CareSource

PHARMACY POLICY STATEMENT **Ohio 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, Humira and Cosentyx QUANTITY LIMIT— 90 units per 56 days (after loading dose)
LIST OF DIAGNOSES CONSIDERED **NOT** MEDICALLY NECESSARY	Click Here

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 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; AND
6. Member has tried and failed treatment with Humira. Treatment failure requires at least for 12 weeks of therapy.
7. **Dosage allowed:** Induction: 260 mg - 520 mg (depending on weight, see prescribing information for details) intravenously as a single dose. A subcutaneous 90 mg dose 8 weeks after the initial intravenous dose, then every 8 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.

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: Humira, Enbrel and Cosentyx. 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 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; tanning beds emit mostly UVA light and therefore would not meet this criteria);
   c) At least a 4 week 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 12 weeks.
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: Humira, Enbrel, and Cosentyx. Treatment failure requires at least for 12 weeks 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 4 weeks 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 8-week trial of methotrexate and NSAID taken at the maximum recommended dosages (if unable to tolerate or has contraindication to methotrexate than 8-week trial of sulfasalazine or azathioprine or cyclosporine).

9. **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.

ULCERATIVE COLITIS (UC)

For **initial** authorization:

1. Member is 18 years of age or older with moderately to severely active UC as defined by Mayo score of 6 or greater with an endoscopy subscore of 2 or 3; AND
2. Medication must be prescribed by a gastroenterologist; AND
3. 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
4. Member have had a documented history of an inadequate response with, lost response to, or were intolerant to one of the following:
   a) A tumor necrosis factor (TNF) blocker (e.g., Humira, Remicade, Cimzia, etc.);
   b) Immunomodulator (e.g., 6-mercaptopurine, azathioprine);
   c) Corticosteroids (or demonstrated dependence on corticosteroids);
   d) Salicylates (e.g., Asacol HD, Lialda, Pentasa, Delzicol, mesalamine, sulfasalazine, olsalazine, etc.).
5. **Dosage allowed:** Induction: 260 mg - 520 mg (depending on weight, see prescribing information for details) intravenously as a single dose. A subcutaneous 90 mg dose 8 weeks after the initial intravenous dose, then every 8 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)
- Giant-cell arteritis
- Infectious uveitis
- Lupus perino
- Multiple sclerosis
- Osteoarthritis
- Relapsing polychondritis
- Rheumatoid Arthritis
- Sarcoidosis
- Sciatica
- Spondyloarthritis
- Takayasu's arteritis
- 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.
10/31/2019	New indication of Ulcerative Colitis added. Based on the Ohio Department of Medicaid requirement Cimzia, Otezla, Siliq and Xeljanz were removed from trial agents list; Humira was added back.

References:

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