Clinical Policy: Secukinumab (Cosentyx)

Reference Number: IL.PHAR.261
Effective Date: 1.1.20
Last Review Date: 12.22.22
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
- Adults with active psoriatic arthritis (PsA)
- Adults with active ankylosing spondylitis (AS)
- Adults with active non-radiographic axial spondyloarthritis (nr-axSpA) with objective signs of inflammation

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 ≥ 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 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 at up to maximally indicated doses, unless contraindicated or clinically significant adverse effects are experienced;
   c. Member has intolerance or contraindication to MTX and cyclosporine, and failure of phototherapy, unless contraindicated or clinically significant adverse effects are experienced;
   `
5. 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

B. 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. 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)
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. 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 the following, used for ≥ 3 consecutive months, unless clinically significant adverse effects are experienced or both are contraindicated: Enbrel®;
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

D. 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 contraindicated or clinically significant adverse effects are experienced;
   For AS: Failure of at least TWO of the following, each used for ≥ 3 consecutive months, unless contraindicated or clinically significant adverse effects are experienced: Enbrel®, Humira®, Cimzia;**Prior authorization is required for Humira, and Cimzia*
5. For nr-axSpA: Failure of Cimzia, used for ≥ 3 consecutive months, unless clinically significant adverse effects are experienced or both are contraindicated:
   **Prior authorization is required for Cimzia*
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

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

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
ILAR: International League of Associations for Rheumatology
JAKi: Janus kinase inhibitor
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
cyclosporine (Sandimmune®, Neoral®)	**PsO** 2.5 – 4 mg/kg/day PO divided BID	4 mg/kg/day
methotrexate (Rheumatrex®)	**PsO** 10 – 25 mg/week PO or 2.5 mg PO Q12 hr for 3 doses/week	30 mg/week
NSAIDs (e.g., indomethacin, ibuprofen, naproxen, celecoxib)	**AS, nr-axSpA** Varies	Varies
Enbrel® (etanercept)	**AS, nr-axSpA** 50 mg SC once weekly	50 mg/week

Drug Name	Dosing Regimen	Dose Limit/ Maximum Dose
	PsA 25 mg SC twice weekly or 50 mg SC once weekly	
Humira® (adalimumab)	**AS, PsA** 40 mg SC every other week **PsO** Initial dose: 80 mg SC Maintenance dose: 40 mg SC every other week starting one week after initial dose	40 mg every other week
Xeljanz® (tofacitinib)	**PsA, PsO** 5 mg PO BID	10 mg/day
Xeljanz XR® (tofacitinib extended-release)	**PsA, PsO** 11 mg PO QD	11 mg/day
Cimzia® (certolizumab)	**AS, PsA, nr-axSpA** Initial dose: 400 mg SC at 0, 2, and 4 weeks Maintenance dose: 200 mg SC every other week (or 400 mg SC every 4 weeks) **PsO** 400 mg SC every other week. For some patients (with body weight ≤ 90 kg), a dose of 400 mg SC at 0, 2 and 4 weeks, followed by 200 mg SC every other week may be considered.	AS, PsA: 400 mg every 4 weeks PsO: 400 mg every other week

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 D: 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)	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) 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 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 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 Without loading dose: 150 mg SC every 4 weeks If a patient continues to have active psoriatic arthritis, consider a dosage of 300 mg.	300 mg every 4 weeks

Indication	Dosing Regimen	Maximum Dose
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 • Without loading dose: 150 mg SC every 4 weeks. • For AS only: if a patient continues to have active ankylosing spondylitis, consider a dosage of 300 mg.	AS: 300 mg every 4 weeks nr-axSpA: 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.
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 & Rheumatology. 2019. doi: 10.1002/art.41042.
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;80:102972. 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

Reviews, Revisions, and Approvals	Date	P&T Approval Date
New policy created, adapted CP.PHAR.261 Secukinumab (Cosentyx) policy.	12.11.19	1.7.20
Criteria added for new FDA indication: nr-axSpA; required redirection to only Cimzia due to off-label status of Enbrel for nr-	12.3.20	

Reviews, Revisions, and Approvals	Date	P&T Approval Date
axSpA while maintaining redirection to Cimzia, Enbrel, when the diagnosis is AS; references reviewed and updated. 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.		
2Q 2021: updated PsO age requirement from ≥ 18 years to ≥ 6 years per FDA pediatric expansion; added new 75 mg/0.5 mL prefilled syringe for pediatric patients; reference reviewed and updated ;	6.14.21	
2Q 2022 annual review: for AS, added redirection to Xeljanx if failed prior TNF blocker per August SDC and updated FDA labeling; RT4: applied FDA-approved pediatric use extension down to 2 years of age for active PsA; for PsA, modified redirection to apply for age 18 or older; added newly approved indication for active ERA; for PsO, allowed phototherapy as alternative to systemic conventional DMARD if contraindicated or clinically significant adverse effects are experienced; references reviewed and updated.	7.11.22	
Updated redirections in section I per HFS PDL	12.22.22	

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.

For Health Insurance Marketplace members, when applicable, this policy applies only when the prescribed agent is on your health plan approved formulary. Request for non-formulary drugs must be reviewed using the formulary exception policy.