Drug Coverage Policy

Effective Date……06/15/2025
Coverage Policy Number…… DQM001
Policy Title… Inflammatory Conditions – Ustekinumab Subcutaneous Drug Quantity Management

Inflammatory Conditions – Ustekinumab Subcutaneous Drug Quantity Management Policy – Per Days

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

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

Ustekinumab subcutaneous (SC), an interleukin-12/23 blocker, is indicated for the following uses:[1-8]

- **Crohn's disease**, in patients ≥ 18 years of age with moderate to severe active disease.
- **Plaque psoriasis**, in patients ≥ 6 years of age with moderate to severe disease who are candidates for phototherapy or systemic therapy.
- **Psoriatic arthritis**, in patients ≥ 6 years of age with active disease.
- **Ulcerative colitis**, in patients ≥ 18 years of age with moderate to severe active disease.

Dosing

Dosage recommendations for ustekinumab SC are:[1-8]

- **Plaque psoriasis:**
  - Adults weighing ≤ 100 kg: 45 mg SC at Week 0, Week 4, and then once every 12 weeks (Q12W) thereafter.
  - Adults weighing > 100 kg: 90 mg SC at Week 0, Week 4, and then Q12W thereafter.
  - Pediatric patients ≥ 12 years of age weighing < 60 kg: 0.75 mg/kg SC at Week 0, Week 4, and then Q12W thereafter.
  - Pediatric patients ≥ 12 years of age weighing 60 kg to 100 kg: 45 mg SC at Week 0, Week 4, and then Q12W thereafter.
  - Pediatric patients ≥ 12 years of age weighing < 60 kg: 90 mg SC at Week 0, Week 4, and then Q12W thereafter.
- **Psoriatic arthritis:**
  - Adults weighing > 100 kg with co-existent moderate to severe plaque psoriasis: 90 mg SC at Week 0, Week 4, and then every Q12W thereafter.
  - All other adults: 45 mg SC at Week 0, Week 4, and then Q12W thereafter.
  - Pediatric patients ≥ 6 years of age weighing < 60 kg: 0.75 mg/kg at Week 0, Week 4, and then Q12W thereafter.
  - Pediatric patients ≥ 6 years of age weighing ≥ 60 kg: 45 mg at Week 0, Week 4, and then Q12W thereafter.
  - Pediatric patients ≥ 6 years of age weighing > 100 kg with co-existent moderate-to-severe plaque psoriasis: 90 mg at Week 0, Week 4, and then Q12W thereafter.
- **Crohn's disease:** Starting 8 weeks after an initial intravenous (IV) dose, the maintenance dose is 90 mg SC injection once every 8 weeks (Q8W).
- **Ulcerative colitis:** Starting 8 weeks after an initial IV dose, the maintenance dose is 90 mg SC Q8W.

Dose Escalation in Crohn's Disease and Ulcerative Colitis

There are data to support dose escalation of ustekinumab SC from Q8W to Q4W or Q6W in patients with inflammatory bowel disease who do not achieve remission with the Q8W dosing.[9-13]

In STARDUST (n = 440), a phase 3b, multicenter, randomized study, patients with moderate to severe, active Crohn's disease initially received ustekinumab 90 mg SC Q8W or Q12W.[9] At Week 20 or 24, if the patient had not achieved clinical, biochemical, or endoscopic remission, the dose could be increased to Q8W (if previously receiving Q12W) or Q4W (if previously receiving Q8W). Similar efficacy was demonstrated in the treat to target (dose escalation) group vs. the standard of care group, but some patients benefited from Q4W dosing. Additional systematic literature reviews, meta-analyses, and retrospective cohort studies have also reported that dose intensification may benefit some patients.[10-13]

Availability

Refer to Table 1 for the available strengths and dosage forms of ustekinumab products.[1-8]

Table 1. FDA-Approved Ustekinumab Products.[1-8]

Dosage Form/ Strength		Stelara ustekinumab	Imuldosa	Otulfi	Pyzchiva ustekinumab-ttwe	Selarsdi ustekinumab-aekn	Steqeyma	Wezlana	Yesintek
PFS	45 mg/0.5 mL	√	√	√	√	√	√	√	√
	90 mg/mL	√	√	√	√	√	√	√	√
Vial	45 mg/0.5 mL	√						√	√

[Ω] These products are FDA-approved, but may or may not be currently available; [α] Ustekinumab products may be FDA-approved for additional strengths/package sizes not noted here. This table reflects the availability of the products as of the date on this policy; PFS – Prefilled syringe; [β] Institutional use only; [*] Starter packs may have different names depending on the individual product's FDA-approved indications.

Of note, all of the ustekinumab products, with the exception of ustekinumab-aekn are also available as a 130 mg/26 mL single-dose vial for IV administration.[1-6] This dosage form is not targeted in this policy.

Coverage Policy

Policy Statement

This Drug Quantity Management program has been developed to promote the safe, effective, and economic use of ustekinumab SC, and to manage potential premature dose escalation. If the Drug Quantity Management rule is not met at the point of service, coverage will be determined by the Criteria below. All approvals are provided for 1 year in duration, unless otherwise noted below. Of note, all ustekinumab SC products of the same strength (i.e., vials, prefilled syringes) accumulate toward the total quantity limit.

Drug Quantity Limits

Product	Strength and Form	Retail and Home Delivery Maximum Quantity Limit
Stelara® (ustekinumab SC injection) ustekinumab SC injection	45 mg/0.5 mL vial (Stelara, ustekinumab, and Yesintek only)	45 mg (1 syringe or vial) per 84 days

Imuldosa™ (ustekinumab-srlf SC injection) Otulfi™ (ustekinumab-aauz subcutaneous injection) Pyzchiva™ (ustekinumab-ttwe subcutaneous injection) ustekinumab-ttwe SC injection Selarsdi™ (ustekinumab-aekn SC injection) ustekinumab-aekn SC injection Steqeyma™ (ustekinumab-stba SC injection) Yesintek (ustekinumab-kfce SC injection)	45 mg/0.5 mL prefilled syringe	
	90 mg/mL prefilled syringe	90 mg (1 syringe) per 84 days

SC – Subcutaneous.

Exceptions to the quantity limits listed above are covered as medically necessary when the following criteria are met. Any other exception is considered not medically necessary.

CRITERIA

Ustekinumab 45 mg prefilled syringes or vials

1. If the patient is initiating treatment for plaque psoriasis or psoriatic arthritis or requires additional induction dosing for plaque psoriasis or psoriatic arthritis, as verified by the absence of claims for ustekinumab in the past 130 days, approve an override for an additional 90 mg at retail or home delivery.
Note: The approval quantity should be the number of ustekinumab mg the patient has received in the past 84 days plus 90 mg.

Ustekinumab 90 mg prefilled syringes

1. If the patient is initiating treatment for plaque psoriasis or psoriatic arthritis or requires additional induction dosing for plaque psoriasis or psoriatic arthritis, as verified by the absence of claims for ustekinumab in the past 130 days, approve an override for an additional 180 mg at retail or home delivery.
Note: The approval quantity should be the number of ustekinumab mg the patient has received in the past 56 days plus 180 mg.

2. If the patient is using for Crohn's disease or ulcerative colitis, approve 90mg per 56 days at retail or home delivery

3. Approve 90 mg per 28 days at retail or 270 mg per 84 days at home delivery if the patient meets ALL of the following (A, B, and C):

A) Ustekinumab is being used to treat Crohn's disease or ulcerative colitis; AND
B) Patient has received ustekinumab 90 mg subcutaneous (SC) once every 8 weeks for 24 weeks or longer; AND
C) According to the prescriber, the patient has continued evidence of inflammation based on one or more of the following: elevated C-reactive protein, elevated erythrocyte sedimentation rate, elevated fecal calprotectin, or signs of inflammation on endoscopic evaluation.

4. Approve 90 mg per 28 days at retail or 270 mg per 84 days at home delivery if the patient meets BOTH of the following (A and B):
A) Ustekinumab is being used to treat Crohn's disease or ulcerative colitis; AND
B) Patient has been receiving ustekinumab 90 mg SC once every 4 weeks or 90 mg once every 6 weeks.

References

1. Stelara® subcutaneous injection [prescribing information]. Horsham, PA: Janssen; April 2025.
2. Wezlana™ subcutaneous injection [prescribing information]. Thousand Oaks, CA: Amgen; December 2024.
3. Yesintek subcutaneous injection [prescribing information]. Cambridge, MA: Biocon; November 2024.
4. Steqeyma® subcutaneous injection [prescribing information]. Jersey City, NJ: Celltrion; April 2025.
5. Pyzchiva® subcutaneous injection [prescribing information]. Princeton, NJ: Sandoz. June 2024.
6. Selarsdi™ subcutaneous injection [prescribing information]. Parsippany, NJ: Teva; February 2025.
7. Otulfi® subcutaneous injection [prescribing information]. Lake Zurich, IL: Fresenius; April 2025.
8. Imuldosa™ subcutaneous injection [prescribing information]. Raleigh, NC: Accord; October 2024.
9. Danese S, Vermeire S, Haens GD, et al. Treat to target versus standard of care for patients with Crohn's disease treated with ustekinumab (STARDUST): an open-label, multicenter, randomized phase 3b trial. *Lancet Gastroenterol Hepatol.* 2022;7(4):294-306.
10. Peyrin-Biroulet L, Vermeire S, D'Haens G, et al. Clinical trial: clinical and endoscopic outcomes with ustekinumab in patients with Crohn's disease: results from the long-term extension period of STARDUST. *Aliment Pharmacol Ther*. 2024;59(2):175-185.
11. Dalal RS, Pruce JC, Allegretti JR. Long-term outcomes after ustekinumab dose intensification for inflammatory bowel diseases. *Inflamm Bowel Dis*. 2023;29(5):830-833.
12. Meserve J, Ma C, Dulai PS, et al. Effectiveness of reinduction and/or dose escalation of ustekinumab in Crohn's disease: a systematic review and meta-analysis. *Clin Gastroenterol Hepatol*. 2022;20(12):2728-2740.
13. Panaccione R, Lee WJ, Clark R, et al. Dose escalation patterns of advanced therapies in Crohn's disease and ulcerative colitis: a systematic literature review. *Adv Ther*. 2023;40(5):2051-2081.

Revision Details

Type of Revision	Summary of Changes	Date
New	New policy	06/01/2025

Selected Revision	**Ustekinumab 45 mg vials, 45 mg prefilled syringes, and 90 mg prefilled syringes (unbranded Stelara):** New quantity limits were added to the policy. The same quantity limits and overrides apply to ustekinumab as have previously applied to the other ustekinumab products. **Imuldosa 45 mg prefilled syirnges and 90 mg prefilled syringes:** New quantity limits were added to the policy. The same quantity limits and overrides apply to Imuldosa as have previously applied to the other ustekinumab products. **Ustekinumab-aekn 45 mg prefilled syringes and 90 mg prefilled syringes (unbranded Selarsdi):** New quantity limits were added to the policy. The same quantity limits and overrides apply to ustekinumab-aekn as have previously applied to the other ustekinumab products.	06/15/2025

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

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