

OmvoH (mirikizumab-mrkz) injection, for intravenous use

Policy Number: MC/PC 029
Effective Date: March 1, 2025

[Instructions for Use](#)

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Related Policies

- N/A

Coverage Rationale

This policy is applicable for OmvoH (mirikizumab-mrkz) injection for intravenous infusion only.

Ulcerative Colitis

For initial coverage of OmvoH IV for ulcerative colitis, the following will be required:

- All of the following:
 - Diagnosis of moderately to severely active ulcerative colitis **and**
 - Patient is 18 years of age or older **and**
 - One of the following:
 - Greater than 6 stools per day
 - Frequent blood in the stools
 - Frequent urgency
 - Presence of ulcers
 - Abnormal lab values (e.g., hemoglobin, erythrocyte sedimentation rate, C-reactive protein)
 - Dependent on, or refractory to, corticosteroids **and**
 - Prescribed by or in consultation with a gastroenterologist **and**
 - An adequate trial and failure, a contraindication, or an intolerance to ONE of the following conventional therapies:
 - 6-mercaptopurine
 - Aminosalicylate (e.g., mesalamine, olsalazine, sulfasalazine)
 - Azathioprine
 - Corticosteroids (e.g., prednisone) **and**
 - Will be administered as an intravenous induction dose **and**

OR

- For continuation of prior therapy, defined as no more than a 45-day gap in therapy

Applicable Codes

The following list(s) of procedure and/or diagnosis codes is provided for reference purposes only and may not be all inclusive. Listing of a code in this policy does not imply that the service described by the code is a covered or non-covered health service. Benefit coverage for health services is determined by the member specific benefit plan document and applicable laws that may require coverage for a specific service. The inclusion of a code does not imply any right to reimbursement or guarantee claim payment. Other Policies and Guidelines may apply.

HCPSC Code	Description
C9168	Injection, mirikizumab-mrkz, 1 mg
J3490	Unclassified drugs
J3590	Unclassified biologics
C9399	Unclassified drugs or biologicals
J2267	Injection, mirikizumab-mrkz, 1 mg

ICD-10 Code	Description
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) recto sigmoiditis without complications
K51.311	Ulcerative (chronic) recto sigmoiditis with rectal bleeding
K51.312	Ulcerative (chronic) recto sigmoiditis with intestinal obstruction
K51.313	Ulcerative (chronic) recto sigmoiditis with fistula
K51.314	Ulcerative (chronic) recto sigmoiditis with abscess
K51.318	Ulcerative (chronic) recto sigmoiditis with other complication
K51.319	Ulcerative (chronic) recto sigmoiditis with unspecified complications
K51.40	Inflammatory polyps of colon without complications
K51.411	Inflammatory polyps of colon with rectal bleeding
K51.412	Inflammatory polyps of colon with intestinal obstruction
K51.413	Inflammatory polyps of colon with fistula
K51.414	Inflammatory polyps of colon with abscess

ICD-10 Code	Description
K51.418	Inflammatory polyps of colon with other complication
K51.419	Inflammatory polyps of colon 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
K52.1	Toxic gastroenteritis and colitis

Background

Ulcerative colitis (UC) and Crohn’s disease (CD) are 2 forms of IBD that differ in pathophysiology and presentation; as a result of these differences, the approach to the treatment of each condition often differs (*Peppercorn and Cheifetz 2024*). UC is characterized by recurrent episodes of inflammation of the mucosal layer of the colon. The inflammation, limited to the mucosa, commonly involves the rectum and may extend in a proximal and continuous fashion to affect other parts of the colon. The hallmark clinical symptom is an inflamed rectum accompanied by urgency, bleeding, and tenesmus (*Peppercorn and Kane 2024, Rubin et al 2019*).

OmvoH is a humanized IgG4 monoclonal antibody that selectively binds to the p19 subunit of human IL-23 cytokine and inhibits its interaction with the IL-23 receptor (*Clinical Pharmacology 2024*). IL-23 is involved in mucosal inflammation and affects the differentiation, expansion, and survival of T cell subsets, and innate immune cell subsets, which represent sources of pro-inflammatory cytokines.

Clinical Evidence

The efficacy of Omvoh (mirikizumab-mrkz) was evaluated in 1281 adults with moderate to severe active UC in 2 clinical trials (LUCENT-1 and LUCENT-2). Eligible patients had an inadequate response to, a loss of response to, or an inability to take 1 or more glucocorticoids or immunomodulators for the treatment of UC or biologic therapy or a Janus kinase (JAK) inhibitor for the treatment of UC (*D'Haens et al 2023*). In LUCENT-1, patients were randomized to induction therapy consisting of mirikizumab 300 mg IV every 4 weeks or placebo. Patients with clinical response in LUCENT-1 were randomized to maintenance therapy in LUCENT-2 with mirikizumab 200 mg SQ every 4 weeks or placebo. In the induction trial, clinical remission at 12 weeks was achieved in 24.2% vs 13.3% of patients receiving mirikizumab vs placebo, respectively ($p < 0.001$). Clinical response occurred in 63.5% receiving mirikizumab vs 42.2% receiving placebo ($p < 0.001$). A total of 544 continued to the maintenance trial, of which 49.9% and 25.1% achieved clinical remission at 40 weeks (52 weeks overall) with mirikizumab and placebo, respectively ($p < 0.001$).

Place in Therapy

A 2019 guideline from the American College of Gastroenterology (ACG) recommends 5-ASA therapy for induction of remission in mildly active UC, and budesonide, systemic corticosteroids, TNF inhibitor therapy (adalimumab, golimumab, or infliximab), vedolizumab, and tofacitinib for induction of remission in moderately to severely active disease. Vedolizumab and tofacitinib are recommended for induction of remission in patients who have failed previous TNF inhibitor therapy. For maintenance of remission in patients with previously mildly active disease, 5-ASA therapy is recommended, and in patients with previously moderately to severely active disease, continuation of TNF inhibitor therapy, vedolizumab, or tofacitinib is recommended after induction of remission with these agents (*Rubin et al 2019*).

For adult outpatients with moderate to severe UC, a 2020 AGA guideline strongly recommends using infliximab, adalimumab, golimumab, vedolizumab, tofacitinib, or ustekinumab over no treatment (*Feuerstein et al 2020*). However, for patients with less severe disease who place a higher value on the safety of 5-ASA therapy and a lower value on the efficacy of biologic agents, it is reasonable to choose gradual step therapy with 5-ASA.

The European Crohn's and Colitis Organisation (ECCO) recommends thiopurines for maintenance of remission in patients with steroid-dependent UC who are intolerant of 5-ASA. Remission can be induced with TNF inhibitors, vedolizumab, tofacitinib, or ustekinumab in patients with moderate to severe disease that has not responded to conventional therapy. Remission can be maintained with the same biologic agent that was used for induction therapy (*Raine et al 2022*).

It should be noted that these guidelines were updated prior to the FDA approval of the new entity, mirikizumab, for UC.

U.S. Food and Drug Administration (FDA)

This section is to be used for informational purposes only. FDA approval alone is not a basis for coverage.

[Omvoh](#) is an interleukin-23 antagonist indicated for the treatment of moderately to severely active ulcerative colitis in adults.

References

1. D'Haens G, Dubinsky M, Kobayashi T, et al. Mirikizumab as Induction and Maintenance Therapy for Ulcerative Colitis [published correction appears in N Engl J Med. 2023 Aug 24;389(8):772]. N Engl J Med. 2023;388(26):2444-2455. doi:10.1056/NEJMoa2207940

2. Feuerstein JD, Isaacs KL, Schneider Y, et al. AGA clinical practice guidelines severe ulcerative colitis. Gastroenterol. 2020;158:1450-1461.
3. Mirikizumab. Clinical Pharmacology powered by ClinicalKey. Philadelphia (PA): Elsevier; 2024. Available from: <http://www.clinicalkey.com>. Accessed on December 12, 2024.
4. Omvoh prescribing information. Eli Lilly & Co. Indianapolis, IN. April 2024.
5. Raine T, Bonovas S, Burisch J, et al. ECCO Guidelines on Therapeutics in Ulcerative Colitis: Medical Treatment. J Crohns Colitis. 2022;16(1):2-17. doi:10.1093/ecco-jcc/jjab178
6. Rubin DT, Ananthakrishnan AN, Siegel CA, et al. ACG clinical guideline: ulcerative colitis in adults. Am J Gastroenterol. 2019;114:384-413.
7. Peppercorn MA and Cheifetz AS. Definitions, epidemiology, and risk factors for inflammatory bowel disease. UpToDate Web site. Updated September 2, 2024. <http://www.uptodate.com>. Accessed December 12, 2024.
8. Peppercorn MA and Kane SV. Clinical manifestations, diagnosis, and prognosis of ulcerative colitis in adults. UpToDate Web site. Updated May 17, 2024. <http://www.uptodate.com>. Accessed December 12, 2024.

Policy History/Revision Information

Date	Summary of Changes
6/19/2024	Approved by OptumRx P&T Committee.
2/20/2025	Annual Review. No changes made. Updated references.

Instructions for Use

This Medical Benefit Drug Policy provides assistance in interpreting standard benefit plans. When deciding coverage, the member specific benefit plan document must be referenced as the terms of the member specific benefit plan may differ from the standard plan. In the event of a conflict, the member specific benefit plan document governs. Before using this policy, please check the member specific benefit plan document and any applicable federal or state mandates. The insurance reserves the right to modify its Policies and Guidelines as necessary. This Medical Benefit Drug Policy is provided for informational purposes. It does not constitute medical advice.

OptumRx may also use tools developed by third parties to assist us in administering health benefits. OptumRx Medical Benefit Drug Policies are intended to be used in connection with the independent professional medical judgment of a qualified health care provider and do not constitute the practice of medicine or medical advice.

Archived Policy Versions (Internal Only)

Effective Date	Policy Number	Policy Title
mm/dd/yyyy – mm/dd/yyyy	#####	Title of Policy Hyperlinked to KL or Other Internal Location

Nondiscrimination & Language Access Policy



Discrimination is Against the Law. Aspirus Health Plan, Inc. complies with applicable Federal civil rights laws and does not discriminate on the basis of race, color, national origin, age, disability, or sex, (including sex characteristics, including intersex traits; pregnancy or related conditions; sexual orientation, gender identity and sex stereotypes), consistent with the scope of sex discrimination described at 45 CFR § 92.101(a)(2). Aspirus Health Plan, Inc. does not exclude people or treat them less favorably because of race, color, national origin, age, disability, or sex.

Aspirus Health Plan, Inc.:

Provides people with disabilities reasonable modifications and free appropriate auxiliary aids and services to communicate effectively with us, such as:

- Qualified sign language interpreters.
- Written information in other formats (large print, audio, accessible electronic formats, other formats).

Provides free language assistance services to people whose primary language is not English, which may include:

- Qualified interpreters.
- Information written in other languages.

If you need reasonable modifications, appropriate auxiliary aids and services, or language assistance services, contact the Nondiscrimination Grievance Coordinator at the address, phone number, fax number, or email address below.

If you believe that Aspirus Health Plan, Inc. has failed to provide these services or discriminated in another way on the basis of race, color, national origin, age, disability, or sex, you can file a *grievance* with:

Nondiscrimination Grievance Coordinator
Aspirus Health Plan, Inc.
PO Box 1890
Southampton, PA 18966-9998
Phone: 1-866-631-5404 (TTY: 711)
Fax: 763-847-4010
Email: customerservice@aspirushealthplan.com

You can file a *grievance* in person or by mail, fax, or email. If you need help filing a *grievance*, the Nondiscrimination Grievance Coordinator is available to help you.

You can also file a civil rights complaint with the U.S. Department of Health and Human Services, Office for Civil Rights, electronically through the Office for Civil Rights Complaint Portal, available at <https://ocrportal.hhs.gov/ocr/portal/lobby.jsf>, or by mail or phone at:

U.S. Department of Health and Human Services
200 Independence Avenue, SW
Room 509F, HHH Building
Washington, D.C. 20201
1.800.368.1019, 800.537.7697 (TDD)

Complaint forms are available at <http://www.hhs.gov/ocr/office/file/index.html>. This notice is available at Aspirus Health Plan, Inc.'s website: https://aspirushealthplan.com/webdocs/70021-AHP-NonDiscrim_Lang-Assist-Notice.pdf.

Language Assistance Services

Albanian: KUJDES: Nëse flitni shqip, për ju ka në dispozicion shërbime të asistencës gjuhësore, pa pagesë. Telefononi në 1-800-332-6501 (TTY: 711).

Arabic: تنبيه: إذا كنت تتحدث اللغة العربية، فإن خدمات المساعدة اللغوية متاحة لك مجاناً. اتصل بن أعلى رقم الهاتف 1-800-332-6501 (رقم هاتف الصم والبك : 711)

French: ATTENTION: Si vous parlez français, des services d'aide linguistique vous sont proposés gratuitement. Appelez le 1-800-332-6501 (ATS: 711).

German: ACHTUNG: Wenn Sie Deutsch sprechen, stehen Ihnen kostenlos sprachliche Hilfsdienstleistungen zur Verfügung. Rufnummer: 1-800-332-6501 (TTY: 711).

Hindi: यान द : य द आप िहंदी बोलते ह तो आपके िलए मु त म भाषा सहायता सेवाएं उपल थ ह 1-800-332-6501 (TTY: 711) पर कॉल कर ।

Hmong: LUS CEEV: Yog tias koj hais lus Hmoob, cov kev pab txog lus, muaj kev pab dawb rau koj. Hu rau 1-800-332-6501 (TTY: 711).

Korean: 주의: 한국어를 사용하시는 경우, 언어 지원 서비스를 무료로 이용하실 수 있습니다. 1-800-332-6501 (TTY: 711) 번으로 전화해 주십시오.

Polish: UWAGA: Jeżeli mówisz po polsku, możesz skorzystać z bezpłatnej pomocy językowej. Zadzwoń pod numer 1-800-332-6501 (TTY: 711).

Russian: ВНИМАНИЕ: Если вы говорите на русском языке, то вам доступны бесплатные услуги перевода. Звоните 1-800-332-6501 (телетайп: 711).

Spanish: ATENCIÓN: si habla español, tiene a su disposición servicios gratuitos de asistencia lingüística. Llame al 1-800-332-6501 (TTY: 711).

Tagalog: PAUNAWA: Kung nagsasalita ka ng Tagalog, maaari kang gumamit ng mga serbisyo ng tulong sa wika nangwalang bayad. Tumawag sa 1-800-332-6501 (TTY: 711).

Traditional Chinese: 注意：如果您使用繁體中文，您可以免費獲得語言援助服務。請致電 1-800-332-6501 (TTY: 711)

Vietnamese: CHÚ Ý: Nếu bạn nói Tiếng Việt, có các dịch vụ hỗ trợ ngôn ngữ miễn phí dành cho bạn. Gọi số 1-800-332-6501 (TTY: 711).

Pennsylvania Dutch: Wann du Deutsch (Pennsylvania German / Dutch) schwetzscht, kannst du mitaue Koschte ebbergricke, ass dihr helft mit die englisch Schprooch. Ruf selli Nummer uff: Call 1-800-332-6501 (TTY: 711).

Lao: ໂປດຊາບ: ຖ້າວ່າທ່ານເວົ້າພາສາລາວ, ການບໍລິການຊ່ວຍເຫຼືອດ້ານພາສາໂດຍບໍ່ເສັຽຄ່າ, ຄວນມີພ້ອມໃຫ້ທ່ານ. ໂທ 1-800-332-6501 (TTY: 711).