Cosentyx (secukinumab)

NOTICE

This policy contains information which is clinical in nature. The policy is not medical advice. The information in this policy is used by Wellmark to make determinations whether medical treatment is covered under the terms of a Wellmark member's health benefit plan. Physicians and other health care providers are responsible for medical advice and treatment. If you have specific health care needs, you should consult an appropriate health care professional. If you would like to request an accessible version of this document, please contact customer service at 800-524-9242.

BENEFIT APPLICATION

Benefit determinations are based on the applicable contract language in effect at the time the services were rendered. Exclusions, limitations or exceptions may apply. Benefits may vary based on contract, and individual member benefits must be verified. Wellmark determines medical necessity only if the benefit exists and no contract exclusions are applicable. This medical policy may not apply to FEP. Benefits are determined by the Federal Employee Program.

DESCRIPTION

The intent of the Cosentyx drug policy is to ensure appropriate selection of patients for therapy based on product labeling, clinical guidelines and clinical studies. For intravenous Cosentyx requests, Avsola, Inflectra, Skyrizi, and Simponi Aria are the preferred products and will apply to members requesting treatment with intravenous Cosentyx for an indication that is FDA-approved for the preferred product. Coverage for targeted products is provided based on clinical circumstances that would exclude the use of the preferred product and may be based on previous use of a product. The coverage review process will ascertain situations where a clinical exception can be made. Additionally, documentation must support that self-administration of Cosentyx pen or prefilled syringe by the patient or caregiver is not appropriate.

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

Cosentyx pen and prefilled syringe

1. Moderate to severe plaque psoriasis (PsO) in patients of age 6 years and older who are candidates for systemic therapy or phototherapy
2. Active psoriatic arthritis (PsA) in patients 2 years of age and older
3. Adults with active ankylosing spondylitis (AS)
4. Adults with active non-radiographic axial spondyloarthritis (nr-axSpA) with objective signs of inflammation
5. Active enthesitis-related arthritis (ERA) in patients 4 years of age and older
6. Moderate to severe hidradenitis suppurativa (HS) in patients 12 years of age and older

Cosentyx Intravenous formulation

1. Adults with active psoriatic arthritis (PsA)
2. Adults with active ankylosing spondylitis (AS)
3. Adults with active non-radiographic axial spondyloarthritis (nr-axSpA) with objective signs of inflammation

Note: For Intravenous Cosentyx requests, Avsola, Inflectra, Skyrizi, and Simponi Aria are the preferred products and will apply to members requesting treatment with intravenous Cosentyx for an indication that is FDA-approved for the preferred product. Coverage for targeted products is provided based on clinical circumstances that would exclude the use of the preferred product and may be based on previous use of a product. The coverage review process will ascertain situations where a clinical exception can be made.

POLICY

Required Documentation

Submission of the following information is necessary to initiate the prior authorization review:

A. Plaque psoriasis (PsO)

1. Initial requests:
   a. Chart notes or medical record documentation of affected area(s) and body surface area (BSA) affected (if applicable).
   b. Chart notes, medical record documentation, or claims history supporting previous medications tried (if applicable), including response to therapy. If therapy is not advisable, documentation of clinical reason to avoid therapy.
2. Continuation requests: Chart notes or medical record documentation of decreased body surface area (BSA) affected and/or improvement in signs and symptoms.

B. Psoriatic arthritis (PsA), Ankylosing spondylitis (AS), non-radiographic axial spondyloarthritis (nr-axSpA), Enthesitis-related arthritis (ERA), and hidradenitis suppurativa (HS):

1. Initial requests: Chart notes, medical record documentation, or claims history supporting previous medications tried (if applicable), including response to therapy. If therapy if not advisable, documentation of clinical reason to avoid therapy.
2. Continuation requests: Chart notes or medical record documentation supporting positive clinical response.

Must meet BOTH the Preferred Drug Plan Design and Criteria for Initial Approval/Continuation of Therapy when both are applicable.

Preferred Drug Plan Design for Intravenous Cosentyx requests

A. Psoriatic Arthritis

1. Criteria for initial approval on psoriatic arthritis will only apply when all of the following criteria are met:
   a. Member meets at least ONE of the following criteria:
      i. Member has a documented inadequate response or intolerable adverse event with each of the following:
         a) Avsola
         b) Inflectra
         c) Simponi Aria
         d) Skyrizi

ii. Member has a documented clinical reason to avoid TNF inhibitors (See Appendix A) AND member has a documented inadequate response or intolerable adverse event with Skyrizi

b. Member has a documented reason where self-administration is not appropriate due to one of the following:
   i. The patient or caregiver is unable to perform subcutaneous injections with Cosentyx pen or prefilled syringe with proper technique; or
   ii. The patient or caregiver is unable to adhere to the prescribed dosing regimen

B. Ankylosing Spondylitis

1. Criteria for initial approval on ankylosing spondylitis will only apply when all of the following criteria are met:
   a. Member meets at least ONE of the following criteria:
      i. Member has a documented inadequate response or intolerable adverse event with each of the following:
         a) Avsola
         b) Inflectra
         c) Simponi Aria
      ii. Member has a documented clinical reason to avoid TNF inhibitors (See Appendix A)
   b. Member has a documented reason where self-administration is not appropriate due to one of the following:
      i. The patient or caregiver is unable to perform subcutaneous injections with Cosentyx pen or prefilled syringe with proper technique; or
      ii. The patient or caregiver is unable to adhere to the prescribed dosing regimen

C. Non-radiographic Axial Spondyloarthritis (nr-axSpA)

1. Criteria for initial approval on non-radiographic axial spondyloarthritis will only apply when all of the following criteria are met:
   a. Member has a documented reason where self-administration is not appropriate due to one of the following:
      i. The patient or caregiver is unable to perform subcutaneous injections with Cosentyx pen or prefilled syringe with proper technique; or
      ii. The patient or caregiver is unable to adhere to the prescribed dosing regimen

Prescriber Specialties (initial approvals only)

This medication must be prescribed by or in consultation with one of the following:

A. Plaque psoriasis: dermatologist
B. Psoriatic arthritis and hidradenitis suppurativa: rheumatologist or dermatologist
C. Ankylosing spondylitis, non-radiographic axial spondyloarthritis, and enthesis-related arthritis: rheumatologist

Criteria for Initial Approval

A. Moderate to severe plaque psoriasis (PsO)

1. Authorization of 12 months (Cosentyx subcutaneous formulations only) may be granted for members 6 years of age and older who have previously received a biologic or targeted synthetic drug (e.g., Sotyktu, Otezla) indicated for the treatment of moderate to severe plaque psoriasis.

2. Authorization of 12 months may be granted for members 6 years of age and older for the treatment of moderate to severe plaque psoriasis in members when any of the following criteria is met:

a. Crucial body areas (e.g., hands, feet, face, neck, scalp, genitals/groin, intertriginous areas) are affected.
b. At least 10% of the body surface area (BSA) is affected
c. At least 3% of body surface area (BSA) is affected and the member meets any of the following criteria:
    i. Member has had an inadequate response or intolerance to either phototherapy (e.g., UVB, PUVA) or pharmacologic treatment with methotrexate, cyclosporine or acitretin.
    ii. Member has a clinical reason to avoid pharmacologic treatment with methotrexate, cyclosporine and acitretin (see Appendix B).

B. Active psoriatic arthritis (PsA)

1. Authorization of 12 months may be granted for members 2 years of age and older who have previously received a biologic or targeted synthetic drug (e.g., Rinvoq, Otezla) indicated for active psoriatic arthritis.

2. Authorization of 12 months may be granted for members 2 years of age and older for treatment of active psoriatic arthritis when either of the following criteria is met:
    a. Member has mild to moderate disease and meets one of the following criteria:
        i. Member has had an inadequate response to methotrexate, leflunomide, or another conventional synthetic drug (e.g., sulfasalazine) administered at an adequate dose and duration.
        ii. Member has an intolerance or contraindication to methotrexate or leflunomide (see Appendix B), or another conventional synthetic drug (e.g., sulfasalazine).
        iii. Member has enthesitis or predominantly axial disease.
    b. Member has severe disease.

C. Active ankylosing spondylitis (AS) and active non-radiographic axial spondyloarthritis (nr-axSpA)

1. Authorization of 12 months may be granted for adult members who have previously received a biologic or targeted synthetic drug (e.g., Rinvoq, Xeljanz) indicated for active ankylosing spondylitis or active non-radiographic axial spondyloarthritis

2. Authorization of 12 months may be granted for adult members for treatment of active ankylosing spondylitis or active non-radiographic axial spondyloarthritis 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.

D. Active enthesitis-related arthritis (ERA)

1. Authorization of 12 months (Cosentyx subcutaneous formulations only) may be granted for members 4 years of age and older who have previously received a biologic for the treatment of active enthesitis-related arthritis.

2. Authorization of 12 months may be granted for members 4 years of age and older for the treatment of active enthesitis-related arthritis when both of the following criteria are met:
    a. Member has active disease demonstrated by three active joints involved and at least one site of active enthesitis at baseline or documented by history.
    b. Member meets either of the following:
        i. Member has an inadequate response or intolerance to nonsteroidal anti-inflammatory drugs (NSAIDs), sulfasalazine, or methotrexate.

ii. Member has an intolerance or contraindication to NSAIDs, sulfasalazine (e.g., porphyria, intestinal or urinary obstruction), and methotrexate (see Appendix B).

E. Moderate to severe hidradenitis suppurativa

1. Authorization of 12 months (Cosentyx subcutaneous formulations only) may be granted for members 12 years of age and older who have previously received a biologic indicated for treatment of moderate to severe hidradenitis suppurativa.

2. Authorization of 12 months may be granted for members 12 years of age and older for treatment of moderate to severe hidradenitis suppurativa when either of the following is met:
   a) Member has experienced an inadequate response to an oral antibiotic used for the treatment of hidradenitis suppurativa for at least 90 days.
   b) Member has an intolerance or contraindication to oral antibiotics used for the treatment of hidradenitis suppurativa.

Continuation of Therapy

A. Plaque psoriasis (PsO)

Authorization of 12 months (Cosentyx subcutaneous formulations only) may be granted for all members (including new members) who are using the requested medication for moderate to severe plaque psoriasis and who achieve or maintain positive clinical response as evidenced by low disease activity or improvement in signs and symptoms of the condition when either of the following is met:

1. Reduction in body surface area (BSA) affected from baseline
2. Improvement in signs and symptoms from baseline (e.g., itching, redness, flaking, scaling, burning, cracking, pain)

B. Psoriatic arthritis (PsA)

Authorization of 12 months may be granted for all members (including new members) who are using the requested medication for psoriatic arthritis and who achieve or maintain positive clinical response as evidenced by low disease activity or improvement in signs and symptoms of the condition when there is improvement in any of the following from baseline:

1. Number of swollen joints
2. Number of tender joints
3. Dactylitis
4. Enthesitis
5. Axial disease
6. Skin and/or nail involvement
7. Functional status
8. C-reactive protein (CRP)

C. Ankylosing spondylitis (AS) and non-radiographic axial spondyloarthritis (nr-axSpA)

Authorization of 12 months may be granted for all members (including new members) who are using the requested medication for active ankylosing spondylitis or active non-radiographic axial spondyloarthritis and who achieve or maintain positive clinical response with the requested medication as evidenced by low disease activity or improvement in signs and symptoms of the condition when there is improvement in any of the following from baseline:

1. Functional status
2. Total spinal pain
3. Inflammation (e.g., morning stiffness)

4. Swollen joints
5. Tender joints
6. C-reactive protein (CRP)

D. Enthesitis-Related Arthritis (ERA)

Authorization of 12 months (Cosentyx subcutaneous formulations only) may be granted for all members (including new members) who are using the requested medication for enthesitis-related arthritis and who achieve or maintain positive clinical response as evidenced by low disease activity or improvement in signs and symptoms of the condition when there is improvement in any of the following from baseline:

1. Number of flares
2. Number of joints with active arthritis (e.g., swelling, pain)
3. Number of joints with limited movement
4. Dactylitis
5. Enthesitis

E. Moderate to severe hidradenitis suppurativa

Authorization of 12 months (Cosentyx subcutaneous formulations only) may be granted for all members (including new members) who are using the requested medication for moderate to severe hidradenitis suppurativa and who achieve or maintain a positive clinical response as evidenced by low disease activity or improvement in signs and symptoms of the condition when any of the following is met:

1. Reduction in abscess and inflammatory nodule count from baseline
2. Reduced formation of new sinus tracts and scarring
3. Decrease in frequency of inflammatory lesions from baseline
4. Reduction in pain from baseline
5. Reduction in suppuration from baseline
6. Improvement in frequency of relapses from baseline
7. Improvement in quality of life from baseline
8. Improvement on a disease severity assessment tool from baseline

Other

For all indications: Member has had a documented negative TB test (which can include a tuberculosis skin test [TST] or an interferon-release assay [IGRA])* within 12 months of initiating therapy for persons who are naïve to biologic drugs or targeted synthetic drugs associated with an increased risk of TB.

* If the screening testing for TB is positive, there must be further testing to confirm there is no active disease (e.g., chest x-ray). Do not administer the requested medication to members with active TB infection. If there is latent disease, TB treatment must be started before initiation of the requested medication.

For all indications: Member cannot use the requested medication concomitantly with any other biologic drug or targeted synthetic drug for the same indication.

Cosentyx is considered **not medically necessary** for members who do not meet the criteria set forth above.

Members currently receiving the requested medication as samples or via the manufacturer's patient assistance program will be required to meet the criteria for initial approval. This ensures that members are treated equally regardless of their provider's ability to access medication samples.

Dosage and Administration

Approvals may be subject to dosing limits in accordance with FDA-approved labeling, accepted compendia, and/or evidence-based practice guidelines.

Quantity/Dosing Limits

Trade Name	Generic Name	Quantity Limit
Cosentyx® prefilled Syringe/Sensoready pen	secukinumab	**Moderate to severe plaque psoriasis (PsO)** Initiation of therapy (pediatric patients): 5 x 75 mg syringes per first 28 days if weighing less than 50 kg; 4 x 150 mg syringes/pens per first 28 days if weighing greater than or equal to 50 kg Maintenance (pediatric patients): 1 x 75mg syringe per 28 days if weighing less than 50 kg; 2 x 150 mg syringes/pens per 56 days if weighing greater than or equal to 50 kg Initiation of therapy (adult patients): 10 x 150 mg syringes/pens per first 28 days Maintenance (adult patients): 2 x 150mg syringes/pens per 28 days **Active psoriatic arthritis (PsA)*** Initiation of therapy (pediatric patients): 5 x 75 mg syringes per first 28 days if weighing greater than or equal to 15 kg and less than 50 kg; 4 x 150 mg syringes/pens per first 28 days if weighing greater than or equal to 50 kg Maintenance (pediatric patients): 1 x 75mg syringe per 28 days if weighing greater than or equal to 15 kg and less than 50 kg; 2 x 150 mg syringes/pens per 56 days if weighing greater than or equal to 50 kg Initiation of therapy(adult patients): 4 x 150 mg syringes/pens per first 28 days Maintenance (adult patients): 2 x 150 mg syringes/pens per 56 days **Active psoriatic arthritis with co-existent plaque psoriasis** Initiation of therapy (pediatric patients): 5 x 75 mg syringes per first 28 days if weighing less than 50 kg; 4 x 150 mg syringes/pens per first 28 days if weighing greater than or equal to 50 kg Maintenance (pediatric patients): 1 x 75mg syringe per 28 days if weighing less than 50 kg; 2 x 150 mg syringes/pens per 56 days if weighing greater than or equal to 50 kg Initiation of therapy (adult patients): 10 x 150 mg syringes/pens per first 28 days Maintenance (adult patients): 2 x 150 mg syringes/pens per 28 days **Ankylosing spondylitis (AS)*** Initiation of therapy: 4 x 150 mg syringes/pens per first 28 days Maintenance: 2 x 150 mg syringes/pens per 56 days **Active Non-Radiographic axial spondyloarthritis** Initiation of therapy: 4 x 150 mg syringes/pens per first 28 days Maintenance: 2 x 150 mg syringes/pens per 56 days **Enthesitis-related arthritis** Initiation of therapy (pediatric patients): 5 x 75 mg syringes per first 28 days if weighing greater than or equal to15 kg and less than 50 kg; 4 x 150 mg syringes/pens per first 28 days if weighing greater than or equal to 50 kg Maintenance (pediatric patients): 1 x 75mg syringe per 28 days if weighing greater than or equal to 15 kg and less than 50 kg; 2 x 150 mg syringes/pens per 56 days if weighing greater than or equal to 50 kg Initiation of therapy (adult patients): 4 x 150 mg syringes/pens per first 28 days Maintenance (adult patients): 2 x 150 mg syringes/pens per 56 days **Hidradenitis Suppurativa (HS)** Initiation of therapy (pediatric patients): 5 x 150 mg syringes/pens per first 28 days if weighing greater than or equal to 30 kg and less than 90 kg, greater than 90 kg refer to adult dosing

Trade Name	Generic Name	Quantity Limit
		Maintenance (pediatric patients): 1 x 150mg syringes/pens per 28 days if weighing greater than or equal to 30 kg and less than 90 kg, greater than 90 kg refer to adult dosing Initiation of therapy (adult patients): 10 x 150 mg syringes/pens per first 28 days Maintenance (adult patients): 2 x 150mg syringes/pens per 28 days If patient does not adequately respond, consider increasing the dosage to 300 mg every 2 weeks: 4 x 150 mg syringes/pens per 28 days
Cosentyx® UnoReady pen	secukinumab	**Moderate to severe plaque psoriasis (PsO)** Initiation of therapy (adult patients): 5 x 300mg pens per first 28 days Maintenance (adult patients): 1 x 300mg pen per 28 days **Active psoriatic arthritis (PsA)** Maintenance (adult patients): 1 x 300mg pen per 28 days **Active psoriatic arthritis with co-existent plaque psoriasis** Initiation of therapy (adult patients): 5 x 300mg pens per first 28 days Maintenance (adult patients): 1 x 300mg pen per 28 days **Ankylosing spondylitis (AS)** Maintenance: 1 x 300mg pen per 28 days **Hidradenitis Suppurativa (HS)** Initiation of therapy (adult patients): 5 x 300mg pens per first 28 days Maintenance (adult patients): 1 x 300mg pen per 28 days If patient does not adequately respond, consider increasing the dosage to 300 mg every 2 weeks: 2 x 300 mg syringes/pens per 28 days
Cosentyx® vial for intravenous use	secukinumab	**Active psoriatic arthritis (PsA)**, **Ankylosing spondylitis (AS) and Active Non-Radiographic axial spondyloarthritis** Maintenance: 3 x 125mg/5 mL vials per 28 days

*Quantity Limit of up to 10 x 150 mg syringes/pens per 28 days available for Psoriatic arthritis (PsA) & Ankylosing spondylitis (AS) if patient continues to have active disease

Appendix

Appendix A: Clinical reasons to avoid TNF-inhibitors

1. History of demyelinating disorder
2. History of congestive heart failure
3. History of hepatitis B infection
4. Autoantibody formation/lupus-like syndrome
5. Risk of lymphoma

Appendix B: Examples of Clinical Reasons to Avoid Pharmacologic Treatment with Methotrexate, Cyclosporine, Acitretin or Leflunomide.

1. Clinical diagnosis of alcohol use disorder, alcoholic liver disease or other chronic liver disease
2. Breastfeeding
3. Drug interaction
4. Risk of treatment-related toxicity
5. Pregnancy or currently planning pregnancy
6. Significant comorbidity prohibits use of systemic agents (e.g., include liver or kidney disease, blood dyscrasias, uncontrolled hypertension)
7. Hypersensitivity
8. History of intolerance or adverse event

PROCEDURES AND BILLING CODES

To report provider services, use appropriate CPT* codes, Alpha Numeric (HCPCS level 2) codes, Revenue codes, and/or ICD diagnostic codes.

- C9166 – Injection, secukinumab, intravenous, 1 mg (cancelled 7/1/2024)
- J3247 – Injection, secukinumab, intravenous, 1 mg (effective 7/1/2024)
- J3490 – Unclassified drugs (when specified as [Cosentyx] (secukinumab) (intravenous))
- J3590 – Unclassified biologics (when specified as [Cosentyx] (secukinumab) (intravenous))

REFERENCES

- Cosentyx [package insert]. East Hanover, NJ: Novartis Pharmaceuticals Corporation; March 2026.
- Menter A, Korman NJ, Elmets CA, et al. Guidelines of care for the management of psoriasis and psoriatic arthritis. Section 6: Guidelines of care for the treatment of psoriasis and psoriatic arthritis: case-based presentations and evidence-based conclusions. J Am Acad Dermatol. 2011;65(1):137-174.
- Gossec L, baraliakos X, Kerschbaumer A, et al. European League Against Rheumatism (EULAR) recommendations for the management of psoriatic arthritis with pharmacological therapies: 2019 update. *Ann Rheum Dis*. 2020;79(6):700-712.
- McInnes IB, Mease PJ, Kirkham B, 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):1137-46.
- Braun J, van den Berg R, Baraliakos, X et al. 2010 update of the ASAS/EULAR recommendations for the management of ankylosing spondylitis. Ann Rheum Dis. 2011;70:896–904.
- 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):1285-1299.
- Baeten D, Sieper J, Braun J, et al. Secukinumab, an Interleukin-17A Inhibitor, in Ankylosing Spondylitis. *N Engl J Med*. 2015;373(26):2534-48.
- 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.
- Tuberculosis (TB). TB risk factors. Centers for Disease Control and Prevention. Retrieved on January 22, 2025 from: https://www.cdc.gov/tb/testing/index.html.
- 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.* 2018;71:5-32.
- Weiss PF. Diagnosis and treatment of enthesitis-related arthritis. *Adolesc Health Med Ther*. 2012;2012(3):67-74.
- Clinical Trials.gov. Secukinumab Safety and Efficacy in Juvenile Psoriatic Arthritis (JPsA) and Enthesitis-related Arthritis (ERA). Available from: https://clinicaltrials.gov/ct2/show/NCT03031782. Last accessed: January 2022.
- Coates LC, Soriano ER, Corp N, et al. Group for Research and Assessment of Psoriasis and Psoriatic Arthritis (GRAPPA): updated treatment recommendations for psoriatic arthritis 2021. *Nat Rev Rheumatol.* 2022;18(8):465-479.
- Ramiro S, Nikiphorou E, Sepriano A, et al. ASAS-EULAR recommendations for the management of axial spondyloarthritis: 2022 update. Ann Rheum Dis. 2023;82:19-34.
- 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 I: Diagnosis, evaluation, and the use of complementary and procedural management. J Am Acad Dermatol. 2019; 81(1): 76-90.
- 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.

*Some content reprinted from CVSHealth

POLICY HISTORY

Policy #: 05.02.06
Reviewed: December 2025
Revised: April 2025
Current Effective Date: June 4, 2026