OVERVIEW

Cosentyx, a human interleukin (IL)-17A antagonist, is indicated for moderate to severe plaque psoriasis, active psoriatic arthritis (PsA), and ankylosing spondylitis (AS) in adults. It is a recombinant human monoclonal Immunoglobulin G (IgG)1/κ antibody binds specifically to the IL-17A cytokine and inhibits its interaction with the IL-17 receptor. IL-17A is a naturally occurring cytokine involved in normal inflammatory and immune responses; therefore, Cosentyx inhibits the release of proinflammatory cytokines and chemokines. The recommended dose for plaque psoriasis is 300 mg by subcutaneous (SC) injection at every week for five doses followed by 300 mg every 4 weeks thereafter. For some patients, a dose of 150 mg may be acceptable. Recommended dosing for active psoriatic arthritis (PsA) and ankylosing spondylitis (AS) is either: a loading dose of 150 mg at weeks 0, 1, 2, 3, and 4 and 150 mg every four weeks thereafter or 150 mg every four weeks without a loading dose. For PsA the dose can be increased to 300 mg. Cosentyx is intended for use under the guidance and supervision of a physician. Those trained in SC injection technique using the pen or prefilled syringe may self-inject when deemed appropriate.

POLICY STATEMENT

Prior authorization is recommended for prescription benefit coverage of Cosentyx. Because of the specialized skills required for evaluation of plaque psoriasis, psoriatic arthritis, and ankylosing spondylitis approval requires Cosentyx to be prescribed by or in consultation with a physician who specializes in the condition being treated. Food and Drug Administration (FDA)-approved indications are approved for an initial 3-month approval duration (where 1 month is equal to 30 days), then for a 1-year approval duration for patients currently receiving Cosentyx. Cosentyx is subject to the Inflammatory Conditions Care Value Step Therapy.

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

Food and Drug Administration (FDA)-Approved Indications

A) Initial Therapy for Plaque Psoriasis. Approve for 3 months if the patient meets ALL of the following criteria (i, ii, and iii):
   i. Patient is an adult ≥ 18 years of age; AND
   ii. Patient meets ONE of the following conditions (a, b, or c):
      a) Patient has tried at least one of the following agents for at least 3 months for plaque psoriasis: an oral therapy for psoriasis (e.g., methotrexate [MTX], cyclosporine, acitretin tablets); oral methoxsalen plus ultraviolet A light (PUVA); or a biologic agent (e.g., Enbrel, Humira® [adalimumab for SC injection],
Remicade® [infliximab for intravenous (IV) infusion], or Stelara [ustekinumab for SC injection]; OR
b) Patient experienced an intolerance to a trial of at least one oral or biologic therapy for plaque psoriasis (e.g., MTX, cyclosporine, acitretin, Enbrel, Humira, Remicade, or Stelara); OR

c) Patient has a contraindication to one oral agent for psoriasis such as MTX, as determined by the prescribing physician; AND

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

B) Initial Therapy for Active Psoriatic Arthritis (PsA)  Approve for 3 months if the patient meets ALL of the following criteria (i and ii):
   i. Patient is an adult ≥ 18 years of age; AND
   ii. Cosentyx is prescribed by or in consultation with a rheumatologist or dermatologist.

C) Initial Therapy for Active Ankylosing Spondylitis (AS).  Approve for 3 months if the patient meets ALL of the following criteria (i and ii):
   i. Patient is an adult ≥ 18 years of age; AND
   ii. Cosentyx is prescribed by or in consultation with a rheumatologist.

D) Patient is Currently Receiving Cosentyx.  Approve for 1 year if the patient has responded, as determined by the prescriber. The patient may not have a full response, but there should have been a recent or past response to Cosentyx.

Cosentyx is indicated for moderate to severe plaque psoriasis in adults who are candidates for systemic therapy or phototherapy. Guidelines developed by the National Psoriasis Foundation Medical Board (2012), prior to the availability of Cosentyx, note that Stelara, Humira, and Enbrel are appropriate first-line biologics for treatment of psoriasis. It is also stated that oral agents for psoriasis (i.e., acitretin, cyclosporine, and MTX) may be used first-line in various clinical situations. For example, acitretin is a first-line systemic drug for palmoplantar or pustular psoriasis and is especially useful in those with severely sundamaged skin, in which it may suppress actinic 2andomize and even invasive malignant neoplasms. Cyclosporine may be effective long-term, but is normally reserved for intermittent use (up to 12 weeks) to control a flare so the patient can transition to another drug for long-term maintenance. When used intermittently, a course of cyclosporine can induce an average decrease of > 75% in psoriasis severity. MTX is considered a first-line systemic agent for plaque psoriasis that can be used continuously for many years or decades with durable benefits.

Cosentyx is also indicated for active psoriatic arthritis (PsA) and ankylosing spondylitis (AS). Guidelines have yet to be updated to address Cosentyx for these indications. Initial therapy for moderate or severe active PsA currently recommends methotrexate and/or TNF blockade. For ankylosing spondylitis, guidelines strongly recommend use of nonsteroidal anti-inflammatory drugs (NSAIDs) and use of tumor necrosis factor inhibitors (TNFi) if activity persists despite NSAID treatment. For patients with active nonradiographic axial SpA despite treatment with NSAIDs, guidelines conditionally recommend treatment with TNFi.

**CONDITIONS NOT RECOMMENDED FOR APPROVAL**
Cosentyx has not been shown to be effective, or there are limited or preliminary data or potential safety concerns that are not supportive of general approval for the following conditions. Rationale for non-coverage for these specific conditions is provided below. (Note: This is not an exhaustive list of Conditions Not Recommended for Approval.)
1. **Concurrent Use with other Biologics or Targeted Synthetic Disease-Modifying Antirheumatic Drugs (DMARDs).** Cosentyx should not be administered in combination with another biologic agent for an inflammatory condition (e.g., Enbrel, Humira, Remicade, Stelara). Combination therapy with two biologic agents is generally not recommended due to a higher rate of adverse effects with combinations and lack of additive efficacy. Targeted synthetic DMARDs such as Otezla® (apremilast tablets) should not be used in combination with a biologic such as Cosentyx. Note: This does NOT exclude the use of MTX (a conventional synthetic DMARD used to treat psoriasis) 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. According to the manufacturer, Cosentyx is not being developed for treatment of Crohn’s disease. In a Phase II published study in patients with Crohn’s disease (n = 59), an IV formulation of Cosentyx did not reduce the Crohn’s disease activity index (CDAI) by ≥ 50 points compared with placebo and the study was terminated prematurely.

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.

4. **Rheumatoid Arthritis (RA).** According to the manufacturer, Cosentyx is not being developed for treatment of RA. There is a published Phase II dose-ranging study (n = 237) evaluating Cosentyx SC in RA. The American College of Rheumatology (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).

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].

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

**Dosing**

**Plaque Psoriasis** — 300 mg by subcutaneous injection at weeks 0, 1, 2, 3, and 4 followed by 300 mg every 4 weeks. Each 300 mg dose is given as 2 subcutaneous injections of 150 mg. For some patients, a dose of 150 mg may be acceptable.

**Psoriatic Arthritis (PsA)** — a loading dose of 150 mg at weeks 0, 1, 2, 3, and 4 and 150 mg every four weeks thereafter or 150 mg every four weeks without a loading dose. Dose may be increased to 300 mg.

**Ankylosing Spondylitis (AS)** — a loading dose of 150 mg at weeks 0, 1, 2, 3, and 4 and 150 mg every four weeks thereafter or 150 mg every four weeks without a loading dose.
Approval Duration

Initial Approval = 90 Days
Extended Approval = 365 Days

REFERENCES

- Cosentyx™ [prescribing information]. East Hanover, NJ: Novartis Pharmaceuticals; September 2017.
- Otezla® tablets [prescribing information]. Summit, NJ: Celgene Corporation; March 2014.