

## 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)

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

##### II. CRITERIA FOR INITIAL APPROVAL

###### A. Moderate to severe plaque psoriasis

1. Authorization of 24 months may be granted for members who are 18 years of age or older who have received Cosentyx, Otezla, or any other biologic DMARD indicated for the treatment of moderate to severe plaque psoriasis in a paid claim through a pharmacy or medical benefit in the previous 120 days of the initial request for Cosentyx.
2. Authorization of 24 months may be granted for treatment of moderate to severe plaque psoriasis in members who are 18 years of age and older when all of the following criteria are met:
  - a. At least 5% of body surface area (BSA) is affected OR crucial body areas (e.g., hands, feet, face, neck, scalp, genitals/groin, intertriginous areas) are affected.
  - b. 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 or acitretin (see Appendix A).
    - iii. Member has severe psoriasis that warrants a biologic DMARD as first-line therapy.

###### B. Active psoriatic arthritis (PsA)

1. Authorization of 24 months may be granted for members who are 18 years of age or older and who have received Cosentyx, Stelara or Otezla in a paid claim through a pharmacy or medical benefit in the previous 120 days of the initial request for Cosentyx.
2. Authorization of 24 months may be granted for treatment of active PsA in members 18 years of age or older when any of the following criteria is met:
  - a. Member has had an inadequate response to at least a 3-month trial of at least one TNF inhibitor indicated for PsA (see Appendix B).
  - b. Member has experienced an intolerance or adverse event to a trial of at least one TNF inhibitor indicated for PsA.
  - c. All TNF inhibitors indicated for PsA are not appropriate for the member (e.g., due to comorbidities or a history of infections).

###### C. Active ankylosing spondylitis (AS)

1. Authorization of 24 months may be granted for members who are 18 years of age or older and who have received Cosentyx or any other biologic DMARD indicated for active ankylosing spondylitis in a paid claim through a pharmacy or medical benefit within the previous 120 days of the initial request for Cosentyx.
2. Authorizations of 24 months may be granted for treatment of active AS in members 18 years of age or older 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) over a 4-week period in total at maximum recommended or tolerated anti-inflammatory dose.
  - b. Member has an intolerance and/or contraindication to two or more NSAIDs (see Appendix C).

### III. CONTINUATION OF THERAPY

#### A. For plaque psoriasis:

Authorization of 24 months may be granted for all members (including new members) who meet all initial authorization criteria and achieve or maintain positive clinical response after at least 3 months of therapy with Cosentyx as evidenced by low disease activity or improvement in signs and symptoms of the condition.

#### B. For psoriatic arthritis and ankylosing spondylitis:

Authorization of 24 months may be granted for all members (including new members) who meet all initial authorization criteria and achieve or maintain positive clinical response after at least 4 months of therapy with Cosentyx as evidenced by low disease activity or improvement in signs and symptoms of the condition.

### IV. OTHER

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) in a paid claim through a pharmacy or medical benefit in the previous 120 days of the continuation request are exempt from requirements related to TB screening in this Policy.

### V. APPENDICES

#### Appendix A: Examples of Clinical Reasons to Avoid Pharmacologic Treatment with Methotrexate, Cyclosporine or Acitretin.

1. Alcoholism, 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 planning pregnancy (male or female)
6. Significant comorbidity prohibits use of systemic agents (examples include liver or kidney disease, blood dyscrasias, uncontrolled hypertension)

#### Appendix B: TNF Inhibitors Indicated for Psoriatic Arthritis

1. Cimzia® (certolizumab pegol)
2. Enbrel® (etanercept)
3. Humira® (adalimumab)
4. Remicade® (infliximab)
5. Simponi® (golimumab)

### Appendix C: Examples of Contraindications to the Use of NSAIDs

1. Allergic-type reaction following aspirin or other NSAID administration
2. Asthma
3. Gastrointestinal bleeding
4. History of intolerance or adverse event
5. Significant drug interaction
6. Urticaria

### VI. REFERENCES

1. Cosentyx [package insert]. East Hanover, NJ: Novartis Pharmaceuticals Corporation; January 2016.
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.
5. Braun J, van den Berg R, Baraliakos, X et al. 2010 update of the ASAS/EULAR recommendations for the management of ankylosing spondylitis. *Ann Rheum Dis*. 2011;70:896–904.
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.