Cosentyx® (secukinumab)  
Effective 02/20/2019

Plan Benefits
☐ MassHealth  ☒ Commercial/Exchange
☒ Pharmacy Benefit  ☐ Medical Benefit (NLX)

Program Type
☒ Prior Authorization  ☐ Quantity Limit  ☐ Step Therapy

Specialty Limitations
This medication has been designated specialty and must be filled at a contracted specialty pharmacy.

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<tr>
<th>Specialty Medications</th>
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<tbody>
<tr>
<td>All Plans</td>
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<tr>
<td>Phone: 866-814-5506</td>
</tr>
<tr>
<td>Fax: 866-249-6155</td>
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<tr>
<th>Non-Specialty Medications</th>
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<tbody>
<tr>
<td>MassHealth</td>
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<tr>
<td>Phone: 877-433-7643</td>
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<tr>
<td>Fax: 866-255-7569</td>
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<tr>
<td>Commercial</td>
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<tr>
<td>Phone: 800-294-5979</td>
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<tr>
<td>Fax: 888-836-0730</td>
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<tr>
<td>Exchange</td>
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<tr>
<td>Phone: 855-582-2022</td>
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<tr>
<td>Fax: 855-245-2134</td>
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<th>Medical Specialty Medications (NLX)</th>
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<tr>
<td>All Plans</td>
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<tr>
<td>Phone: 844-345-2803</td>
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<td>Fax: 844-851-0882</td>
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Exceptions
N/A

Overview
The indications below including FDA-approved indications and compendial uses are considered a covered benefit provided that all the approval criteria are met, and the member has no exclusions to the prescribed therapy.

FDA-Approved Indications
1. Moderate to severe plaque psoriasis (PsO)
2. Active psoriatic arthritis (PsA)
3. Active ankylosing spondylitis (AS)

All other indications are considered experimental/investigational and are not a covered benefit.

Coverage Guidelines

A. Moderate to severe plaque psoriasis
1. Authorization may be granted for members who have previously received Cosentyx, Otezla, or any other biologic DMARD indicated for the treatment of moderate to severe plaque psoriasis.
   a. Authorization may be granted for treatment of moderate to severe plaque psoriasis when all the following criteria are met:
      a. At least 5% of body surface area (BSA) is affected OR crucial body areas (e.g., hands, feet, face, neck, scalp, genitals/groin, intertriginous areas) are affected.
      b. Member meets any of the following criteria:
i. Member has had an inadequate response or intolerance to TWO conventional therapies in any of the following combinations:
   o 1 topical agent + 1 systemic agent (methotrexate, cyclosporine, or acitretin)
   o 1 topical agent + 1 phototherapy (e.g., UVB, PUVA)
   o 1 systemic agent + 1 phototherapy (e.g., UVB, PUVA)
   o 2 systemic agents

ii. Member has a clinical reason to avoid ALL conventional therapies (topical agents, phototherapy, and systemic agents). See Appendix A

iii. Member has severe psoriasis that warrants a biologic DMARD as first-line therapy.

B. Active psoriatic arthritis (PsA)

1. Authorization may be granted for members who have previously received Cosentyx, Otezla, Stelara, or Taltz.

2. Authorization may be granted for treatment of active PsA when BOTH of the following criteria is met:
   a. One of the following:
      o Member has had an inadequate response to at least a 3-month trial of at least one TNF inhibitor indicated for PsA (see Appendix B).
      o Member has experienced an intolerance to a trial of at least one TNF inhibitor indicated for PsA.
      OR
      o All TNF inhibitors indicated for PsA are not appropriate for the member (e.g., due to comorbidities or a history of infections).

   AND

   b. One of the following:
      o Patient has had an intolerance to or inadequate response (after at least 3 months of treatment) with methotrexate OR leflunomide.
      o Patient has a contraindication to BOTH methotrexate and leflunomide AND has experienced an inadequate response, intolerance, or contraindication to sulfasalazine.

C. Active ankylosing spondylitis (AS)

1. Authorization may be granted for members who have previously received Cosentyx or any other biologic DMARD indicated for active ankylosing spondylitis.

2. Authorization of 24 months may be granted for treatment of active AS when any of the following criteria is met:
   a. Member has experienced an inadequate response to at least two non-steroidal anti-inflammatory drugs (NSAIDs).
   b. Member has an intolerance or contraindication to two or more NSAIDs.

Continuation of Therapy

A. For plaque psoriasis:
   Authorization may be granted for all members (including new members) who meet all initial authorization criteria and achieve or maintain positive clinical response after at least 3 months of
therapy with Cosentyx as evidenced by low disease activity or improvement in signs and symptoms of the condition.

B. For psoriatic arthritis and ankylosing spondylitis:
Authorization may be granted for all members (including new members) who meet all initial authorization criteria and achieve or maintain positive clinical response after at least 4 months of therapy with Cosentyx as evidenced by low disease activity or improvement in signs and symptoms of the condition.

Limitations
1. Initial approvals will be granted for 24 months
2. Reauthorizations will be granted for 24 months

Appendices

Appendix A: Examples of Clinical Reasons to Avoid Pharmacologic Treatment with Methotrexate, Cyclosporine or Acitretin.
1. Alcoholism, alcoholic liver disease or other chronic liver disease
2. Breastfeeding
3. Drug interaction
4. Cannot be used due to risk of treatment-related toxicity
5. Pregnancy or planning pregnancy (male or female)
6. Significant comorbidity prohibits use of systemic agents (examples include liver or kidney disease, blood dyscrasias, uncontrolled hypertension)

Appendix B: TNF Inhibitors Indicated for Psoriatic Arthritis
1. Cimzia (certolizumab pegol)
2. Enbrel (etanercept)
3. Humira (adalimumab)
4. Inflectra (infliximab-dyyb)
5. Renflexis (infliximab-abda)
6. Remicade (infliximab)
7. Simponi (golimumab)

Other
For all indications: Member has a pretreatment tuberculosis (TB) screening with a TB skin test or an interferon gamma release assay (e.g., QFT-GIT, T-SPOT.TB).

Note: Members who have received Cosentyx or any other biologic DMARD or targeted synthetic DMARD (e.g., Xeljanz) are exempt from requirements related to TB screening in this Policy.

References
1. Cosentyx (secukinumab) [prescribing information]. East Hanover, NJ: Novartis Pharmaceuticals; June 2018


Review History
02/22/2016: Reviewed P&T Mtg
02/27/2017: Reviewed & Revised (added Step)
02/26/2018: Reviewed & Revised P&T Mtg
02/20/2019: Reviewed & Revised P&T Mtg

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