

Specialty Pharmacy Program

Stelara™ (ustekinumab)

DESCRIPTION

Stelara is an interleukin-12 and -23 blocker indicated for the treatment of adult patients (18 years or older) with moderate to severe plaque psoriasis who are candidates for phototherapy or systemic therapy.

APPROVAL DURATION AND QUANTITY LIMITS

Initial therapy

Approval duration: 16 weeks

Quantity limit: 3 doses (45 mg/dose) – 1 vial initially, then 1 vial 4 weeks later and 1 vial 12 weeks later

Maintenance therapy

Approval duration: lifetime

Quantity limit: 1 dose (45 mg/dose or 90 mg/dose*) every 12 weeks

* Must meet additional criteria for approval in section III below.

APPROVAL CRITERIA

- I. None of the following are present:
 - A. Tuberculosis (active or untreated) or any other active serious infection.
 - B. Patients who have not had a tuberculin skin test (TST), or a CDC-recommended equivalent, to rule out latent tuberculosis.
 - C. Use of Stelara in combination with any other biologic medication.
- II. Chronic moderate to severe plaque psoriasis
 - A. Patient is 18 years of age or older AND
 - B. Patient has a diagnosis of moderate to severe plaque psoriasis with either of the following:
 1. Patient has greater than $\geq 5\%$ of body surface area with psoriasis OR
 2. Less than 5% of body surface area with plaque psoriasis involving sensitive areas (such as palms, soles of feet, head/neck, or genitalia) OR involving areas that would significantly impact daily functionAND
 - C. Patient has had an inadequate response to systemic therapies (see below) AND patient was adherent to therapy AND therapy was optimized with respect to dose and route of administration.
 1. Methotrexate
 2. Acitretin (Soriatane)
 3. Cyclosporine (Neoral, Sandimmune)OR
 - D. Patient has a documented intolerance, contraindication, or other clinical reason to avoid systemic therapy.
- III. The following criteria must be present for approval of a dose of 90 mg:
 - A. Patient weight is >100 kg (220 lbs) AND
 - B. Patient has had an inadequate response to a dose of 45 mg.