Drug Coverage Policy

Effective Date……01/15/2025
Coverage Policy Number……PSM019
Policy Title……Omvoh Intravenous Preferred Specialty Management Policy: Legacy Prescription Drug Lists

Inflammatory Conditions – Omvoh Intravenous Preferred Specialty Management Policy: Legacy Prescription Drug Lists

- Omvoh® (mirikizumab-mrkz intravenous infusion – 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 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 Healthcare Coverage Policy

OVERVIEW

Several products are available for use in inflammatory conditions such as ulcerative colitis.[1-4] This policy involves the use of Omvoh intravenous.

Medical Necessity Criteria

Policy Statement

For all medications, this program requires the patient to meet the respective standard *Prior Authorization Policy* criteria. Additionally, this program requires trial(s) of the Preferred Product(s) according to the table below, when clinically appropriate, prior to the approval of the Non-Preferred Products. There are also situations when trials of Non-Preferred Products will be considered; see criteria below.

Preferred and Non-Preferred Products.

	Gastroenterology
	Ulcerative Colitis
Step 1 **Preferred**	• Adalimumab Products – Humira (NDCs starting with 00074), Cyltezo/adalimumab-adbm, adalimumab-adaz, Simlandi/ adalimumab-ryvk • Skyrizi IV • Stelara IV • Tremfya IV • Infliximab IV Products – (Avsola, Inflectra) • Entyvio IV
Step 2 **Non-Preferred** (directed to **ONE** Step 1 agent)	• Omvoh Intravenous

Omvoh intravenous is considered medically necessary when the following non-preferred product exception criteria is met. Any other exception is considered not medically necessary.

NON-PREFERRED PRODUCT EXCEPTION CRITERIA

Non-Preferred Products	Exception Criteria
Omvoh Intravenous	**1. Ulcerative Colitis – Induction Therapy.** **A)** Approve for three doses for induction if the patient meets BOTH of the following (i and ii): **i.** Patient meets the standard *Inflammatory Conditions – Omvoh Intravenous Prior Authorization Policy* criteria; AND **ii.** Patient meets ONE of the following (a or b): **a)** Patient has tried one of an adalimumab product, Skyrizi intravenous, Stelara intravenous, Tremfya intravenous,

	Entyvio intravenous, or an infliximab intravenous product; OR Note: Examples of adalimumab products include Humira, Abrilada, adalimumab-aacf, adalimumab-adaz, adalimumab-adbm, adalimumab-fkjp, adalimumab-aaty, adalimumab-ryvk, Simlandi, Amjevita, Cyltezo, Hadlima, Hulio, Hyrimoz, Idacio, Yuflyma, and Yusimry. A trial of multiple adalimumab products counts as **ONE** product. Examples of infliximab intravenous products include Avsola, Inflectra, infliximab intravenous infusion, Remicade, and Renflexis. A trial of multiple infliximab products counts as **ONE** product. Simponi subcutaneous, Entyvio subcutaneous, Skyrizi subcutaneous, Stelara subcutaneous, Tremfya subcutaneous, or Zymfentra also counts. **b)** According to the prescriber, the patient has already started on or is currently undergoing induction therapy with Omvoh intravenous. **B)** If the patient has met criterion 1Ai (the standard *Inflammatory Conditions – Omvoh Intravenous Prior Authorization Policy* criteria), but criterion 1Aii is not met, a request for a Preferred Product may be reviewed (Humira [NDCs starting with 00074], adalimumab-adbm, Cyltezo, adalimumab-adaz, adalimumab-ryvk, Simlandi, Skyrizi IV, Stelara IV, Tremfya IV, Avsola, Inflectra, or Entyvio IV) using the respective standard *Inflammatory Conditions Prior Authorization Policy* criteria.

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.

References

1. Omvoh™ intravenous infusion and subcutaneous injection [prescribing information]. Indianapolis, IN: Eli Lilly; October 2023.

Revision Details

Type of Revision	Summary of Changes	Date
New	**New policy:** Criteria for Legacy Drug List Plans was previously located within Inflammatory Conditions – Omvoh Intravenous Preferred Specialty Management Policy (PSM011). The following changes were made to update the criteria upon relocation to this new policy: **Hyrimoz:** Throughout the policy, NDCs starting with 61314 were removed from the Preferred	01/01/2025

	Products. A previous trial of these NDCs counts towards a trial of an adalimumab product. For **Ulcerative Colitis – Induction Therapy**, Tremfya was added as an agent that counts towards a trial of a Preferred Product.	
Selected Revision	**Added** Tremfya IV as a Step 1 Preferred product. Updated the Note to clarify that a trial of the "subcutaneous" Tremfya formulation also counts towards a trial of a Preferred Product.	01/15/2024

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