Reference number
1738-H

SPECIALTY QUANTITY LIMIT PROGRAM

STELARA (ustekinumab)

I. PROGRAM DESCRIPTION

The standard limit is designed to allow a quantity sufficient for the most common uses of the medication. If member's plan allows a quantity limit exception review for the requested medication, coverage of an additional quantity may be provided up to the exception limit with prior authorization.

II. COVERED QUANTITIES

Medication	Standard Limit	Exception Limit*	FDA-recommended dosing
Stelara (ustekinumab) 130 mg/26 mL single-dose vial	4 vials (1 dose)	N/A	**CD, UC intravenous induction** • ≤ 55 kg: 260 mg (2 vials) • > 55 kg to 85 kg: 390 mg (3 vials) • > 85 kg: 520 mg (4 vials)
Stelara (ustekinumab) subcutaneous injection 45 mg/0.5 mL vial/syringe	1 vial/syringe per 12 weeks	2 vials/syringes per 35 days	**Psoriasis with or without co-existent PsA, adult** • ≤ 100 kg: 45 mg initially and 4 weeks later, followed by 45 mg every 12 weeks • > 100 kg: 90 mg initially and 4 weeks later, followed by 90 mg every 12 weeks **Psoriasis, adolescent (12 years and older)** Weight based dosing at the initial dose, 4 weeks later, and then every 12 weeks thereafter • < 60 kg: 0.75 mg/kg • 60 kg to 100 kg: 45 mg • > 100 kg: 90 mg **PsA, without co-existent plaque psoriasis** • 45 mg initially and 4 weeks later, followed by 45 mg every 12 weeks **CD, UC maintenance dose** • 90 mg 8 weeks after the initial intravenous dose, then every 8 weeks thereafter
Stelara (ustekinumab) subcutaneous injection 90 mg/mL syringe	1 syringe per 8 weeks	2 syringes per 35 days	

Abbreviations: PsA = psoriatic arthritis; CD = Crohn's disease, UC = ulcerative colitis

*Coverage up to the exception limits may be provided with prior authorization via the Specialty Post Limit Quantity Exception Criteria for approval.

III. REFERENCE

1. Stelara [package insert]. Horsham, PA: Janssen Biotech, Inc.; October 2019.