DRUG QUANTITY MANAGEMENT POLICY – PER DAYS

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

REVIEW DATE: 12/19/2022

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]
- **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).
- **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 Week 0, Week 4, and then Q12W thereafter.
- **Ulcerative colitis:** Starting 8 weeks after an initial IV dose, the maintenance dose is 90 mg SC Q8W.

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 dose 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.

Automation: None.

Drug Quantity Limits

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

CRITERIA

Stelara 45 mg prefilled syringes or vials

1. If the patient is initiating treatment 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 2 syringes or vials at retail or home delivery.

Stelara 90 mg prefilled syringes

1. If the patient is initiating treatment 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 2 syringes at retail or home delivery.

REFERENCES

1. Stelara® subcutaneous injection [prescribing information]. Horsham, PA: Janssen; July 2022.