

Omvo[™] (Mirikizumab-mrkz) (for Louisiana Only)

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[Instructions for Use](#)

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Application

This Medical Benefit Drug Policy only applies to the state of Louisiana.

Coverage Rationale

This policy refers to Omvoh (mirikizumab-mrkz) injection. Omvoh (mirikizumab-mrkz) for self-administered subcutaneous injection is obtained under the pharmacy benefit.

Ulcerative Colitis (UC)

Omvoh is proven and medically necessary for the treatment of ulcerative colitis when all of the following criteria are met:

- Diagnosis of moderately to severely active ulcerative colitis; and
- One of the following:
 - Patient has had prior or concurrent inadequate response to a therapeutic course of oral corticosteroids and/or immunosuppressants (e.g., azathioprine, 6-mercaptopurine); or
 - Patient has been previously treated with a targeted immunomodulator FDA-approved for the treatment of ulcerative colitis [e.g., adalimumab, Simponi (golimumab), Stelara (ustekinumab), Xeljanz (tofacitinib), Rinvoq (upadacitinib)]
- and
- History of failure, contraindication or intolerance to two biologic DMARDs FDA-approved for the treatment of ulcerative colitis (document drug, date, and duration of trial); and
- Omvoh is to be administered as three intravenous induction doses; and
- Omvoh induction dosing is in accordance with the United States Food and Drug Administration (FDA) labeled dosing for UC; and
- Patient is not receiving Omvoh in combination with either of the following:
 - Biologic DMARD [e.g., Cimzia (certolizumab), Humira (adalimumab), Stelara (ustekinumab)]
 - Janus kinase inhibitor [e.g., Xeljanz (tofacitinib), Rinvoq (upadacitinib)]
- and

- Prescribed by or in consultation with a gastroenterologist; and
- Authorization will be issued for 3 induction doses

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 federal, state, or contractual requirements 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.

<u>HCPCS Code</u>	<u>Description</u>
<u>C9399</u>	<u>Unclassified drugs or biologicals</u>
<u>J3490</u>	<u>Unclassified drugs</u>
<u>J3590</u>	<u>Unclassified biologics</u>

<u>Diagnosis Code</u>	<u>Description</u>
<u>K51.00</u>	<u>Ulcerative (chronic) pancolitis without complications</u>
<u>K51.011</u>	<u>Ulcerative (chronic) pancolitis with rectal bleeding</u>
<u>K51.012</u>	<u>Ulcerative (chronic) pancolitis with intestinal obstruction</u>
<u>K51.013</u>	<u>Ulcerative (chronic) pancolitis with fistula</u>
<u>K51.014</u>	<u>Ulcerative (chronic) pancolitis with abscess</u>
<u>K51.018</u>	<u>Ulcerative (chronic) pancolitis with other complication</u>
<u>K51.019</u>	<u>Ulcerative (chronic) pancolitis with unspecified complications</u>
<u>K51.20</u>	<u>Ulcerative (chronic) proctitis without complications</u>
<u>K51.211</u>	<u>Ulcerative (chronic) proctitis with rectal bleeding</u>
<u>K51.212</u>	<u>Ulcerative (chronic) proctitis with intestinal obstruction</u>
<u>K51.213</u>	<u>Ulcerative (chronic) proctitis with fistula</u>
<u>K51.214</u>	<u>Ulcerative (chronic) proctitis with abscess</u>
<u>K51.218</u>	<u>Ulcerative (chronic) proctitis with other complication</u>
<u>K51.219</u>	<u>Ulcerative (chronic) proctitis with unspecified complications</u>
<u>K51.30</u>	<u>Ulcerative (chronic) recto sigmoiditis without complications</u>
<u>K51.311</u>	<u>Ulcerative (chronic) recto sigmoiditis with rectal bleeding</u>
<u>K51.312</u>	<u>Ulcerative (chronic) recto sigmoiditis with intestinal obstruction</u>
<u>K51.313</u>	<u>Ulcerative (chronic) recto sigmoiditis with fistula</u>
<u>K51.314</u>	<u>Ulcerative (chronic) recto sigmoiditis with abscess</u>
<u>K51.318</u>	<u>Ulcerative (chronic) recto sigmoiditis with other complication</u>
<u>K51.319</u>	<u>Ulcerative (chronic) recto sigmoiditis with unspecified complications</u>
<u>K51.40</u>	<u>Inflammatory polyps of colon without complications</u>
<u>K51.411</u>	<u>Inflammatory polyps of colon with rectal bleeding</u>
<u>K51.412</u>	<u>Inflammatory polyps of colon with intestinal obstruction</u>
<u>K51.413</u>	<u>Inflammatory polyps of colon with fistula</u>
<u>K51.414</u>	<u>Inflammatory polyps of colon with abscess</u>
<u>K51.418</u>	<u>Inflammatory polyps of colon with other complication</u>
<u>K51.419</u>	<u>Inflammatory polyps of colon with unspecified complications</u>
<u>K51.50</u>	<u>Left sided colitis without complications</u>
<u>K51.511</u>	<u>Left sided colitis with rectal bleeding</u>

<u>Diagnosis Code</u>	<u>Description</u>
<u>K51.512</u>	<u>Left sided colitis with intestinal obstruction</u>
<u>K51.513</u>	<u>Left sided colitis with fistula</u>
<u>K51.514</u>	<u>Left sided colitis with abscess</u>
<u>K51.518</u>	<u>Left sided colitis with other complication</u>
<u>K51.519</u>	<u>Left sided colitis with unspecified complications</u>
<u>K51.80</u>	<u>Other ulcerative colitis without complications</u>
<u>K51.811</u>	<u>Other ulcerative colitis with rectal bleeding</u>
<u>K51.812</u>	<u>Other ulcerative colitis with intestinal obstruction</u>
<u>K51.813</u>	<u>Other ulcerative colitis with fistula</u>
<u>K51.814</u>	<u>Other ulcerative colitis with abscess</u>
<u>K51.818</u>	<u>Other ulcerative colitis with other complication</u>
<u>K51.819</u>	<u>Other ulcerative colitis with unspecified complications</u>
<u>K51.90</u>	<u>Ulcerative colitis, unspecified, without complications</u>
<u>K51.911</u>	<u>Ulcerative colitis, unspecified with rectal bleeding</u>
<u>K51.912</u>	<u>Ulcerative colitis, unspecified with intestinal obstruction</u>
<u>K51.913</u>	<u>Ulcerative colitis, unspecified with fistula</u>
<u>K51.914</u>	<u>Ulcerative colitis, unspecified with abscess</u>
<u>K51.918</u>	<u>Ulcerative colitis, unspecified with other complication</u>
<u>K51.919</u>	<u>Ulcerative colitis, unspecified with unspecified complications</u>
<u>K52.1</u>	<u>Toxic gastroenteritis and colitis</u>

Background

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. 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

Proven

Ulcerative Colitis

The safety and efficacy of mirikizumab-mrkz was evaluated in two randomized, double-blind, placebo-controlled clinical studies, one induction study [UC-1 (NCT03518086)] and one maintenance study [UC-2 (NCT03524092)], in adult subjects with moderately to severely active ulcerative colitis who had inadequate response, loss of response, or failed to tolerate any of the following: corticosteroids, 6-mercaptopurine, azathioprine, biologic therapy (TNF blocker, vedolizumab), or tofacitinib. The 12-week intravenous induction study (UC-1) was followed by the 40-week subcutaneous randomized withdrawal maintenance study (UC-2).

Study UC-1

In UC-1, efficacy was evaluated in 1062 subjects who were randomized 3:1 at Week 0 to receive 300 mg mirikizumab-mrkz or placebo by intravenous infusion at Week 0, Week 4, and Week 8. Subjects had a mean age of 43 years (range 18 to 79

years); 40% were female; and 71% identified as White, 25% as Asian, 1% as American Indian or Alaska Native, 1% as Black or African American, and <2% as another racial group or did not report their racial group. Subjects were permitted to use stable doses of aminosalicylates, immunomodulators (6-mercaptopurine, azathioprine, methotrexate), and oral corticosteroids (prednisone ≤20 mg/day or equivalent, extended-release budesonide 9 mg/day, beclomethasone dipropionate 5 mg/day). At baseline, 41% of subjects were receiving oral corticosteroids, 24% were receiving immunomodulators, and 75% were receiving aminosalicylates.

At baseline, 57% were biologic and Janus Kinase inhibitor (JAKi) naive, 41% had failed at least one biologic, 3% had failed a JAKi, and 2% had previously received but had not failed a biologic or JAKi.

Disease activity was assessed based on the modified Mayo score (mMS), which ranges from 0 to 9 and has three subscores that are each scored from 0 (normal) to 3 (most severe): stool frequency, rectal bleeding, and findings on centrally read endoscopy subscore. At baseline, subjects had a mMS of 5 to 9, including a centrally read endoscopy subscore of 2 or 3. An endoscopy subscore of 2 was defined by marked erythema, absent vascular pattern, friability, and erosions; and a subscore of 3 was defined by spontaneous bleeding and ulceration. Subjects had a median mMS of 7, and 58% had severely active disease (mMS of 7 to 9).

The primary endpoint was clinical remission at Week 12. The secondary endpoints were clinical response, endoscopic improvement, and histologic-endoscopic mucosal improvement.

Study UC-1 was not designed to evaluate the relationship of histologic-endoscopic mucosal improvement at Week 12 to disease progression and long-term outcomes.

Rectal Bleeding and Stool Frequency Subscores

Decreases in rectal bleeding and stool frequency subscores were observed as early as Week 3 in subjects treated with OMVOH compared to subjects on placebo.

After 12 weeks of induction, 65% of patients achieved clinical response and 24% achieved clinical remission compared to placebo (43% and 15%, for clinical response and clinical remission, respectively). Decreases in rectal bleeding and stool frequency subscores were observed as early as week 3 in patients treated with mirikizumab compared to patients on placebo.

Study UC-2

The maintenance study (UC-2) evaluated 506 subjects who achieved clinical response at Week 12 in Study UC-1. These subjects were randomized 2:1 to receive 200 mg mirikizumab-mrkz or placebo subcutaneously every 4 weeks for 40 weeks in UC2, for a total of 52 weeks of treatment. Subjects who were on concomitant ulcerative colitis therapies during UC-1 were required to continue on stable doses of oral aminosalicylates and immunomodulators (6-mercaptopurine, azathioprine, methotrexate). Corticosteroid tapering was required for subjects who were receiving corticosteroids at baseline and achieved clinical response in UC-1.

The primary endpoint was clinical remission at Week 40. The secondary endpoints were endoscopic improvement,

maintenance of clinical remission in subjects who achieved clinical remission at Week 12, corticosteroid-free clinical remission, and histologic-endoscopic mucosal improvement.

Study UC-2 was not designed to evaluate the relationship of histologic-endoscopic mucosal improvement at Week 40 to disease progression and long-term outcomes.

Bowel Urgency
Bowel urgency was assessed during UC-1 and UC-2 with an Urgency Numeric Rating Scale (NRS) of 0 to 10. A greater proportion of subjects with a baseline Urgency NRS weekly average score ≥ 3 treated with OMVOH compared to placebo reported an Urgency NRS weekly average score of 0 or 1 (39% versus 23%) at Week 40. Urgency NRS weekly average scores of 0 to 1 were also observed in a greater proportion of subjects treated with OMVOH compared to placebo at Week 12.

Endoscopic Assessment
Normalization of the endoscopic appearance of the mucosa (endoscopic remission) was defined as a Mayo endoscopic subscore of 0. At Week 40 in UC-2, endoscopic remission was observed in a greater proportion of subjects treated with OMVOH compared to placebo (22% versus 14%).

Among those who achieved clinical response at 12 weeks, 51% of all patients and 45% of patients who failed prior treatment with a biologic or Janus kinase inhibitor achieved clinical remission at 52 weeks compared to placebo (27% and 15%, respectively). Of the patients who achieved clinical response at 12 weeks, 50% achieved steroid-free clinical remission at 52 weeks, compared to 27% of patients receiving placebo. Patients in steroid-free clinical remission were steroid-free for at least 12 weeks prior to the end of the 52-week assessment. Among patients who achieved clinical remission at 12 weeks, 66% of patients maintained clinical remission through 1 year of continuous treatment compared 40% of patients receiving placebo.

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. Omvoh [package insert]. Indianapolis, IN: Eli Lilly and Company; October 2023.
2. Feuerstein JD, Isaacs KL, Schneider Y, et al. AGA Clinical Practice Guidelines on the Management of Moderate to Severe Ulcerative Colitis. Gastroenterology. 2020 Jan 13.
3. Rubin DT, Ananthakrishnan AN, Siegel CA, et al. ACG Clinical Guideline: Ulcerative Colitis in Adults. Am J Gastroenterol. 2019 Mar;114(3):384-413.Yese.

Policy History/Revision Information

Date	Summary of Changes
TBD	New policy CSLA2024D00129A.

Instructions for Use

This Medical Benefit Drug Policy provides assistance in interpreting UnitedHealthcare standard benefit plans. When deciding coverage, the federal, state or contractual requirements for benefit plan coverage must be referenced as the terms of the federal, state or contractual requirements for benefit plan coverage may differ from the standard benefit plan. In the event of a conflict, the federal, state or contractual requirements for benefit plan coverage govern. Before using this policy, please check the federal, state or contractual requirements for benefit plan coverage. UnitedHealthcare 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.

UnitedHealthcare may also use tools developed by third parties, such as the InterQual® criteria, to assist us in administering health benefits. The UnitedHealthcare 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

Effective Date	Policy Number	Policy Title