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| AETNA BETTER HEALTH® Coverage Policy/Guideline | | |
| Name: | Cosentyx | Page: 1 of 8 |
| Effective Date: | 1/30/2025 | Last Review Date: 11/2023; 4/2024; 12/2024 |
| Applies to: | <input type="checkbox"/> Illinois <input checked="" type="checkbox"/> New Jersey <input type="checkbox"/> Pennsylvania Kids | <input type="checkbox"/> Florida <input type="checkbox"/> Maryland <input type="checkbox"/> Virginia <input type="checkbox"/> Florida Kids <input type="checkbox"/> Michigan <input type="checkbox"/> Kentucky PRMD |

Intent:

The intent of this policy/guideline is to provide information to the prescribing practitioner outlining the coverage criteria for Cosentyx under the patient's prescription drug benefit.

Description:

FDA-Approved Indications

- A. Moderate to severe plaque psoriasis (PsO) in patients 6 years of age and older who are candidates for systemic therapy or phototherapy (Reference the Biological Response Modifiers (BRMs) in the Treatment of Plaque Psoriasis NJ Protocol)
- B. Active psoriatic arthritis (PsA) in patients 2 years of age and older
- C. Adults with active ankylosing spondylitis (AS)
- D. Adults with active non-radiographic axial spondyloarthritis (nr-axSpA) with objective signs of inflammation
- E. Active enthesitis-related arthritis (ERA) in patients 4 years of age and older
- F. Adults with moderate to severe hidradenitis suppurativa (HS)

All other indications are considered experimental/investigational and not medically necessary.

Applicable Drug List:

Non-preferred: Cosentyx

Policy/Guideline:

Documentation for all indications:

The patient is unable to take a preferred adalimumab product OR Enbrel and ONE additional preferred product (Otezla or Rinvoq), where indicated, for the given diagnosis due to a trial and inadequate treatment response or intolerance, or a contraindication. Documentation is required for approval.

Documentation:

- A. **Psoriatic arthritis (PsA), ankylosing spondylitis (AS), non-radiographic axial spondyloarthritis (nr-axSpA), and enthesitis-related arthritis (ERA), hidradenitis suppurativa**



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1. Initial requests: 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 supporting positive clinical response.

Prescriber Specialty:

This medication must be prescribed by or in consultation with one of the following:

- A. Psoriatic arthritis and hidradenitis suppurativa: rheumatologist or dermatologist
- B. Ankylosing spondylitis, non-radiographic axial spondyloarthritis, and enthesitis-related arthritis: rheumatologist


Criteria for Initial Approval:

A. Psoriatic arthritis (PsA)

- I. Authorization of 12 months may be granted for members 2 years of age or older who have previously received a biologic or targeted synthetic drug indicated for active psoriatic arthritis.
- II. Authorization of 12 months may be granted for members 2 years of age or older for treatment of active psoriatic arthritis when either of the following criteria is met:
 - a. Member has mild to moderate disease and meets one of the following criteria:
 - i. Member has had an inadequate response to methotrexate, leflunomide, or another conventional synthetic drug (e.g., sulfasalazine) administered at an adequate dose and duration.
 - ii. Member has an intolerance or contraindication to methotrexate or leflunomide (see Appendix), or another conventional synthetic drug (e.g., sulfasalazine).
 - iii. Member has enthesitis or predominantly axial disease.
 - b. Member has severe disease.

B. Ankylosing spondylitis (AS) and non-radiographic axial spondyloarthritis (nr-axSpA)

1. Authorization of 12 months may be granted for adult members who have previously received a biologic or targeted synthetic drug indicated for active ankylosing spondylitis or active non-radiographic axial spondyloarthritis.
2. Authorization of 12 months may be granted for adult members for treatment of active ankylosing spondylitis or active non-radiographic axial spondyloarthritis when any of the following criteria is met:
 - i. Member has had an inadequate response to at least two nonsteroidal anti-inflammatory drugs (NSAIDs).

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- ii. Member has an intolerance or contraindication to two or more NSAIDs.

D. Enthesitis-related arthritis (ERA)

1. Authorization of 12 months may be granted for members 4 years of age or older who have previously received a biologic for treatment of active enthesitis-related arthritis.
2. Authorization of 12 months may be granted for members 4 years of age or older for treatment of active enthesitis-related arthritis when both of the following criteria are met:
 - i. 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.
 - ii. Member meets either of the following:
 - a. Member has had an inadequate response to nonsteroidal anti-inflammatory drugs (NSAIDs), sulfasalazine, or methotrexate.
 - b. Member has an intolerance or contraindication to NSAIDs, sulfasalazine (e.g., porphyria, intestinal or urinary obstruction), and methotrexate (see Appendix).

E. Hidradenitis suppurativa

1. Authorization of 12 months may be granted for adult members who have previously received a biologic indicated for treatment of moderate to severe hidradenitis suppurativa.
2. Authorization of 12 months may be granted for adult members for treatment of moderate to severe hidradenitis suppurativa when either of the following is met:
 - i. Member has had an inadequate response to an oral antibiotic used for the treatment of hidradenitis suppurativa for at least 90 days (e.g., clindamycin, metronidazole, moxifloxacin, rifampin, tetracyclines).
 - ii. Member has an intolerance or contraindication to oral antibiotics used for the treatment of hidradenitis suppurativa.

Continuation of Therapy:

A. Psoriatic arthritis (PsA)

Authorization of 12 months may be granted for all members 2 years of age or older (including new members) who are using the requested medication for psoriatic arthritis 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 there is improvement in any of the following from baseline:

1. Number of swollen joints



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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)

B. Ankylosing spondylitis (AS) and non-radiographic axial spondyloarthritis (nr-axSpA)

Authorization of 12 months may be granted for all adult members (including new members) who are using the requested medication for ankylosing spondylitis or non-radiographic axial spondyloarthritis 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 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)

C. Enthesitis-related arthritis (ERA)

Authorization of 12 months may be granted for all members 4 years of age or older (including new members) who are using the requested medication for active enthesitis-related arthritis 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 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

D. Hidradenitis suppurativa

Authorization of 12 months may be granted for all adult members (including new members) who are using the requested medication for moderate to severe hidradenitis



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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

Other Criteria:

For all indications: Member has had a documented negative tuberculosis (TB) test (which can include a tuberculosis skin test [TST] or an interferon-release assay [IGRA])* within 6 months of initiating therapy for persons who are naïve to biologic drugs or targeted synthetic drugs 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 (e.g., chest x-ray). Do not administer the requested medication to members with active TB infection. If there is latent disease, TB treatment must be started before initiation of the requested medication.

For all indications: Member cannot use the requested medication concomitantly with any other biologic drug or targeted synthetic drug for the same indication.

APPENDIX

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

1. Clinical diagnosis of alcohol use disorder, alcoholic liver disease, or other chronic liver disease
2. Drug interaction
3. Risk of treatment-related toxicity
4. Pregnancy or currently planning pregnancy



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5. Breastfeeding
6. Significant comorbidity prohibits use of systemic agents (e.g., liver or kidney disease, blood dyscrasias, uncontrolled hypertension)
7. Hypersensitivity
8. History of intolerance or adverse event

Approval Duration and Quantity Restrictions:

Approval:

Initial Approval: 12 months

Renewal Approval: 12 months

Quantity Level Limit:

| Medication | Standard Limit | Exception Limit* | FDA-recommended dosing |
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| Cosentyx (secukinumab): 75 mg/0.5 mL pre-filled syringe | 1 syringe per 28 days | 5 syringes per 28 days | Psoriatic arthritis (PsA)/Ankylosing spondylitis (AS)/Non-radiographic axial spondyloarthritis (NR-axSpA), adults: <ul style="list-style-type: none">• Loading doses (optional): 150 mg at weeks 0, 1, 2, 3, 4• Maintenance dose: 150 mg every 4 weeks• Continued active PsA/AS: 300 mg every 4 weeks Psoriatic arthritis, pediatric (2 years and older): <ul style="list-style-type: none">• ≥ 15 kg to < 50 kg: 75 mg at weeks 0, 1, 2, 3, and 4, then 75 mg every 4 weeks• ≥ 50 kg: 150 mg at weeks 0, 1, 2, 3, and 4, then 150 mg every 4 weeks |
| Cosentyx (secukinumab): 150 mg/mL pre-filled pen or syringe | 1 pen/syringe per 28 days | 5 pens/syringes per 28 days | |
| Cosentyx (secukinumab): 300 mg/2 mL pre-filled pen or syringe | 1 pen/syringe per 28 days | 5 pens/syringes per 28 days | |



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| Medication | Standard Limit | Exception Limit* | FDA-recommended dosing |
|--|------------------------------|-------------------------------|--|
| Cosentyx (secukinumab): 300 mg dose carton containing (2) 150 mg/mL pre- filled pens or (2) 150 mg/mL pre- filled syringes | 1 dose carton per 28 days | 5 dose cartons per 28 days | Plaque psoriasis, with or without coexistent psoriatic arthritis, adults: <ul style="list-style-type: none">• Loading doses: 300 mg at weeks 0, 1, 2, 3, 4• Maintenance dose: 300 mg every 4 weeks (150 mg every 4 weeks may be acceptable) Plaque psoriasis, pediatric (6 years and older): <ul style="list-style-type: none">• < 50 kg: 75 mg at weeks 0, 1, 2, 3, and 4, then 75 mg every 4 weeks• ≥ 50 kg: 150 mg at weeks 0, 1, 2, 3, and 4, then 150 mg every 4 weeks Enthesitis-Related Arthritis (4 years and older): <ul style="list-style-type: none">• ≥ 15 kg to < 50 kg: 75 mg at weeks 0, 1, 2, 3, and 4, then 75 mg every 4 weeks• ≥ 50 kg: 150 mg at weeks 0, 1, 2, 3 and 4, then 150 mg every 4 weeks |

*Exception limits apply to loading doses.

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