Commercial PA Criteria

Effective: March 28, 2024

Prior Authorization: Omvoh

Products Affected: Omvoh (mirikizumab-mrkz) subcutaneous injection

Medication Description: Omvoh subcutaneous injection, a monoclonal antibody against the p19 subunit of the interleukin (IL)-23 cytokine, is indicated for the maintenance treatment of ulcerative colitis (UC), in adults with moderate to severe active disease.

Covered Uses:

1. Ulcerative colitis in adults with moderate to severe active disease

Exclusion Criteria:

1. Concurrent use with other Biologics or DMARD

Required Medical Information:

1. Diagnosis
2. Previous therapies tried/failed

Age Restrictions: 18 years of age or older

Prescriber Restrictions: Must be prescribed by, or in consultation with, a gastroenterologist.

Coverage Duration:

Initial: 6 Months
Continuation: 1 year

Other Criteria:

1. Ulcerative Colitis.

Initial Therapy. Approve if the patient meets the following criteria

A. According to the prescriber, the patient will receive three induction doses with Omvoh intravenous within 3 months of initiating therapy with Omvoh subcutaneous; **AND**

B. Patient meets ONE of the following (i **OR** ii):

i. Patient has had a trial of one systemic agent for ulcerative colitis: **OR**

Note: Examples include 6-mercaptopurine, azathioprine, cyclosporine, tacrolimus, or a corticosteroid such as prednisone, methylprednisolone. A trial of a mesalamine product does not count as a systemic therapy for ulcerative colitis. A trial of one biologic other than the requested drug also counts as a trial of one systemic agent for ulcerative colitis. A biosimilar of the requested biologic does not count.

ii. Patient meets BOTH of the following [(a) **AND** (b)]:

a. Patient has pouchitis; **AND**

b. Patient has tried an antibiotic, probiotic, corticosteroid enema, or mesalamine enema **AND**

Note: Examples of antibiotics include metronidazole and ciprofloxacin. Examples of corticosteroid enemas include hydrocortisone enema.

C. Patient must have a trial and documented failure of, or intolerance to **ONE** of the following products:

Ulcerative Colitis
Adalimumab Product
Stelara SC

Continuation

A. Patient meets all initial authorization criteria; **AND**
B. Patient achieves or maintains a positive clinical response after at least 6 months of therapy as evidenced by low disease activity or improvement in signs and symptoms of the condition **AND**
C. Member has not experienced unacceptable toxicity from the drug

References:

1. Omvoh injection [prescribing information]. Indianapolis, IN: Eli Lilly; October 2023.
2. Rubin DT, Ananthakrishnan AN, Siegel CA, et al. ACG clinical guideline: ulcerative colitis in adults. Am J Gastroenterol. 2019;114(3):384-413.
3. Feuerstein JD, Isaacs KL, Schneider Y, et al. AGA clinical practice guidelines on the management of moderate to severe ulcerative colitis. Gastroenterology. 2020 Apr158(5):1450-1461.

Policy Revision history

Rev #	Type of Change	Summary of Change	Sections Affected	Date
1	New Policy	New Policy	All	3/28/2024