

## PHARMACY POLICY STATEMENT North Carolina Marketplace

<b>DRUG NAME</b>	<b>Cosentyx (secukinumab)</b>
BENEFIT TYPE	Pharmacy or Medical
STATUS	Prior Authorization Required

Cosentyx is a human interleukin-17A antagonist initially approved by the FDA in 2015 for moderate-to-severe plaque psoriasis. Since then, it has also been granted approval for psoriatic arthritis, ankylosing spondylitis, non-radiographic axial spondylitis, enthesitis-related arthritis and hidradenitis suppurativa. This humanized IgG1 monoclonal antibody works by selectively binding to the IL-17 cytokine, inhibiting its interaction with the IL-17 receptor. IL-17 is a naturally occurring cytokine that is involved in inflammatory and immune responses.

Cosentyx (secukinumab) will be considered for coverage when the following criteria are met:

### **Ankylosing Spondylitis (AS), Non-radiographic Axial Spondyloarthritis (nr-axSpA), or Enthesitis-related Arthritis (ERA)**

*Note:* Diagnosis of axial spondyloarthritis (axSpA) is also accepted. SpA comprises of 2 subtypes – ankylosing spondylitis (AS) and non-radiographic axial spondyloarthritis (nr-axSpA).

For **initial** authorization:

1. **Enthesitis-related arthritis:** member must be at least 4 years of age;  
**Ankylosing spondylitis and non-radiographic axial spondylitis:** member must be at least 18 years of age; AND
2. Member has a documented diagnosis of active ankylosing spondylitis (AS), active non-radiographic axial spondyloarthritis (nr-axSpA) or active enthesitis-related arthritis; AND
3. Medication must be prescribed by or in consultation with a rheumatologist; AND
4. Member has had back pain for at least 3 months that began before the age of 50; AND
5. Member shows at least **ONE** of the following signs or symptoms of Spondyloarthritis:
  - a) Elevated serum C-reactive protein (CRP) or erythrocyte sedimentation rate (ESR);
  - b) Positive HLA-B27 test;
  - c) Sacroiliitis; AND
6. Member has tried and failed to respond to treatment with at least **TWO** NSAIDs taken at the maximum recommended dosages. Treatment failure requires at least 4 weeks of therapy with each NSAID without an adequate response; AND
7. Member has had a negative tuberculosis test within the past 12 months.
8. **Dosage allowed/Quantity limit:**  
**AS:**
  - a) Administer 150 mg subcutaneously at week 0, 1, 2, 3, and 4 and every 4 weeks thereafter. May increase dose to 300 mg every 4 weeks if needed; OR
  - b) Administer 150 mg subcutaneously every 4 weeks. May increase dose to 300 mg every 4 weeks if needed; OR
  - c) Administer 6 mg/kg by IV infusion at week 0 followed by 1.75 mg/kg every 4 weeks thereafter (max maintenance dose 300 mg per infusion); OR
  - d) Administer 1.75 mg/kg by IV infusion every 4 weeks (max maintenance dose 300 mg per infusion).**nr-axSpA:**

- a) Administer 150 mg subcutaneously at week 0, 1, 2, 3, and 4 and every 4 weeks thereafter. May increase dose to 300 mg every 4 weeks if needed; OR
- b) Administer 150 mg subcutaneously every 4 weeks. May increase dose to 300 mg every 4 weeks if needed; OR
- c) Administer 6 mg/kg by IV infusion at week 0 followed by 1.75 mg/kg every 4 weeks thereafter (max maintenance dose 300 mg per infusion); OR
- d) Administer 1.75 mg/kg by IV infusion every 4 weeks (max maintenance dose 300 mg per infusion).

**ERA:**

- a) Weight-based dosage (see below) is administered by subcutaneous injection at weeks 0, 1, 2, 3, and 4 followed by every 4 weeks.

Body Weight at Time of Dosing	Recommended Dose
≥ 15 kg and less than 50 kg	75 mg
Greater than or equal to 50 kg	150 mg

***If all the above requirements are met, the medication will be approved for 12 months.***

For **reauthorization**:

- 1. Chart notes must show improvement or stabilized signs and symptoms of disease, demonstrated by improvement in joint pain, inflammation, morning stiffness, etc.

***If all the above requirements are met, the medication will be approved for an additional 12 months.***

## Plaque Psoriasis (PsO)

For **initial** authorization:

- 1. Member must be 6 years of age or older; AND
- 2. Medication must be prescribed by or in consultation with a dermatologist; AND
- 3. Member has clinical documentation of moderate to severe plaque psoriasis characterized by 3% or more of body surface area (BSA) or disease affecting sensitive areas (e.g., hands, feet, face, genitals, etc.); AND
- 4. 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);
  - c) At least a 4-week trial with topical antipsoriatic agents (i.e., anthralin, calcipotriene, coal tar, corticosteroids, tazarotene, tacrolimus, pimecrolimus); AND
- 5. Member has tried and failed, or unable to tolerate a systemic non-biologic DMARD (i.e., cyclosporine, methotrexate, acitretin) for at least 12 weeks; AND
- 6. Member has had a negative tuberculosis test within the past 12 months.
- 7. **Dosage allowed/Quantity limit:**  
Adult: 300 mg (2 injections of 150 mg) by subcutaneous injection at weeks 0, 1, 2, 3, and 4 followed by 300 mg every 4 weeks.  
Pediatric: weight-based dosage (see below) is administered by subcutaneous injection at Weeks 0, 1, 2, 3, and 4 and every 4 weeks thereafter.

Body Weight at Time of Dosing	Recommended Dose
Less than 50 kg	75 mg
Greater than or equal to 50 kg	150 mg

***If all the above requirements are met, the medication will be approved for 12 months.***

For **reauthorization**:

- Chart notes must show** improvement or stabilized signs and symptoms of disease, demonstrated by **BSA improvement, etc.**

*If all the above requirements are met, the medication will be approved for an additional 12 months.*

## Psoriatic Arthritis (PsA)

For **initial** authorization:

- Member must be 2 years of age or older; AND
- Medication must be prescribed by or in consultation with a rheumatologist or a dermatologist; AND
- Member has a documented diagnosis of active psoriatic arthritis (PsA); AND
- Member has met a 4-week trial of an NSAID taken at maximally tolerated doses **AND** a 3-month trial of a conventional DMARD agent (e.g., methotrexate, sulfasalazine, cyclosporine, etc.) **unless ONE** of the following situations is met:
  - Conventional DMARD is **NOT** required for:
    - Concomitant axial disease (i.e., involving sacroiliac joint and spine) or enthesitis; OR
  - NSAID and conventional DMARD are **NOT** required for:
    - Severe PsA (defined as having at least **ONE** of the following: erosive disease, active PsA at many sites including dactylitis or enthesitis, elevated levels of ESR or CRP, joint deformities, or major impairment in quality of life); AND
- Member has had a negative tuberculosis test within the past 12 months.

**Dosage allowed/Quantity limit:**

Adult:

- Administer 150 mg by subcutaneous injection at weeks 0, 1, 2, 3, and 4 and every 4 weeks thereafter. May increase to 300 mg every 4 weeks if PsA is still active; OR
- Administer 150 mg by subcutaneous injection every 4 weeks. May increase to 300 mg every 4 weeks if PsA is still active; OR
- Administer 6 mg/kg by IV infusion at week 0 followed by 1.75 mg/kg every 4 weeks thereafter (max maintenance dose 300 mg per infusion); OR
- Administer 1.75 mg/kg by IV infusion every 4 weeks (max maintenance dose 300 mg per infusion).

Pediatric:

- Administer weight-based dosage (see below) is administered by subcutaneous injection at weeks 0, 1, 2, 3, and 4 followed by every 4 weeks.

Body Weight at Time of Dosing	Recommended Dose
≥ 15 kg and less than 50 kg	75 mg
Greater than or equal to 50 kg	150 mg

*If all the above requirements are met, the medication will be approved for 12 months.*

For **reauthorization**:

- Chart notes must show** improvement or stabilized signs and symptoms of disease, as demonstrated by improvement in joint pain, inflammation, skin lesions, etc.

*If all the above requirements are met, the medication will be approved for an additional 12 months.*

## Hidradenitis Suppurativa (HS)

For **initial** authorization:

- Member must be 18 years of age or older; AND
- Medication must be prescribed by or in consultation with a dermatologist; AND
- Member has a documented diagnosis of moderate to severe HS with Hurley stage II or III disease; AND

4. Member has been counseled on weight loss if they are overweight or obese; AND
5. Member is a non-smoker or has been counseled on smoking cessation and advised to quit; AND
6. Member has tried and failed at least **ONE** of the following:
  - a. Topical clindamycin x 12 weeks and an oral tetracycline x 12 weeks (sequential or concomitant);
  - b. Oral clindamycin plus rifampicin x 8-12 weeks; AND
7. Member has had a negative tuberculosis test within the past 12 months.
8. **Dosage allowed/Quantity limit:** Recommended dosage is 300 mg administered by subcutaneous injection at weeks 0, 1, 2, 3 and 4 and every 4 weeks thereafter. If a patient does not adequately respond, consider increasing the dosage to 300 mg every 2 weeks.

***If all the above requirements are met, the medication will be approved for 6 months.***

For **reauthorization**:

1. Chart notes must include documentation of a positive clinical response such as reduced count of total abscesses and inflammatory nodules or reduction of skin pain.

***If all the above requirements are met, the medication will be approved for an additional 12 months.***

**CareSource considers Cosentyx (secukinumab) not medically necessary for the treatment of conditions that are not listed in this document. For any other indication, please refer to the Off-Label policy.**

DATE	ACTION/DESCRIPTION
05/08/2017	New policy for Cosentyx created. Policies SRx-0043 achieved. New diagnoses of AS and PsA with criteria were added. For diagnosis of PsO: 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.
02/26/2019	Status changed to preferred. Trials of Humira and Enbrel removed from criteria. Clarifications entered for AS and PsA on NSAIDs trial length. References updated. TB test allowed to be done within 12 months prior to initiation of therapy; chest x-ray option removed. Symptoms of back pain for AS extended till before age of 50. Other drugs options allowed for PsA if there is an intolerance or contraindication to methotrexate. "Immunosuppressant therapies" changed to "treatment of traditional first-line oral/systemic" therapies. Reauthorization criteria on documented member's PASI score improvement incorporated into general chart noted documentation requirements.
09/25/2020	Status changed to preferred. Trials of Humira and Enbrel removed from criteria. Clarifications entered for AS and PsA on NSAIDs trial length. References updated. TB test allowed to be done within 12 months prior to initiation of therapy; chest x-ray option removed. Symptoms of back pain for AS extended till before age of 50. Other drugs options allowed for PsA if there is an intolerance or contraindication to methotrexate. "Immunosuppressant therapies" changed to "treatment of traditional first-line oral/systemic" therapies. Reauthorization criteria on documented member's PASI score improvement incorporated into general chart noted documentation requirements.
07/26/2021	Plaque psoriasis: Age indication expanded to include patients as young as 6 years.
02/04/2022	Transferred to new format. Lowered PsA age to 2 years and updated pediatric dosing. Lowered enthesitis-related arthritis to 4 years and updated pediatric dosing. Changed

	the wording of “non-biologic” DMARD to “conventional” DMARD. Clarified reauthorization criteria. Updated references.
<b>11/08/2023</b>	Added HS diagnosis; added/updated references; added IV dosing to applicable dx; simplified TB test requirement wording; added medical benefit option.

References:

1. Cosentyx [package insert]. East Hanover, NJ: Novartis Pharmaceuticals Corporation; 2023.
2. 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 Oct;71(10):1599-1613. doi: 10.1002/art.41042. Epub 2019 Aug 22.
3. Akgul O, Ozgocmen S. Classification criteria for spondyloarthropathies. *World J Orthop*. 2011;2(12):107-115. doi:10.5312/wjo.v2.i12.07.
4. ClinicalTrials.gov. Study of Efficacy and Safety of Secukinumab in Patients With Non-radiographic Axial Spondyloarthritis (PREVENT). Identifier: NCT02696031. Available at: <https://www.clinicaltrials.gov/ct2/show/NCT02696031>.
5. Yu DT, Tubergen AV. Treatment of axial spondyloarthritis (ankylosing spondylitis and nonradiographic axial spondyloarthritis) in adults. In: Post TW, ed. UpToDate. Waltham, MA: UpToDate Inc.
6. Elmets CA, Korman NJ, Prater EF, et al. Joint AAD-NPF Guidelines of care for the management and treatment of psoriasis with topical therapy and alternative medicine modalities for psoriasis severity measures [published online ahead of print, 2020 Jul 30]. *J Am Acad Dermatol*. 2020;S0190-9622(20)32288-X.
7. Menter A, Gelfand JM, Connor C, et al. Joint American Academy of Dermatology-National Psoriasis Foundation guidelines of care for the management of psoriasis with systemic nonbiologic therapies. *J Am Acad Dermatol*. 2020;82(6):1445-1486.
8. 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(4):1029-1072.
9. Elmets CA, Lim HW, Stoff B, et al. Joint American Academy of Dermatology-National Psoriasis Foundation guidelines of care for the management and treatment of psoriasis with phototherapy [published correction appears in *J Am Acad Dermatol*. 2020 Mar;82(3):780]. *J Am Acad Dermatol*. 2019;81(3):775-804.
10. Menter A, Cordoro KM, Davis DM, et al. Joint AAD-NPF Guidelines of care for the management and treatment of psoriasis in pediatric patients. *J Am Acad Dermatol* 2020;82:161-201
11. Bissonnette R, et al. Secukinumab demonstrates high sustained efficacy and a favorable safety profile through 5 years of treatment in moderate to severe psoriasis. *J Eur Acad Dermatol Venereol*. 2018 Sep;32(9):1507-1514.
12. Gladman DD, Ritchlin C. Clinical manifestations and diagnosis of psoriatic arthritis. In: Post TW, ed. UpToDate. Waltham, MA: UpToDate Inc. Accessed September 23, 2020.
13. Gladman DD, Ritchlin C. Treatment of psoriatic arthritis. In: Post TW, ed. UpToDate. Waltham, MA: UpToDate Inc. Accessed September 23, 2020.
14. Coates LC, Kavanaugh A, Mease PJ, et al. Group for Research and Assessment of Psoriasis and Psoriatic Arthritis 2015 Treatment Recommendations for Psoriatic Arthritis. *Arthritis Rheumatol*. 2016 May;68(5):1060-71.
15. McInnes IB, et al. Secukinumab, a human anti-interleukin-17A monoclonal antibody, in patients with psoriatic arthritis (FUTURE 2): a randomised, double-blind, placebo-controlled, phase 3 trial. *Lancet*. 2015;386(9999):1137-1146.
16. Singh JA, Guyatt G, Ogdie A, et al. 2018 American College of Rheumatology/National Psoriasis Foundation Guideline for the treatment of Psoriatic Arthritis. *Arthritis Rheumatol*. 2019 Jan;71(1):5-32.
17. Mease PJ, et al. Secukinumab Provides Sustained Improvements in the Signs and Symptoms of Active Psoriatic Arthritis through 3 Years: Efficacy and Safety Results from a Phase 3 Trial. *Ann Rheum Dis*. 2017;76:952-953.
18. 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(1):91-101. doi:10.1016/j.jaad.2019.02.068
19. Hendricks AJ, Hsiao JL, Lowes MA, Shi VY. A Comparison of International Management Guidelines for Hidradenitis Suppurativa. *Dermatology*. 2021;237(1):81-96. doi:10.1159/000503605

Effective date: 04/01/2024

Revised date: 11/08/2023