Drug Coverage Policy

Effective Date……04/15/2026
Coverage Policy Number……PSM011
Policy Title……Omvoh Intravenous Preferred Specialty Management Policy for Individual and Family Plans

Inflammatory Conditions – Omvoh Intravenous Preferred Specialty Management Policy for Individual and Family Plan 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 where appropriate and have discretion in making individual coverage determinations. Where coverage for care or services does not depend on specific circumstances, reimbursement will only be provided if a requested service(s) is submitted in accordance with the relevant criteria outlined in the applicable Coverage Policy, including covered diagnosis and/or procedure code(s). Reimbursement is not allowed for services when billed for conditions or diagnoses that are not covered under this Coverage Policy (see "Coding Information" below). When billing, providers must use the most appropriate codes as of the effective date of the submission. Claims submitted for services that are not accompanied by covered code(s) under the applicable Coverage Policy

will be denied as not covered. 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.

OVERVIEW

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

Coverage Policy

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	
	Crohn's Disease	**Ulcerative Colitis**
Step 1 **Preferred**	• Adalimumab Products – Cyltezo/adalimumab-adbm, Simlandi/adalimumab-ryvk (-ryvk NDCs starting with 82009) • Skyrizi IV • Ustekinumab IV Products – Imuldosa IV (NDCs starting with 69448), Selarsdi IV, ustekinumab-ttwe IV, Yesintek IV • Tremfya IV • Infliximab IV Products – (Avsola, Inflectra) • Entyvio IV	• Adalimumab Products – Cyltezo/adalimumab-adbm, Simlandi/ adalimumab-ryvk (-ryvk NDCs starting with 82009) • Skyrizi IV • Ustekinumab IV Products – Imuldosa IV (NDCs starting with 69448), Selarsdi IV, ustekinumab-ttwe IV, Yesintek IV • Tremfya IV • Infliximab IV Products – (Avsola, Inflectra) • Entyvio IV
Step 2 **Non-Preferred** (directed to **ONE** Step 1 agent)	• Omvoh Intravenous	

For Non-Preferred Adalimumab Products, refer to the *Inflammatory Conditions – Adalimumab Products Preferred Specialty Management Policy for Individual and Family Plans for Individual and Family Plans (PSM014);* For Non-Preferred Ustekinumab Products, refer to the *Inflammatory Conditions – Ustekinumab Subcutaneous Products Preferred Specialty Management Policy for Individual and Family Plans (PSM023)*; ^ A trial of more than one adalimumab product counts as ONE Preferred Product; A trial of more than one ustekinumab product counts as ONE Preferred Product; IV – 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. <u>Crohn's Disease – Induction Therapy.</u>** **A)** Approve for three doses for induction if the patient meets BOTH of the following (i <u>and</u> ii): **i.** Patient meets the standard *Inflammatory Conditions – Omvoh Intravenous Prior Authorization Policy* criteria; AND **ii.** Patient meets ONE of the following (a <u>or</u> b): **a)** Patient has tried one of an adalimumab product, Skyrizi intravenous, Tremfya intravenous, ustekinumab intravenous product, Entyvio intravenous, or an infliximab intravenous product; OR <u>Note</u>: 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. Examples of ustekinumab products include Stelara/ustekinumab, Imuldosa, Otulfi, Pyzchiva, ustekinumab-ttwe, Selarsdi, ustekinumab-aekn, Starjemza, Steqeyma, Wezlana, and Yesintek. A trial of multiple adalimumab products counts as **ONE** product. A trial of multiple ustekinumab 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, Tremfya subcutaneous, ustekinumab 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 (<u>adalimumab-adbm, Cyltezo, adalimumab-ryvk [NDCs starting with 82009], Simlandi, Skyrizi IV, Imuldosa IV [NDCs starting with 69448], Selarsdi IV, ustekinumab-ttwe IV, Yesintek IV, Tremfya IV, Avsola, Inflectra, or Entyvio IV</u>) using the respective standard *Inflammatory Conditions Prior Authorization Policy* criteria.

	2. <u>Ulcerative Colitis – Induction Therapy.</u> **A)** Approve for three doses for induction if the patient meets BOTH of the following (i <u>and</u> ii): **i.** Patient meets the standard *Inflammatory Conditions – Omvoh Intravenous Prior Authorization Policy* criteria; AND **ii.** Patient meets ONE of the following (a <u>or</u> b): **a)** Patient has tried one of an adalimumab product, Skyrizi intravenous, ustekinumab intravenous product, Tremfya intravenous, Entyvio intravenous, or an infliximab intravenous product; OR <u>Note</u>: 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. Examples of ustekinumab products include Stelara/ustekinumab, Imuldosa, Otulfi, Pyzchiva, ustekinumab-ttwe, Selarsdi, ustekinumab-aekn, Starjemza, Steqeyma, Wezlana, and Yesintek. A trial of multiple adalimumab products counts as **ONE** product. A trial of multiple ustekinumab 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, ustekinumab 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 (<u>adalimumab-adbm, Cyltezo, adalimumab-ryvk [NDCs starting with 82009], Simlandi, Skyrizi IV, Imuldosa IV [NDCs starting with 69448], Selarsdi IV, ustekinumab-ttwe IV, Yesintek IV, Tremfya IV, Avsola, Inflectra, or Entyvio IV</u>) using the respective standard *Inflammatory Conditions Prior Authorization Policy* criteria.

References

1. Omvoh™ intravenous infusion and subcutaneous injection [prescribing information]. Indianapolis, IN: Eli Lilly; January 2025.

Revision Details

Type of Revision	Summary of Changes	Date
New	New policy	11/01/2024

Selected Revision	**Updated** policy title **from** Inflammatory Conditions – Omvoh Intravenous Preferred Specialty Management Policy **to** Inflammatory Conditions – Omvoh Intravenous Preferred Specialty Management Policy for Employer Plans: Standard/Performance, Value/Advantage, Total Savings; Individual and Family Plan Prescription Drug Lists. **Humira:** Throughout the policy, NDCs starting with 00074 were removed from the Preferred Products. A previous trial of these NDCs counts towards a trial of an adalimumab product. **Hyrimoz:** Throughout the policy, NDCs starting with 61314 were removed from the Preferred 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.	01/01/2025
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
Selected Revision	**For Crohn's Disease**, Omvoh intravenous was added as a Step 2 Non-Preferred Product and is directed to a trial of one Step 1 Product.	03/15/2025
Selected Revision	**Updated Policy Title: Removed** Employer Plans: Standard/Performance, Value/Advantage, Total Savings from the previous title. Omvoh intravenous is moving to a preferred product for Employer Plans. This policy will now only apply for Individual and Family Plans.	04/01/2025
Selected Revision	**For Crohn's Disease and Ulcerative Colitis:** Selarsdi intravenous, ustekinumab-ttwe intravenous, and Yesintek intravenous were added as Preferred ustekinumab intravenous products. A note was added indicating that a trial of multiple ustekinumab products counts as one product and examples of ustekinumab products were added including Stelara, Wezlana, Otufli, Pyzchiva, ustekinumab-ttwe, Selarsdi, Steqeyma, and Yesintek. The note that refers to a previous trial of Stelara subcutaneous was changed to more generally refer to an ustekinumab subcutaneous product.	04/15/2025

Selected Revision	**Tremfya intravenous (IV)** was added as a Preferred Product for Crohn's Disease. Updated the Note to include a previous trial of Tremfya subcutaneous also counts.	05/15/2025
Selected Revision	Ustekinumab intravenous (unbranded Stelara [Janssen]) was added to the policy as a Preferred product. Throughout the policy, the note was updated for the examples of ustekinumab products which include Stelara, ustekinumab (unbranded Stelara), Imuldosa, Otulfi, Pyzchiva, ustekinumab-ttwe, Selarsdi, ustekinumab-aekn, Starjemza, Steqeyma, Wezlana, and Yesintek.	09/01/2025
Annual Revision	**Adalimumab-adaz** was removed as a Preferred Product throughout the policy. Throughout the policy, it was specified that adalimumab-ryvk NDCs starting with 82009 are the Preferred product. For **Crohn's Disease** and **Ulcerative Colitis,** Stelara IV/ustekinumab IV were removed as a Preferred ustekinumab IV product.	01/01/2026
Selected Revision	**For Crohn's Disease and Ulcerative Colitis:** Imuldosa intravenous (NDCs starting with 69448) was added as a Preferred ustekinumab intravenous product.	04/15/2026

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