**PHARMACY POLICY STATEMENT**

**Ohio Medicaid**

<table>
<thead>
<tr>
<th>DRUG NAME</th>
<th>Stelara (ustekinumab)</th>
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<tbody>
<tr>
<td>BILLING CODE</td>
<td>J3358 (1 unit = 1 mg)</td>
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<tr>
<td>Must have valid NDC for self-administered product</td>
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<tr>
<td>BENEFIT TYPE</td>
<td>Medical or Pharmacy</td>
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<tr>
<td>SITE OF SERVICE ALLOWED</td>
<td>Office/Outpatient Hospital/Home</td>
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<tr>
<td>COVERAGE REQUIREMENTS</td>
<td>Prior Authorization Required (Non-Preferred Product)</td>
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<tr>
<td>Alternative preferred products include Enbrel and Humira</td>
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<tr>
<td>QUANTITY LIMIT</td>
<td>90 units per 56 days (after loading dose)</td>
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<tr>
<td>LIST OF DIAGNOSES CONSIDERED NOT MEDICALLY NECESSARY</td>
<td>Click Here</td>
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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), or a chest x-ray) within 6 months prior to starting therapy; AND
3. Medication must be prescribed by a gastroenterologist; AND
4. Member has documented trial and failure of or contraindication to Humira. Treatment failure requires at least 12 weeks of therapy without an adequate response; AND
5. Member has had a documented inadequate response to 6-mercaptopurine, azathioprine or methotrexate; OR
6. Member has severe esophageal or gastroduodenal disease; OR
7. Member has extensive small-bowel disease involving more than 100 cm; OR
8. Member has a history of colonic resection; OR
9. Member has a history of two or more small bowel resections; OR
10. Member has perianal or rectal disease.
11. **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 (PP)

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), or a chest x-ray) within 6 months prior to starting therapy; AND
3. Medication must be prescribed by a rheumatologist or dermatologist; AND
4. Member has PP involves 10% or more of the member’s body surface area; AND
5. Member has tried and failed treatment with both Enbrel and Humira (Humira applied only for those who 18 years of age or older); AND
6. Member’s Psoriasis Area and Severity Index (PASI) score is greater than or equal to 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 of an immunosuppressant (i.e. cyclosporine, methotrexate, acetretin) for at least a 12 week trial.
9. Dosage allowed: ≤ 100kg: 45mg subcutaneously at 0 and 4 weeks, and then every 12 weeks thereafter; ≥ 100kg: 90mg 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.

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), or a chest x-ray) within 6 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 both Enbrel and Humira; 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 without an adequate response; OR
   c) Member has predominately non-axial disease and has tried and failed to respond to treatment with at least an 8 week trial of methotrexate and NSAID.
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

<table>
<thead>
<tr>
<th>DATE</th>
<th>ACTION/DESCRIPTION</th>
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<tbody>
<tr>
<td>05/10/2017</td>
<td>Policy for Stelara created. Policies SRx-0042 and SRx-0043 archived. New diagnosis of Crohn’s disease was added. For diagnosis of PP: 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.</td>
</tr>
<tr>
<td>11/13/2017</td>
<td>Age requirement for diagnosis of PP updated.</td>
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</tbody>
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References:
2. US Food and Drug Administration Drug Safety Data. 
   http://www.accessdata.fda.gov/drugsatfda_docs/label/2014/125261s114lbl.pdf
   (October 14, 2014)
   Section 6. Guidelines of care for the treatment of psoriasis and psoriatic arthritis: Case-based presentations and
   monoclonal antibody, in patients with psoriasis: 76-week results from a randomized, double-blind, placebo-
    arthritis: 1 year results of the phase 3, multicentre, double-blind, placebo-controlled PSUMMIT 1 trial. Lancet.

Effective date: 11/29/2017
Revised date: 11/13/2017