# Clinical Policy: Secukinumab (Cosentyx)

Reference Number: CP.PHAR.261
Effective Date: 08.16
Last Review Date: 05.20
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 adult patients who are candidates for systemic therapy or phototherapy
- Adults with active psoriatic arthritis (PsA)
- Adults with active ankylosing spondylitis (AS)

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

1. Diagnosis of PsO:
2. Prescribed by or in consultation with a dermatologist or rheumatologist;
3. Age ≥ 18 years;
4. Member meets one of the following (a or b):
   a. Failure of a ≥ 3 consecutive month trial of methotrexate (MTX) at up to maximally indicated doses unless contraindicated or clinically significant adverse effects are experienced;
   b. If intolerance or contraindication to MTX (*see Appendix D*), failure of a ≥ 3 consecutive month trial of cyclosporine or acitretin at up to maximally indicated doses, 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 is required for Taltz*
6. Dose does not exceed 300 mg at weeks 0, 1, 2, 3, and 4, followed by maintenance dose of 300 mg every 4 weeks.

**Approval duration: 6 months**

**B. Psoriatic Arthritis** (must meet all)**:**
1. Diagnosis of PsA;
2. Prescribed by or in consultation with a dermatologist or rheumatologist;
3. Age ≥ 18 years;
4. Failure of at least THREE of the following, each used for ≥ 3 consecutive months, unless contraindicated or clinically significant adverse effects are experienced: Enbrel®, Otezla®, Simponi®/Simponi Aria®, Taltz®, Xeljanz®/Xeljanz XR®;
   **Prior authorization is required for Enbrel, Otezla, Simponi/Simponi Aria, Taltz, Xeljanz/Xeljanz XR*
5. 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**

**C. Ankylosing Spondylitis** (must meet all)**:**
1. Diagnosis of AS;
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 contraindicated or clinically significant adverse effects are experienced;
5. Failure of at least TWO of the following, each used for ≥ 3 consecutive months, unless contraindicated or clinically significant adverse effects are experienced: Cimzia®, Enbrel  Taltz;
   **Prior authorization is required for Cimzia, Enbrel, and Taltz*
6. 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**

**D. 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. If request is for a dose increase, new dose does not exceed one of the following (a, b, or c):
   a. PsO alone: 300 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 (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.

**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.

## IV. Appendices/General Information

*Appendix A: Abbreviation/Acronym Key*

AS: ankylosing spondylitis
FDA: Food and Drug Administration
IL-17A: interleukin-17A
MTX: methotrexate
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 |
| methotrexate (Rheumatrex®) | **PsO**<br>10 – 25 mg/week PO or 2.5 mg PO Q12 hr for 3 doses/week | 30 mg/week |
| NSAIDs (e.g., indomethacin, | **AS**<br>Varies | Varies |

| Drug Name | Dosing Regimen | Dose Limit/ Maximum Dose |
|---|---|---|
| ibuprofen, naproxen, celecoxib) | | |
| Enbrel® (etanercept) | **AS**<br>50 mg SC once weekly<br><br>**PsA**<br>25 mg SC twice weekly or 50 mg SC once weekly | 50 mg/week |
| Cimzia® (certolizumab) | **AS**<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® (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 |
| Simponi® | **PsA**<br>50 mg SC once monthly | 50 mg/month |
| Simponi Aria® | **PsA**<br>Initial dose:<br>2 mg/kg IV at weeks 0 and 4<br>Maintenance dose:<br>2 mg/kg IV every 8 weeks | 2 mg/kg every 8 weeks |
| Taltz® (ixekizumab) | **AS, 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: | 80 mg every 4 weeks |

| Drug Name | Dosing Regimen | Dose Limit/ Maximum Dose |
|---|---|---|
| | 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 | |
| Xeljanz®<br>(tofacitinib) | **PsA**<br>5 mg PO BID | 10 mg/day |
| Xeljanz XR®<br>(tofacitinib extended-release) | **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.

## V. Dosage and Administration

| Indication | Dosing Regimen | Maximum Dose |
|---|---|---|
| PsO (with or without PsA) | 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) | 300 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 | • 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>• If a patient continues to have active psoriatic arthritis, consider a dosage of 300 mg. | 300 mg every 4 weeks |

## VI. Product Availability

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

## VII. References

1. Cosentyx Prescribing Information. East Hanover, NJ: Novartis Pharmaceuticals Corporation; January 2020. Available at https://www.pharma.us.novartis.com/sites/www.pharma.us.novartis.com/files/cosentyx.pdf. Accessed February 26, 2020.
2. Menter A, Korman NJ, Elmets CA, Feldman SR, Gelfand JM, Gordon KM, et al. American Academy of Dermatology. Guidelines of care for the management of psoriasis and psoriatic arthritis: section 4. Guidelines of care for the management and treatment of psoriasis with traditional systemic agents. J Am Acad Dermatol. 2009 Sep; 6(3):451-85.
3. Menter A, Gottlieb A, Feldman SR, Van Voorhees AS, Leonardi CL, Gordon KB, et al. American Academy of Dermatology. Guidelines of care for the management of psoriasis and psoriatic arthritis: Section 1. Overview of psoriasis and guidelines of care for the treatment of psoriasis with biologics. J Am Acad Dermatol 2008 May; 58 (5):826-50.
4. Gossec L, Smolen JS, Ramiro S, et al European League Against Rheumatism (EULAR) recommendations for the management of psoriatic arthritis with pharmacological therapies: 2015 update Annals of the Rheumatic Diseases Published Online First: 07 December 2015. doi: 10.1136/annrheumdis-2015-208337.
5. 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
6. Boulos P, Dougados M, MacLeod SM, et al. Pharmacological Treatment of Ankylosing Spondylitis. Drugs. 2005; 65: 2111-2127.

7. Braun J, Davis J, Dougados M, et al. First update of the international ASAS consensus statement for the use of anti-TNF agents in patients with ankylosing spondylitis. Ann Rheum Dis. 2006;65:316-320.
8. Braun J, van den Berg R, Baraliako X, et al. 2010 Update of the ASAS/EULAR recommendations for the management of ankylosing spondylitis. Ann Rheum Dis 2011; 70:896-904.

| Reviews, Revisions, and Approvals | Date | P&T Approval Date |
|---|---|---|
| Policy split from CP.PHAR.85.Psoriasis Treatments. Plaque psoriasis: removed criteria related to malignant disease and concurrent use with another biologic agent; removed Otezla as an option for failure of DMARD; removed duration of trial for topical and phototherapy; added requirement for trial and failure of Enbrel and Humira, unless contraindicated; added max dose; updated contraindications per FDA labeling; re-auth: modified specific efficacy criteria related to Psoriasis Area and Severity Index (PASI)-75 to general efficacy statement. For PsA: required trial of MTX and added requirement for the following if MTX cannot be used: leflunomide, cyclosporine, sulfasalazine, azathioprine. Added criteria for coverage of ankylosing spondylitis and psoriatic arthritis. Re-auth: Combined into All Indications; added max dose and reasons to discontinue;<br>Modified approval duration to 6 months for initial approval and 12 months for continued approval. | 06.16 | 08.16 |
| Converted to new template. For PsO, preferencing requirement for Enbrel removed due to class review clinical guidance approved in Q3 2017. Trial requirement modified to require the concomitant use of oral and topical or phototherapy. Safety criteria was applied according to the safety guidance discussed at CPAC and endorsed by Centene Medical Affairs. Exception made to retain the TB test requirement. | 08.17 | 08.17 |
| Added maximum dose allowance for PsA with PsO under the PsA diagnosis for clarity. Already reflected under PsO indication, therefore change is not significant | 12.17 | |
| 2Q 2018 annual review: policies combined for HIM and Medicaid lines of business; HIM: modified trial and failure to require both Enbrel and Humira for PsA and AS, modified requirements for dose increase to 300 mg for PsA to require trial and failure of at least 3 consecutive months on 150 mg dose or evidence of coexistent PsO; Medicaid and HIM: removed specific diagnosis requirements for PsO, removed trial and failure of phototherapy and topical therapy for PsO, removed TB testing for all indications; references reviewed and updated. | 02.27.18 | 05.18 |

| Reviews, Revisions, and Approvals | Date | P&T Approval Date |
|---|---|---|
| 4Q 2018 annual review: allowed bypassing conventional DMARDs for axial PsA and required trial of NSAIDs; references reviewed and updated. | 09.04.18 | 11.18 |
| 2Q 2019 annual review: removed trial and failure of conventional DMARDs (e.g., MTX)/NSAIDs for PsA per 2018 ACR/NPF guidelines; revised approval duration to 6 months if request is for continuation of therapy with a new (e.g., increased dose/frequency) regimen; references reviewed and updated. | 03.05.19 | 05.19 |
| Removed HIM line of business; updated preferred redirections based on SDC recommendation and prior clinical guidance: for PsA, changed redirection from adalimumab and etanercept to a trial of 3 of 5 (Enbrel, Simponi/Simponi Aria, Taltz, Otetzla, Xeljanz/Xeljanz XR); for PsO, removed redirection to adalimumab and added redirection to Taltz; for AS, removed redirection to adalimumab and added redirection to 2 of 3 (Enbrel, Cimzia, Taltz). | 12.13.19 | |
| 2Q 2020 annual review: no significant changes; for AS, added requirement of inadequate response to a ≥ 3 consecutive month trial of 150 mg every 4 weeks for increased maintenance dosing of 300 mg every 4 weeks per updated PI; references reviewed and updated. | 03.02.20 | 05.20 |

**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.

This clinical policy is the property of the Health Plan. Unauthorized copying, use, and distribution of this clinical policy or any information contained herein are strictly prohibited. Providers, members and their representatives are bound to the terms and conditions expressed herein through the terms of their contracts. Where no such contract exists, providers, members and their representatives agree to be bound by such terms and conditions by providing services to members and/or submitting claims for payment for such services.

**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.