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SPECIALTY GUIDELINE MANAGEMENT

COSENTYX (secukinumab)

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)
2. Active psoriatic arthritis (PsA)
3. Active ankylosing spondylitis (AS)
4. Active non-radiographic axial spondyloarthritis (nr-axSpA)
5. Active enthesitis-related arthritis (ERA)
6. Adults with moderate to severe hidradenitis suppurativa (HS)

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

II. DOCUMENTATION

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

A. Plaque psoriasis (PsO)
   1. Initial requests
      i. Chart notes or medical record documentation of affected area(s) and body surface area (BSA) affected (if applicable).
      ii. 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 (PsA), ankylosing spondylitis (AS), non-radiographic axial spondyloarthritis (nr-axSpA), and enthesitis-related arthritis (ERA), hidradenitis suppurativa
   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.

III. CRITERIA FOR INITIAL AND CONTINUATION OF THERAPY

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.

IV. CRITERIA FOR INITIAL APPROVAL

For all indications:

- Member has a pretreatment tuberculosis (TB) screening with a TB skin test or an interferon gamma release assay (e.g., QFT-GIT, T-SPOT.TB). *[Note: Members who have received Cosentyx or any other biologic DMARD or targeted synthetic DMARD (e.g., Xeljanz) are exempt from requirements related to TB screening in this Policy.];* AND
- Cosentyx will not be used concomitantly with an injectable biologic response modifier including TNF-inhibitors (e.g., Humira (adalimumab), Enbrel (etanercept), Remicade (infliximab), etc.) and IL-inhibitors (e.g., Stelara (ustekinumab), Tremfya (guselkumab), Ilumya (tildrakizumab), Skyrizi (risankizumab), Bimzelx (bimekizumab), etc.) or other oral non-biologic agent (e.g., Otezla (apremilast), Xeljanz (tofacitinib), 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 who are 6 years of age or older when all of the following criteria are met:

1. Cosentyx is prescribed by, or in consultation with, a specialist in dermatology or rheumatology.
2. At least 10% of body surface area (BSA) is affected OR crucial body areas (e.g., hands, feet, face, neck, scalp, genitals/groin, intertriginous areas) are affected.
3. Member meets either of the following criteria:
   a. Member has had an inadequate response to at least a 3 month trial of methotrexate, cyclosporine or acitretin, or experienced clinically significant adverse effects from methotrexate, cyclosporine or acitretin
   b. Member has had an inadequate response to at least a 3-month trial of phototherapy (e.g., UVB, PUVA), unless intolerance experienced
4. Member experienced an inadequate treatment response or intolerance from Zoryve (roflumilast) cream within the last 12 months. Contraindications, adverse effects and/or intolerance must be documented (Note: If the member's BSA is greater than 20%, they are not required to trial Zoryve before Cosentyx)
5. Member has had an inadequate response, intolerance or contraindication to at least a 3-month trial of adalimumab at maximum tolerated doses

B. Active psoriatic arthritis (PsA)

Authorization of 6 months may be granted for treatment of active psoriatic arthritis in members who are 2 years of age or older when all of the following criteria are met:

1. Cosentyx is prescribed by, or in consultation with, a specialist in dermatology or rheumatology
2. Documented moderate to severe active disease and member meets either of the following criteria:
   a. If member has predominantly axial disease , member has experienced an inadequate response or intolerance to at least a 4 week trial of one non-steroidal anti-inflammatory drugs (NSAIDs), unless use is contraindicated
   b. If member has peripheral arthritis dactylitis OR active enthesitis, member has experienced an inadequate response to at least a 3-month trial of one oral disease-modifying anti-rheumatic agent (DMARD) such as methotrexate, azathioprine, or sulfasalazine, unless intolerance experienced
3. 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 (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 in members 18 years of age or older when all of the following criteria are met:

a. Cosentyx is prescribed by, or in consultation with, a specialist in rheumatology.
b. Member has documented active disease
c. Member has experienced an inadequate response or intolerance to at least two non-steroidal anti-inflammatory drugs (NSAIDs) over 4 weeks (in total) unless use is contraindicated.
d. 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 ankylosing spondylitis in members 18 years of age or older when all of the following criteria are met:

a. Cosentyx is prescribed by, or in consultation with, a specialist in rheumatology.
b. Member has objective signs of inflammation noted by an elevation of C-reactive protein (CRP) above the upper limit of normal and/or sacroiliitis on magnetic resonance imaging (MRI)
c. Member is without definitive radiographic evidence of structural damage on sacroiliac joints
e. Member has experienced an inadequate response or intolerance to at least two non-steroidal anti-inflammatory drugs (NSAIDs) over 4 weeks (in total), unless use is contraindicated.
f. 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, in members 4 years of age or older when the following are met:

1. Cosentyx is prescribed by, or in consultation with, a specialist in rheumatology.
2. Member meets all of the following criteria:
    a. Member has active disease demonstrated by three active joints involved and at least one site of active enthesitis at baseline or documented by history
    b. Member has an inadequate response or intolerance to nonsteroidal anti-inflammatory drugs (NSAIDs), sulfasalazine or methotrexate

F. Moderate to severe hidradenitis suppurativa (HS)

1. Prescribed by, or in consultation with, a specialist in dermatology.
2. Authorization of 6 months may be granted for members who have previously received a biologic indicated for treatment of moderate to severe hidradenitis suppurativa
3. Authorization of 6 months may be granted for treatment of moderate to severe hidradenitis suppurativa when either of the following is met:
    a. Member has experienced an inadequate response to oral antibiotics for at least 90 days.
    b. Member has an intolerance or contraindication to oral antibiotics.
4. Member has had an inadequate response, intolerance or contraindication to at least a 3-month trial of adalimumab at maximum tolerated doses

V. 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 the requested medication 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 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. 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 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)

D. Active enthesitis-related arthritis (ERA)

Authorization of 12 months may be granted for all members (including new members) 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 limited movement
3. Dactylitis
4. Enthesitis

E. Moderate to severe hidradenitis suppurativa

Authorization of 12 months may be granted for all members (including new members) 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.

VI. 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.

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. 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 & Non-radiographic Axial Spondyloarthritis	Adults: 150 mg at Weeks 0, 1, 2, 3, and 4 followed by 150 mg every 4 weeks
Psoriatic Arthritis	Adults: 150 mg at Weeks 0, 1, 2, 3, and 4 followed by 150 mg every 4 weeks Pediatrics: *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	*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.*

VII. REFERENCES

1. Cosentyx [package insert]. East Hanover, NJ: Novartis Pharmaceuticals Corporation; January 2024.
2. Menter A, Korman NJ, Elmets CA, et al. Guidelines of care for the management of psoriasis and psoriatic arthritis. Section 6: Guidelines of care for the treatment of psoriasis and psoriatic arthritis: case-based presentations and evidence-based conclusions. *J Am Acad Dermatol.* 2011;65(1):137-174.
3. 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. *Ann Rheum Dis*. 2016;75(3):499-510.
4. McInnes IB, Mease PJ, Kirkham B, et al. Secukinumab, a human anti-interleukin-17A monoclonal antibody, in patients with psoriatic arthritis (FUTURE 2): a randomised, double-blind, placebo-controlled, phase 3 trial. *Lancet*. 2015;386(9999):1137-46.
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6. 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 Rheumatol.* 2015: 10.1002/art.39298. [Epub ahead of print].
7. Baeten D, Sieper J, Braun J, et al. Secukinumab, an Interleukin-17A Inhibitor, in Ankylosing Spondylitis. *N Engl J Med.* 2015;373(26):2534-48.