Cosentyx (secukinumab)

NOTICE

This policy contains information which is clinical in nature. The policy is not medical advice. The information in this policy is used by Wellmark to make determinations whether medical treatment is covered under the terms of a Wellmark member's health benefit plan. Physicians and other health care providers are responsible for medical advice and treatment. If you have specific health care needs, you should consult an appropriate health care professional. If you would like to request an accessible version of this document, please contact customer service at 800-524-9242.

BENEFIT APPLICATION

Benefit determinations are based on the applicable contract language in effect at the time the services were rendered. Exclusions, limitations or exceptions may apply. Benefits may vary based on contract, and individual member benefits must be verified. Wellmark determines medical necessity only if the benefit exists and no contract exclusions are applicable. This medical policy may not apply to FEP. Benefits are determined by the Federal Employee Program.

DESCRIPTION

The intent of the Cosentyx drug policy is to ensure appropriate selection of patients for therapy based on product labeling, clinical guidelines and clinical studies.

The indications below including FDA-approved indications and compendial uses are considered a covered benefit provided that all the approval criteria are met and the member has no exclusions to the prescribed therapy.

FDA-Approved Indications

1. Moderate to severe plaque psoriasis (PsO) in patients 6 years and older who are candidates for systemic therapy or phototherapy
2. Active psoriatic arthritis (PsA) in patients 2 years of age and older
3. Adults with active ankylosing spondylitis (AS)
4. Adults with active non-radiographic axial spondyloarthritis (nr-axSpA) with objective signs of inflammation
5. Active enthesitis-related arthritis (ERA) in patients 4 years of age and older

POLICY

Required Documentation

Submission of the following information is necessary to initiate the prior authorization review:

A. Plaque psoriasis

1. Initial requests:
   a. Chart notes or medical record documentation of affected area(s) and body surface area (BSA) affected.

b. Chart notes, medical record documentation, or claims history supporting previous medications tried (if applicable), including response to therapy. If therapy is not advisable, documentation of clinical reason to avoid therapy.

2. Continuation requests: Chart notes or medical record documentation of decreased body surface area (BSA) affected and/or improvement in signs and symptoms.

B. Psoriatic arthritis: For continuation requests: Chart notes or medical record documentation supporting positive clinical response.

C. Ankylosing spondylitis and axial spondyloarthritis:

1. Initial requests: Chart notes, medical record documentation, or claims history supporting previous medications tried (if applicable), including response to therapy. If therapy if not advisable, documentation of clinical reason to avoid therapy.
2. Continuation requests: Chart notes or medical record documentation supporting positive clinical response.

D. Enthesitis-related arthritis (ERA) in patients 4 years of age and older: For continuation requests: Chart notes or medical record documentation supporting positive clinical response.

Criteria for Initial Approval

A. Moderate to severe plaque psoriasis (PsO)

1. Authorization of 12 months may be granted for members who have previously received Otezla or a biologic indicated for the treatment of moderate to severe plaque psoriasis.
2. Authorization of 12 months may be granted for treatment of moderate to severe plaque psoriasis in members when any of the following criteria is met:
   a. Crucial body areas (e.g., hands, feet, face, neck, scalp, genitals/groin, intertriginous areas) are affected.
   b. At least 10% of the body surface area (BSA) is affected
   c. At least 3% of body surface area (BSA) is affected and the member meets any of the following criteria:
      i. Member has had an inadequate response or intolerance to either phototherapy (e.g., UVB, PUVA) or pharmacologic treatment with methotrexate, cyclosporine or acitretin.
      ii. Member has a clinical reason to avoid pharmacologic treatment with methotrexate, cyclosporine and acitretin (see Appendix).

B. Active psoriatic arthritis (PsA)

Authorization of 12 months may be granted for treatment of active psoriatic arthritis.

C. Active ankylosing spondylitis (AS) and active axial spondyloarthritis

1. Authorization of 12 months may be granted for members who have previously received a biologic indicated for active ankylosing spondylitis or active axial spondyloarthritis
2. Authorization of 12 months may be granted for treatment of active ankylosing spondylitis or active axial spondyloarthritis when any of the following criteria is met:
   a. Member has experienced an inadequate response to at least two non-steroidal anti-inflammatory drugs (NSAIDs).
   b. Member has an intolerance or contraindication to two or more NSAIDs.

D. Active enthesistis-related arthritis (ERA)

Authorization of 12 months may be granted for treatment of active enthesitis-related arthritis.

Continuation of Therapy

A. Moderate to severe plaque psoriasis (PsO)

Authorization of 12 months may be granted for all members (including new members) who are using Cosentyx for moderate to severe plaque psoriasis and who achieve or maintain positive clinical response as evidenced by low disease activity or improvement in signs and symptoms of the condition when any of the following is met:

1. Reduction in body surface area (BSA) affected from baseline
2. Improvement in signs and symptoms from baseline (e.g., itching, redness, flaking, scaling, burning, cracking, pain)

B. Active psoriatic arthritis (PsA)

Authorization of 12 months may be granted for all members (including new members) who are using Cosentyx for active psoriatic arthritis and who achieve or maintain positive clinical response as evidenced by low disease activity or improvement in signs and symptoms of the condition when there is improvement in any of the following from baseline:

1. Number of swollen joints
2. Number of tender joints
3. Dactylitis
4. Enthesitis
5. Skin and/or nail involvement

C. Active ankylosing spondylitis (AS) and active axial spondyloarthritis

Authorization of 12 months may be granted for all members (including new members) who are using Cosentyx for active ankylosing spondylitis or active axial spondyloarthritis and who achieve or maintain positive clinical response with Cosentyx as evidenced by low disease activity or improvement in signs and symptoms of the condition when there is improvement in any of the following from baseline:

1. Functional status
2. Total spinal pain
3. Inflammation (e.g., morning stiffness)

D. Enthesistis-Related Arthritis (ERA)

Authorization of 12 months may be granted for all members (including new members) who are using Cosentyx for enthesistis-related arthritis and who achieve or maintain positive clinical response as evidenced by low disease activity or improvement in signs and symptoms of the condition when there is improvement in any of the following from baseline:

1. Number of swollen joints
2. Number of tender joints
3. Dactylitis
4. Enthesitis
5. Skin and/or nail involvement

<u>Other</u>

For all indications: Member has had a documented negative TB test (which can include a tuberculosis skin test [PPD], an interferon-release assay [IGRA], or a chest x-ray)* within 6 months of initiating therapy for persons who are naïve to biologic DMARDs or targeted synthetic DMARDs associated with an increased risk of TB.

* If the screening testing for TB is positive, there must be further testing to confirm there is no active disease. Do not administer Cosentyx to members with active TB infection. If there is latent disease, TB treatment must be started before initiation of Cosentyx.

For all indications: Member cannot use Cosentyx concomitantly with any other biologic DMARD or targeted synthetic DMARD.

Cosentyx is considered **not medically necessary** for members who do not meet the criteria set forth above.

Dosage and Administration

Approvals may be subject to dosing limits in accordance with FDA-approved labeling, accepted compendia, and/or evidence-based practice guidelines.

Quantity Limits

Trade Name	Generic Name	Quantity Limit
Cosentyx® prefilled Syringe/Sensoready pen	secukinumab	**Moderate to severe plaque psoriasis (PsO)** Initiation of therapy (pediatric patients): 5 x 75 mg syringes per first 28 days if weighing less than 50 kg; 6 x 150 mg syringes/pens per first 56 days if weighing greater than or equal to 50 kg Maintenance (pediatric patients): 1 x 75mg syringe per 28 days if weighing less than 50 kg; 2 x 150 mg syringes/pens per 56 days if weighing greater than or equal to 50 kg Initiation of therapy (adult patients): 10 x 150 mg syringes/pens per first 28 days Maintenance (adult patients): 2 x 150mg syringes/pens per 28 days **Active psoriatic arthritis (PsA)*** Initiation of therapy (pediatric patients): 5 x 75 mg syringes per first 28 days if weighing greater than or equal to 15 kg and less than 50 kg; 6 x 150 mg syringes/pens per first 56 days if weighing greater than or equal to 50 kg Maintenance (pediatric patients): 1 x 75mg syringe per 28 days if weighing greater than or equal to 15 kg and less than 50 kg; 2 x 150 mg syringes/pens per 56 days if weighing greater than or equal to 50 kg Initiation of therapy(adult patients): 6 x 150 mg syringes/pens per first 56 days Maintenance (adult patients): 2 x 150 mg syringes/pens per 56 days **Active psoriatic arthritis with co-existent plaque psoriasis** Initiation of therapy (pediatric patients): 5 x 75 mg syringes per first 28 days if weighing less than 50 kg; 6 x 150 mg syringes/pens per first 56 days if weighing greater than or equal to 50 kg Maintenance (pediatric patients): 1 x 75mg syringe per 28 days if weighing less than 50 kg; 2 x 150 mg syringes/pens per 56 days if weighing greater than or equal to 50 kg Initiation of therapy (adult patients) : 10 x 150 mg syringes/pens per first 28 days Maintenance (adult patients): 2 x 150 mg syringes/pens per 28 days **Ankylosing spondylitis (AS)*** Initiation of therapy: 6 x 150 mg syringes/pens per first 56 days Maintenance: 2 x 150 mg syringes/pens per 56 days **Active axial spondyloarthritis** Initiation of therapy: 6 x 150 mg syringes/pens per first 56 days Maintenance: 2 x 150 mg syringes/pens per 56 days **Enthesistis-related arthritis** Initiation of therapy (pediatric patients): 5 x 75 mg syringes per first 28 days if weighing greater than or equal to15 kg and less than 50 kg; 6 x 150 mg syringes/pens per first 56 days if weighing greater than or equal to 50 kg

Trade Name	Generic Name	Quantity Limit
		Maintenance (pediatric patients): 1 x 75mg syringe per 28 days if weighing greater than or equal to 15 kg and less than 50 kg; 2 x 150 mg syringes/pens per 56 days if weighing greater than or equal to 50 kg Initiation of therapy(adult patients): 6 x 150 mg syringes/pens per first 56 days Maintenance (adult patients): 2 x 150 mg syringes/pens per 56 days

*Quantity Limit of up to 10 x 150 mg syringes/pens per 28 days available for Psoriatic arthritis (PsA) & Ankylosing spondylitis (AS) if patient continues to have active disease

Appendix

Examples of Clinical Reasons to Avoid Pharmacologic Treatment with Methotrexate, Cyclosporine or Acitretin.

1. Clinical diagnosis of alcohol use disorder, alcoholic liver disease or other chronic liver disease
2. Breastfeeding
3. Drug interaction
4. Cannot be used due to risk of treatment-related toxicity
5. Pregnancy or currently planning pregnancy
6. Significant comorbidity prohibits use of systemic agents (examples include liver or kidney disease, blood dyscrasias, uncontrolled hypertension)

PROCEDURES AND BILLING CODES

To report provider services, use appropriate CPT* codes, Alpha Numeric (HCPCS level 2) codes, Revenue codes, and/or ICD diagnostic codes.

- N/A

REFERENCES

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*Some content reprinted from CVSHealth

POLICY HISTORY

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