Utilization Review Policy 330

POLICY: Inflammatory Conditions – Omvoh Intravenous Utilization Management Medical Policy
- Omvoh® (mirikizumab-mrkz intravenous infusion – Eli Lilly)

EFFECTIVE DATE: 3/15/2024
LAST REVISION DATE: 01/22/2025

COVERAGE CRITERIA FOR: All UCare Plans

OVERVIEW

Omvoh intravenous, a monoclonal antibody against the p19 subunit of the interleukin (IL)-23 cytokine, is indicated for the **induction treatment of**:[1]

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

Dosing

Crohn's disease

In Crohn's disease, a three-dose induction regimen (900 mg at Weeks 0, 4, and 8) is administered by intravenous (IV) infusion.[1] Following induction therapy with the IV product, the recommended maintenance dose is Omvoh 300 mg administered as a subcutaneous injection at Week 12 (4 weeks following the last induction dose), then once every 8 weeks thereafter.

Ulcerative colitis

In ulcerative colitis, a three-dose induction regimen (300 mg at Weeks 0, 4, and 8) is administered by intravenous (IV) infusion.[1] Following induction therapy with the IV product, the recommended maintenance dose is Omvoh 200 mg administered as a subcutaneous injection at Week 12 (4 weeks following the last induction dose), then once every 4 weeks thereafter.

Guidelines

The following guidelines address indications for which Omvoh IV is indicated.

- **Crohn's Disease:** Omvoh is not addressed in current guidelines. The American College of Gastroenterology (ACG) has guidelines for Crohn's disease (2018).[2] 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.[3]
- **Ulcerative colitis:** The AGA (2024) and ACG (2019) have clinical practice guidelines on the management of moderate to severe ulcerative colitis in adults.[4,5] AGA recognizes all of the FDA-approved advanced therapies as potential options for adults with moderate to severe UC.[4] 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.[5] The guidelines also recommend that any drug that effectively treats induction should be continued for maintenance.

POLICY STATEMENT

Prior Authorization is recommended for medical benefit coverage of Omvoh IV. Approval is recommended for those who meet the **Criteria** and **Dosing** for the listed indications. Extended approvals are allowed if the patient continues to meet the Criteria and Dosing. Requests for doses outside of the established dosing documented in this policy will be considered on a case-by-case basis by a clinician (i.e., Medical Director or Pharmacist). Because of the specialized skills required for evaluation and diagnosis of patients treated with Omvoh as well as the monitoring required for adverse events and long-term efficacy, initial approval requires Omvoh IV to be prescribed by or in consultation with a physician who specializes in the condition being treated. All approvals are provided for three months, which is an adequate duration for the patient to receive three doses.

Automation: None.

RECOMMENDED AUTHORIZATION CRITERIA

Coverage of Omvoh intravenous is recommended in those who meet one of the following criteria:

FDA-Approved Indications

1. **Crohn's Disease**. Approve three doses for induction if the patient meets ALL of the following (A, B, C, and D):
   - **A)** Patient is ≥ 18 years of age; AND
   - **B)** The medication will be used as induction therapy; AND
   - **C)** Patient meets ONE of the following (i, ii, iii, or iv):
     - **i.** Patient has tried or is currently taking a systemic corticosteroid, or a systemic corticosteroid is contraindicated in this patient; OR
     - **ii.** 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.
     - **iii.** Patient has enterocutaneous (perianal or abdominal) or rectovaginal fistulas; OR
     - **iv.** Patient had ileocolonic resection (to reduce the chance of Crohn's disease recurrence); AND
   - **D)** The medication is prescribed by or in consultation with a gastroenterologist.

   Dosing: Approve 900 mg as an intravenous infusion administered at Weeks 0, 4, and 8.

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2. **Ulcerative Colitis.** Approve three doses for induction if the patient meets ALL of the following (A, B, C, and D):
   - **A)** Patient is ≥ 18 years of age; AND
   - **B)** The medication will be used as induction therapy; AND
   - **C)** Patient meets ONE of the following (i or ii):
     - **i.** Patient has tried one systemic therapy; OR

Note: Examples include 6-mercaptopurine, azathioprine, cyclosporine, tacrolimus, or a corticosteroid such as prednisone or 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 medication 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.

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.

D) The medication is prescribed by or in consultation with a gastroenterologist.

Dosing: Approve 300 mg as an intravenous infusion administered at Weeks 0, 4, and 8.

CONDITIONS NOT RECOMMENDED FOR APPROVAL

Coverage of Omvoh intravenous is not recommended in the following situations:

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 DMARDs (e.g., methotrexate, leflunomide, hydroxychloroquine, or sulfasalazine) in combination with this medication.

2. Coverage is not recommended for circumstances not listed in the Recommended Authorization Criteria. Criteria will be updated as new published data are available.

REFERENCES

1. Omvoh® intravenous infusion, subcutaneous injection [prescribing information]. Indianapolis, IN: Eli Lilly; April 2024.
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	Conditions Not Recommended for Approval: 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
UCare P&T Review	Policy reviewed and approved by UCare P&T committee. Annual review process	09/16/2024
Annual Revision	No criteria changes.	12/04/2024
Selected Revision	**Crohn's disease:** 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
		IV formulation: UC
Entyvio® (vedolizumab IV infusion, vedolizumab SC injection)	Integrin receptor antagonist	CD, UC

APPENDIX (CONTINUED)

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