Clinical Policy: Secukinumab (Cosentyx)

Reference Number: ERX.SPA.165
Effective Date: 10.01.16
Last Review Date: 05.21
Line of Business: Commercial, Medicaid

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.

Health plan approved formularies should be reviewed for all coverage determinations. Requirements to use preferred alternative agents apply only when such requirements align with the health plan approved formulary.

It is the policy of health plans affiliated with Envolve Pharmacy Solutions™ 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), each used for ≥ 4 weeks at up to maximally indicated doses unless clinically significant adverse effects are experienced or all are contraindicated;
5. 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. 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 or b):
   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;

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

C. 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. 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

D. Other diagnoses/indications
1. Refer to ERX.PA.01 if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized).

II. Continued Therapy

A. All Indications in Section I (must meet all)**:**
1. Currently receiving medication via a health plan affiliated with Envolve Pharmacy Solutions 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 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 a health plan affiliated with Envolve Pharmacy Solutions and documentation supports positive response to therapy.
   Approval duration: Duration of request or 6 months (whichever is less); or
2. Refer to ERX.PA.01 if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized).

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 policy – ERX.PA.01 or evidence of coverage documents;

B. Combination use of biological disease-modifying antirheumatic drugs (bDMARDs), including any tumor necrosis factor (TNF) antagonists [Cimzia®, Enbrel®, Simponi®, Avsola™, Inflectra™, Remicade®, Renflexis™], interleukin agents [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) [Xeljanz®/Xeljanz® XR, Rinvoq™], anti-CD20 monoclonal antibodies [Rituxan®, Riabni™, Ruxience™, Truxima®, and Rituxan Hycela®], selective co-stimulation modulators [Orencia®], or integrin receptor antagonists [Entyvio®] because of the possibility of increased immunosuppression, neutropenia and increased risk of infection.

IV. Appendices/General Information

Appendix A: Abbreviation/Acronym Key

AS: ankylosing spondylitis
FDA: Food and Drug Administration
IL-17A: interleukin-17A
MTX: methotrexate
nr-axSpA: nonradiographic axial spondyloarthritis
NSAID: non-steroidal anti-inflammatory drug
PsO: plaque psoriasis
PsA: psoriatic arthritis

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** 25 or 50 mg PO daily	50 mg/day PO
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 PO
NSAIDs (e.g., indomethacin, ibuprofen, naproxen, celecoxib)	**AS, nr-axSpA** Varies	Varies

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.

- Inability to try phototherapy due to scheduling conflicts is not an acceptable clinical rationale for bypassing conventional therapy. A partial trial due to non-compliance is not classified as an acceptable trial and failure of any therapy. In such a case, the patient would still be required to try a systemic conventional DMARD therapy.

- 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 week 0, 1, 2, 3, and 4, followed by 300 mg 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 SC every 4 weeks
PsA	With loading dose: 150 mg SC at week 0, 1, 2, 3, and 4, followed by 150 mg 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
AS, nr-axSpA	With loading dose: 150 mg at weeks 0, 1, 2, 3, and 4, followed by 150 mg every 4 weeks Without loading dose: 150 mg every 4 weeks For AS only: if a patient continues to have active ankylosing spondylitis, consider a dosage of 300 mg SC every 4 weeks.	AS: 300 mg every 4 weeks nr-axSpA: 150 mg every 4 weeks

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; May 2021. Available at: https://www.cosentyx.com/. Accessed June 4, 2021.
2. Boulos P, Dougados M, MacLeod SM, et al. Pharmacological Treatment of Ankylosing Spondylitis. *Drugs*. 2005; 65: 2111-2127.
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;58(5):826-50.

4. 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;61(3):451-85.
5. 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.
6. van der Heijde D, Ramiro S, Landewe R, et al. 2016 update of the ASAS-EULAR management recommendations for axial spondyloarthritis. *Ann Rheum Dis*. 2017;76:978-991. doi:10.1136/annrheumdis-2016-210770.
7. 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.
8. 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
9. 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.

Reviews, Revisions, and Approvals	Date	P&T Approval Date
4Q17 Annual Review Converted to new template. For all indications: Diagnostic criteria modified to require verifiable information; Specified trial of conventional and biologic DMARDs for 3 months or greater; provided alternatives if intolerance or contraindication to MTX AS: removed trial of another biologic per TCR; PsO: removed requirement for trial of phototherapy and topical therapy.	10.02.17	11.17
2Q 2018 annual review: 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; references reviewed and updated.	02.27.18	05.18
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 biologic trial and failure requirement to TNF inhibitors and Otezla per ACR/NPF 2018 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
2Q 2020 annual review: no significant changes; for PsA, removed redirections to non-conventional DMARDs due to the preferred formulary status of Cosentyx; 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
Criteria added for new FDA-approved indication: nr-axSpA; references reviewed and updated.	06.25.20	11.20
2Q 2021 annual review: added additional criteria related to diagnosis of moderate-to-severe PsO per 2019 AAD/NPF guidelines specifying at least 3% BSA involvement or involvement of areas that severely impact daily function;	02.23.21	05.21

Reviews, Revisions, and Approvals	Date	P&T Approval Date
added combination of bDMARDs under Section III; references reviewed and updated.		
RT4: 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.	06.04.21	

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.

This Clinical Policy is not intended to dictate to providers how to practice medicine, nor does it constitute a contract or guarantee regarding payment or results. 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.