

PHARMACY POLICY STATEMENT Kentucky Medicaid	
DRUG NAME	Stelara (ustekinumab)
BILLING CODE	J3357 (1 unit = 1 mg) Must have valid NDC for self-administered product
BENEFIT TYPE	Medical or Pharmacy
SITE OF SERVICE ALLOWED	Office/Outpatient/Home
COVERAGE REQUIREMENTS	Prior Authorization Required (Non-Preferred Product) Alternative preferred products include Enbrel, Cimzia, Cosentyx, Xeljanz, Otezla and Siliq QUANTITY LIMIT— 90 units per 56 days (after loading dose)
LIST OF DIAGNOSES CONSIDERED <b>NOT</b> MEDICALLY NECESSARY	<a href="#">Click Here</a>

Stelara (ustekinumab) is a **non-preferred** product and will only be considered for coverage under the **medical or pharmacy** benefit when the following criteria are met:

Members must be clinically diagnosed with one of the following disease states and meet their individual criteria as stated.

### CROHN'S DISEASE (CD)

For **initial** authorization:

1. Member is 18 years of age or older with moderate to severe, active CD with demonstrated corticosteroid dependence; AND
2. Must have a documented negative TB test (i.e., tuberculosis skin test (PPD), an interferon-release assay (IGRA)) within 12 months prior to starting therapy; AND
3. Medication must be prescribed by a gastroenterologist; AND
4. Member has had a documented trial and inadequate response to a 30-day trial at least one of the following: 6-mercaptopurine, azathioprine, methotrexate or corticosteroids; OR
5. Member has severe disease, as indicated by at least one of the following:
  - a) Esophageal or gastroduodenal disease;
  - b) Extensive small-bowel disease involving more than 100 cm;
  - c) History of colonic resection;
  - d) History of two or more small-bowel resections;
  - e) Perianal or rectal disease.
6. **Dosage allowed:** Induction: 260 mg - 520 mg (depending on weight) intravenously as a single dose then 8 weeks after induction dose, 90 mg subcutaneously every eight weeks.

***If member meets all the requirements listed above, the medication will be approved for 12 months.***

For **reauthorization**:

1. Must have been retested for TB with a negative result within the past 12 months; AND
2. Member must be in compliance with all other initial criteria; AND
3. Chart notes have been provided that show the member has shown improvement of signs and symptoms of disease.

***If member meets all the reauthorization requirements above, the medication will be approved for an additional 12 months.***

## **PLAQUE PSORIASIS (PsO)**

For **initial** authorization:

1. Member must be 12 years of age or older; AND
2. Must have a documented negative TB test (i.e., tuberculosis skin test (PPD), an interferon-release assay (IGRA)) within 12 months prior to starting therapy; AND
3. Medication must be prescribed by a rheumatologist or dermatologist; AND
4. Member has PsO involves 10% or more of the member's body surface area; AND
5. Member has tried and failed treatment with at least **two** of the following: Cimzia, Cosentyx, Enbrel, Otezla and Siliq (Only applicable to members who ≥ 18 years old; if member is < 18 years of age - must try Enbrel only). Treatment failure requires at least for 12 weeks of therapy with each drug; AND
6. Member's Psoriasis Area and Severity Index (PASI) score ≥ 12; AND
7. Member has tried and failed to respond to treatment with at least **one** of the following:
  - a) At least 30 days of photochemotherapy (i.e., psoralen plus ultraviolet A therapy);
  - b) At least 30 days of phototherapy (i.e., UVB light therapy, Excimer laser treatments; tanning beds emit mostly UVA light and therefore would not meet this criteria);
  - c) At least a 30-day trial with topical antipsoriatic agents (i.e., anthralin, calcipotriene, coal tar, corticosteroids, tazarotene); AND
8. Member has tried and failed to respond to treatment with traditional first-line oral/systemic therapies (i.e., cyclosporine, methotrexate, acitretin) for at least 30 days.
9. **Dosage allowed:** ≤ 100 kg: 45 mg subcutaneously at 0 and 4 weeks, and then every 12 weeks thereafter; ≥ 100 kg: 90 mg subcutaneously at 0 and 4 weeks, and then every 12 weeks thereafter.

***If member meets all the requirements listed above, the medication will be approved for 12 months.***

For **reauthorization**:

1. Must have been retested for TB with a negative result within the past 12 months; AND
2. Member must be in compliance with all other initial criteria; AND
3. Chart notes have been provided that show the member has shown improvement of signs and symptoms of disease (e.g., documented member's PASI score improvement, etc.).

***If member meets all the reauthorization requirements above, the medication will be approved for an additional 12 months.***

## **PSORIATIC ARTHRITIS (PsA)**

For **initial** authorization:

1. Member must be 18 years of age or older; AND
2. Must have a documented negative TB test (i.e., tuberculosis skin test (PPD), an interferon-release assay (IGRA)) within 12 months prior to starting therapy; AND
3. Medication must be prescribed by a rheumatologist or dermatologist; AND
4. Member has tried and failed treatment with at least **two** of the following: Enbrel, Cimzia, Cosentyx, Otezla and Xeljanz. Treatment failure requires at least for 30 days of therapy with each drug; AND
5. Member meets at least **one** of the following scenarios:
  - a) Member has predominantly axial disease (i.e., sacroiliitis or spondylitis) as indicated by radiographic evidence; OR

- b) Member has shown symptoms of predominantly axial disease (i.e., sacroiliitis or spondylitis) for more than 3 months (i.e., limited spinal range of motion, spinal morning stiffness for more than 30 minutes) and has tried and failed to respond to treatment with at least 2 prescription NSAIDs taken at the maximum recommended dosages. Treatment failure requires at least 30 days of therapy with each NSAID without an adequate response; OR
  - c) Member has predominately non-axial disease (e.g., peripheral synovitis or dactylitis or nail involvement) and has tried and failed to respond to treatment with at least 30-day trial of methotrexate and NSAID taken at the maximum recommended dosages (if unable to tolerate or has contraindication to methotrexate than 30-day trial of sulfasalazine or azathioprine or cyclosporine).
6. **Dosage allowed:** 45 mg subcutaneously at 0 and 4 weeks, and then every 12 weeks thereafter.

***If member meets all the requirements listed above, the medication will be approved for 12 months.***

For reauthorization:

1. Must have been retested for TB with a negative result within the past 12 months; AND
2. Member must be in compliance with all other initial criteria; AND
3. Chart notes have been provided that show the member has shown improvement of signs and symptoms of disease.

***If member meets all the reauthorization requirements above, the medication will be approved for an additional 12 months.***

**CareSource considers Stelara (ustekinumab) not medically necessary for the treatment of the following disease states based on a lack of robust clinical controlled trials showing superior efficacy compared to currently available treatments:**

- Active infections
- Ankylosing Spondylitis
- Asthma
- Cellulitis
- Dissecting scalp cellulitis
- For use in combination with TNF-inhibitors (i.e., Enbrel, Humira, Remicade, Kineret)
- Giant-cell arteritis
- Infectious uveitis
- Lupus perino
- Multiple sclerosis
- Osteoarthritis
- Relapsing polychondritis
- Rheumatoid Arthritis
- Sarcoidosis
- Sciatica
- Spondyloarthritis
- Takayasu’s arteritis

- Ulcerative colitis
- Vogt-Koyanagi

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.

References:

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7. Leonardi CL, Kimball AB, Yeilding N, et al. Efficacy and safety of ustekinumab, a human interleukin-12/23 monoclonal antibody, in patients with psoriasis: 76-week results from a randomized, double-blind, placebo-controlled trial (PHOENIX-1). *Lancet* 2008;371:1665-74.
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Effective date: 04/01/2019

Revised date: 02/26/2019