# Cosentyx (secukinumab)

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

| Medications | Quantity Limit* |
|---|---|
| Cosentyx (secukinumab) 75 mg/0.5 mL Prefilled Syringe* | 1 syringe per 28 days |
| Cosentyx (secukinumab) 150 mg/mL Sensoready pen* | 1 pen per 28 days |
| Cosentyx (secukinumab) 150 mg/mL Sensoready Pen 2-Pack*^ | 1 pack (2 x 150 mg/mL pens) |
| Cosentyx (secukinumab) 150 mg/mL Prefilled Syringe* | 1 syringe per 28 days |
| Cosentyx (secukinumab) 150 mg/mL Prefilled Syringe 2-Pack*^ | 1 pack (2 x 150 mg/mL syringes) |
| Cosentyx (secukinumab) 300 mg/2mL UnoReady Pen/Prefilled Syringe*^ | 1 pen/syringe per 28 days |
| Cosentyx (secukinumab) 125 mg/ 5 mL single-dose vial* | 3 vials every 4 weeks |
| | **Dosing Limit** |
| Cosentyx (secukinumab) 125 mg/ 5 mL single-dose vial* | 1.75 mg/kg, up to a max limit of 300 mg [3 vials], every 4 weeks |

*FDA recommended dosing for Adult Psoriatic Arthritis (PsA) without coexistent plaque psoriasis (Ps), Ankylosing Spondylitis (AS) or non-radiographic axial spondyloarthritis (nr-axSpA): Optional loading doses of 150 mg at weeks 0, 1, 2, 3, 4; maintenance dose of 150 mg every 4 weeks; continued active PsA/AS maintenance dose of 300 mg every 4 weeks
*FDA recommended dosing for Enthesis-related arthritis (ERA) or Pediatric PsA without coexistent Ps: Loading doses of 150 mg or 75 mg (depending on weight) at weeks 0, 1, 2, 3, 4; maintenance dose of 150 mg or 75 mg (depending on weight) every 4 weeks.
*FDA recommended dosing Plaque Psoriasis (Ps) with or without coexisting Psoriatic Arthritis (PsA): Adults: Loading doses of 300 mg at weeks 0, 1, 2, 3, 4; maintenance dose of 300 mg every 4 weeks; loading and maintenance doses of 150 mg every 4 weeks may be acceptable. Pediatric: Loading doses of 150 mg or 75 mg (depending on weight) at weeks 0, 1, 2, 3, 4; maintenance dose of 150 mg or 75 mg (depending on weight) every 4 weeks.
*FDA recommended dosing for Hidradenitis Suppurativa: Loading doses of 300 mg at weeks 0, 1, 2, 3, 4; maintenance dose of 300 mg every 4 weeks; may increase to 300 mg every 2 weeks for inadequate response.
*FDA recommended intravenous dosing for adult PsA, AS, and nr-axSpA: Optional 6 mg/kg loading dose followed by maintenance dosing of 1.75 mg/kg [max 300 mg] every 4 weeks thereafter.

*Initiation of therapy:

May approve a total of 5 (five) single pens (150 mg/mL) or 5 (five) single syringes (150 mg/mL or 75 mg/0.5 mL) in the first 35 days of treatment; **OR**

May approve a total of 5 (five) 2-pack pens (2 x 150 mg/mL) or 5 (five) 2-pack syringes (2 x 150 mg/mL) in the first 35 days of treatment; **OR**

May approve a total or 5 (five) 300 mg pens or 5 (five) 300 mg syringes in the first 35 days of treatment; **OR**

May approve enough single-dose vials for a single 6 mg/kg loading dose for initiating intravenous treatment in PsA, nr-axSpA, and AS.

^Maintenance therapy: May approve up to two 2-pack pens (2 x 150 mg/mL) OR up to two 2-pack syringes (2 x 150 mg/mL) OR up to two 300 mg pen/syringes every 28 days for individuals with Hidradenitis Suppurativa who do not respond to standard dosing of 300 mg every 4 weeks.

## APPROVAL CRITERIA

Initial 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 or is intolerant of conventional therapy [such as NSAIDs or nonbiologic disease-modifying anti-rheumatic drugs (DMARDs) (such as sulfasalazine)]; **OR**
   C. Individual has a contraindication to NSAIDs or sulfasalazine;

**OR**

II. Non-radiographic axial spondyloarthritis (nr-axSpA) when each of the following criteria are met:
   A. Individual is 18 years of age or older with moderate to severe nr-axSpA; **AND**
   B. Individual has had an inadequate response to or is intolerant of conventional therapy [such as NSAIDs or nonbiologic DMARDs (such as sulfasalazine)] (ACR 2019); **OR**
   C. Individual has a contraindication to NSAIDs or sulfasalazine;

**OR**

III. Plaque Psoriasis (Ps) (Psoriasis vulgaris) when each of the following criteria are met:
   A. Individual is 6 years of age or older with chronic moderate to severe (that is, extensive or disabling) plaque Ps with either of the following: (AAD 2019):
      1. Plaque Ps (psoriasis vulgaris) involving greater than three percent (3%) body surface area (BSA); **OR**
      2. Plaque Ps (psoriasis vulgaris) involving less than or equal to three percent (3%) 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 or is intolerant of phototherapy or other systemic therapy (such as acitretin, cyclosporine, or methotrexate); **OR**
   C. Individual has a contraindication to phototherapy, acitretin, cyclosporine, and methotrexate;

**OR**

IV. Psoriatic arthritis (PsA) when each of the following criteria are met:
   A. Individual is 2 years of age or older with moderate to severe PsA;
   **AND**
   B. Individual has had an inadequate response to or is intolerant of conventional therapy [nonbiologic disease modifying anti-rheumatic drugs (DMARDs) (such as methotrexate, sulfasalazine, cyclosporine or leflunomide)] (ACR 2019); **OR**

C. Individual has a contraindication to methotrexate, sulfasalazine, cyclosporine, and leflunomide;

**OR**

V. Enthesitis-Related Arthritis (ERA) when each of the following criteria are met:
   A. Individual is 4 years of age or older with moderate to severe ERA; **AND**
   B. Individual has had an inadequate response to or is intolerant of conventional therapy [such as NSAIDs or nonbiologic DMARDs (such as methotrexate or sulfasalazine)]; **OR**
   C. Individual has a contraindication to NSAIDs or sulfasalazine or methotrexate;

**OR**

VI. Hidradenitis suppurativa (HS) when each of the following criteria are met:
   A. Individual is 18 years of age or older; **AND**
   B. Individual has moderate to severe HS; **AND**
   C. Individual has had an inadequate response to or is intolerant of conventional therapy (such as oral antibiotics); **OR**
   D. Individual has a contraindication to oral antibiotics.

Continuation requests for Cosentyx (secukinumab) may be approved if the following criterion is met:

I. Individual has been receiving and is maintained on a stable dose of Cosentyx. Medication samples/coupons/discount cards are excluded from consideration as a trial.; **AND**
II. There is clinically significant improvement or stabilization in clinical signs and symptoms of disease.

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

I. In combination with phototherapy; **OR**
II. In combination with topical or oral JAK inhibitors, ozanimod, etrasimod, apremilast, deucravacitinib, or any of the following biologic immunomodulators: TNF antagonists, IL-23 inhibitors, other IL-17 inhibitors, vedolizumab, ustekinumab, abatacept, IL-1 inhibitors, IL-6 inhibitors, rituximab or natalizumab; **OR**
III. Tuberculosis, other active serious infections, or a history of recurrent infections [repeat TB testing not required for ongoing therapy]; **OR**
IV. If initiating therapy, 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 (unless switching therapy from another targeted immune modulator and no new risk factors); **OR**
V. When the above criteria are not met and for all other indications.

**Key References**:


1. Alikhan A, Sayed C, Alavi A et al. North American clinical management guidelines for hidradenitis suppurativa: A publication from the United States and Canadian Hidradenitis Suppurativa Foundations: Part II: Topical, intralesional, and systemic medical management. J Am Acad Dermatol. 2019; 81:91-101.
2. Centers for Disease Control and Prevention (CDC). Tuberculosis (TB). Available at: https://www.cdc.gov/tb/risk-factors/?CDC_AAref_Val=https://www.cdc.gov/tb/topic/basics/risk.htm. Last updated: March 12, 2024.
3. DailyMed. Package inserts. U.S. National Library of Medicine, National Institutes of Health website. http://dailymed.nlm.nih.gov/dailymed/about.cfm. Accessed: September 24, 2024.
4. DrugPoints® System [electronic version]. Truven Health Analytics, Greenwood Village, CO. Updated periodically.
5. Lexi-Comp ONLINE™ with AHFS™, Hudson, Ohio: Lexi-Comp, Inc.; 2024; Updated periodically.
6. Menter A, Strober BE, Kaplan DH, et al. Joint AAD-NPF guidelines of care for the management and treatment of psoriasis with biologics. *J Am Acad Dermatol*. 2019; 80: 1029-72.
7. Singh JA, Guyatt G, Ogdie A, et al. 2018 American College of Rheumatology/National Psoriasis Foundation Guideline for the Treatment of Psoriatic Arthritis. Arthritis Rheum. 2019; 71(1): 5-32.
8. Ward MM. Deodhar A, Gensler LS, et al. 2019 Update of the American College of Rheumatology/Spondylitis Association of America/ Spondyloarthritis Research and Treatment Network Recommendations for the Treatment of Ankylosing Spondylitis and Nonradiographic Axial Spondyloarthritis. Arthritis Rheumatol. 2019; 71(10):1599-1613.


Federal and state laws or requirements, contract language, and Plan utilization management programs or polices may take precedence over the application of this clinical criteria.