Drug Coverage Policy

Effective Date.....4/15/2024
Coverage Policy Number.....IP0602
Policy Title.....Omvoh Subcutaneous

Inflammatory Conditions – Omvoh Subcutaneous

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

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 patient 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 Healthcare Coverage Policy

OVERVIEW
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.[1]

In UC, a three-dose induction regimen (300 mg at Weeks 0, 4, and 8) is administered by IV infusion.[1] Following induction therapy with the IV product, the recommended maintenance is

Omvoh subcutaneous injection, given as a 200 mg subcutaneous injection administered at Week 12 (4 weeks following the last induction dose), then once every 4 weeks thereafter.

Guidelines
Current guidelines do not address the use of Omvoh for UC. The American Gastroenterological Association (2020) and the American College of Gastroenterology (2019) have clinical practice guidelines on the management of moderate to severe UC and make recommendations for the use of biologics for induction and maintenance of remission in adults.[2,3] Generally TNF inhibitors, Entyvio® (vedolizumab intravenous infusion/subcutaneous injection), Stelara® (ustekinumab intravenous infusion/subcutaneous injection), or Xeljanz®/Xeljanz® XR (tofacitinib tablets, tofacitinib extended-release tablets) are recommended for induction treatment of moderate to severe disease (strong recommendations, moderate quality of evidence). The guidelines also recommend that any drug that effectively treats induction should be continued for maintenance.

Medical Necessity Criteria

Omvoh subcutaneous is considered medically necessary when the following criteria is met:

1. **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, iv and v):
     - **i.** Patient is ≥ 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 failure, contraindication, or intolerance to 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; AND
     - **v.** Preferred product criteria is met for the product(s) as listed in the below table(s) - **Ulcerative Colitis (Maintenance Therapy) – Initial Therapy**.

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

iii. Preferred product criteria is met for the product(s) as listed in the below table(s) - **Ulcerative Colitis (Maintenance Therapy) – Patient is Currently Receiving Omvoh Subcutaneous**

Employer Plans:

Product	Criteria
Omvoh subcutaneous (mirikizumab-mrkz subcutaneous injection)	**Ulcerative Colitis (Maintenance Therapy) – Initial Therapy.** Patient meets ONE of the following (1 or 2): **1.** Failure, contraindication, or intolerance to ONE of the following (A or B): **Standard/Performance/Legacy Drug List Plans** **A.** Adalimumab Product (Adalimumab-adaz/Hyrimoz [by Sandoz/Novartis], Adalimumab – adbm/Cyltezo, or Humira) [requires prior authorization] **B.** Stelara SC [requires prior authorization] **Value/Advantage/Total Savings Drug List Plans** **A.** Adalimumab Product (Adalimumab-adaz/Hyrimoz [by Sandoz/Novartis], Adalimumab – adbm/Cyltezo, Hadlima, or Humira) [requires prior authorization] **B.** Stelara SC [requires prior authorization] Note: Examples of adalimumab products include Humira, Abrilada, adalimumab-aacf, adalimumab-adaz, adalimumab-adbm, adalimumab-fkjp, Amjevita, Cyltezo, Hadlima, Hulio, Hyrimoz, Idacio, Yuflyma, and Yusimry. A trial of an infliximab product (e.g., Remicade, biosimilars; Zymfentra), Simponi subcutaneous, or Stelara intravenous also counts. **2.** According to the prescriber, the patient has already started on or is currently undergoing induction therapy with Omvoh intravenous. **Ulcerative Colitis (Maintenance Therapy) – Patient is Currently Receiving Omvoh Subcutaneous** Patient meets ONE of the following (1 or 2): **1.** Failure, contraindication, or intolerance to ONE of the following (A or B): **Standard/Performance/Legacy Drug List Plans** **A.** Adalimumab Product (Adalimumab-adaz/Hyrimoz [by Sandoz/Novartis], Adalimumab – adbm/Cyltezo, or Humira) [requires prior authorization] **B.** Stelara SC [requires prior authorization]

Product	Criteria
	Value/Advantage/Total Savings Drug List Plans **A.** Adalimumab Product (Adalimumab-adaz/Hyrimoz [by Sandoz/Novartis], Adalimumab – adbm/Cyltezo, Hadlima, or Humira) [requires prior authorization] **B.** Stelara SC [requires prior authorization] Note: Examples of adalimumab products include Humira, Abrilada, adalimumab-aacf, adalimumab-adaz, adalimumab-adbm, adalimumab-fkjp, Amjevita, Cyltezo, Hadlima, Hulio, Hyrimoz, Idacio, Yuflyma, and Yusimry. A trial of an infliximab product (e.g., Remicade, biosimilars; Zymfentra), Simponi subcutaneous, or Stelara intravenous also counts. **2.** Patient has been established on Omvoh subcutaneous for at least 90 days and prescription claims history indicates at least a 90-day supply of Omvoh subcutaneous was dispensed within the past 130 days, or if claims history is not available, according to the prescriber. Note: In cases where 130 days of the patient's prescription claim history file is unavailable to be verified, an exception to this requirement is allowed if the prescriber has verified that the patient has been receiving Omvoh subcutaneous for at least 90 days AND the patient has been receiving Omvoh subcutaneous via paid claims (e.g., patient has not been receiving samples or coupons or other types of waivers in order to obtain access to Omvoh subcutaneous).

Individual and Family Plans:

Product	Criteria
Omvoh subcutaneous (mirikizumab-mrkz subcutaneous injection)	**Ulcerative Colitis (Maintenance Therapy) – Initial Therapy.** Patient meets ONE of the following (1 or 2): **1.** Failure, contraindication, or intolerance to ONE of the following (A or B): **A.** Adalimumab Product (Adalimumab-adaz/Hyrimoz [by Sandoz/Novartis], Adalimumab – adbm/Cyltezo, Hadlima, or Humira) [requires prior authorization] **B.** Stelara SC [requires prior authorization] Note: Examples of adalimumab products include Humira, Abrilada, adalimumab-aacf, adalimumab-adaz, adalimumab-adbm, adalimumab-fkjp, Amjevita, Cyltezo, Hadlima, Hulio, Hyrimoz, Idacio, Yuflyma, and Yusimry. A trial of an infliximab product (e.g., Remicade, biosimilars; Zymfentra), Simponi subcutaneous, or Stelara intravenous also counts. **2.** According to the prescriber, the patient has already started on or is currently undergoing induction therapy with Omvoh intravenous.

Product	Criteria
	Ulcerative Colitis (Maintenance Therapy) – Patient is Currently Receiving Omvoh Subcutaneous Patient meets ONE of the following (1 or 2): **1.** Failure, contraindication, or intolerance to ONE of the following (A or B): **A.** Adalimumab Product (Adalimumab-adaz/Hyrimoz [by Sandoz/Novartis], Adalimumab – adbm/Cyltezo, Hadlima, or Humira) [requires prior authorization] **B.** Stelara SC [requires prior authorization] Note: Examples of adalimumab products include Humira, Abrilada, adalimumab-aacf, adalimumab-adaz, adalimumab-adbm, adalimumab-fkjp, Amjevita, Cyltezo, Hadlima, Hulio, Hyrimoz, Idacio, Yuflyma, and Yusimry. A trial of an infliximab product (e.g., Remicade, biosimilars; Zymfentra), Simponi subcutaneous, or Stelara intravenous also counts. **2.** Patient has been established on Omvoh subcutaneous for at least 90 days and prescription claims history indicates at least a 90-day supply of Omvoh subcutaneous was dispensed within the past 130 days, or if claims history is not available, according to the prescriber. Note: In cases where 130 days of the patient's prescription claim history file is unavailable to be verified, an exception to this requirement is allowed if the prescriber has verified that the patient has been receiving Omvoh subcutaneous for at least 90 days AND the patient has been receiving Omvoh subcutaneous via paid claims (e.g., patient has not been receiving samples or coupons or other types of waivers in order to obtain access to Omvoh subcutaneous).

When coverage is available and medically necessary, the dosage, frequency, duration of therapy, and site of care should be reasonable, clinically appropriate, and supported by evidence-based literature and adjusted based upon severity, alternative available treatments, and previous response to therapy.

Receipt of sample product does not satisfy any criteria requirements for coverage.

Conditions Not Covered

Any other use is considered experimental, investigational or unproven, including the following (this list may not be all inclusive):

1. **Concurrent Use with a Biologic or with a Targeted Synthetic Disease-Modifying Antirheumatic Drug (DMARD).** Omvoh should not be administered in combination with another biologic or with a targeted synthetic DMARD for an inflammatory condition (see Appendix for examples). Data are lacking evaluating concomitant use of Omvoh with another biologic or with a targeted synthetic DMARD for an inflammatory condition (see Appendix for examples). Combination therapy is generally not recommended due to a potential for a higher rate of adverse effects and lack of controlled data supporting additive efficacy. Note:

This does NOT exclude the use of conventional agents (e.g., methotrexate, 6-mercaptopurine, azathioprine, and sulfasalazine) in combination with Omvoh.

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.

Revision Details

Type of Revision	Summary of Changes	Date
New	New policy	4/15/2024

The policy effective date is in force until updated or retired.

APPENDIX

	Mechanism of Action	Examples of Inflammatory 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
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
Actemra® (tocilizumab IV infusion, tocilizumab SC injection)	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

Stelara® (ustekinumab SC injection, ustekinumab IV infusion)	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)	Inhibition of IL-17A	AS, ERA, nr-axSpA, PsO, PsA
Taltz® (ixekizumab SC injection)	Inhibition of IL-17A	AS, nr-axSpA, PsO, 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
		IV formulation: CD
Tremfya™ (guselkumab SC injection)	Inhibition of IL-23	PsO
Entyvio™ (vedolizumab IV infusion, vedolizimab SC injection)	Integrin receptor antagonist	SC: UC
		IV: CD, UC
Oral Therapies/Targeted Synthetic DMARDs		
Otezla® (apremilast tablets)	Inhibition of PDE4	PsO, PsA
Cibinqo™ (abrocitinib tablets)	Inhibition of JAK pathways	AD
Olumiant® (baricitinib tablets)	Inhibition of JAK pathways	RA
Rinvoq® (upadacitinib extended-release tablets)	Inhibition of JAK pathways	AD, AS, nr-axSpA, RA, PsA, UC
Sotyktu™ (deucravacitinib tablets)	Inhibition of TYK2	PsO
Xeljanz® (tofacitinib tablets)	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 (e.g., oncology indications and rare inflammatory conditions are not listed). 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; TYK2 – Tyrosine kinase 2.