Clinical Policy: Secukinumab (Cosentyx, Cosentyx Sensoready)
Reference Number: HIM.PA.SP29
Effective Date: 05/17
Last Review Date:
Line of Business: Health Insurance Marketplace

Coding Implications
Revision Log

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

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

FDA approved indication
Cosentyx is indicated:
- For the treatment of moderate to severe plaque psoriasis in adult patients who are candidates for systemic therapy or phototherapy
- For the treatment of adults with active psoriatic arthritis (PsA)
- For the treatment of adults with active ankylosing spondylitis (AS)

Policy/Criteria
Provider must submit documentation (including office chart notes and lab results) supporting that member has met all approval criteria

I. Initial Approval Criteria

A. Plaque Psoriasis (must meet all)**:**
1. Diagnosis of moderate to severe plaque psoriasis and at least one of the following:
   a. Greater than 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 or rheumatologist;
3. 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;
4. Failure of topical therapy for plaque psoriasis (e.g., calcipotriene, medium-to-high potency corticosteroids, tazarotene) and phototherapy unless all are contraindicated or clinically significant adverse effects are experienced;
5. Failure of all of the following therapies (a and b), unless all are contraindicated or clinically significant adverse effects are experienced:
   a. Humira;
   b. At least one oral systemic therapy for plaque psoriasis (e.g., methotrexate [MTX], cyclosporine, acitretin) for ≥ 3 consecutive months;
6. Dose does not exceed 300 mg at weeks 0, 1, 2, 3, and 4 (loading dosage), then 300 mg every 4 weeks thereafter.

Approval duration: 6 months

B. Psoriatic Arthritis (must meet all)**:**
1. Diagnosis of psoriatic arthritis (PsA);
2. Prescribed by or in consultation with a dermatologist or rheumatologist;

3. 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;
4. Failure of all of the following therapies (a, b, and c) unless all are contraindicated or clinically significant adverse effects are experienced:
   a. Humira or Enbrel;
   b. MTX for ≥ 3 consecutive months;
   c. If member has contraindication or intolerance to MTX, failure of sulfasalazine, leflunomide, cyclosporine, or azathioprine for ≥ 3 consecutive months;
5. Dose does not exceed 150 mg at weeks 0, 1, 2, 3, and 4 (loading dosage), then 300 mg every 4 weeks thereafter.

Approval duration: 6 months

C. Ankylosing Spondylitis (must meet all)**:**

1. Diagnosis of ankylosing spondylitis;
2. Prescribed by or in consultation with a rheumatologist;
3. 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;
4. Failure of all of the following therapies (a and b), unless all are contraindicated or clinically significant adverse effects are experienced:
   a. Humira or Enbrel;
   b. At least 2 nonsteroidal anti-inflammatory drugs (NSAIDs) at maximum tolerated doses, each trialed for ≥ 4 weeks;
5. Dose does not exceed 150 mg at weeks 0, 1, 2, 3, and 4 (loading dosage), then 150 mg every 4 weeks thereafter.

Approval duration: 6 months

D. Other diagnoses/indications

1. Refer to HIM.PHAR.21 if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized).

II. Continued Therapy

A. All Indications (must meet all)**:**

1. Currently receiving medication via Centene benefit or member has previously met initial approval criteria;
2. Documentation of positive response to therapy;
3. If request is for a dose increase, new dose does not exceed the following:
   a. For plaque psoriasis or psoriatic arthritis: 300 mg every 4 weeks;
   b. For ankylosing spondylitis: 150 mg every 4 weeks.

Approval duration: 12 months

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

1. Currently receiving medication via Centene benefit and documentation supports positive response to therapy; or
2. Refer to HIM.PHAR.21 if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized).

Approval duration: 12 months

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 – HIM.PHAR.21 or evidence of coverage documents

IV. Appendices/General Information

Appendix A: Abbreviation/Acronym Key
AS: ankylosing spondylitis
FDA: Food and Drug Administration
NSAIDs: nonsteroidal anti-inflammatory drugs
MTX: methotrexate
PsA: psoriatic arthritis
TB: tuberculosis

V. References

1. Cosentyx Prescribing Information. East Hanover, NJ: Novartis Pharmaceuticals Corporation; January 2016. Available at: https://www.cosentyx.com/. Accessed January 30, 2017.
2. Menter A, Korman NJ, Elmets CA, Feldman SR, Gelfand JM, Gordon KB,et al. Guidelines of care for the management of psoriasis and psoriatic arthritis. Section 3. Guidelines of care for the management and treatment of psoriasis with topical therapies. J Am Acad Dermatol. 2009 Apr;60(4):643-59.
3. Menter A, Korman NJ, Elmets CA, Feldman SR, Gelfand JM, Gordon KB, et al. Guidelines of care for the management of psoriasis and psoriatic arthritis: Section 5. Guidelines of care for the treatment of psoriasis with phototherapy and photochemotherapy. J Am Acad Dermatol. 2010 Jan;62(1):114-35.
4. Menter A, Korman NJ, Elmets CA, Feldman SR, Gelfand JM, Gordon KB, et al. 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. Menter A, Gottlieb A, Feldman SR, Van Voorhees AS, Leonardi CL, Gordon KB, et al. 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.
6. Gottlieb A, Korman NJ, Gordon KB, Feldman SR, Lebwohl M, Koo JY, et al. Guidelines of care for the management of psoriasis and psoriatic arthritis: Section 2. Psoriatic arthritis: overview and guidelines of care for treatment with an emphasis on the biologics. J Am Acad Dermatol. 2008 May;58(5):851-64.
7. Ward MM, Deodhar A, Akl EA, et al. American College of Rheumatology/Spondylitis Association of America/Spondyloarthritis Research and Treatment Network 2015 recommendations for the treatment of ankylosing spondylitis and nonradiographic axial spondyloarthritis. Arthritis & rheumatology (Hoboken, NJ). 2016;68(2):282-298.

Reviews, Revisions, and Approvals	Date	P&T Approval Date
Policy created	01/17	

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.

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.