PHARMACY POLICY STATEMENT
Ohio Medicaid

<table>
<thead>
<tr>
<th>DRUG NAME</th>
<th>Cosentyx (secukinumab)</th>
</tr>
</thead>
<tbody>
<tr>
<td>BILLING CODE</td>
<td>Must use valid NDC code</td>
</tr>
<tr>
<td>BENEFIT TYPE</td>
<td>Pharmacy</td>
</tr>
<tr>
<td>SITE OF SERVICE ALLOWED</td>
<td>Home</td>
</tr>
<tr>
<td>COVERAGE REQUIREMENTS</td>
<td>Prior Authorization Required (Non-Preferred Product)</td>
</tr>
<tr>
<td></td>
<td>Alternative preferred products include Enbrel and Humira</td>
</tr>
<tr>
<td>QUANTITY LIMIT</td>
<td>1 per 28 days (after loading dose)</td>
</tr>
</tbody>
</table>

LIST OF DIAGNOSES CONSIDERED NOT MEDICALLY NECESSARY
Click Here

Cosentyx (secukinumab) is a non-preferred product and will only be considered for coverage under the 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.

**ANKYLOSING SPONDYLITIS (AS)**

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; AND
4. Member has had back pain for 3 months or more that began before the age of 45; AND
5. Current imaging results show an inflammation of one or both of the sacroiliac joints; AND
6. Member shows at least one of the following signs or symptoms of Spondyloarthritis:
   a) Arthritis;
   b) Elevated serum C-reactive protein;
   c) Inflammation at the tendon, ligament or joint capsule insertions;
   d) Positive HLA-B27 test;
   e) Limited chest expansion;
   f) Morning stiffness for 1 hour or more; AND
7. Member meets at least one of the following scenarios:
   a) Member has Axial (spinal) disease;
   b) Member has peripheral arthritis without axial involvement and has tried and failed treatment with methotrexate or sulfasalazine. Treatment failure requires at least 3 months of therapy without an adequate response; AND
8. Member 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.
9. Member has tried and failed treatment with both Enbrel and Humira.
10. Dosage allowed: With a loading dosage is 150 mg at weeks 0, 1, 2, 3, and 4 and every 4 weeks thereafter; without a loading dosage is 150 mg every 4 weeks.

*If member meets all the requirements listed above, the medication will be approved for 12 months.*
For **reauthorization**:
1. Member must be 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 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 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; 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:** 300 mg by subcutaneous injection at Weeks 0, 1, 2, 3, and 4 followed by 300 mg every 4 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.**

---

### 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 a nd 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 8-week trial of methotrexate and NSAID.

6. **Dosage allowed:** With a loading dosage is 150 mg at weeks 0, 1, 2, 3, and 4 and every 4 weeks thereafter; without a loading dosage is 150 mg every 4 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.

CareSource considers Cosentyx (secukinumab) 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
- Asthma
- Cellulitis
- Crohn’s Disease
- Dissecting scalp cellulitis
- For use in combination with other TNF-inhibitors (i.e. Kineret, Enbrel, Remicade)
- Giant-cell arteritis
- Guttate psoriasis
- Infectious uveitis
- Lupus perin
- Osteoarthritis
- Recurrent pregnancy loss
- Relapsing polychondritis
- Sarcoidosis
- Sciatica
- Spondyloarthritis (other than ankylosing spondylitis)
- Takayasu’s arteritis
- Vogt-Koyanagi

<table>
<thead>
<tr>
<th>DATE</th>
<th>ACTION/DESCRIPTION</th>
</tr>
</thead>
<tbody>
<tr>
<td>05/08/2017</td>
<td>New policy for Cosentyx created. Policies SRx-0043 achieved. New diagnoses of AS and PsA with criteria were 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. List of diagnoses considered not medically necessary was added.</td>
</tr>
</tbody>
</table>

References:


Effective date: 05/08/2017
Revised date: 05/08/2017