Medical Benefit Drug Policy

Omvoh (mirikizumab-mrkz) injection, for intravenous use

Policy Number: MC/PC 029
Effective Date: March 1, 2026

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. Omvoh (mirikizumab-mrkz) injection, for self-administered subcutaneous injection is obtained under the pharmacy benefit.

Crohn's Disease

For initial coverage of Omvoh IV for Crohn's disease, the following will be required:

- Diagnosis of moderately to severely active Crohn's disease (CD) **and**
- One of the following:
  - Frequent diarrhea and abdominal pain
  - At least 10% weight loss
  - Complications such as obstruction, fever, abdominal mass
  - Abnormal lab values (e.g., C-reactive protein [CRP])
  - CD Activity Index (CDAI) greater than 220 **and**
- Prescribed by or in consultation with a gastroenterologist **and**
- Will be administered as an intravenous induction dose

Ulcerative Colitis

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

- Diagnosis of moderately to severely active ulcerative colitis **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**
- Will be administered as an intravenous induction dose

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.

HCPCS Code	Description
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
K51.418	Inflammatory polyps of colon with other complication
K51.419	Inflammatory polyps of colon with unspecified complications

ICD-10 Code	Description
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
K50.00	Crohn's disease of small intestine without complications
K50.01	Crohn's disease of small intestine with 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
K50.11	Crohn's disease of large intestine with 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
K50.81	Crohn's disease of both small and large intestine with complications

ICD-10 Code	Description
K50.811	Crohn's disease of both small and large intestine with rect
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
K50.91	Crohn's disease, unspecified, with 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

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 2025, Rubin et al 2025). CD can involve any component of the gastrointestinal tract from the oral cavity to the anus and is characterized by transmural inflammation.CD also may involve the colon, either exclusively (Crohn colitis) or in combination with small intestinal involvement (Crohn ileocolitis). (Peppercorn and Kane 2025).

Omvoh is a humanized IgG4 monoclonal antibody that selectively binds to the p19 subunit of human interleukin-23 (IL-23) cytokine and inhibits its interaction with the IL-23 receptor (Clinical Pharmacology 2025). 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

Crohn's disease (CD)
Omvoh (mirikizumab) was evaluated in patients with moderately-to-severely active CD who had prior inadequate response, loss of response, or intolerance to ≥ 1 biological or conventional therapy (N = 1152) in the Phase 3 VIVID-1 trial (Ferrante et al 2024). Patients were randomized to receive mirikizumab, ustekinumab, or placebo. Clinical remission, defined as response by patient reported outcome at week 12 and clinical remission by CDAI score at week 52 was reported in 45.4% of patients receiving mirikizumab, 40.8% receiving ustekinumab, and 19.6% receiving placebo ($p < 0.0001$ for each group vs placebo). Endoscopic response at week 52 was observed in 38% of the mirikizumab group, 37.3% with ustekinumab, and 9% with placebo ($p < 0.0001$ for each group vs placebo).

Ulcerative Colitis (UC)
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 (JAK) inhibitor for the treatment of UC (D'Haens et al 2023). In LUCENT-1, patients w 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

Crohn's disease (CD)
A 2025 American College of Gastroenterology (ACG) guideline on the management of CD in adults recommends controlled ileal release budesonide at a dose of 9 mg once daily for induction of symptomatic remission for patients with mild to moderate ileocecal CD (Lichtenstein et al 2025).

- For mild to moderate disease and those at lower risk for progression, the guideline also recommends against the use of oral mesalamine to treat patients with active CD, since it has not consistently been shown effective for inducing remission and achieving mucosal healing when compared to placebo. Sulfasalazine should only be considered for patients with symptomatic mild colonic CD.
- For patients with moderate to severe disease, ACG recommends oral corticosteroids for short-term induction of remission and against induction with azathioprine and mercaptopurine; however, azathioprine and mercaptopurine are suggested as an option for maintenance of remission following induction with corticosteroids. Methotrexate is also suggested for maintenance of remission following induction with corticosteroids. The TNF inhibitors adalimumab, certolizumab, and infliximab are recommended for induction and maintenance of remission. Due to the potential for immunogenicity and loss of response to TNF therapy, combination with immunotherapy may be considered. The combination of infliximab with an immunomodulator (thiopurine) is more effective than monotherapy with individual agents in patients with moderate to severe CD and who are naïve to both agents. Subcutaneous infliximab is an option for maintenance of remission following IV infliximab induction. Vedolizumab can be used for induction and maintenance of remission in patients with moderate to severe CD, and subcutaneous vedolizumab may be considered as a maintenance option in patients who respond to 2 doses of IV vedolizumab induction. Ustekinumab and risankizumab are also recommended as options for induction and maintenance of remission, with risankizumab being preferred over ustekinumab in patients with prior TNF inhibitor therapy. Other recommended options for induction and maintenance of remission include mirikizumab and subcutaneous guselkumab (with option to use IV for induction). Upadacitinib is recommended for induction and maintenance of remission in patients who were exposed to prior TNF therapy.
- In patients with fistulizing CD, infliximab is recommended for induction of remission. Other options that are suggested include adalimumab, vedolizumab, ustekinumab, and upadacitinib.
- The guideline acknowledges the effectiveness of biosimilars of infliximab, adalimumab, and ustekinumab for the management of moderate to severe CD, as well as the safety and efficacy of transitioning to a biosimilar infliximab or adalimumab in patients with stable disease.

A 2021 American Gastroenterological Association (AGA) guideline on the medical management of moderate to severe CD strongly recommends the use of biologic monotherapy over thiopurine monotherapy for the induction of remission in adult outpatients and recommends TNF inhibitors or ustekinumab over no treatment for induction and maintenance of remission. In patients who are naïve to biologic drugs, infliximab, adalimumab, or ustekinumab are recommended over certolizumab pegol for the induction of remission and vedolizumab is suggested over certolizumab pegol. In patients who never responded to TNF inhibitors, the use of ustekinumab is recommended and the use of vedolizumab is suggested over no treatment for the induction of remission. In patients who previously responded to infliximab, the use of adalimumab or ustekinumab is recommended and the use of vedolizumab is suggested over no treatment for the induction of remission. The AGA recommends against the use of 5-ASA or sulfasalazine over no treatment for the induction or maintenance of remission. In patients with CD and active perianal fistula, infliximab is recommended over

no treatment for the induction and maintenance of fistula remission. In patien
without perianal abscess, the use of biologic agents in combination with an an
recommended for the induction of fistula remission (Feuerstein et al 2021).

The 2024 European Crohn's and Colitis Organisation (ECCO) guideline on medical treatment in CD recommends the use of infliximab, adalimumab, ustekinumab, risankizumab, vedolizumab, and upadacitinib to induce remission and maintenance of remission in patients with moderate-to-severe CD (Gordon et al 2024). Other immunomodulator-related recommendations within the guideline include:

- Recommending combination therapy with infliximab and thiopurines when starting infliximab as induction therapy in patients with moderate-to-severe CD and recommending combination therapy for a minimum of 6 to 12 months.
- Suggesting against the combination of adalimumab and thiopurines over adalimumab alone to achieve clinical remission and response.
- Suggesting certolizumab can be used as induction therapy and maintenance therapy in moderate-to-severe CD.
- Suggesting adalimumab or ustekinumab are equally effective as induction and maintenance therapy in biologic-naïve patients with moderate-to-severe CD.

Ulcerative Colitis (UC)

A 2025 guideline from the ACG recommends 5-ASA therapy for induction of remission in mildly active UC, and budesonide, systemic corticosteroids, S1P receptor modulators (ozanimod and etrasimod), ustekinumab, IL-23p19 inhibitors (guselkumab, mirikizumab, and risankizumab), TNF inhibitors (infliximab in combination with a thiopurine, adalimumab, and golimumab), vedolizumab, and JAK inhibitors (tofacitinib and upadacitinib) for induction of remission in moderately to severely active disease. For maintenance of remission in patients with previously mildly active disease, 5-ASA therapy is recommended. In patients with previously moderately to severely active disease, continuation of TNF inhibitor, S1P receptor modulator, ustekinumab, guselkumab, mirikizumab, risankizumab, infliximab (in combination with a thiopurine), vedolizumab, or JAK inhibitor therapy is recommended after induction of remission with these agents. Thiopurines may be used after corticosteroid induction in patients with moderate to severe UC (Rubin et al 2025).

For adult outpatients with moderate to severe UC, an AGA clinical practice guideline was last updated in 2024, and recommends using infliximab, golimumab, vedolizumab, tofacitinib, upadacitinib, ustekinumab, ozanimod, etrasimod, risankizumab, and guselkumab over no treatment and suggests use of adalimumab, filgotinib (not approved in the U.S.) or mirikizumab over no treatment (Singh et al 2024). Biosimilars of infliximab, adalimumab, and ustekinumab are considered equivalent to the reference drug. Subcutaneous formulations of infliximab and vedolizumab have comparable efficacy to the intravenous maintenance doses. In patients with severe disease, extended induction regimens up to 16 weeks or dose escalation may be beneficial for certain agents. In patients with moderate to severe UC naïve to advanced therapies, the AGA suggests using a higher efficacy medication (infliximab, vedolizumab, ozanimod, etrasimod, upadacitinib, risankizumab, guselkumab) or an intermediate efficacy medication (golimumab, ustekinumab, tofacitinib, filgotinib, mirikizumab), instead of a lower efficacy medication (adalimumab). JAK inhibitors may be associated with higher risk of major adverse cardiovascular events and cancer than TNF antagonists in older adults with cardiovascular risk factors. JAK inhibitors are recommended in those with failure or intolerance to TNF antagonists. Vedolizumab and anti-IL therapies may be associated with a lower infection risk than TNF antagonists and may be preferred in those at risk of immunosuppression-related infections or malignancies. JAK inhibitors and S1P receptor modulators should be avoided in women of childbearing age contemplating pregnancy.

The 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).

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
- moderately to severely active Crohn's disease in adults.

References

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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.
2/19/2026	Annual Review. Coverage rationale, ICD-10 codes, clinical evidence and FDA section updated. 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.

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 اعلى رقم الهاتف1-800-332-6501(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 zurVerfügung. 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_ध 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 numer1-800-332-6501 (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 al1-800-332-6501 (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 Deitsch (Pennsylvania German / Dutch) schwetzscht, kannscht du mitaus Koschte ebbergricke, ass dihr helft mit die englisch Schprooch. Ruf selli Nummer uff: Call 1-800-332-6501 (TTY: 711).

Lao: ໂປດຊາບ: ຖ້າວ່າ ທ່ານເວົ້າພາສາ ລາວ, ການບໍລິການຊ່ວຍເຫຼືອດ້ານພາສາ,ໂດຍບໍ່ເສັງຄ່າ, ແມ່ນມີພ້ອມໃຫ້ທ່ານ. ໂທຣ 1-800-332-6501 (TTY: 711).