# Clinical Policy: Secukinumab (Cosentyx)

Reference Number: DE.PHAR.261
Effective Date: 01.23
Last Review Date: 01.23
Line of Business: Medicaid

Coding Implications
Revision Log

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

## Description

Secukinumab (Cosentyx®) is an interleukin-17A (IL-17A) antagonist.

## FDA Approved Indication(s)

Cosentyx is indicated for the treatment of:

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

## Policy/Criteria

*Provider must submit documentation (such as office chart notes, lab results or other clinical information) supporting that member has met all approval criteria.*

It is the policy of health plans affiliated with Centene Corporation® that Cosentyx is **medically necessary** when the following criteria are met:

**I. Initial Approval Criteria**

**A. Axial Spondyloarthritis** (must meet all)**:**

1. Diagnosis of AS or nr-axSpA;
2. Prescribed by or in consultation with a rheumatologist;
3. Age ≥ 18 years;
4. Failure of at least TWO non-steroidal anti-inflammatory drugs (NSAIDs) at up to maximally indicated doses, each used for ≥ 4 weeks unless clinically significant adverse effects are experienced or all are contraindicated;
5. For AS, failure of ALL of the following, each used for ≥ 3 consecutive months, unless clinically significant adverse effects are experienced or all are contraindicated:
   a. Enbrel®, and Taltz®;
   b. Member has not responded or is intolerant to one or more TNF blockers (i.e. Xeljanz®) unless member has cardiovascular risk and benefits do not outweigh the risk of treatment;

   **Prior authorization may be required for Enbrel, Xeljanz, and Taltz*
6. For nr-axSpA: Failure of the following, each used for ≥ 3 consecutive months, unless clinically significant adverse effects are experienced or contraindicated: Taltz;

**Prior authorization may be required for Taltz*

7. Member does not have combination use with biological disease-modifying antirheumatic drugs or Janus kinase inhibitors (*see Section III: Diagnoses/Indications for which coverage is NOT authorized*);
8. Dose does not exceed 150 mg at weeks 0, 1, 2, 3, and 4, followed by maintenance dose of 150 mg every 4 weeks.

**Approval duration: 6 months**

**B. Enthesitis-related Arthritis** (must meet all)**:**

1. Diagnosis of ERA;
2. Prescribed by or in consultation with a rheumatologist;
3. Age ≥ 4 years and < 18 years;
4. Failure of at least TWO non-steroidal anti-inflammatory drugs (NSAIDs) at up to maximally indicated doses, each used for ≥ 4 weeks unless clinically significant adverse effects are experienced or all are contraindicated;
5. Member meets one of the following (a or b):
   a. Failure of a ≥ 3 consecutive month trial of MTX at up to maximally indicated doses;
   b. Member has intolerance or contraindication to MTX (*see Appendix D*), and failure of a ≥ 3 consecutive month trial of at least ONE conventional disease-modifying anti-rheumatic drug (e.g., sulfasalazine, leflunomide) at up to maximally indicated doses, unless contraindicated or clinically significant adverse effects are experienced;
6. If disease is polyarticular (≥ 5 joints ever involved), failure of Enbrel used for ≥ 3 consecutive months, unless clinically significant adverse effects are experienced or is contraindicated;
7. Member does not have combination use with biological disease-modifying antirheumatic drugs or Janus kinase inhibitors (*see Section III: Diagnoses/Indications for which coverage is NOT authorized*);
8. Dose does not exceed one of the following (a or b):
   a. Weight > 15 kg and < 50 kg: 75 mg at weeks 0, 1, 2, 3, and 4, followed by maintenance dose of 75 mg every 4 weeks;
   b. Weight ≥ 50 kg: 150 mg at weeks 0, 1, 2, 3, and 4, followed by maintenance dose of 150 mg every 4 weeks.

**Approval duration: 6 months**

**C. Plaque Psoriasis** (must meet all)**:**

1. Diagnosis of moderate-to-severe PsO as evidenced by involvement of one of the following (a or b):
   a. ≥ 3% of total body surface area;
   b. Hands, feet, scalp, face, or genital area;
2. Prescribed by or in consultation with a dermatologist or rheumatologist;
3. Age ≥ 6 years;
4. Member meets one of the following (a, b, or c):
   a. Failure of a ≥ 3 consecutive month trial of methotrexate (MTX) at up to maximally indicated doses;

   b. Member has intolerance or contraindication to MTX (*see Appendix D*), and failure of a ≥ 3 consecutive month trial of cyclosporine or acitretin at up to maximally indicated doses, unless clinically significant adverse effects are experienced or both are contraindicated;
   c. Member has intolerance or contraindication to MTX, cyclosporine, and acitretin, and failure of phototherapy, unless contraindicated or clinically significant adverse effects are experienced;
5. Failure of a ≥ 3 consecutive month trial of Taltz®, unless contraindicated or clinically significant adverse effects are experienced;
   **Prior authorization may be required for Taltz*
6. Member does not have combination use with biological disease-modifying antirheumatic drugs or Janus kinase inhibitors (*see Section III: Diagnoses/Indications for which coverage is NOT authorized*);
7. Dose does not exceed the following:
   a. Age ≥ 18 years: 300 mg at weeks 0, 1, 2, 3, and 4, followed by maintenance dose of 300 mg every 4 weeks;
   b. Age 6 to 17 years and weight < 50 kg: 75 mg at weeks 0, 1, 2, 3 and 4, followed by maintenance dose of 75 mg every 4 weeks;
   c. Age 6 to 17 years and weight ≥ 50 kg: 150 mg at weeks 0, 1, 2, 3 and 4, followed by maintenance dose of 150 mg every 4 weeks.

**Approval duration: 6 months**

**D. Psoriatic Arthritis** (must meet all)**:**
1. Diagnosis of PsA;
2. Prescribed by or in consultation with a dermatologist or rheumatologist;
3. Age ≥ 2 years;
4. For members ≥ 18 years, failure of ALL of the following, each used for ≥ 3 consecutive months, unless clinically significant adverse effects are experienced or all are contraindicated (a and b):
   a. Enbrel®, Otezla®, and Taltz®;
   b. Member has not responded or is intolerant to one or more TNF blockers (i.e. Xeljanz®) unless member has cardiovascular risk and benefits do not outweigh the risk of treatment;
   **Prior authorization may be required for Enbrel, Otezla, Taltz, Xeljanz*
5. Member does not have combination use with biological disease-modifying antirheumatic drugs or Janus kinase inhibitors (*see Section III: Diagnoses/Indications for which coverage is NOT authorized*);
6. Dose does not exceed one of the following (a or b):
   a. PsA alone: 150 mg at weeks 0, 1, 2, 3, and 4, followed by maintenance dose of 150 mg every 4 weeks;
   b. PsA with PsO: 300 mg at weeks 0, 1, 2, 3, and 4, followed by maintenance dose of 300 mg every 4 weeks.

**Approval duration: 6 months**

**E. Other diagnoses/indications**

1. Refer to the off-label use policy for the relevant line of business if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized): CP.PMN.53 for Medicaid.

**II. Continued Therapy**

**A. All Indications in Section I** (must meet all)**:**

1. Currently receiving medication via Centene benefit or member has previously met initial approval criteria;
2. Member is responding positively to therapy;
3. Member does not have combination use with biological disease-modifying antirheumatic drugs or Janus kinase inhibitors (*see Section III: Diagnoses/Indications for which coverage is NOT authorized*);
4. If request is for a dose increase, new dose does not exceed one of the following (a, b, c, or d):
   a. PsO alone (i, ii, or iii):
      i. Age ≥ 18 years: 300 mg every 4 weeks;
      ii. Age 6 to 17 years and weight < 50 kg: 75 mg every 4 weeks;
      iii. Age 6 to 17 years and weight ≥ 50 kg: 150 mg every 4 weeks;
   b. PsA (i or ii):
      i. 150 mg every 4 weeks;
      ii. 300 mg every 4 weeks, if documentation supports inadequate response to a ≥ 3 consecutive month trial of 150 mg every 4 weeks or member has coexistent PsO;
   c. AS, nr-axSpA (i or ii):
      i. 150 mg every 4 weeks;
      ii. For AS only: 300 mg every 4 weeks, if documentation supports inadequate response to a ≥ 3 consecutive month trial of 150 mg every 4 weeks;
   d. ERA (i or ii):
      i. Weight > 15 kg and < 50 kg: 75 mg at weeks 0, 1, 2, 3, and 4, followed by maintenance dose of 75 mg every 4 weeks;
      ii. Weight ≥ 50 kg: 150 mg at weeks 0, 1, 2, 3, and 4, followed by maintenance dose of 150 mg every 4 weeks.

**Approval duration: 12 months** ***(If new dosing regimen, approve for 6 months)***

**B. Other diagnoses/indications** (must meet 1 or 2)**:**

1. Currently receiving medication via Centene benefit and documentation supports positive response to therapy.
   **Approval duration: Duration of request or 6 months (whichever is less)**; or
2. Refer to the off-label use policy for the relevant line of business if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized): CP.PMN.53 for Medicaid.

**III. Diagnoses/Indications for which coverage is NOT authorized:**

**A.** Non-FDA approved indications, which are not addressed in this policy, unless there is sufficient documentation of efficacy and safety according to the off label use policies – CP.PMN.53 for Medicaid or evidence of coverage documents;

**B.** Combination use with biological disease-modifying antirheumatic drugs (bDMARDs) or potent immunosuppressants, including but not limited to any tumor necrosis factor (TNF) antagonists [e.g., Cimzia®, Enbrel®, Humira®, Simponi®, Avsola™, Inflectra™, Remicade®, Renflexis™], interleukin agents [e.g., Arcalyst® (IL-1 blocker), Ilaris® (IL-1 blocker), Kineret® (IL-1RA), Actemra® (IL-6RA), Kevzara® (IL-6RA), Stelara® (IL-12/23 inhibitor), Cosentyx® (IL-17A inhibitor), Taltz® (IL-17A inhibitor), Siliq™ (IL-17RA), Ilumya™ (IL-23 inhibitor), Skyrizi™ (IL-23 inhibitor), Tremfya® (IL-23 inhibitor)], Janus kinase inhibitors (JAKi) [e.g., Xeljanz®/Xeljanz® XR, Cibinqo™, Olumiant™, Rinvoq™], anti-CD20 monoclonal antibodies [Rituxan®, Riabni™, Ruxience™, Truxima®, Rituxan Hycela®], selective co-stimulation modulators [Orencia®], and integrin receptor antagonists [Entyvio®] because of the additive immunosuppression, increased risk of neutropenia, as well as increased risk of serious infections.

## IV. Appendices/General Information

*Appendix A: Abbreviation/Acronym Key*

AS: ankylosing spondylitis
ERA: enthesitis-related arthritis
FDA: Food and Drug Administration
IL-17A: interleukin-17A
ILAR: International League of Associations for Rheumatology
JAKi: Janus kinase inhibitors
MTX: methotrexate
nr-axSpA: non-radiographic axial spondyloarthritis
NSAID: non-steroidal anti-inflammatory drug
PsA: psoriatic arthritis
PsO: plaque psoriasis

*Appendix B: Therapeutic Alternatives*

*This table provides a listing of preferred alternative therapy recommended in the approval criteria. The drugs listed here may not be a formulary agent for all relevant lines of business and may require prior authorization.*

| Drug Name | Dosing Regimen | Dose Limit/ Maximum Dose |
|---|---|---|
| acitretin (Soriatane®) | **PsO**<br>25 or 50 mg PO QD | 50 mg/day |
| cyclosporine (Sandimmune®, Neoral®) | **PsO**<br>2.5 – 4 mg/kg/day PO divided BID | 4 mg/kg/day |
| leflunomide (Arava®) | **ERA**<br>Weight < 20 kg: 10 mg every other day<br>Weight 20 - 40 kg: 10 mg/day<br>Weight > 40 kg: 20 mg/day | 20 mg/day |
| methotrexate (Rheumatrex®) | **PsO, ERA**<br>10 – 25 mg/week PO or 2.5 mg PO Q12 hr for 3 doses/week | 30 mg/week |
| sulfasalazine (Azulfidine®) | **ERA**<br>2 g/day PO in divided doses | 3 g/day |

| Drug Name | Dosing Regimen | Dose Limit/ Maximum Dose |
|---|---|---|
| NSAIDs (e.g., indomethacin, ibuprofen, naproxen, celecoxib) | **AS, nr-axSpA, ERA**<br>Varies | Varies |
| Actemra®<br>(tocilizumab) | **PJIA (includes ERA with polyarticular disease)**<br>• Weight < 30 kg: 10 mg/kg IV every 4 weeks or 162 mg SC every 3 weeks<br>• Weight ≥ 30 kg: 8 mg/kg IV every 4 weeks or 162 mg SC every 2 weeks<br>*See Appendix E for dose rounding guidelines* | IV: 10 mg/kg every 4 weeks<br><br>SC: 162 mg every 2 weeks |
| Enbrel®<br>(etanercept) | **AS**<br>50 mg SC once weekly<br><br>**PsA**<br>25 mg SC twice weekly or 50 mg SC once weekly<br><br>**PJIA (includes ERA with polyarticular disease)**<br>0.8 mg/kg weekly | 50 mg/week |
| Cimzia®<br>(certolizumab) | **AS, nr-axSpA**<br>Initial dose: 400 mg SC at 0, 2, and 4 weeks<br>Maintenance dose: 200 mg SC every other week (or 400 mg SC every 4 weeks) | 400 mg every 4 weeks |
| Otezla®<br>(apremilast) | **PsA**<br>Initial dose:<br>Day 1: 10 mg PO QAM<br>Day 2: 10 mg PO QAM and 10 mg PO QPM<br>Day 3: 10 mg PO QAM and 20 mg PO QPM<br>Day 4: 20 mg PO QAM and 20 mg PO QPM<br>Day 5: 20 mg PO QAM and 30 mg PO QPM<br><br>Maintenance dose:<br>Day 6 and thereafter: 30 mg PO BID | 60 mg/day |

| Drug Name | Dosing Regimen | Dose Limit/ Maximum Dose |
|---|---|---|
| Taltz®<br>(ixekizumab) | **AS, nr-axSpA, PsA**<br>Initial dose: 160 mg (two 80 mg injections) SC at week 0<br>Maintenance dose:<br>80 mg SC every 4 weeks<br><br>**PsO**<br>Initial dose:<br>160 mg (two 80 mg injections) SC at week 0, then 80 mg SC at weeks 2, 4, 6, 8, 10, and 12<br>Maintenance dose:<br>80 mg SC every 4 weeks | 80 mg every 4 weeks |
| Xeljanz®<br>(tofacitinib) | **AS, PsA**<br>5 mg PO BID | 10 mg/day |
| Xeljanz XR®<br>(tofacitinib extended-release) | **AS, PsA**<br>11 mg PO QD | 11 mg/day |

*Therapeutic alternatives are listed as Brand name® (generic) when the drug is available by brand name only and generic (Brand name®) when the drug is available by both brand and generic.*
**Off-label*

*Appendix C: Contraindications/Boxed Warnings*

- Contraindication(s): serious hypersensitivity reaction to secukinumab or to any of the excipients
- Boxed warning(s): none reported

*Appendix C: General Information*

- Definition of failure of MTX or DMARDs
  - Child-bearing age is not considered a contraindication for use of MTX. Each drug has risks in pregnancy. An educated patient and family planning would allow use of MTX in patients who have no intention of immediate pregnancy.
  - Social use of alcohol is not considered a contraindication for use of MTX. MTX may only be contraindicated if patients choose to drink over 14 units of alcohol per week. However, excessive alcohol drinking can lead to worsening of the condition, so patients who are serious about clinical response to therapy should refrain from excessive alcohol consumption.
- Examples of positive response to therapy may include, but are not limited to:
  - Reduction in joint pain/swelling/tenderness
  - Improvement in ESR/CRP levels
  - Improvements in activities of daily living
- PsA: According to the 2018 American College of Rheumatology and National Psoriasis Foundation guidelines, TNF inhibitors or oral small molecules (e.g., methotrexate, sulfasalazine, cyclosporine, leflunomide, apremilast) are preferred over other biologics

(e.g., interleukin-17 inhibitors or interleukin-12/23 inhibitors) for treatment-naïve disease. TNF inhibitors are also generally recommended over oral small molecules as first-line therapy unless disease is not severe, member prefers oral agents, or TNF inhibitor therapy is contraindicated.

- ERA: Current International League of Associations for Rheumatology (ILAR) classification criteria divide JIA into 7 mutually exclusive categories defined by the number of joints involved, presence or absence of extraarticular manifestations, and presence or absence of additional markers including rheumatoid factor (RF) and HLA–B27. While the current ILAR classification criteria have been useful for identifying homogeneous groups of patients for research, more recent data suggest that these categories may not entirely reflect the underlying genetic and clinical heterogeneity of the disease or be relevant for guiding treatment decisions. According to the 2019 American College of Rheumatology, current treatment guideline focuses treatment approaches based on broad clinical phenotypes rather than ILAR categories.

## V. Dosage and Administration

| Indication | Dosing Regimen | Maximum Dose |
|---|---|---|
| PsO (with or without PsA) | Adults: 300 mg SC at weeks 0, 1, 2, 3, and 4, followed by 300 mg SC every 4 weeks. (for some patients, a dose of 150 mg may be acceptable)<br><br>Pediatric patients age 6 to 17 years and weight < 50 kg (PsO only): 75 mg SC at weeks 0, 1, 2, 3 and 4, followed by maintenance dose of 75 mg every 4 weeks<br><br>Pediatric patients age 6 to 17 years and weight ≥ 50 kg (PsO only): 150 mg SC at weeks 0, 1, 2, 3 and 4, followed by maintenance dose of 150 mg every 4 weeks | Adults: 300 mg every 4 weeks<br><br>Pediatric patients: 150 mg every 4 weeks |
| PsA | • With loading dose: 150 mg SC at week 0, 1, 2, 3, and 4, followed by 150 mg SC every 4 weeks<br>• Without loading dose: 150 mg SC every 4 weeks.<br>• If a patient continues to have active psoriatic arthritis, consider a dosage of 300 mg. | 300 mg every 4 weeks |
| AS, nr-axSpA | • With loading dose: 150 mg SC at weeks 0, 1, 2, 3, and 4, followed by 150 mg SC every 4 weeks thereafter<br>• Without loading dose: 150 mg SC every 4 weeks.<br>• For AS only: if a patient continues to have active ankylosing spondylitis, consider a dosage of 300 mg. | AS: 300 mg every 4 weeks<br>nr-axSpA: 150 mg every 4 weeks (after loading doses) |
| ERA | • Weight > 15 kg and < 50 kg: 75 mg at weeks 0, 1, 2, 3, and 4, followed by maintenance dose of 75 mg every 4 weeks | Weight < 50 kg: 75 mg every 4 weeks (after loading doses) |

| Indication | Dosing Regimen | Maximum Dose |
|---|---|---|
| | • Weight ≥ 50 kg: 150 mg at weeks 0, 1, 2, 3, and 4, followed by maintenance dose of 150 mg every 4 weeks | Weight ≥ 50 kg: 150 mg every 4 weeks (after loading doses) |

## VI. Product Availability

- Single-dose Sensoready® pen: 150 mg/mL
- Single-dose prefilled syringe: 75 mg/0.5 mL, 150 mg/mL
- Single-use vial: 150 mg

## VII. References

1. Cosentyx Prescribing Information. East Hanover, NJ: Novartis Pharmaceuticals Corporation; December 2021. Available at: https://www.accessdata.fda.gov/drugsatfda_docs/label/2021/125504_S050_S051lbl.pdf. Accessed February 17, 2022.
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3. Ringold S, Angeles-Han ST, Beukelman T, et al. 2019 American College of Rheumatology/Arthritis Foundation guideline for the treatment of juvenile idiopathic arthritis: therapeutic approaches for non-systemic polyarthritis, sacroiliitis, and enthesitis. Arthritis Care and Research. 2019:71(6):717-734. DOI 10.1002/acr.23870.
4. 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. doi:10.1016/j.aad.201811.057.
5. Gossec L, Baraliakos X, Kerschbaumer A, et al. EULAR recommendations for the maagement of psoriatic arthritis with pharmacological therapies: 2019 update. Ann Rheum Dis. 2020;79:700–712. doi:10.1136/annrheumdis-2020-217159
6. Singh JA, Guyatt G, Ogdie A, et al. 2018 American College of Rheumatology/National Psoriasis Foundation Guideline for the treatment of psoriatic arthritis. American College of Rheumatology. 2019; 71(1):5-32. doi: 10.1002/art.40726

## Coding Implications

Codes referenced in this clinical policy are for informational purposes only. Inclusion or exclusion of any codes does not guarantee coverage. Providers should reference the most up-to-date sources of professional coding guidance prior to the submission of claims for reimbursement of covered services.

| HCPCS Codes | Description |
|---|---|
| J3590, C9399 | Unclassified drugs or biologicals |

| Reviews, Revisions, and Approvals | Date | P&T Approval Date |
|---|---|---|
| Policy created | 01.23 | 01.23 |

**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. The Health Plan makes no representations and accepts no liability with respect to the content of any external information used or relied upon in developing this clinical policy. This clinical policy is consistent with standards of medical practice current at the time that this clinical policy was approved. "Health Plan" means a health plan that has adopted this clinical policy and that is operated or administered, in whole or in part, by Centene Management Company, LLC, or any of such health plan's affiliates, as applicable.

The purpose of this clinical policy is to provide a guide to medical necessity, which is a component of the guidelines used to assist in making coverage decisions and administering benefits. It does not constitute a contract or guarantee regarding payment or results. Coverage decisions and the administration of benefits are subject to all terms, conditions, exclusions and limitations of the coverage documents (e.g., evidence of coverage, certificate of coverage, policy, contract of insurance, etc.), as well as to state and federal requirements and applicable Health Plan-level administrative policies and procedures.

This clinical policy is effective as of the date determined by the Health Plan. The date of posting may not be the effective date of this clinical policy. This clinical policy may be subject to applicable legal and regulatory requirements relating to provider notification. If there is a discrepancy between the effective date of this clinical policy and any applicable legal or regulatory requirement, the requirements of law and regulation shall govern. The Health Plan retains the right to change, amend or withdraw this clinical policy, and additional clinical policies may be developed and adopted as needed, at any time.

This clinical policy does not constitute medical advice, medical treatment or medical care. It is not intended to dictate to providers how to practice medicine. 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 clinical policy is not intended to recommend treatment for members. Members should consult with their treating physician in connection with diagnosis and treatment decisions.

Providers referred to in this clinical policy are independent contractors who exercise independent judgment and over whom the Health Plan has no control or right of control. Providers are not agents or employees of the Health Plan.

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**Note:**
**For Medicaid members**, when state Medicaid coverage provisions conflict with the coverage provisions in this clinical policy, state Medicaid coverage provisions take precedence. Please refer to the state Medicaid manual for any coverage provisions pertaining to this clinical policy.

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