

Cosentyx® (secukinumab) Intravenous

When requesting Cosentyx® (secukinumab) intravenous, the individual requiring treatment must be diagnosed with an FDA-approved indication and meet the specific coverage guidelines and applicable safety criteria for the covered indication.

FDA-Approved Indications

Cosentyx intravenous is indicated for the treatment of:

- Adult patients with active psoriatic arthritis;
- Adult patients with active ankylosing spondylitis;
- Adult patients with active non-radiographic axial spondyloarthritis with objective signs of inflammation.

Coverage Guidelines

Ankylosing Spondylitis

The individual must meet **both** of the following criteria for an initial authorization:

- Is 18 years of age or older;
- Cosentyx is prescribed by or in consultation with a rheumatologist.

The individual must meet **both** of the following criteria for re-authorization:

- Has been established on Cosentyx therapy for at least 6 months (*Note: A patient who has received < 6 months of therapy or who is restarting therapy with Cosentyx is reviewed under initial authorization criteria.*);
- Meets one of the following:
 - o Has experienced a beneficial clinical response from baseline when assessed by at least one objective measure (e.g., Ankylosing Spondylitis Disease Activity Score [ASDAS], Ankylosing Spondylitis Quality of Life Scale [ASQoL], Bath Ankylosing Spondylitis Disease Activity Index [BASDAI], Bath Ankylosing Spondylitis Functional Index [BASFI], Bath Ankylosing Spondylitis Global Score [BAS-G], etc.); OR
 - o Has experienced an improvement in at least one symptom compared to baseline (e.g., decreased pain or stiffness, or improvement in function or activities of daily living).

Non-Radiographic Axial Spondyloarthritis

The individual must meet **all** of the following criteria for an initial authorization:

- Is 18 years of age or older;
- Has objective signs of inflammation, defined as at least one of the following:

- o C-reactive protein elevated beyond the upper limit of normal for the reporting laboratory; OR
- o Sacroiliitis reported on magnetic resonance imaging;
- Cosentyx is prescribed by or in consultation with a rheumatologist.

The individual must meet **both** of the following criteria for re-authorization:

- Has been established on Cosentyx therapy for at least 6 months (*Note: A patient who has received < 6 months of therapy or who is restarting therapy with Cosentyx is reviewed under initial authorization criteria.*);
- Meets one of the following:
 - o Has experienced a beneficial clinical response from baseline when assessed by at least one objective measure (e.g., Ankylosing Spondylitis Disease Activity Score [ASDAS], Ankylosing Spondylitis Quality of Life Scale [ASQoL], Bath Ankylosing Spondylitis Disease Activity Index [BASDAI], Bath Ankylosing Spondylitis Functional Index [BASFI], Bath Ankylosing Spondylitis Global Score [BAS-G], etc.); OR
 - o Has experienced an improvement in at least one symptom compared to baseline (e.g., decreased pain or stiffness, or improvement in function or activities of daily living).

Psoriatic Arthritis

The individual must meet **both** of the following criteria for an initial authorization:

- Is 18 years of age or older;
- Cosentyx is prescribed by or in consultation with a rheumatologist or a dermatologist.

The individual must meet **both** of the following criteria for re-authorization:

- Has been established on Cosentyx therapy for at least 6 months (*Note: A patient who has received < 6 months of therapy or who is restarting therapy with Cosentyx is reviewed under initial authorization criteria.*);
- Meets one of the following:
 - o Has experienced a beneficial clinical response from baseline when assessed by at least one objective measure (e.g., Disease Activity Index for Psoriatic Arthritis [DAPSA], Composite Psoriatic Disease Activity Index [CPDAI], Psoriatic Arthritis Disease Activity Score [PsA DAS], Psoriatic Arthritis Impact of Disease [PsAID-12], etc.); OR
 - o Has experienced an improvement in at least one symptom compared to baseline (e.g., less joint pain, morning stiffness, or fatigue; improved function or activities of daily living; decreased soft tissue swelling in joints or tendon sheaths).

Approval duration (initial and renewal): 12 months

Dosing Recommendations

The recommended intravenous dosages are:

- With a loading dosage: 6 mg/kg given at Week 0 as a loading dose, followed by 1.75 mg/kg every 4 weeks thereafter (maximum maintenance dose 300 mg per infusion).
- Without a loading dosage: 1.75 mg/kg every 4 weeks (maximum maintenance dose 300 mg per infusion).

References

1. Cosentyx® [prescribing information]. East Hanover, NJ: Novartis; October 2023.
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. 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.
4. 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.
5. 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.
6. Genovese MC, Durez P, Richards HB, et al. One-year efficacy and safety results of secukinumab in patients with rheumatoid arthritis: phase II, dose-finding, double-blind, randomized, placebo-controlled study. *J Rheumatol*. 2014;41(3):414-421.
7. Genovese MC, Durez P, Richards HB, et al. Efficacy and safety of secukinumab in patients with rheumatoid arthritis: a phase II, dose-finding, double-blind, randomised, placebo controlled study. *Ann Rheum Dis*. 2013;72(6):863-869.
8. Strand V, Kosinski M, Gnanasakthy A, et al. Secukinumab treatment in rheumatoid arthritis is associated with incremental benefit in the clinical outcomes and HRQoL improvements that exceed minimally important thresholds. *Health Qual Life Outcomes*. 2014;12:31.
9. Tlustochowicz W, Rahman P, Seriolo B, et al. Efficacy and safety of subcutaneous and intravenous loading dose regimens of secukinumab in patients with active rheumatoid arthritis: results from a randomized Phase II study. *J Rheumatol*. 2016;43(3):495-503.
10. 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.