Effective Date **2/1/2024**
Next Review Date… **2/1/2025**
Coverage Policy Number **IP0594**

Secukinumab Intravenous

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Related Coverage Resources

INSTRUCTIONS FOR USE
The following Coverage Policy applies to health benefit plans administered by Cigna Companies. Certain Cigna Companies and/or lines of business only provide utilization review services to clients and do not make coverage determinations. References to standard benefit plan language and coverage determinations do not apply to those clients. Coverage Policies are intended to provide guidance in interpreting certain standard benefit plans administered by Cigna Companies. Please note, the terms of a customer's particular benefit plan document [Group Service Agreement, Evidence of Coverage, Certificate of Coverage, Summary Plan Description (SPD) or similar plan document] may differ significantly from the standard benefit plans upon which these Coverage Policies are based. For example, a customer's benefit plan document may contain a specific exclusion related to a topic addressed in a Coverage Policy. In the event of a conflict, a customer's benefit plan document always supersedes the information in the Coverage Policies. In the absence of a controlling federal or state coverage mandate, benefits are ultimately determined by the terms of the applicable benefit plan document. Coverage determinations in each specific instance require consideration of 1) the terms of the applicable benefit plan document in effect on the date of service; 2) any applicable laws/regulations; 3) any relevant collateral source materials including Coverage Policies and; 4) the specific facts of the particular situation. Coverage Policies relate exclusively to the administration of health benefit plans. Coverage Policies are not recommendations for treatment and should never be used as treatment guidelines. In certain markets, delegated vendor guidelines may be used to support medical necessity and other coverage determinations.

Overview

This policy supports medical necessity review for **Cosentyx®** (secukinumab) intravenous infusion.

Receipt of sample product does not satisfy any criteria requirements for coverage.

Medical Necessity Criteria

Secukinumab intravenous infusion (Cosentyx) is considered medically necessary when ONE of the following is met:

1. **Ankylosing Spondylitis (AS).** Individual meets **ALL** of the following criteria:
   A. 18 years of age or older
   B. Documentation of **ONE** of the following:
      i. Failure, contraindication or intolerance to **ONE** non-steroidal anti-inflammatory drug (NSAID)
      ii. Already tried a biologic or targeted synthetic DMARD (tsDMARD)

C. Medication is being prescribed by, or in consultation with, a rheumatologist
D. Non-Preferred Product Criteria is met, refer to the below table(s)

Dosing. ONE of the following dosing regimens:[1]
1. A single 6 mg/kg intravenous loading dose followed by 1.75 mg/kg (up to a maximum of 300 mg per dose) given once every 4 weeks thereafter, up to a maximum of 300 mg per dose
2. 1.75 mg/kg (up to a maximum of 300 mg per dose) given intravenously once every 4 weeks

2. **Non-Radiographic Axial Spondyloarthritis (nr-axSpA).** Individual meets **ALL** of the following criteria:
   A. 18 years of age or older
   B. Has objective signs of inflammation, defined as **ONE** of the following:
      i. C-reactive protein (CRP) elevated beyond the upper limit of normal for the reporting laboratory
      ii. Sacroiliitis reported on magnetic resonance imaging (MRI)
   C. Medication is being prescribed by, or in consultation with, a rheumatologist
   D. Non-Preferred Product Criteria is met, refer to the below table(s)

Dosing. ONE of the following dosing regimens:[1]
1. A single 6 mg/kg intravenous loading dose followed by 1.75 mg/kg (up to a maximum of 300 mg per dose) given once every 4 weeks thereafter, up to a maximum of 300 mg per dose
2. 1.75 mg/kg (up to a maximum of 300 mg per dose) given intravenously once every 4 weeks

3. **Psoriatic Arthritis.** Individual meets **ALL** of the following criteria:
   A. 18 years of age or older
   B. Documentation of **ONE** of the following:
      i. For Non-axial disease, failure to **ONE** disease-modifying anti-rheumatic drug (DMARD), unless contraindicated or intolerant
      ii. For Axial disease, failure to **ONE** disease-modifying anti-rheumatic drug (DMARD), OR a nonsteroidal anti-inflammatory drug (NSAID), unless contraindicated or intolerant
      iii. Already tried a biologic or targeted synthetic DMARD (tsDMARD
   C. Medication is being prescribed by, or in consultation with a, rheumatologist or dermatologist
   D. Non-Preferred Product Criteria is met, refer to the below table(s)

Dosing. ONE of the following dosing regimens:[1]
1. A single 6 mg/kg intravenous loading dose followed by 1.75 mg/kg (up to a maximum of 300 mg per dose) given once every 4 weeks thereafter, up to a maximum of 300 mg per dose
2. 1.75 mg/kg (up to a maximum of 300 mg per dose) given intravenously once every 4 weeks

Coverage for varies across plans and requires the use of preferred products. Refer to the customer's benefit plan document for coverage details.

Employer Group Plans	
Condition	**Non-Preferred Product Criteria**
Ankylosing Spondylitis	**Standard/Performance/Legacy Drug List Plans** Documentation of failure, contraindication, or intolerance to **TWO** of the following: A. **Adalimumab Product** (**adalimumab-adaz/Hyrimoz** [manufactured by Sandoz/Novartis], **adalimumab – adbm/Cyltezo**, or **Humira**) [requires prior authorization] B. **Enbrel** [requires prior authorization]

Employer Group Plans	
Condition	**Non-Preferred Product Criteria**
	C. **Rinvoq** [requires prior authorization] D. **Taltz** [requires prior authorization] E. **Xeljanz/XR** [requires prior authorization] **<u>Value/Advantage/Cigna Total Savings Drug List Plans</u>** Documentation of failure, contraindication, or intolerance to **TWO** of the following: A. **Adalimumab Product** (**adalimumab-adaz/Hyrimoz** [manufactured by Sandoz/Novartis], **adalimumab – adbm/Cyltezo**, **Hadlima,** or **Humira**) [requires prior authorization] B. **Enbrel** [requires prior authorization] C. **Rinvoq** [requires prior authorization] D. **Taltz** [requires prior authorization] E. **Xeljanz/XR** [requires prior authorization]
Non-Radiographic Axial Spondyloarthritis	Documentation of failure, contraindication, or intolerance to **TWO** of the following: A. **Cimzia** [requires prior authorization] B. **Rinvoq** [requires prior authorization] C. **Taltz** [requires prior authorization]
Psoriatic Arthritis	**<u>Standard/Performance/Legacy Drug List Plans</u>** Documentation of failure, contraindication, or intolerance to **TWO** of the following: A. **Adalimumab Product** (**adalimumab-adaz/Hyrimoz** [manufactured by Sandoz/Novartis], **adalimumab – adbm/Cyltezo**, or **Humira**) [requires prior authorization] B. **Enbrel** [requires prior authorization] C. **Otezla** [requires prior authorization] D. **Rinvoq** [requires prior authorization] E. **Skyrizi SC** [requires prior authorization] F. **Stelara SC** [requires prior authorization] G. **Taltz** [requires prior authorization] H. **Tremfya** [requires prior authorization] I. **Xeljanz/XR** [requires prior authorization] **<u>Value/Advantage/Cigna Total Savings Drug List Plans</u>** Documentation of failure, contraindication, or intolerance to **TWO** of the following: A. **Adalimumab Product** (**adalimumab-adaz/Hyrimoz** [manufactured by Sandoz/Novartis], **adalimumab – adbm/ Cyltezo**, **Hadlima,** or **Humira**) [requires prior authorization] B. **Enbrel** [requires prior authorization] C. **Otezla** [requires prior authorization] D. **Rinvoq** [requires prior authorization] E. **Skyrizi SC** [requires prior authorization] F. **Stelara SC** [requires prior authorization] G. **Taltz** [requires prior authorization] H. **Tremfya** [requires prior authorization] I. **Xeljanz/XR** [requires prior authorization]

Individual and Family Plan	
Condition	**Non-Preferred Product Criteria**
Ankylosing Spondylitis	Documentation of failure, contraindication, or intolerance to **TWO** of the following: A. **Adalimumab Product** (**adalimumab-adaz/Hyrimoz** [manufactured by Sandoz/Novartis], **adalimumab – adbm/Cyltezo**, **Hadlima**, or **Humira**) [requires prior authorization] B. **Cimzia** [requires prior authorization] C. **Cosentyx subcutaneous injection** [requires prior authorization] D. **Enbrel** [requires prior authorization] E. **Rinvoq** [requires prior authorization] F. **Xeljanz/XR** [requires prior authorization]
Non-Radiographic Axial Spondyloarthritis	Documentation of failure, contraindication, or intolerance to **BOTH** of the following: A. **Cimzia** [requires prior authorization] B. **Cosentyx subcutaneous injection** [requires prior authorization] [requires prior authorization]
Psoriatic Arthritis	Documentation of failure, contraindication, or intolerance to **THREE** of the following: A. **Adalimumab Product** (**adalimumab-adaz/Hyrimoz** [manufactured by Sandoz/Novartis], **adalimumab – adbm/Cyltezo**, **Hadlima**, or **Humira**) [requires prior authorization] B. **Cimzia** [requires prior authorization] C. **Cosentyx subcutaneous injection** [requires prior authorization] D. **Enbrel** [requires prior authorization] E. **Otezla** [requires prior authorization] F. **Rinvoq** [requires prior authorization] G. **Skyrizi SC** [requires prior authorization] H. **Stelara SC** [requires prior authorization] I. **Tremfya** [requires prior authorization] J. **Xeljanz/XR** [requires prior authorization]

When coverage is available and medically necessary, the dosage, frequency, duration of therapy, and site of care should be reasonable, clinically appropriate, and supported by evidence-based literature and adjusted based upon severity, alternative available treatments, and previous response to therapy.

Reauthorization Criteria

Continuation of secukinumab intravenous infusion (Cosentyx) is considered medically necessary for **ALL** covered diagnoses when initial criteria are met AND beneficial response is demonstrated.

Authorization Duration

Initial approval duration is up to 12 months.
Reauthorization approval duration is up to 12 months.

Conditions Not Covered

Any other use is considered experimental, investigational or unproven, including the following (this list may not be all inclusive):

1. **Concurrent Use with other Biologics or Targeted Synthetic Disease-Modifying Antirheumatic Drugs (DMARDs).** Cosentyx intravenous 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 the potential for a higher rate of adverse effects with combination therapies 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 intravenous.

2. **Crohn's Disease.** Exacerbations of Crohn's disease, in some cases serious, occurred in clinical trials in patients treated with Cosentyx.[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.[4]

3. **Enthesitis-Related Arthritis.** Cosentyx subcutaneous is indicated and has approved dosing regimens for treatment of enthesitis-related arthritis.[1]

4. **Plaque Psoriasis.** Cosentyx subcutaneous is indicated and has approved dosing regimens for treatment of plaque psoriasis.[1]

5. **Rheumatoid Arthritis.** In a published, double-dummy Phase III study, Cosentyx was less effective than current treatments in patients with rheumatoid arthritis who were previously treated with a tumor necrosis factor inhibitor (TNFi).[5] 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 subcutaneous (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 from that of placebo (9%/5%). The group treated with Orencia intravenous 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.[6-8] 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 had sustained 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.[9] 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 subcutaneous. 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.[10]

Coding Information

1) This list of codes may not be all-inclusive.
2) Deleted codes and codes which are not effective at the time the service is rendered may not be eligible for reimbursement.

Considered Medically Necessary when criteria in the applicable policy statements listed above are met:

HCPCS Codes	Description
C9399	Unclassified drugs or biologicals
J3490	Unclassified drugs
J3590	Unclassified biologics

Background

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

- **Psoriatic arthritis**, in adults with active disease.
- **Ankylosing spondylitis**, in adults with active disease.
- **Non-radiographic axial spondyloarthritis**, in adults with active disease and objective signs of inflammation.

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.

Dosing Information
For approved uses, Cosentyx intravenous may be given with or without a single 6 mg/kg loading dose. The maintenance dose is 1.75 mg/kg given intravenously once every 4 weeks.

Guidelines
The intravenous formulation of Cosentyx has not been addressed in any guidelines. However, Il-17 blockers, including the subcutaneous formulation of Cosentyx, are mentioned in guidelines for treatment of inflammatory conditions.

- **Ankylosing Spondylitis and Non-Radiographic Axial Apondyloarthritis:** Guidelines for ankylosing spondylitis and non-radiographic axial spondyloarthritis are published by the ACR/Spondylitis Association of America/Spondyloarthritis Research and Treatment Network (2019).[2] Following primary nonresponse to a TNFi, either Cosentyx or Taltz® (ixekizumab injection) 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.
- **Psoriatic Arthritis:** Guidelines from the American College of Rheumatology (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.[3]

References

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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.
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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.
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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.
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