MED RX POLICY

POLICY: Inflammatory Conditions – Ustekinumab Intravenous Products Med Rx Policy

- Stelara® (ustekinumab intravenous infusion– Janssen Biotech)
- Ustekinumab intravenous infusion – Janssen Biotech
- Otulfi™ (ustekinumab-aauz intravenous infusion – Formycon/Fresenius)
- Pyzchiva™ (ustekinumab-ttwe intravenous infusion – Sandoz/Samsung)
- Selarsdi™ (ustekinumab-aekn intravenous infusion – Alvotech/Teva)
- Steqeyma™ (ustekinumab-stba intravenous infusion – Celltrion)
- Wezlana™ (ustekinumab-auub intravenous infusion – Amgen)
- Yesintek™ (ustekinumab-kfce intravenous infusion – Biocon)

REVIEW DATE: 04/09/2025; selected revision 05/28/2025 (effective 08/01/2025)

OVERVIEW

Ustekinumab products are indicated for the treatment of a variety of inflammatory conditions.[1-8] Multiple ustekinumab products were approved as biosimilars to Stelara. Biosimilar indicates no clinically meaningful differences in safety and effectiveness and the same mechanism of action, route of administration, dosage form, and strength as Stelara. However, minor differences in clinically inactive components are allowed.

POLICY STATEMENT

This Med Rx program has been developed to encourage the use of Preferred Products. For all Non-Preferred Products, the patient is required to meet the standard *Inflammatory Conditions – Ustekinumab Intravenous Products Utilization Management Medical Policy* criteria. This program also directs the patient to two Preferred Products prior to the approval of a Non-Preferred Product. Requests for Non-Preferred Products will also be reviewed using the exception criteria (below). All approvals are provided for the duration noted in the standard *Inflammatory Conditions – Ustekinumab Intravenous Products Utilization Management Medical Policy*.

Documentation: Documentation will be required where noted in the criteria as **[documentation required]**. Documentation may include, but is not limited to chart notes, prescription claims records, and prescription receipts.

Automation: None.

Preferred Products:	Stelara intravenous/ustekinumab intravenous, Yesintek intravenous, Selarsdi intravenous
Non-Preferred Products:	Wezlana intravenous, Otulfi intravenous, Steqeyma intravenous, Pyzchiva intravenous

RECOMMENDED EXCEPTION CRITERIA

Non-Preferred Products	Exception Criteria
Wezlana intravenous, Otulfi intravenous, Steqeyma intravenous, Pyzchiva intravenous	**1.** Approve if the patient meets BOTH of the following (A and B): **A)** Patient meets the standard *Inflammatory Conditions – Ustekinumab Intravenous Products Utilization Management Medical Policy* criteria; AND **B)** Patient meets BOTH of the following (i and ii): **i.** Patient has tried TWO of Stelara/ustekinumab, Yesintek, or Selarsdi intravenous products **[documentation required]**; AND **ii.** Patient cannot continue to use the Preferred medications due to a formulation difference in the inactive ingredient(s) [e.g., differences in stabilizing agent, buffering agent, and/or surfactant] which, according to the prescriber, would result in a significant allergy or serious adverse reaction **[documentation required]**.

REFERENCES

1. Stelara® intravenous infusion, subcutaneous injection [prescribing information]. Horsham, PA: Janssen Biotech; March 2024.
2. Ustekinumab intravenous infusion, subcutaneous injection [prescribing information]. Horsham, PA: Janssen Biotech; April 2025.
3. Wezlana® intravenous infusion, subcutaneous injection [prescribing information]. Thousand Oaks, CA: Amgen; October 2023.
4. Otulfi® intravenous infusion, subcutaneous injection [prescribing information]. Lake Zurich, IL: Fresenius; December 2024.
5. Pyzchiva® intravenous infusion, subcutaneous injection [prescribing information]. Princeton, NJ: Sandoz; June 2024.
6. Selarsdi® intravenous infusion, subcutaneous injection [prescribing information]. Parsippany, NJ: Teva; October 2024.
7. Steqeyma® intravenous infusion, subcutaneous injection [prescribing information]. Incheon, Republic of Korea: Celltrion; December 2024.
8. Yesintek® intravenous infusion, subcutaneous injection [prescribing information]. Cambridge, MA: Biocon; December 2024.

HISTORY

Type of Revision	Summary of Changes	Review Date
New Policy	--	04/09/2025
Selected Revision	**Effective 08/01/2025.** Ustekinumab intravenous (unbranded Stelara [Janssen]) was added to the policy as a Preferred product. Ustekinumab-ttwe intravenous was removed from the policy.	05/28/2025