Clinical Policy: Secukinumab (Cosentyx)

Reference Number: PA.CP.PHAR.261
Effective Date: 01/18
Last Review Date: 08/17
Line of Business: Medicaid

Revision Log

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 Pennsylvania Health and Wellness® 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 AS;
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. For Axial Disease
      i. A documented history of therapeutic failure of a six (6) week trial of two (2) NSAIDs or
      ii. A documented contraindication or intolerance to NSAIDs
   b. For Peripheral Disease:
      i. A documented history of therapeutic failure of a six (6) week trial of two (2) NSAIDs AND
      ii. A documented history of therapeutic failure of a three (3) or more month trial of methotrexate OR an alternate DEMARD OR
      iii. A documented contraindication or intolerance to NSAIDs, methotrexate, or an alternate DMARD.
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, then every 4 weeks thereafter.

Approval duration: 6 months

D. Other diagnoses/indications

1. Refer to PA.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 Pennsylvania Health and Wellness benefit or member has previously met initial approval criteria; or the Continuity of Care policy (PA.LTSS.PHAR.01) applies;
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 Pennsylvania Health and Wellness benefit and documentation supports positive response to therapy; or the Continuity of Care policy (PA.LTSS.PHAR.01) applies.

Approval duration: Duration of request or 12 months (whichever is less); or
2. Refer to PA.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 PA.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