



## PRIOR AUTHORIZATION POLICY

**POLICY:** Inflammatory Conditions – Omvoh Subcutaneous Prior Authorization Policy

- Omvoh® (mirikizumab-mrkz subcutaneous injection – Eli Lilly)

**REVIEW DATE:** 12/04/2024; selected revision 01/22/2025

### INSTRUCTIONS FOR USE

THE FOLLOWING COVERAGE POLICY APPLIES TO HEALTH BENEFIT PLANS ADMINISTERED BY CIGNA COMPANIES. CERTAIN CIGNA COMPANIES AND/OR LINES OF BUSINESS ONLY PROVIDE UTILIZATION REVIEW SERVICES TO CLIENTS AND DO NOT MAKE COVERAGE DETERMINATIONS. REFERENCES TO STANDARD BENEFIT PLAN LANGUAGE AND COVERAGE DETERMINATIONS DO NOT APPLY TO THOSE CLIENTS. COVERAGE POLICIES ARE INTENDED TO PROVIDE GUIDANCE IN INTERPRETING CERTAIN STANDARD BENEFIT PLANS ADMINISTERED BY CIGNA COMPANIES. PLEASE NOTE, THE TERMS OF A CUSTOMER'S PARTICULAR BENEFIT PLAN DOCUMENT [GROUP SERVICE AGREEMENT, EVIDENCE OF COVERAGE, CERTIFICATE OF COVERAGE, SUMMARY PLAN DESCRIPTION (SPD) OR SIMILAR PLAN DOCUMENT] MAY DIFFER SIGNIFICANTLY FROM THE STANDARD BENEFIT PLANS UPON WHICH THESE COVERAGE POLICIES ARE BASED. FOR EXAMPLE, A CUSTOMER'S BENEFIT PLAN DOCUMENT MAY CONTAIN A SPECIFIC EXCLUSION RELATED TO A TOPIC ADDRESSED IN A COVERAGE POLICY. IN THE EVENT OF A CONFLICT, A CUSTOMER'S BENEFIT PLAN DOCUMENT ALWAYS SUPERSEDES THE INFORMATION IN THE COVERAGE POLICIES. IN THE ABSENCE OF A CONTROLLING FEDERAL OR STATE COVERAGE MANDATE, BENEFITS ARE ULTIMATELY DETERMINED BY THE TERMS OF THE APPLICABLE BENEFIT PLAN DOCUMENT. COVERAGE DETERMINATIONS IN EACH SPECIFIC INSTANCE REQUIRE CONSIDERATION OF 1) THE TERMS OF THE APPLICABLE BENEFIT PLAN DOCUMENT IN EFFECT ON THE DATE OF SERVICE; 2) ANY APPLICABLE LAWS/REGULATIONS; 3) ANY RELEVANT COLLATERAL SOURCE MATERIALS INCLUDING COVERAGE POLICIES AND; 4) THE SPECIFIC FACTS OF THE PARTICULAR SITUATION. EACH COVERAGE REQUEST SHOULD BE REVIEWED ON ITS OWN MERITS. MEDICAL DIRECTORS ARE EXPECTED TO EXERCISE CLINICAL JUDGMENT AND HAVE DISCRETION IN MAKING INDIVIDUAL COVERAGE DETERMINATIONS. COVERAGE POLICIES RELATE EXCLUSIVELY TO THE ADMINISTRATION OF HEALTH BENEFIT PLANS. COVERAGE POLICIES ARE NOT RECOMMENDATIONS FOR TREATMENT AND SHOULD NEVER BE USED AS TREATMENT GUIDELINES. IN CERTAIN MARKETS, DELEGATED VENDOR GUIDELINES MAY BE USED TO SUPPORT MEDICAL NECESSITY AND OTHER COVERAGE DETERMINATIONS.

## CIGNA NATIONAL FORMULARY COVERAGE:

### OVERVIEW

Omvoh subcutaneous (SC) injection, a monoclonal antibody against the p19 subunit of the interleukin (IL)-23 cytokine, is indicated for the **maintenance treatment of:**<sup>1</sup>

- **Crohn's disease**, in adults with moderate to severe active disease; AND
- **Ulcerative colitis**, in adults with moderate to severe active disease.

Omvoh is also available in an intravenous (IV) formulation that is dually indicated as induction therapy in Crohn's disease and ulcerative colitis. It is given as an IV infusion at Weeks 0, 4, and 8, followed by Omvoh SC once every 8 weeks thereafter for maintenance.<sup>1</sup>

### Guidelines

- **Crohn's Disease:** Omvoh is not addressed in current guidelines. The American College of Gastroenterology (ACG) has guidelines for Crohn's disease (2018).<sup>2</sup> Biologics are a treatment option in patients who have moderate to severe disease despite treatment with another agent (e.g., corticosteroid, thiopurine, methotrexate, or tumor necrosis factor inhibitors). Guidelines from the American Gastroenterological Association (AGA 2021)

include biologics among the therapies for moderate to severe Crohn's disease, for induction and maintenance of remission.<sup>3</sup>

- **Ulcerative colitis:** The AGA (2024) and ACG (2019) have clinical practice guidelines on the management of moderate to severe ulcerative colitis in adults.<sup>4,5</sup> AGA recognizes all of the FDA-approved advanced therapies as potential options for adults with moderate to severe UC.<sup>4</sup> Advanced therapies include the biologics and targeted synthetic small molecule drugs. In general, the AGA recommends starting with advanced therapies and/or immunomodulators. Immunomodulators are recommended in the setting of maintenance of clinical remission induced by corticosteroids. The ACG recommend TNF inhibitors, Entyvio® (vedolizumab IV infusion/subcutaneous injection), Stelara® (ustekinumab IV infusion/subcutaneous injection), or Xeljanz®/Xeljanz® XR (tofacitinib tablets, tofacitinib extended-release tablets) for induction treatment of moderate to severe disease.<sup>5</sup> The guidelines also recommend that any drug that effectively treats induction should be continued for maintenance.

## **POLICY STATEMENT**

Prior Authorization is recommended for prescription benefit coverage of Omvoh subcutaneous. All approvals are provided for the duration noted below. In cases where the approval is authorized in months, 1 month is equal to 30 days. Because of the specialized skills required for evaluation and diagnosis of patients treated with Omvoh subcutaneous as well as the monitoring required for adverse events and long-term efficacy, approval requires Omvoh subcutaneous to be prescribed by or in consultation with a physician who specializes in the condition being treated.

- **Omvoh® (mirikizumab-mrkz subcutaneous injection – Eli Lilly)**  
**is(are) covered as medically necessary when the following criteria is(are) met for FDA-approved indication(s) or other uses with supportive evidence (if applicable):**

## **FDA-Approved Indications**

1. **Crohn's Disease.** Approve for the duration noted if the patient meets ONE of the following (A or B):
  - A) **Initial Therapy.** Approve for 6 months if the patient meets ALL of the following (i, ii, iii, and iv):
    - i. Patient is  $\geq$  18 years of age; AND
    - ii. According to the prescriber, the patient will receive induction dosing with Omvoh intravenous within 3 months of initiating therapy with Omvoh subcutaneous; AND
    - iii. Patient meets ONE of the following (a, b, c, or d):
      - a) Patient has tried or is currently taking corticosteroids, or corticosteroids are contraindicated in this patient; OR

Note: Examples of corticosteroids are prednisone or methylprednisolone.

- b)** Patient has tried one other conventional systemic therapy for Crohn's disease; OR

Note: Examples of conventional systemic therapy for Crohn's disease include azathioprine, 6-mercaptopurine, or methotrexate. An exception to the requirement for a trial of or contraindication to steroids or a trial of one other conventional systemic agent can be made if the patient has already tried at least one biologic other than the requested medication. A biosimilar of the requested biologic does not count. Refer to [Appendix](#) for examples of biologics used for Crohn's disease. A trial of mesalamine does not count as a systemic agent for Crohn's disease.

- c)** Patient has enterocutaneous (perianal or abdominal) or rectovaginal fistulas; OR

- d)** Patient had ileocolonic resection (to reduce the chance of Crohn's disease recurrence); AND

- iv.** The medication is prescribed by or in consultation with a gastroenterologist; OR

- B) Patient is Currently Receiving Omvoh Subcutaneous.** Approve for 1 year if the patient meets BOTH of the following (i and ii):

- i.** Patient has been established on therapy for at least 6 months; AND

Note: A patient who has received < 6 months of therapy or who is restarting therapy is reviewed under criterion A (Initial Therapy).

- ii.** Patient meets at least ONE of the following (a or b):

- a)** When assessed by at least one objective measure, patient experienced a beneficial clinical response from baseline (prior to initiating Omvoh); OR

Note: Examples of objective measures include fecal markers (e.g., fecal lactoferrin, fecal calprotectin), serum markers (e.g., C-reactive protein), imaging studies (magnetic resonance enterography, computed tomography enterography), endoscopic assessment, and/or reduced dose of corticosteroids.

- b)** Compared with baseline (prior to initiating Omvoh), patient experienced an improvement in at least one symptom, such as decreased pain, fatigue, stool frequency, and/or blood in stool.

- 2. Ulcerative Colitis.** Approve for the duration noted if the patient meets ONE of the following (A or B):

- A) Initial Therapy.** Approve for 6 months if the patient meets ALL of the following (i, ii, iii, and iv):

- i.** Patient is  $\geq 18$  years of age; AND

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

- iii.** Patient meets ONE of the following (a or b):

- a)** 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. Refer to [Appendix](#) for examples of biologics used for ulcerative colitis.

**b)** Patient meets BOTH of the following [(1) and (2)]:

**(1)** Patient has pouchitis; AND

**(2)** 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.

**iv.** The medication is prescribed by or in consultation with a gastroenterologist; OR

**B)** Patient is Currently Receiving Omvoh Subcutaneous. Approve for 1 year if the patient meets BOTH of the following (i and ii):

**i.** Patient has been established on the requested drug for at least 6 months; AND

Note: A patient who has received < 6 months of therapy or who is restarting therapy with the requested drug is reviewed under criterion A (Initial Therapy).

**ii.** Patient meets at least ONE of the following (a or b):

**a)** When assessed by at least one objective measure, patient experienced a beneficial clinical response from baseline (prior to initiating the requested drug); OR

Note: Examples of assessment for inflammatory response include fecal markers (e.g., fecal calprotectin), serum markers (e.g., C-reactive protein), endoscopic assessment, and/or reduced dose of corticosteroids.

**b)** Compared with baseline (prior to initiating the requested drug), patient experienced an improvement in at least one symptom, such as decreased pain, fatigue, stool frequency, and/or decreased rectal bleeding.

## **CONDITIONS NOT COVERED**

• **Omvoh® (mirikizumab-mrkz subcutaneous injection – Eli Lilly) is(are) considered experimental, investigational or unproven for ANY other use(s) including the following (this list may not be all inclusive; criteria will be updated as new published data are available):**

**1. Concurrent Use with a Biologic or with a Targeted Synthetic Oral Small Molecule Drug.** This medication should not be administered in combination with another biologic or with a targeted synthetic oral small molecule drug used

for an inflammatory condition (see [Appendix](#) for examples). Combination therapy is generally not recommended due to a potentially higher rate of adverse events and lack of controlled clinical data supporting additive efficacy. Note: This does NOT exclude the use of conventional synthetic disease-modifying antirheumatic drugs (e.g., methotrexate, leflunomide, hydroxychloroquine, or sulfasalazine) in combination with this medication.

## REFERENCES

1. Omvoh® intravenous infusion, subcutaneous injection [prescribing information]. Indianapolis, IN: Eli Lilly; January 2025.
2. Lichtenstein GR, Loftus EV, Isaacs KL, et al. ACG clinical guideline: management of Crohn's disease in adults. *Am J Gastroenterol*. 2018;113(4):481-517.
3. Feuerstein JD, Ho EY, Shmidt E, et al. AGA clinical practice guidelines on the medical management of moderate to severe luminal and perianal fistulizing Crohn's disease. *Gastroenterology*. 2021;160(7):2496-2508.
4. 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.
5. Rubin DT, Ananthakrishnan AN, Siegel CA, et al. ACG clinical guideline: ulcerative colitis in adults. *Am J Gastroenterol*. 2019;114(3):384-413.

## HISTORY

| Type of Revision  | Summary of Changes   | Review Date |
|-------------------|--|-------------|
| New Policy        | -  | 11/08/2023  |
| Update            | 11/14/2023: No criteria changes. Added Note stating trial of a mesalamine product does not count as systemic therapy.  | NA          |
| Selected Revision | <b>Conditions Not Covered:</b> Concurrent use with a Biologic or with a Targeted Synthetic Oral Small Molecule Drug was changed to as listed (previously oral small molecule drug was listed as Disease-Modifying Antirheumatic Drug). | 09/11/2024  |
| Annual Revision   | No criteria changes.   | 12/04/2024  |
| Selected Revision | <b>Crohn's disease:</b> This newly approved condition was added to the policy.   | 01/22/2025  |

## APPENDIX

|  | Mechanism of Action              | Examples of Indications*                    |
|--|----------------------------------|---|
| Biologics  |                                  |   |
| Adalimumab SC Products (Humira®, biosimilars)                            | Inhibition of TNF                | AS, CD, JIA, PsO, PsA, RA, UC               |
| Cimzia® (certolizumab pegol SC injection)                                | Inhibition of TNF                | AS, CD, nr-axSpA, PsO, PsA, RA              |
| Etanercept SC Products (Enbrel®, biosimilars)                            | Inhibition of TNF                | AS, JIA, PsO, PsA, RA                       |
| Infliximab IV Products (Remicade®, biosimilars)                          | Inhibition of TNF                | AS, CD, PsO, PsA, RA, UC                    |
| Zymfentra® (infliximab-dyyb SC injection)                                | Inhibition of TNF                | CD, UC                                      |
| Simponi®, Simponi Aria® (golimumab SC injection, golimumab IV infusion)  | Inhibition of TNF                | SC formulation: AS, PsA, RA, UC             |
|  |                                  | IV formulation: AS, PJIA, PsA, RA           |
| Tocilizumab Products (Actemra® IV, biosimilar; Actemra SC, biosimilar)   | Inhibition of IL-6               | SC formulation: PJIA, RA, SJIA              |
|  |                                  | IV formulation: PJIA, RA, SJIA              |
| Kevzara® (sarilumab SC injection)  | Inhibition of IL-6               | RA  |
| Orencia® (abatacept IV infusion, abatacept SC injection)                 | T-cell costimulation modulator   | SC formulation: JIA, PSA, RA                |
|  |                                  | IV formulation: JIA, PsA, RA                |
| Rituximab IV Products (Rituxan®, biosimilars)                            | CD20-directed cytolytic antibody | RA  |
| Kineret® (anakinra SC injection)   | Inhibition of IL-1               | JIA^, RA                                    |
| Omvoh® (mirikizumab IV infusion, SC injection)                           | Inhibition of IL-23              | CD, UC                                      |
| Ustekinumab Products (Stelara® IV, biosimilar; Stelara SC, biosimilar)   | Inhibition of IL-12/23           | SC formulation: CD, PsO, PsA, UC            |
|  |                                  | IV formulation: CD, UC                      |
| Siliq® (brodalumab SC injection)   | Inhibition of IL-17              | PsO   |
| Cosentyx® (secukinumab SC injection; secukinumab IV infusion)            | Inhibition of IL-17A             | SC formulation: AS, ERA, nr-axSpA, PsO, PsA |
|  |                                  | IV formulation: AS, nr-axSpA, PsA           |
| Taltz® (ixekizumab SC injection)   | Inhibition of IL-17A             | AS, nr-axSpA, PsO, PsA                      |
| Bimzelx® (bimekizumab-bkzx SC injection)                                 | Inhibition of IL-17A/17F         | PsO, AS, nr-axSpA, PsA                      |
| Ilumya® (tildrakizumab-asmn SC injection)                                | Inhibition of IL-23              | PsO   |
| Skyrizi® (risankizumab-rzaa SC injection, risankizumab-rzaa IV infusion) | Inhibition of IL-23              | SC formulation: CD, PSA, PsO, UC            |
|  |                                  | IV formulation: CD, UC                      |
| Tremfya® (guselkumab SC injection, guselkumab IV infusion)               | Inhibition of IL-23              | SC formulation: PsA, PsO, UC                |
| Entyvio® (vedolizumab IV infusion, vedolizumab SC injection)             | Integrin receptor antagonist     | IV formulation: UC                          |
|  |                                  | CD, UC                                      |
| Oral Therapies/Targeted Synthetic Oral Small Molecule Drugs              |                                  |   |
| Otezla® (apremilast tablets)   | Inhibition of PDE4               | PsO, PsA                                    |
| Cibinqo™ (abrocitinib tablets)   | Inhibition of JAK pathways       | AD  |
| Olumiant® (baricitinib tablets)  | Inhibition of JAK pathways       | RA, AA                                      |
| Litfulo® (ritlecitinib capsules)   | Inhibition of JAK pathways       | AA  |

|   |  |                               |
|---|--|-------------------------------|
| <b>Leqselvi®</b> (deuruxolitinib tablets)                 | Inhibition of JAK pathways                 | AA                            |
| <b>Rinvoq®</b> (upadacitinib extended-release tablets)    | Inhibition of JAK pathways                 | AD, AS, nr-axSpA, RA, PsA, UC |
| <b>Rinvoq® LQ</b> (upadacitinib oral solution)            | Inhibition of JAK pathways                 | PsA, PJIA                     |
| <b>Sotyktu®</b> (deucravacitinib tablets)                 | Inhibition of TYK2                         | PsO                           |
| <b>Xeljanz®</b> (tofacitinib tablets/oral solution)       | Inhibition of JAK pathways                 | RA, PJIA, PsA, UC             |
| <b>Xeljanz® XR</b> (tofacitinib extended-release tablets) | Inhibition of JAK pathways                 | RA, PsA, UC                   |
| <b>Zeposia®</b> (ozanimod tablets)                        | Sphingosine 1 phosphate receptor modulator | UC                            |
| <b>Velsipity®</b> (etrasimod tablets)                     | Sphingosine 1 phosphate receptor modulator | UC                            |

\* Not an all-inclusive list of indications. Refer to the prescribing information for the respective agent for FDA-approved indications; SC – Subcutaneous; TNF – Tumor necrosis factor; AS – Ankylosing spondylitis; CD – Crohn’s disease; JIA – Juvenile idiopathic arthritis; PsO – Plaque psoriasis; PsA – Psoriatic arthritis; RA – Rheumatoid arthritis; UC – Ulcerative colitis; nr-axSpA – Non-radiographic axial spondyloarthritis; IV – Intravenous, PJIA – Polyarticular juvenile idiopathic arthritis; IL – Interleukin; SJIA – Systemic juvenile idiopathic arthritis; ^ Off-label use of Kineret in JIA supported in guidelines; ERA – Enthesitis-related arthritis; DMARD – Disease-modifying antirheumatic drug; PDE4 – Phosphodiesterase 4; JAK – Janus kinase; AD – Atopic dermatitis; AA – Alopecia areata; TYK2 – Tyrosine kinase 2.

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