Effective Date: 2/2020
Reviewed: 12/2019, 8/2020, 12/2020, 5/2021, 6/2021, 5/2022, 9/2022, 8/2023, 2/2024, 5/2024, 01/2025, 07/2025, 08/2026 Scope: Medicaid

COSENTYX (secukinumab) Subcutaneous

POLICY

I. INDICATIONS

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 adults and pediatric patients 6 years and older who are candidates for systemic therapy or phototherapy
2. Active psoriatic arthritis (PsA) in adults and pediatric patients 2 years of age and older
3. Active ankylosing spondylitis (AS) in adults and pediatric patients 12 years of age and older
4. Active non-radiographic axial spondyloarthritis (nr-axSpA) in adults with objective signs of inflammation
5. Active enthesitis-related arthritis (ERA) in pediatric patients 4 years of age and older
6. Moderate to severe hidradenitis suppurativa (HS) in adults and pediatric patients 12 and older

All other indications are considered experimental/investigational and are not a covered benefit.

II. CRITERIA FOR INITIAL APPROVAL

For all indications:

- Submission of the member's chart or medical record is required, documenting medical necessity based on the criteria corresponding to the applicable indication; AND
- Physician has assessed baseline disease severity utilizing an objective measure/tool; AND
- Member is free of any clinically important active infection, including clinically important localized infections; AND
- Member will not receive live vaccines during therapy; AND
- Member has been evaluated and screened for the presence of latent tuberculosis (TB) infection prior to initiating treatment and will receive ongoing monitoring for the presence of TB during treatment; AND
- Cosentyx will not be used concomitantly with an injectable biologic response modifier including TNF-inhibitors (e.g., adalimumab e.g. Hadlima), Enbrel (etanercept), infliximab (e.g., Inflectra), etc.) and IL-inhibitors (e.g., ustekinumab (e.g., Stelara, Otufli, Selarsdi, Steqeyma, and Yesintek, etc.), Tremfya (guselkumab), Icotyde (icotrokinra), Ilumya (tildrakizumab), Skyrizi

(risankizumab), Bimzelx (bimekizumab), etc.) or other oral non-biologic agent (e.g., Otezla (apremilast), tofacitinib (Xeljanz), Olumiant (baricitinib), Rinvoq (upadacitinib), etc.).

A. Moderate to severe plaque psoriasis (PsO)

Authorization of 6 months may be granted for treatment of moderate to severe plaque psoriasis in members when all of the following criteria are met:

1. Member is 6 years of age or older; AND
2. Prescribed by, or in consultation with, a specialist in dermatology; AND.
3. Documentation has been submitted of one or more of the following:
    a. BSA affected is at least 10%; OR
    b. Crucial body areas affected (e.g., face, hands, feet, genitals, scalp); OR
    c. Inadequate treatment response to topical therapy (corticosteroids, calcineurin inhibitors (e.g. tacrolimus), vitamin D analogs (e.g. calcipotriene), retinoids (e.g. tazarotene); AND
4. Documentation has been submitted that the member meets any of the following criteria:
    a. Member has had an inadequate response, intolerance, or contraindication to at least a 3-month trial of a conventional oral agent for PsO (e.g., methotrexate, cyclosporine or acitretin); OR
    b. Member has had an inadequate response, intolerance, or contraindication to at least a 3-month trial of phototherapy (e.g., UVB, PUVA); OR
    c. Clinical rationale has been provided indicating member's disease severity warrants a biologic DMARD as first-line therapy; AND
5. Documentation has been submitted that the member meets either of the following criteria:
    a. If member is 18 years of age or older, member has had an inadequate response, intolerance, or contraindication to at least a 3-month trial of adalimumab AND at least a 6-month trial of ustekinumab biosimilar at maximum tolerated doses; OR
    b. If member is 6 years of age or older but under 18, member has had an inadequate response, intolerance, or contraindication to at least a 6-month trial of ustekinumab biosimilar at maximum tolerated doses.

B. Active psoriatic arthritis (PsA)

Authorization of 6 months may be granted for treatment of active psoriatic arthritis when all of the following criteria are met:

1. Member is 2 years of age or older; AND
2. Prescribed by, or in consultation with, a specialist in dermatology or rheumatology
3. Documentation has been submitted indicating one of the following criteria:
    a. Member has mild to moderate disease and meets one of the following criteria:
        i. Member has had an inadequate response, intolerance, or contraindication to methotrexate or another conventional synthetic DMARD (e.g., leflunomide, sulfasalazine, etc.); OR
        ii. Member has enthesitis or predominantly axial disease; OR
    b. Member has severe disease; AND

4. If member is 18 years of age or older, documentation has been submitted that the member has had an inadequate response, intolerance or contraindication to at least a 3-month trial of adalimumab at maximum tolerated doses AND a 6-month trial of ustekinumab biosimilar at maximum tolerated doses.
5. If member is 6 years of age or older but under 18, documentation has been submitted that the member has had an inadequate response, intolerance or contraindication to at least a 6-month trial of ustekinumab biosimilar at maximum tolerated doses.

Note: Patients new to therapy must initiate treatment at the lower dosing regimen of the 150 mg dose before increasing to the 300 mg dose (unless they have co-existent plaque psoriasis)

C. Active ankylosing spondylitis (AS)

Authorization of 6 months may be granted for treatment of active ankylosing spondylitis when all of the following criteria are met:

1. Member is 12 years of age or older; AND
2. Prescribed by, or in consultation with, a specialist in rheumatology; AND
3. Member has documented active disease; AND
4. Documentation has been submitted of all of the following:
    a. Member has had an inadequate response, intolerance or contraindication to at least two (2) NSAIDs; AND
    b. If 18 years of age or older, member has had an inadequate response, intolerance, or contraindication to at least a 3-month trial of adalimumab at maximum tolerated doses.

Note: Patients new to therapy must initiate treatment at the lower dosing regimen of the 150 mg dose before increasing to the 300 mg dose

D. Active non-radiographic axial spondyloarthritis (nr-axSpA)

Authorization of 6 months may be granted for treatment of active non-radiographic axial spondyloarthritis (nr-axSpA) when all of the following criteria are met:

1. Member is 18 years of age or older; AND
2. Prescribed by, or in consultation with, a specialist in rheumatology; AND
3. Member has documented active disease with objective signs of inflammation noted by an elevation of C-reactive protein (CRP) above the upper limit of normal and/or sacroiliitis on MRI and is without definitive radiographic evidence of structural damage on sacroiliac joints; AND
4. Documentation has been submitted that the member meets all of the following criteria:
    a. Member has had an inadequate response, intolerance or contraindication to at least two (2) NSAIDs; AND
    b. Member has had an inadequate response, intolerance, or contraindication to at least a 3-month trial of adalimumab at maximum tolerated doses.

E. Active enthesitis-related arthritis (ERA)

Authorization of 6 months may be granted for treatment of active enthesitis-related arthritis, which is a type of juvenile idiopathic arthritis, when all of the following criteria are met:

1. Member is 4 years of age or older; AND
2. Prescribed by, or in consultation with, a specialist in rheumatology; AND
3. Documentation has been submitted that the member meets all of the following criteria:
    a. Member has active disease demonstrated by at least three active joints involved and at least one site of active enthesitis at baseline or documented by history; AND
    b. Member has had an inadequate response, intolerance, or contraindication to nonsteroidal anti-inflammatory drugs (NSAIDs), sulfasalazine, or methotrexate.

F. Moderate to severe hidradenitis suppurativa (HS)

Authorization of 6 months may be granted for treatment of moderate to severe hidradenitis suppurativa when all of the following are met:

1. Member is 12 years of age or older; AND
2. Prescribed by, or in consultation with, a specialist in dermatology or rheumatology; AND
3. Documentation has been submitted that the member meets all of the following criteria:
    a. Member has experienced an inadequate response, intolerance, or contraindication to oral antibiotics for at least 90 days; AND
    b. If 18 years of age or older, member has had an inadequate response, intolerance or contraindication to at least a 3-month trial of adalimumab AND at least a 6-month trial of ustekinumab at maximum tolerated doses.

III. CONTINUATION OF THERAPY

A. Moderate to severe plaque psoriasis (PsO)

Authorization of 12 months may be granted for all members (including new members) with documentation who are using the requested medication for moderate to severe plaque psoriasis and who achieve or maintain positive clinical response as evidenced by low disease activity (e.g., reduction in BSA from baseline) or improvement in signs and symptoms of the condition (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) with documentation who are using the requested medication 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. Axial disease
6. Skin and/or nail involvement
7. Functional status
8. C-reactive protein (CRP)

C. Active ankylosing spondylitis (AS) and non-radiographic axial spondyloarthritis (nr-axSpA)

Authorization of 12 months may be granted for all members (including new members) with documentation who are using the requested medication for active ankylosing spondylitis or active axial spondyloarthritis and who achieve or maintain positive clinical response with the requested medication 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)
4. Swollen joints
5. Tender joints
6. C-reactive protein (CRP)

D. Active enthesitis-related arthritis (ERA)

Authorization of 12 months may be granted for all members (including new members) with documentation who are using the requested medication for active-enthesitis 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 flares
2. Number of joints with active arthritis (e.g., swelling, pain)
3. Number of joints with limited movement
4. Dactylitis
5. Enthesitis

E. Moderate to severe hidradenitis suppurativa (HS)

Authorization of 6 months may be granted for all members (including new members) with documentation who are using the requested medication for moderate to severe hidradenitis suppurativa and who achieve or maintain a 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 abscess and inflammatory nodule count from baseline
2. Reduced formation of new sinus tracts and scarring
3. Decrease in frequency of inflammatory lesions from baseline
4. Reduction in pain from baseline
5. Reduction in suppuration from baseline
6. Improvement in frequency of relapses from baseline
7. Improvement in quality of life from baseline

8. Improvement on a disease severity assessment tool from baseline

* If the request is for Cosentyx 300mg every 2 weeks, the provider has submitted medical rationale for increased frequency after at least 16 weeks of starting therapy and for continuation of an escalated frequency of every 2 weeks, the patient has shown a response to therapy, as described above, and has had a clinically meaningful incremental benefit from the previous frequency of every 4 weeks.

IV. QUANTITY LIMIT

Formulary Cosentyx has 2 pens/syringes per box.

1. 75mg dose – 0.5 ml per 28 days, with post-limit for loading dose of 375 mg (2.5 ml) per 35 days
2. 150 mg dose – 2 ml per 56 days, with post-limit for loading dose of 900 mg (6 ml) per 60 days
3. 300 mg dose – 2 ml per 28 days, with post-limit for loading dose of 1500 mg (10 ml) per 35 days. A quantity limit exception may be provided for 4 ml per 28 days (daily dose of 0.15) for maintenance dose for hidradenitis suppurativa with medical rationale provided.

V. DOSING

Indication	**Dosing (subcutaneous)**
Plaque Psoriasis	Adults: 300 mg (two 150 mg injections) at Weeks 0, 1, 2, 3, and 4 followed by 300 mg every 4 weeks. *Note: For some patients, a dosage of 150mg may be acceptable* Pediatric (6 years of age and older): *Less than 50 kg*: 75 mg at Weeks 0, 1, 2, 3, and 4 followed by 75 mg every 4 weeks. *Greater than or equal to 50 kg*: 150 mg at Weeks 0, 1, 2, 3, and 4 followed by 150 mg every 4 weeks.
Ankylosing Spondylitis	Adults: 150 mg at Weeks 0, 1, 2, 3, and 4 followed by 150 mg every 4 weeks Pediatric (12 years of age and older): *Less than 50 kg*: 75 mg at Weeks 0, 1, 2, 3, and 4 followed by 75 mg every 4 weeks. *Greater than or equal to 50 kg*: 150 mg at Weeks 0, 1, 2, 3, and 4 followed by 150 mg every 4 weeks.
Non-radiographic Axial Spondyloarthritis	Adults:

	150 mg at Weeks 0, 1, 2, 3, and 4 followed by 150 mg every 4 weeks
Adult Psoriatic Arthritis with coexisting Plaque Psoriasis	Adults: 300 mg (two 150 mg injections) at Weeks 0, 1, 2, 3, and 4 followed by 300 mg every 4 weeks. *Note: For some patients, a dosage of 150mg may be acceptable*
Psoriatic Arthritis	Adults: 150 mg at Weeks 0, 1, 2, 3, and 4 followed by 150 mg every 4 weeks Pediatric (2 years of age and older): *Greater than or equal to 15 kg and < 50 kg*: 75 mg at Weeks 0, 1, 2, 3, and 4 followed by 75 mg every 4 weeks. *Greater than or equal to 50 kg*: 150 mg at Weeks 0, 1, 2, 3, and 4 followed by 150 mg every 4 weeks.
Enthesitis-Related Arthritis	Pediatric (4 years of age and older): *Greater than or equal to 15 kg and < 50 kg*: 75 mg at Weeks 0, 1, 2, 3, and 4 followed by 75 mg every 4 weeks. *Greater than or equal to 50 kg*: 150 mg at Weeks 0, 1, 2, 3, and 4 followed by 150 mg every 4 weeks.
Hidradenitis suppurativa	Adults: 300 mg at Weeks 0, 1, 2, 3, and 4 followed by 300 mg every 4 weeks *If a patient does not adequately respond, consider increasing the dosage to 300 mg every 2 weeks.* Pediatric (12 years of age and older) *Greater than 30 kg and less than 90 kg*: 150 mg at Weeks 0, 1, 2, 3, and 4 followed by 150 mg every 4 weeks. *Greater than or equal to 90 kg*: 300 mg at Weeks 0, 1, 2, 3, and 4 followed by 150 mg every 4 weeks.

I. REFERENCES

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