Clinical Policy: Secukinumab (Cosentyx)

Reference Number: CP.PHAR.261
Effective Date: 08/16
Last Review Date: 08/17
Line of Business: Medicaid

Revision Log

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

Description

Secukinumab (Cosentyx®) is a human interleukin-17A antagonist.

FDA approved indication

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 (which may include office chart notes and lab results) 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 and at least one of the of the following:
   a. > 5% of body surface area is affected;
   b. Palms, soles, face, and neck, body folds, or genitalia is involved;
2. Prescribed by or in consultation with a dermatologist;
3. Age ≥ 18 years;
4. Failure of at least one oral systemic therapy for plaque psoriasis (e.g., methotrexate, cyclosporine, acitretin, or thioguanine) in combination with phototherapy or topical therapy (e.g., corticosteroids, calcipotriene, tazarotene) for ≥ 3 consecutive months, unless contraindicated or clinically significant adverse effects are experienced;
5. Failure of adalimumab *(Humira is preferred)*, used for ≥ 3 consecutive months, unless contraindicated or clinically significant adverse effects are experienced;
   **Prior authorization is required for adalimumab*
6. Tuberculosis (TB) test within the past 12 months is negative, or if positive, active TB has been ruled out and the patient has received treatment for latent TB infection;
7. Prescribed dose does not exceed 300 mg SC at week 0, 1, 2, 3, and 4 followed by 300 mg every 4 weeks.

Approval duration: 6 months

B. Ankylosing Spondylitis (must meet all)**:**
1. Diagnosis of active 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 each trialed for ≥ 4 weeks unless contraindicated or clinically significant adverse effects are experienced;
5. Failure of etanercept *(Enbrel is preferred)* and adalimumab *(Humira is preferred)* each used for ≥ 3 consecutive months, unless contraindicated or clinically significant adverse effects are experienced;
   **Prior authorization is required for etanercept and adalimumab*
6. TB test within the past 12 months is negative, or if positive, active TB has been ruled out and the patient has received treatment for latent TB infection;
7. Prescribed dose does not exceed 150 mg at weeks 0, 1, 2, 3, and 4 (loading dose), then every 4 weeks thereafter.

Approval duration: 6 months

C. Psoriatic Arthritis (must meet all)**:**
1. Diagnosis of active PsA;
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 MTX for ≥ 3 consecutive months unless contraindicated or clinically significant adverse effects are experienced;
   b. If intolerance or contraindication to MTX, failure of sulfasalazine, leflunomide, or cyclosporine for ≥ 3 consecutive months unless contraindicated or clinically significant adverse effects are experienced;
5. Failure of etanercept *(Enbrel is preferred)* and adalimumab *(Humira is preferred)*, each used for ≥ 3 consecutive months, unless contraindicated or clinically significant adverse effects are experienced;
   **Prior authorization is required for etanercept and adalimumab.*
6. TB test within the past 12 months is negative, or if positive, active TB has been ruled out and the patient has received treatment for latent TB infection;
7. Prescribed dose does not exceed
   a. PsA alone: 150 mg at weeks 0, 1, 2, 3, and 4, then every 4 weeks thereafter;
   b. PsA with PsO: 300 mg weeks 0, 1, 2, 3, and 4 followed by 300 mg subcutaneously every 4 weeks.

Approval duration: 6 months

D. Other diagnoses/indications
1. Refer to CP.PHAR.57 if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized).

II. Continued Therapy

A. All Indications Listed 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 (examples: sign/symptom reduction, no disease progression, no significant toxicity);
3. If request is for a dose increase, new dose does not exceed the following:
   a. PsO: 300mg every 4 weeks;
   b. AS: 150mg every 4 weeks;
   c. PsA: 150mg every 4 weeks, unless documentation support inadequate response to a dose of 150mg every 4 weeks, then 300mg every 4 weeks.

Approval duration: 12 months

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

1. Currently receiving medication via Centene benefit and documentation supports positive response to therapy.

Approval duration: Duration of request or 12 months (whichever is less); or

2. Refer to CP.PHAR.57 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 CP.PHAR.57 or evidence of coverage documents.

IV. Appendices/General Information

Appendix A: Abbreviation/Acronym Key

AS: ankylosing spondylitis
IL-17A: interleuking-17A
PsA: psoriatic arthritis
PsO: plaque psoriasis
TB: tuberculosis

V. Dosage and Administration

Indication	Dosing Regimen	Maximum Dose
PsO	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.	300 mg every 4 weeks
PsA	150 mg SC at week 0, 1, 2, 3, and 4 followed by 150 mg every 4 weeks. If a patient continues to have active psoriatic arthritis, consider a dosage of 300 mg.	300 mg every 4 weeks
AS	Loading dose: 150 mg at weeks 0, 1, 2, 3, and 4 and every 4 weeks thereafter Without loading dose: 150 mg every 4 weeks	150 mg every 4 weeks

VI. Product Availability

- 150 mg/mL solution in a single-use Sensoready® pen
- 150 mg/mL solution in a single-use prefilled year

- 150mg, lyophilized powder in a single-use vial for reconstitution for healthcare professional use only

VII. References

1. Cosentyx Prescribing Information. East Hanover, NJ: Novartis Pharmaceuticals Corporation; January 2016. Available at https://www.cosentyx.com/index.jsp. Accessed August 3, 2017.
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.

Reviews, Revisions, and Approvals	Date	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; 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

Reviews, Revisions, and Approvals	Date	Approval Date
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	

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.

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.