PHARMACY POLICY STATEMENT
Marketplace

DRUG NAME	Stelara (ustekinumab)
BILLING CODE	J3357
BENEFIT TYPE	Medical or Pharmacy
SITE OF SERVICE ALLOWED	Home/Office/Outpatient
STATUS	Prior Authorization Required

Stelara is a human interleukin-12 and interleukin-23 antagonist initially approved by the FDA in 2009. It is indicated for the treatment of adult patients with moderate to severe plaque psoriasis who are candidates for phototherapy or systemic therapy, active psoriatic arthritis, moderately to severely active Crohn's disease and moderately to severely active ulcerative colitis. Pediatric patients 6 years and older are also approved to have Stelara for moderate to severe plaque psoriasis treatment.

Stelara (ustekinumab) will be considered for coverage when the following criteria are met:

Crohn's Disease (CD)

For **reauthorization**:

1. Chart notes have been provided showing improvement in signs and symptoms of CD (defined as mucosal healing, fewer flare-ups of symptoms, improved quality of life, etc.).

If all the above requirements are met, the medication will be approved for an additional 12 months.

Plaque Psoriasis (PsO)

For **initial** authorization:

1. Member must be 6 years of age or older; AND
2. Medication must be prescribed by or in consultation with a dermatologist; AND
3. Member has clinical documentation of moderate to severe plaque psoriasis characterized by 3% or more of body surface area (BSA) or disease affecting sensitive areas (e.g., hands, feet, face, genitals, etc.); AND
4. Must have had a negative TB test within the last 12 months; AND
5. Member has tried and failed to respond to treatment with at least **one** of the following:
   a) At least 12 weeks of photochemotherapy (i.e., psoralen plus ultraviolet A therapy);
   b) At least 12 weeks of phototherapy (i.e., UVB light therapy, Excimer laser treatments);
   c) At least a 4 week trial with topical antipsoriatic agents (i.e., anthralin, calcipotriene, coal tar, corticosteroids, tazarotene, tacrolimus, pimecrolimus); AND
6. Member has tried and failed, or unable to tolerate a systemic non-biologic DMARD (i.e., cyclosporine, methotrexate, acitretin) for at least 12 weeks.
7. **Dosage allowed/Quantity limit:**

i) Severe PsA (defined as having at least one of the following: erosive disease, active PsA at many sites including dactylitis or enthesitis, elevated levels of ESR or CRP, joint deformities, or major impairment in quality of life).

6. **Dosage allowed/Quantity limit:**
   a) Adults: 45 mg subcutaneously at 0 and 4 weeks, and then every 12 weeks thereafter. If member has co-existent moderate-to-severe PsO, use the dosing regimen for adult PsO.
   b) Pediatrics (6 to 17): subcutaneous dose by weight at week 0, week 4, and every 12 weeks thereafter.

Weight Range (kilograms)	Dosage Regimen
Less than 60 kg	0.75 mg/kg
60 kg or more	45 mg
Greater than 100 kg with co-existent moderate-to-severe plaque psoriasis	90 mg

If all the above requirements are met, the medication will be approved for 12 months.

For **reauthorization**:
1.

CareSource considers Stelara (ustekinumab) not medically necessary for the treatment of conditions that are not listed in this document. For any other indication, please refer to the Off-Label policy.

DATE	ACTION/DESCRIPTION
05/10/2017	Policy for Stelara created. Policies SRx-0042 and SRx-0043 archived. New diagnosis of Crohn's disease was added. For diagnosis of PsO: immunosuppressive criterion was separated from phototherapies and topical agents trials; TNF inhibitors Humira and Enbrel were listed as required trials; Psoriasis Area and Severity Index (PASI) score requirement was added. For diagnosis of PsA: TNF inhibitors Humira and Enbrel were listed as required trials. List of diagnoses considered not medically necessary was added.
11/13/2017	Age requirement for diagnosis of PsO updated.
02/26/2019	Humira was removed from criteria; Cimzia, Cosentyx, Otezla, Siliq and Xeljanz added to trial agents list. TB test allowed to be done within 12 months prior to initiation of therapy; chest x-ray option removed. Other drugs options allowed for PsA if there is an intolerance or contraindication to methotrexate.
[redacted]	
11/23/2020	Removed repeat TB for reauth for all diagnoses. For CD