Clinical Policy: Secukinumab (Cosentyx)
Reference Number: ERX.SPMN.169
Effective Date: 10/2016
Last Review Date: 12/2016

See Important Reminder at the end of this policy for important regulatory and legal information.

Policy/Criteria
It is the policy of health plans affiliated with Envolve Pharmacy Solutions™ that secukinumab (Cosentyx®) is medically necessary when one of the following criteria are met:

I. Initial Approval Criteria
   A. Plaque Psoriasis (must meet all):
      1. Prescribed by or in consultation with a dermatologist or rheumatologist;
      2. Age ≥ 18 years;
      3. Diagnosis of moderate to severe plaque psoriasis (PsO) and one or more of the following:
         a. Greater than 5% of body surface area is affected;
         b. Palms, soles, face and neck, body folds, or genitalia is involved;
      4. Member has failed phototherapy and a topical therapy (e.g., calcipotriene, coal tar preparations, medium-to-high potency corticosteroids, anthralin, tazarotene);
      5. Member has failed one of the following therapies unless intolerant or contraindicated:
         a. A biologic for PsO other than Cosentyx;
         b. One or more systemic therapies (e.g., methotrexate [MTX], cyclosporine, acitretin, thioguanine) for ≥ 3 consecutive months;
      6. Member has failed Enbrel AND Humira, each trialed for ≥ 3 consecutive months, unless intolerant or contraindicated;
      7. Prescribed dose of Cosentyx does not exceed 300 mg at weeks 0, 1, 2, 3 and 4, then every 4 weeks thereafter.

      Approval duration: 6 months

   B. Ankylosing Spondylitis (must meet all):
      1. Prescribed by or in consultation with a rheumatologist;
      2. Age ≥ 18 years;
      3. Diagnosis of active ankylosing spondylitis;
      4. Member has failed one of the following therapies unless intolerant or contraindicated:
         a. A biologic for ankylosing spondylitis other than Cosentyx;
         b. At least 2 nonsteroidal anti-inflammatory drugs (NSAIDs) at maximum tolerated doses, each for ≥ 4 weeks;
      5. Member has failed Enbrel AND Humira, each trialed for ≥ 3 consecutive months, unless intolerant or contraindicated;
      6. Prescribed dose of Cosentyx does not exceed 150 mg at weeks 0, 1, 2, 3, and 4 (loading dosage), then every 4 weeks thereafter.

      Approval duration: 6 months
C. **Psoriatic Arthritis** (must meet all):
   1. Prescribed by or in consultation with a dermatologist or rheumatologist;
   2. Age ≥ 18 years;
   3. Diagnosis of active psoriatic arthritis (PsA);
   4. Member has failed one of the following therapies unless intolerant or contraindicated:
      a. A biologic for PsA other than Cosentyx;
      b. MTX for ≥ 3 consecutive months;
      c. If intolerance or contraindication to MTX, sulfasalazine, leflunomide, cyclosporine, or azathioprine, for ≥ 3 consecutive months;
   5. Member has failed Enbrel AND Humira, each trialed for ≥ 3 consecutive months, unless intolerant or contraindicated;
   6. Prescribed dose of Cosentyx does not exceed 150 mg at weeks 0, 1, 2, 3 and 4 (loading dosage), then 300 mg every 4 weeks thereafter.

   **Approval duration: 6 months**

D. **Other diagnoses/indications:** Refer to ERX.SPMN.16 - Global Biopharm Policy

II. **Continued Approval**

A. **All Indications** (must meet all):
   1. Currently receiving medication via health plan benefit or member has previously met all initial approval criteria;
   2. Member is responding positively to therapy;
   3. Prescribed dose does not exceed the following:
      a. For plaque psoriasis: 300 mg every 4 weeks;
      b. For ankylosing spondylitis: 150 mg every 4 weeks;
      c. For psoriatic arthritis: 300 mg every 4 weeks.

   **Approval duration: 12 months**

B. **Other diagnoses/indications** (must meet 1 or 2):
   1. Currently receiving medication via health plan benefit and documentation supports positive response to therapy; or
   2. Refer to ERX.SPMN.16 - Global Biopharm Policy.

**Background**

*Description/Mechanism of Action:*
Secukinumab is a human IgG1 monoclonal antibody that selectively binds to the interleukin-17A (IL-17A) cytokine and inhibits its interaction with the IL-17 receptor. IL-17A is a naturally occurring cytokine that is involved in normal inflammatory and immune responses. Secukinumab inhibits the release of proinflammatory cytokines and chemokines.

*Formulations:*
Cosentyx is available as follows:
- Injection: 150 mg/mL solution in a single-use Sensoready pen
Clinical Policy
Secukinumab

- Injection: 150 mg/mL solution in a single-use prefilled syringe
- Injection: 150 mg, lyophilized powder in a single-use vial for reconstitution (for healthcare professional use only)

FDA Approved Indication(s):
Cosentyx is a human interleukin-17A antagonist/injection for subcutaneous use indicated for the treatment of:
- Moderate to severe plaque psoriasis in adult patients who are candidates for systemic therapy or phototherapy.
- Adults with active psoriatic arthritis
- Adults with active ankylosing spondylitis.

Appendices
Appendix A: Abbreviation Key
BSA: body surface area
DMARDs: disease-modifying antirheumatic drugs
IL-17A: interleukin-17A
PsA: psoriatic arthritis
PsO: plaque psoriasis
TB: tuberculosis

Reviews, Revisions, and Approvals

<table>
<thead>
<tr>
<th>Description</th>
<th>Date</th>
<th>Approval Date</th>
</tr>
</thead>
<tbody>
<tr>
<td>Policy created.</td>
<td>08/16</td>
<td>09/16</td>
</tr>
<tr>
<td>For all trial/failure requirements, indicated that member can also meet criteria if intolerant (as opposed to just contraindicated) to therapy in question. Modified the following initial criteria sets: -PsO: indicated that disease must be moderate to severe. -AS: indicated that disease must be active. -PsA: indicated that disease must be active. Modified trial/failure requirement- instead of requiring 2 or more nonbiologic DMARDs (such as cyclosporine, sulfasalazine, azathioprine, hydroxychloroquine), criteria now requires MTX; if MTX is contraindicated, then cyclosporine, sulfasalazine, leflunomide, cyclosporine, or azathioprine may be trialed.</td>
<td>11/16</td>
<td>12/16</td>
</tr>
</tbody>
</table>

References
Clinical Policy
Secukinumab


Important Reminder
This clinical policy has been developed by appropriately experienced and licensed health care professionals based on a review and consideration of currently available generally accepted standards of medical practice; peer-reviewed medical literature; government agency/program approval status; evidence-based guidelines and positions of leading national health professional organizations; views of physicians practicing in relevant clinical areas affected by this clinical policy; and other available clinical information.

This Clinical Policy is not intended to dictate to providers how to practice medicine, nor does it constitute a contract or guarantee regarding payment or results. Providers are expected to exercise professional medical judgment in providing the most appropriate care, and are solely responsible for the medical advice and treatment of members.

This policy is the property of Envolve Pharmacy Solutions. Unauthorized copying, use, and distribution of this Policy or any information contained herein is strictly prohibited. By accessing this policy, you agree to be bound by the foregoing terms and conditions, in addition to the Site Use Agreement for Health Plans associated with Envolve Pharmacy Solutions.

©2016 Envolve Pharmacy Solutions. All rights reserved. All materials are exclusively owned by Envolve Pharmacy Solutions and are protected by United States copyright law and international copyright law. No part of this publication may be reproduced, copied, modified, distributed, displayed, stored in a retrieval system, transmitted in any form or by any means, or otherwise published without the prior written permission of Envolve Pharmacy Solutions. You may not alter or remove any trademark, copyright or other notice contained herein.