PRIOR AUTHORIZATION POLICY

POLICY: Inflammatory Conditions – Cosentyx Prior Authorization Policy
- Cosentyx® (secukinumab for subcutaneous injection – Novartis)

REVIEW DATE: 03/04/2020; selected revision 06/24/2020

OVERVIEW

Cosentyx, a human interleukin (IL)-17A antagonist, is indicated in the following conditions:[1]

- **Plaque psoriasis**, in adults with moderate to severe disease who are candidates for systemic therapy or phototherapy.
- **Psoriatic arthritis**, in adults with active disease (given ± methotrexate).
- **Ankylosing spondylitis**, in adults with active disease.
- **Non-radiographic axial spondyloarthritis**, in adults with active disease and objective signs of inflammation.

Safety and efficacy in patients ≤ 18 years of age has not been established. In the pivotal trial for non-radiographic axial spondyloarthritis, patients were required to have objective signs of inflammation, indicated by elevated C-reactive protein and/or sacroiliitis on magnetic resonance imaging.

Guidelines

Il-17 blockers are mentioned in multiple guidelines for treatment of inflammatory conditions. Guidelines recommend assessment of response to initial therapy, most often following 3 months of therapy.

- **Spondyloarthritis:** Guidelines for ankylosing spondylitis and non-radiographic axial spondyloarthritis are published by the American College of Rheumatology (ACR)/Spondylitis Association of America/Spondyloarthritis Research and Treatment Network (2019).[2] Following primary nonresponse to a tumor necrosis factor inhibitor (TNFi), either Cosentyx or Taltz is recommended; however, if the patient is a secondary nonresponder, a second TNFi is recommended over switching out of the class. In patients with a contraindication to a TNFi, use of an IL-17 blocker is recommended over traditional oral agents such as methotrexate or sulfasalazine.
- **Plaque Psoriasis:** Joint guidelines of care for the management and treatment of psoriasis with biologics were published by the American Academy of Dermatology (AAD) and the National Psoriasis Foundation (2019).[3] All of the biologics are generally recommended for treatment of moderate to severe disease. The AAD also recommends methotrexate (unless contraindicated) and other systemic therapies for treatment of moderate to severe psoriasis.[4] Traditional systemic agents can benefit widespread psoriasis. Studies have assessed response to methotrexate following 6 weeks to 4 months of treatment.
- **Psoriatic Arthritis:** Guidelines from the ACR/National Psoriasis Foundation (2018) generally recommend TNFis as the first-line treatment strategy over other biologics (e.g., IL-17 blockers) with differing mechanisms of action.[5]

Safety

Warnings/Precautions for Cosentyx include infections, pre-treatment evaluation for tuberculosis, exacerbation of Crohn's disease, hypersensitivity reactions, risk of hypersensitivity in latex-sensitive individuals, and vaccinations.

POLICY STATEMENT

Prior Authorization is recommended for prescription benefit coverage of Cosentyx. Because of the specialized skills required for evaluation and diagnosis of patients treated with Cosentyx as well as the monitoring required for adverse events and long-term efficacy, initial approval requires Cosentyx to be prescribed by or in consultation with a physician who specializes in the condition being treated. All approvals are provided for the duration noted below. In cases where the approval is authorized in months, 1 month is equal to 30 days.

Automation: None.

RECOMMENDED AUTHORIZATION CRITERIA

Coverage of Cosentyx is recommended in those who meet the following criteria:

FDA-Approved Indications

1. **Ankylosing Spondylitis.** Approve for the duration noted if the patient meets ONE of the following (A or B):
   - **A)** Initial Therapy. Approve for 3 months if Cosentyx is prescribed by or in consultation with a rheumatologist.
   - **B)** Patient is Currently Receiving Cosentyx. Approve for 3 years if the patient has had a response, as determined by the prescriber.
     Note: Examples of a response include decreased pain or stiffness, improved function or activities of daily living. The patient may not have a full response, but there should have been a recent or past response to Cosentyx.

2. **Non-Radiographic Axial Spondyloarthritis.** Approve for the duration noted if the patient meets ONE of the following (A or B):
   - **A)** Initial Therapy. Approve for 3 months if the patient meets BOTH of the following (i and ii):
     - **i.** Patient has objective signs of inflammation, defined as at least one of the following (a or b):
       - **a)** C-reactive protein elevated beyond the upper limit of normal for the reporting laboratory; OR
       - **b)** Sacroiliitis reported on magnetic resonance imaging; AND
     - **ii.** Cosentyx is prescribed by or in consultation with a rheumatologist.
   - **B)** Patient is Currently Receiving Cosentyx. Approve for 3 years if the patient has had a response, as determined by the prescriber.
     Note: Examples of a response include decreased pain or stiffness, improved function or activities of daily living. The patient may not have a full response, but there should have been a recent or past response to Cosentyx.

3. **Plaque Psoriasis.** Approve for the duration noted if the patient meets ONE of the following (A or B):
   - **A)** Initial Therapy. Approve for 3 months if the patient meets ALL of the following criteria (i, ii, and iii):
     - **i.** Patient is ≥ 18 years of age; AND
     - **ii.** Patient meets ONE of the following conditions (a or b):
       - **a)** Patient has tried at least at least one traditional systemic agent for psoriasis for at least 3 months, unless intolerant; OR
         Note: Examples include methotrexate, cyclosporine, acitretin, or psoralen plus ultraviolet A light (PUVA). An exception to the requirement for a trial of one traditional systemic

agent for psoriasis can be made if the patient has already has a 3-month trial or previous intolerance to at least one biologic for this condition. (Refer to **Appendix** for examples of biologics used for psoriasis.) These patients who have already tried a biologic for psoriasis are not required to "step back" and try a traditional systemic agent for psoriasis).

b) Patient has a contraindication to methotrexate, as determined by the prescriber; AND

iii. Cosentyx is prescribed by or in consultation with a dermatologist.

B) Patient is Currently Receiving Cosentyx. Approve for 3 years if the patient has responded, as determined by the prescriber.
Note: Patient may not have a full response, but there should have been a recent or past response to Cosentyx.

4. **Psoriatic Arthritis.** Approve for the duration noted if the patient meets ONE of the following (A or B):
   A) Initial Therapy. Approve for 3 months if Cosentyx is prescribed by or in consultation with a rheumatologist or a dermatologist.
   B) Patient is Currently Receiving Cosentyx. Approve for 3 years if the patient has responded, as determined by the prescriber.
   Note: Examples of a response include less joint pain, morning stiffness, or fatigue; improved function or activities of daily living; decreased soft tissue swelling in joints or tendon sheaths; improvements in acute phase reactants (for example, C-reactive protein). The patient may not have a full response, but there should have been a recent or past response to Cosentyx.

CONDITIONS NOT RECOMMENDED FOR APPROVAL

Coverage of Cosentyx is not recommended in the following situations:

1. **Concurrent Use with other Biologics or Targeted Synthetic Disease-Modifying Antirheumatic Drugs (DMARDs).** Cosentyx should not be administered in combination with another biologic or targeted synthetic DMARD used for an inflammatory condition (See Appendix for examples). Combination therapy is generally not recommended due to a potential for a higher rate of adverse effects with combinations and lack of evidence for additive efficacy.
   Note: This does NOT exclude the use of conventional synthetic DMARDs (e.g., methotrexate, leflunomide, hydroxychloroquine, and sulfasalazine) in combination with Cosentyx.

2. **Crohn's Disease.** Exacerbations of Crohn's disease, in some cases serious, occurred in clinical trials with Cosentyx-treated patients.[1] In a Phase II published study in patients with Crohn's disease (n = 59), an intravenous formulation of Cosentyx did not reduce the Crohn's disease activity index by ≥ 50 points compared with placebo and the study was terminated prematurely.[6]

3. **Patients < 18 Years of Age.** Cosentyx is indicated in adults ≥ 18 years of age. Safety and efficacy in pediatric patients have not been established.[1]

4. **Rheumatoid Arthritis.** In a published, double-dummy Phase III study, Cosentyx was less effective that current treatments in patients with rheumatoid arthritis who were previously treated with a TNFi.[7] Patients were randomized to one of four treatment groups: 1) induction with an intravenous formulation of Cosentyx (10 mg/kg) followed by Cosentyx 150 mg subcutaneously given once every 4 weeks Q4W) [n = 137]; 2) secukinumab intravenous induction (10 mg/kg) followed by Cosentyx 75 mg subcutaneously Q4W (n = 138). At Week 24, ACR 20 response was significantly better with Cosentyx 150 mg subcutaneously (31%) and Orencia intravenous (43%) vs. placebo (18%). ACR 20

response with Cosentyx 75 mg was 28%, which was not significantly better than the placebo group. ACR 50/70 responses were 17%/10% with Cosentyx 150 mg and 12%/5% with Cosentyx 75 mg which was not significantly different than placebo (9%/5%). The group treated with Orencia intravneous had significantly improved ACR 50/70 responses at Week 24 (28%/12%). Using as observed data, ACR 20/50/70 responses at Week 52 were 63%/46%/19% with Cosentyx 150 mg, 57%/26%/7% with Cosentyx 75 mg, and 75%/52%/23% with Orencia intravenous. There is a published Phase II dose-ranging study (n = 237) evaluating Cosentyx in rheumatoid arthritis.[8-10] The ACR 20 response at Week 16 (using last observation carried forward analysis) was 34%, 46.9%, 46.5%, 53.7% for the 25, 75, 150, and 300 mg doses vs. 36% for placebo; however, this did not achieve statistical significance. After Week 16, patients who responded to Cosentyx sustained their response through Week 52 with patients on the 150 mg dose having the greatest improvement over time (55% and 40% of patients with ACR 50 and ACR 70 responses, respectively, at Week 52). In another Phase II study, Cosentyx did not achieve higher ACR 20 response rates at Week 12 vs. placebo.[11] There was an open-label treatment period where ACR responses were generally maintained through Week 52. Some patients were treated with an intravenous formulation of secukinumab and generally responded similarly to those treated with Cosentyx. In another Phase II study, an intravenous formulation of secukinumab demonstrated limited efficacy in biologic-naïve patients with rheumatoid arthritis associated with the HLA-DRB1 allele.[12]

5. **Uveitis.** Efficacy is not established for this condition. There was not a statistically significant difference between Cosentyx SC and placebo in three Phase III studies that included patients with Behcet's uveitis (n = 118); active, noninfectious, non-Behcet's uveitis (n = 31); and quiescent, noninfectious, non-Behcet's uveitis (n = 125) [SHEILD, INSURE, and ENDURE studies, respectively].[13]

6. Coverage is not recommended for circumstances not listed in the Recommended Authorization Criteria. Criteria will be updated as new published data are available.

REFERENCES

1. Cosentyx® [prescribing information]. East Hanover, NJ: Novartis Pharmaceuticals; June 2020.
2. Ward MM, Deodhar A, Gensler LS, et al. 2019 update of the American College of Rheumatology/Spondylitis Association of America/Spondyloarthritis Research and Treatment Network recommendations for the treatment of ankylosing spondylitis and nonradiographic axial spondyloarthritis. *Arthritis Rheumatol*. 2019;(10):1599-1613.
3. Menter A, Strober BE, Kaplan DH, et al. Joint AAD-NPF guidelines of care for the management and treatment of psoriasis with biologics. *J Am Acad Dermatol.* 2019;80(4):1029-1072.
4. Mentor A, Gelfand JM, Connor C, et al. Joint American Academy of Dermatology and National Psoriasis Foundation guidelines of care for the management of psoriasis with systemic nonbiologic therapies. *Am Acad Dermatol*. 2020;82(6):1445-1486.
5. Singh JA, Guyatt G, Ogdie A, et al. 2018 American College of Rheumatology/National Psoriasis Foundation guideline for the treatment of psoriatic arthritis. *Arthritis Rheumatol.* 2019;71(1):5-32.
6. Hueber W, Sands BE, Lewitzky S, et al. Secukinumab, a human anti-IL-17A monoclonal antibody, for moderate to severe Crohn's disease: unexpected results of a randomised, double-blind placebo-controlled trial. *Gut*. 2012;61(12):1693-1700.
7. Blanco FJ, Möricke R, Dokoupilova E, et al. Secukinumab in active rheumatoid arthritis: a Phase III randomized, double-blind, active comparator- and placebo-controlled study. *Arthritis Rheumatol*. 2017;69(6):1144-1153.
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12. Burmester GR, Durez P, Shestakova G, et al. Association of HLA-DRB1 alleles with clinical responses to the anti-interleukin-17A monoclonal antibody secukinumab in active rheumatoid arthritis. *Rheumatology (Oxford).* 2016;55(1):49-55.
13. Dick AD, Tugal-Tutkun I, Foster S, et al. Secukinumab in the treatment of noninfectious uveitis: results of three randomized, controlled clinical trials. *Ophthalmology.* 2013;120(4):777-787.

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Southampton, PA 18966-9998
Phone: 1-866-631-5404 (TTY: 711)
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200 Independence Avenue, SW
Room 509F, HHH Building
Washington, D.C. 20201
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