PREFERRED SPECIALTY MANAGEMENT POLICY

POLICY: Inflammatory Conditions – Ustekinumab Subcutaneous Products Preferred Specialty Management Policy for National Preferred, High Performance, and Basic Formularies – **Choice**

- Stelara® (ustekinumab subcutaneous injection – Janssen Biotech)
- Ustekinumab subcutaneous injection (Janssen Biotech)
- Ustekinumab-aekn subcutaneous injection (Alvotech/Teva)
- Ustekinumab-ttwe subcutaneous injection (Quallent)
- Imuldosa™ (ustekinumab-srlf subcutaneous injection (Accord BioPharma)
- Otulfi™ (ustekinumab-aauz subcutaneous injection – Formycon/Fresenius)
- Pyzchiva™ (ustekinumab-ttwe subcutaneous injection – Sandoz/Samsung)
- Selarsdi™ (ustekinumab-aekn subcutaneous injection – Alvotech/Teva)
- Steqeyma™ (ustekinumab-stba subcutaneous injection – Celltrion)
- Wezlana™ (ustekinumab-auub subcutaneous injection – Amgen)
- Yesintek™ (ustekinumab-kfce subcutaneous injection – Biocon)

REVIEW DATE: 01/15/2025; selected revision 01/29/2025, 03/12/2025, 04/02/2025, 06/04/2025, 09/10/2025 (effective 10/01/2025)

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.

CIGNA NATIONAL FORMULARY COVERAGE:

OVERVIEW

Ustekinumab subcutaneous products are indicated for the treatment of a variety of inflammatory conditions.[1-11] Multiple ustekinumab products were approved as biosimilar 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 program has been developed to encourage the use of Preferred Products. For all products (Preferred and Non-Preferred), the patient is required to meet the standard *Inflammatory Conditions – Ustekinumab Subcutaneous Products Prior Authorization Policy with Dosing* criteria. This program also directs the patient to try ALL of the 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 Subcutaneous Products Prior Authorization Policy with Dosing*. If the patient meets the standard *Prior Authorization Policy* criteria but has not tried the Preferred Products, approval for the Preferred Products will be authorized.

Documentation: When documentation is required, the prescriber must provide written documentation supporting the trials of these other Products, noted in the criteria as **[documentation required]**. Documentation may include, but is not limited to chart notes, prescription claims records, and/or prescription receipts.

Preferred and Non-Preferred Products.

Preferred Products	• Stelara SC • Imuldosa SC • Selarsdi SC • ustekinumab-ttwe SC • Yesintek SC
Non-Preferred Products (directed to the Preferred Product) **[documentation required]**	• Otulfi SC • Pyzchiva SC – *directed to ustekinumab-ttwe SC* • Steqeyma SC • Ustekinumab SC – *directed to Stelara SC* • Ustekinumab-aekn SC – *directed to Selarsdi SC* • Wezlana SC

SC – subcutaneous.

Inflammatory Conditions – Ustekinumab Subcutaneous Products Preferred Specialty Management Policy **non-preferred product(s) is(are) covered as medically necessary when the following non-preferred product exception criteria is(are) met. Any other exception is considered not medically necessary.**

NON-PREFERRED PRODUCT EXCEPTION CRITERIA

Non-Preferred Products	Exception Criteria
Otulfi SC, Steqeyma SC, Wezlana SC	**1.** Approve if the patient meets BOTH of the following (A and B): **A)** Patient meets the standard *Inflammatory Conditions – Ustekinumab Subcutaneous Products Prior Authorization Policy with Dosing* criteria; AND **B)** Patient meets BOTH of the following (i and ii): **i.** Patient has tried ALL of Stelara, Imuldosa, Selarsdi, ustekinumab-ttwe, and Yesintek subcutaneous **[documentation required]**; AND **ii.** Patient cannot continue to use ALL Preferred medications (i.e., Stelara, Imuldosa, Selarsdi, ustekinumab-ttwe, and Yesintek subcutaneous) due to formulation differences 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]**. Note: A trial of Pyzchiva counts towards a trial of ustekinumab-ttwe. A trial of ustekinumab counts towards a trial of Stelara. A trial of ustekinumab-aekn counts towards a trial of Selarsdi. **2.** If the patient has met the standard *Inflammatory Conditions – Ustekinumab Subcutaneous Products Prior Authorization Policy with Dosing* criteria (1A), but has not met exception criteria (1B): approve the Preferred Products. For selected indications, the patient will also be referred to other Preferred Products. Refer to Appendix A.
Pyzchiva SC	**1.** Pyzchiva SC is not approved. Offer to review for ustekinumab-ttwe using the *Inflammatory Conditions – Ustekinumab Subcutaneous Products Prior Authorization Policy with Dosing* criteria.
Ustekinumab SC	**1.** Ustekinumab SC is not approved. Offer to review for Stelara using the *Inflammatory Conditions – Ustekinumab Subcutaneous Products Prior Authorization Policy with Dosing* criteria.

Ustekinumab-aekn SC	**1.** Ustekinumab-aekn SC is not approved. Offer to review for Selarsdi using the *Inflammatory Conditions – Ustekinumab Subcutaneous Products Prior Authorization Policy with Dosing* criteria.

REFERENCES

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

HISTORY

Type of Revision	Summary of Changes	Review Date
New Policy	--	01/15/2025
Selected Revision	Omvoh subcutaneous was added as a Preferred Non-Ustekinumab Product for Crohn's disease.	01/29/2025
Selected Revision	**Changes effective 03/21/2025:** For the non-preferred products, the option of approval allowing continuation of therapy was removed. **Selarsdi, ustekinumab-ttwe, and Yesintek:** These agents were added to the policy as Preferred ustekinumab subcutaneous (SC) products. **Otulfi and Steqeyma:** These agents were added to the policy as Non-Preferred ustekinumab SC products. A patient is directed to a trial of all the Preferred Products with documentation requirements. Documentation is also required to support the requirement that formulation difference(s) in the inactive ingredient(s) which, according to the prescriber, would result in a significant allergy or serious adverse reaction. **Pyzchiva:** Pyzchiva was added to the policy as a Non-Preferred ustekinumab SC product. All requests for Pyzchiva are directed to ustekinumab-ttwe SC.	03/12/2025
Selected Revision	**Effective 04/18/2025:**	04/02/2025

	Tremfya subcutaneous was added as a Preferred Non-Ustekinumab Product for Crohn's disease.	
Selected Revision	The policy name was changed to include the descriptor "High Performance Formulary". **Ustekinumab and Ustekinumab-aekn:** These agents were added as Non-Preferred subcutaneous products. Requests for ustekinumab are directed to Stelara and requests for ustekinumab-aekn are directed to Selarsdi.	06/04/2025
Selected Revision	**Effective 10/01/2025:** Imuldosa subcutaneous was added as a Preferred Ustekinumab product.	09/10/2025

APPENDIX A.

Other (Non-Ustekinumab) Preferred Products by Indication.

PsA	Psoriasis	CD	UC
• **Adalimumab Products** –Cyltezo/adalimumab-adbm, adalimumab-adaz, Simlandi/ adalimumab-ryvk • **Enbrel** • **Otezla** • **Skyrizi SC#** • **Taltz** • **Tremfya SC**	• **Adalimumab Products** –Cyltezo/adalimumab-adbm, adalimumab-adaz, Simlandi/ adalimumab-ryvk • **Enbrel** • **Otezla** • **Skyrizi SC#** • **Sotyktu** • **Taltz** • **Tremfya SC**	• **Adalimumab Products** –Cyltezo/adalimumab-adbm, adalimumab-adaz, Simlandi/ adalimumab-ryvk • **Omvoh SC** • **Skyrizi SC** (on-body injector) • **Tremfya SC** • **Zymfentra**	• **Adalimumab Products** –Cyltezo/adalimumab-adbm, adalimumab-adaz, Simlandi/ adalimumab-ryvk • **Omvoh SC** • **Skyrizi SC** (on-body injector) • **Tremfya SC** • **Velsipity** • **Zymfentra**

PsA – Psoriatic arthritis; CD – Crohn's disease; UC – Ulcerative colitis; ; # Pen and syringe; SC – Subcutaneous.

"Cigna Companies" refers to operating subsidiaries of The Cigna Group. All products and services are provided exclusively by or through such operating subsidiaries, including Cigna Health and Life Insurance Company, Connecticut General Life Insurance Company, Evernorth Behavioral Health, Inc., Cigna Health Management, Inc., and HMO or service company subsidiaries of The Cigna Group.© 2025 The Cigna Group.