Cosentyx (secukinumab)

Override(s) | Approval Duration
---|---
Prior Authorization Quantity Limit | 1 year

<table>
<thead>
<tr>
<th>Medications</th>
<th>Quantity Limit*</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cosentyx (secukinumab) 150 mg/mL Sensoready pen^*</td>
<td>2 pens per 28 days</td>
</tr>
<tr>
<td>Cosentyx (secukinumab) 150 mg/mL Sensoready Pen 2-Pack**</td>
<td>1 pack (2 x 150 mg/mL pens)</td>
</tr>
<tr>
<td>Cosentyx (secukinumab) 150 mg/mL prefilled syringe^*</td>
<td>2 syringes per 28 days</td>
</tr>
<tr>
<td>Cosentyx (secukinumab) 150 mg/mL prefilled Syringe 2-Pack**</td>
<td>1 pack (2 x 150 mg/mL syringes)</td>
</tr>
</tbody>
</table>

^Initiation of therapy for Psoriatic Arthritis (PsA) without coexistent Plaque Psoriasis (Ps) (Psoriasis vulgaris) or Ankylosing Spondylitis (AS): May approve up to an additional 3 (three) single pens (150 mg/mL) or 3 (three) single syringes (150 mg/mL) in the first month (28 days) of treatment.

* Initiation of therapy for Plaque Ps (Psoriasis vulgaris) or PsA with coexistent Plaque Ps (Psoriasis vulgaris): May approve up to an additional 4 (four) 2-pack pens (2 x 150 mg/mL), 4 (four) 2-pack syringes (2 x 150 mg/mL), 8 (eight) single additional pens (150 mg/mL), or 8 (eight) single syringes (150 mg/mL) in the first month (28 days) of treatment.

** APPROVAL CRITERIA

Requests for Cosentyx (secukinumab) may be approved for the following:

I. Ankylosing spondylitis (AS) when each of the following criteria are met:
   A. Individual is 18 years of age or older with moderate to severe AS;
   AND
   B. Individual has had an inadequate response to, is intolerant of, or has a contraindication to conventional therapy [such as NSAIDs or nonbiologic disease-modifying anti-rheumatic drugs (DMARDs) (such as sulfasalazine)] or a tumor necrosis factor (TNF) antagonist;

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AND
C. Individual has had a trial (medication samples/coupons/discount cards are excluded from consideration as a trial) and inadequate response or intolerance to TWO preferred biologic agents. [Current preferred biologics include – Enbrel (etanercept), Humira (adalimumab)] unless the following criteria is met;
   1. Individual has been receiving and is maintained on a stable dose of Cosentyx (secukinumab); OR
   2. The preferred agents are not FDA-approved and do not have an accepted off-label use per the off-label policy for the prescribed indication and Cosentyx (secukinumab) does; OR
   3. The preferred agents are not acceptable due to concomitant clinical conditions, such as but not limited to any of the following:
      a. Known hypersensitivity to any active or inactive component which is not also associated with Cosentyx (secukinumab); OR
      b. Individual's age; OR
      c. Pregnant or planning on becoming pregnant; OR
      d. Serious infections or concurrent sepsis; OR
   4. The individual has either concomitant clinical condition:
      a. Demyelinating disease; OR
      b. Heart failure with documented left ventricular dysfunction;

OR
II. Plaque Psoriasis (Ps) (Psoriasis vulgaris) when each of the following criteria are met:
   A. Individual is 18 years of age or older with chronic moderate to severe (that is, extensive or disabling) plaque Ps with either of the following: (AAD 2011):
      1. Plaque Ps (psoriasis vulgaris) involving greater than five percent (5%) body surface area (BSA); OR
      2. Plaque Ps (psoriasis vulgaris) involving less than or equal to five percent (5%) BSA involving sensitive areas or areas that significantly impact daily function (such as palms, soles of feet, head/neck, or genitalia);

   AND
   B. Individual has had an inadequate response to, is intolerant of, or has a contraindication to phototherapy or other systemic therapy (such as acitretin, cyclosporine, or methotrexate);

   AND
   C. Individual has had a trial (medication samples/coupons/discount cards are excluded from consideration as a trial) and inadequate response or intolerance to TWO preferred biologic agents. [Current preferred biologics include – Enbrel (etanercept), Humira (adalimumab)] unless the following criteria is met;
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2. The preferred agents are not FDA-approved and do not have an accepted off-label use per the off-label policy for the prescribed indication and Cosentyx (secukinumab) does; OR

3. The preferred agents are not acceptable due to concomitant clinical conditions, such as but not limited to any of the following:
   a. Known hypersensitivity to any active or inactive component which is not also associated with Cosentyx (secukinumab); OR
   b. Individual's age; OR
   c. Pregnant or planning on becoming pregnant; OR
   d. Serious infections or concurrent sepsis; OR

4. The individual has either concomitant clinical condition:
   a. Demyelinating disease; OR
   b. Heart failure with documented left ventricular dysfunction; OR

5. The preferred agent(s) do not have activity against a concomitant clinical condition and Cosentyx (secukinumab) does. Examples include but may not be limited to the following:
   a. Concomitant Crohn’s Disease: TNFi (agents FDA-approved for both indications) or Stelara are preferred; OR
   b. Concomitant Ulcerative Colitis: TNFi (agents FDA-approved for both indications) are preferred.

Requests for Cosentyx (secukinumab) may not be approved for the following:

I. In combination with phototherapy; OR
II. In combination with other IL-17 inhibitors or biologic drugs (such as TNF antagonists or ustekinumab) ; OR
III. Tuberculosis, other active serious infections, or a history of recurrent infections; OR
IV. Individual has not had a tuberculin skin test (TST) or a Centers for Disease Control (CDC-) and Prevention - recommended equivalent test to evaluate for latent tuberculosis prior to initiating secukinumab.
Market Applicability

<table>
<thead>
<tr>
<th>Market</th>
<th>DC</th>
<th>FL &amp; FHA</th>
<th>FL</th>
<th>GA</th>
<th>KS</th>
<th>KY</th>
<th>MD</th>
<th>NJ</th>
<th>NV</th>
<th>NY</th>
<th>TN</th>
<th>TX</th>
<th>WA</th>
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<tbody>
<tr>
<td>Applicable</td>
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<td>NA</td>
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<td>X</td>
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<td>X</td>
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<td>NA</td>
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*FHK- Florida Healthy Kids

State Specific Mandates

<table>
<thead>
<tr>
<th>State name</th>
<th>Date effective</th>
<th>Mandate details (including specific bill if applicable)</th>
</tr>
</thead>
<tbody>
<tr>
<td>N/A</td>
<td>N/A</td>
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</tbody>
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Key References:

4. Lexi-Comp ONLINE™ with AHFS™, Hudson, Ohio: Lexi-Comp, Inc.; 2018; Updated periodically.

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