then continue with 2.5 – 5 mg decrements weekly or IV 50 – 100 mg Q6H for 1 week UC Prednisone 40 mg – 60 mg PO QD, then taper dose by 5 to 10 mg/week budesonide (Entocort EC [®]) 6 – 9 mg PO QD UC Prednisone 40 mg – 60 mg PO QD, then taper dose by 5 to 10 mg/week budesonide (Uceris [®]) 9 mg PO QAM for up to 8 weeks	Varies
6-mercaptopurine (Purixan [®])	CD* 50 mg PO QD or 0.75 – 1.5 mg/kg/day PO	1.5 mg/kg/day
methotrexate (Trexall [®] , Otrexup [™] , Rasuvo [®] , RediTrex [®] , Rheumatrex [®] , Jylamvo [®])	CD* 15 – 25 mg/week IM or SC	30 mg/week
Pentasa [®] (mesalamine)	CD 1,000 mg PO QID	4 g/day
tacrolimus (Prograf [®])	CD* 0.27 mg/kg/day PO in divided doses or 0.15 – 0.29 mg/kg/day PO	N/A
Hadlima (adalimumab-bwwd), Simlandi	CD, UC <u>Initial dose:</u>	40 mg every other week

Drug Name	Dosing Regimen	Dose Limit/ Maximum Dose
(adalimumab-ryvk), Yusimry (adalimumab-aqvh), adalimumab-aaty (Yuflyma®), adalimumab-adaz (Hyrimoz®), adalimumab-fkjp (Hulio®), adalimumab-adbm (Cyltezo®)	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	
Otulfi® (ustekinumab-aauz), Pyzchiva® (ustekinumab-ttwe), Steqeyma® (ustekinumab-stba), Yesintek™ (ustekinumab-kfce)	CD, UC <u>Weight based dosing IV at initial dose:</u> Weight ≤ 55 kg: 260 mg Weight > 55 kg to 85 kg: 390 mg Weight > 85 kg: 520 mg <u>Maintenance dose:</u> 90 mg SC every 8 weeks	90 mg every 8 weeks

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

**Off-label*

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

- The following may be considered for medical justification supporting inability to use an immunomodulator for CD:
 - Inability to induce short-term symptomatic remission with a 3-month trial of systemic glucocorticoids
 - High-risk factors for intestinal complications may include:
 - Initial extensive ileal, ileocolonic, or proximal GI involvement
 - Initial extensive perianal/severe rectal disease
 - Fistulizing disease (e.g., perianal, enterocutaneous, and rectovaginal fistulas)
 - Deep ulcerations
 - Penetrating, structuring or stenosis disease and/or phenotype
 - Intestinal obstruction or abscess
 - High risk factors for postoperative recurrence may include:
 - Less than 10 years duration between time of diagnosis and surgery
 - Disease location in the ileum and colon
 - Perianal fistula
 - Prior history of surgical resection

- Use of corticosteroids prior to surgery
- TNF blockers:
 - Etanercept (Enbrel®), adalimumab (Humira®) and its biosimilars, infliximab (Remicade®) and its biosimilars (Avsola™, Renflexis™, Inflectra®, Zymfentra®), certolizumab pegol (Cimzia®), and golimumab (Simponi®, Simponi Aria®).

Appendix E: Mayo Score or Modified 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

- Modified Mayo Score: developed from the full Mayo score and evaluates ulcerative colitis stage, based on three parameters: stool frequency, rectal bleeding, and endoscopic evaluation. The modified Mayo Score gives a maximum overall score of 9. The FDA currently accepts the modified Mayo Score for the assessment of disease activity in pivotal UC clinical trials.

V. Dosage and Administration

Indication	Dosing Regimen	Maximum Dose
CD	<u>Induction dose:</u> 900 mg IV at Weeks 0, 4, and 8 <u>Maintenance dose:</u> 300 mg SC at Week 12, and every 4 weeks	300 mg/4 weeks (after loading doses)
UC	<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, 200 mg/2 mL
- Single-dose prefilled syringe (for subcutaneous use): 100 mg/mL, 200 mg/2 mL

VII. References

1. Omvoh Prescribing Information. Indianapolis, IN; Eli Lilly and Company; January 2025. Available at: https://www.accessdata.fda.gov/drugsatfda_docs/label/2025/761279s003lbl.pdf. Accessed February 6, 2025.

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.00000000000000152.
4. Ulcerative Colitis: Clinical Trial Endpoints Guidance for Industry. Silver Spring, MD. Food and Drug Administration.; July 2016. Available at: <https://www.fda.gov/files/drugs/published/Ulcerative-Colitis--Clinical-Trial-Endpoints- Guidance-for-Industry.pdf>. Accessed February 3, 2025.
5. Naegeli AN, Hunter T, Dong Y, et al. Full, Partial, and Modified Permutations of the Mayo Score: Characterizing Clinical and Patient-Reported Outcomes in Ulcerative Colitis Patients. *Crohns Colitis 360*. 2021 Feb 23;3(1):otab007. doi: 10.1093/crocol/otab007. PMID: 36777063; PMCID: PMC9802037.
6. Singh S, Loftus EV Jr, Limketkai BN, et al. AGA Living Clinical Practice Guideline on Pharmacological Management of Moderate-to-Severe Ulcerative Colitis. *Gastroenterology*. 2024 Dec;167(7):1307-1343. doi: 10.1053/j.gastro.2024.10.001. PMID: 39572132.

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
Policy created	10/2025