DRUG QUANTITY MANAGEMENT POLICY – PER DAYS

POLICY: Inflammatory Conditions – Stelara Drug Quantity Management Policy – Per Days
- Stelara® (ustekinumab subcutaneous injection – Janssen)

REVIEW DATE: 01/04/2024; selected revision 02/14/2024 and 05/17/2024

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 NATIONAL FORMULARY COVERAGE:

OVERVIEW

Stelara subcutaneous (SC), an interleukin-12/23 blocker, is indicated for the following uses:[1]
- **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 Stelara SC are:[1]
- **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 Stelara SC from Q8W to Q4W or Q6W in patients with inflammatory bowel disease who do not achieve remission with the Q8W dosing.[2-6] In STARDUST (n = 440), a phase IIIb, multicenter, randomized study, patients with moderate to severe, active Crohn's disease initially received Stelara 90 mg SC Q8W or Q12W.[2] 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.[3-6]

Availability

Stelara SC is available in the following forms:

- 45 mg/0.5 mL single-dose vials and prefilled syringes (individually packaged)
- 90 mg/mL single-dose prefilled syringe (individually packaged)

Of note, Stelara is also available as a 130 mg/26 mL single-dose vial for IV administration. This dosage form is not targeted in this policy.

POLICY STATEMENT

This Drug Quantity Management program has been developed to promote the safe, effective, and economic use of Stelara 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.

Drug Quantity Limits

Product	Strength and Form	Retail and Home Delivery Maximum Quantity Limit
Stelara® (ustekinumab subcutaneous injection)	45 mg/0.5 mL vial	45 mg (1 vial) per 84 days
	45 mg/0.5 mL prefilled syringe	45 mg (1 prefilled syringe) per 84 days
	90 mg/mL prefilled syringe	90 mg (1 prefilled syringe) per 56 days

Inflammatory Conditions – Stelara Drug Quantity Management Policy – Per Days product(s) is(are) covered as medically necessary when the following criteria is(are) met. Any other exception is considered not medically necessary.

CRITERIA

Stelara 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 Stelara in the past 130 days, approve a one-time override for 45 mg at retail or home delivery.

Stelara 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 Stelara in the past 130 days, approve a one-time override for 180 mg at retail or home delivery.

2. 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) Stelara is being used to treat Crohn's disease or ulcerative colitis; AND
   B) Patient has received Stelara 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.

3. 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) Stelara is being used to treat Crohn's disease or ulcerative colitis; AND
   B) Patient has been receiving Stelara 90 mg SC once every 4 weeks or once every 6 weeks.

REFERENCES

1. Stelara® subcutaneous injection [prescribing information]. Horsham, PA: Janssen; March 2023.
2. 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.
3. 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.
4. 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.
5. 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.
6. 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.

HISTORY

Type of Revision	Summary of Changes	Review Date
Annual Revision	Policy was updated to reflect the existing quantity limits when a product is obtained via home delivery. No criteria changes.	12/19/2022
Annual Revision	No criteria changes.	01/04/2024
Selected Revision	**Stelara 90 mg prefilled syringes:** New override was added to approve the requested quantity, not to exceed 1 syringe per 28 days at retail or 3 syringes per 84 days at home delivery if Stelara is being used to treat Crohn's disease or ulcerative colitis and the patient has received Stelara subcutaneous 90 mg once every 8 weeks for 24 weeks or longer.	02/14/2024
Selected Revision	Throughout policy changed the quantity approved to be in "mg" units. Previously approval quantities were provided in "# of syringes or vials".	05/17/2024