Clinical Policy: Secukinumab (Cosentyx®)

Reference Number: QCP.PHAR.008
Date of Last Revision: 06/2024

Coding Implications
Revision Log

See Important Reminder at the end of this policy for important regulatory and legal information.

Description
Secukinumab (Cosentyx®) is used for the treatment of ankylosing spondylitis and psoriatic arthritis.

Policy/Criteria
I. Initial Approval Criteria
A. Axial Spondyloarthritis (must meet all):
1. Diagnosis of AS or nr-axSpA;
2. Request is for IV: Cosentyx*
3. Prescribed by or in consultation with a rheumatologist;
4. Age ≥ 18 years;
5. Failure of at least TWO non-steroidal anti-inflammatory drugs (NSAIDs) at up to maximally indicated doses, each used for at ≥ 4 weeks unless contraindicated or clinically significant adverse effects are experienced;
6. Member does not have combination use of biological disease-modifying antirheumatic drugs or JAK inhibitors (see Section III: Diagnoses/Indications for which coverage is NOT authorized);
7. Dose does not exceed maximum dose* indicated in Section V.

*Maximum dose escalation allowed per prescriber information with documentation of inadequate response

Approval duration: 6 months or to member's renewal date, whichever is longer

B. Psoriatic Arthritis (must meet all):
1. Diagnosis of PsA;
2. Request is for Cosentyx*;
3. Prescribed by or in consultation with a dermatologist or rheumatologist;
4. Age ≥ 2 years;
5. Member does not have combination use of biological disease-modifying antirheumatic drugs or JAK inhibitors (see Section III: Diagnoses/Indications for which coverage is NOT authorized);
6. Dose does not exceed maximum dose indicated in Section V.

Approval duration: 6 months or to member's renewal date, whichever is longer

II. Continued Therapy
All Other Indications in Section I (must meet all):
1. Member currently receiving medication via Centene benefit or member has previously met initial approval criteria;
2. Member is responding positively to therapy;

3. Member does not have combination use of biological disease-modifying antirheumatic drugs or JAK inhibitors (see Section III: Diagnoses/Indications for which coverage is NOT authorized);
4. If request is for a dose increase, new dose does not exceed maximum dose indicated in Section V.

Approval duration: 12 months

III. Diagnoses/Indications for which coverage is NOT authorized:

A. Non-FDA approved indications, which are not addressed in this policy, unless there is sufficient documentation of efficacy and safety according to the off-label use policy – HIM.PA.154 for health insurance marketplace or evidence of coverage documents;
B. Combination use with biological disease-modifying antirheumatic drugs (bDMARDs) or potent immunosuppressants, including but not limited to any tumor necrosis factor (TNF) antagonists [e.g., Cimzia®, Enbrel®, Humira® and its biosimilars, Remicade® and its biosimilars (Avsola™, Inflectra™, Renflexis™, Zymfentra®), Simponi®], interleukin agents [e.g., Actemra® (IL-6RA), Arcalyst® (IL-1 blocker), Bimzelx® (IL-17A and F antagonist), Cosentyx® (IL-17A inhibitor), Ilaris® (IL-1 blocker), Ilumya™ (IL-23 inhibitor), Kevzara® (IL-6RA), Kineret® (IL-1RA), Omvoh™ (IL-23 antagonist), Siliq™ (IL-17RA), Skyrizi™ (IL-23 inhibitor), Stelara® (IL-12/23 inhibitor), Taltz® (IL-17A inhibitor), Tofidence™ (IL-6), Tremfya® (IL-23 inhibitor), Tyenne® (IL-6), Wezlana™ (IL-12/23 inhibitor)], Janus kinase inhibitors (JAKi) [e.g., Cibinqo™, Olumiant™, Rinvoq™, Xeljanz®/Xeljanz® XR,], anti-CD20 monoclonal antibodies [Rituxan® and its biosimilars (Riabni™, Ruxience™, Truxima®), Rituxan Hycela®], selective co-stimulation modulators [Orencia®], integrin receptor antagonists [Entyvio®], tyrosine kinase 2 inhibitors [Sotyktu™], and sphingosine 1-phosphate receptor modulator [Velsipity™] because of the additive immunosuppression, increased risk of neutropenia, as well as increased risk of serious infections;

IV. Appendices/General Information

Appendix A: Abbreviation/Acronym Key

AS: ankylosing spondylitis
JAK: janus kinase
nr-axSpA: non-radiographic axial spondyloarthritis
NSAIDs: non-steroidal anti-inflammatory drugs
PsA: psoriatic arthritis

Appendix B: Therapeutic Alternatives

This table provides a listing of preferred alternative therapy recommended in the approval criteria. The drugs listed here may not be a formulary agent and may require prior authorization.

Drug Name	Dosing Regimen	Dose Limit/ Maximum Dose
NSAIDs (e.g., indomethacin, ibuprofen, naproxen, celecoxib)	**AS, nr-axSpA*** Varies	Varies
Biologic DMARDs (e.g., Humira, Enbrel, Cosentyx, Remicade, Simponi Aria, Otezla, Xeljanz/Xeljanz XR, Kevzara)	See Section V. Dosing and Administration	See Section V. Dosing and Administration

Therapeutic alternatives are listed as Brand name® (generic) when the drug is available by brand name only, and generic (Brand name®) when the drug is available by both brand and generic.
*Off-label

Appendix C: Contraindications/Boxed Warnings

Contraindications: Serious hypersensitivity reaction to secukinumab or to any of the excipients

BBW: None reported

Appendix D: General Information

- TNF blockers:
  - Etanercept (Enbrel®), adalimumab (Humira) and its biosimilars, infliximab (Remicade®) and its biosimilars (Avsola™, Renflexis™, Inflectra®, Zymfentra®), certolizumab pegol (Cimzia®), and golimumab (Simponi®, Simponi Aria®).

V. Dosage and Administration

Drug Name	Indication	Dosing Regimen	Maximum Dose
Secukinumab (Cosentyx)	AS, nr-axSpA	IV: • With loading dose: 6 mg/kg IV at week 0, followed by 1.75 mg/kg IV every 4 weeks. • Without loading dose: 1.75 mg/kg IV every 4 weeks.	300 mg every 4 weeks
	PsA	Adult: IV: • With loading dose: 6 mg/kg IV at week 0, followed by 1.75 mg/kg IV every 4 weeks. • Without loading dose: 1.75 mg/kg IV every 4 weeks.	Adults: 300 mg every 4 weeks

VI. Product Availability

Single-dose vial (for IV infusion): 125 mg/5 mL

References

1. Cosentyx Prescribing Information. East Hanover, NJ: Novartis Pharmaceuticals Corporation; November 2023. Available at: https://www.accessdata.fda.gov/drugsatfda_docs/label/2023/125504s066,761349s004lbl.pdf. Accessed January 31, 2024.

Axial Spondylitis

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3. Braun J, Davis J, Dougados M, et al. First update of the international ASAS consensus statement for the use of anti-TNF agents in patients with ankylosing spondylitis. *Ann Rheum Dis*. 2006;65:316-320.
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Psoriasis/Psoriatic Arthritis

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14. ClinicalTrials.gov. A Study of the Safety and Efficacy of Ustekinumab in Patients with Psoriatic Arthritis With and Without Prior Exposure to Anti-TNF Agents (PSUMMIT-2). Available at https://clinicaltrials.gov/ct2/show/NCT01077362. Accessed February 10, 2023.

Coding Implications

Codes referenced in this clinical policy are for informational purposes only. Inclusion or exclusion of any codes does not guarantee coverage. Providers should reference the most up-to-date sources of professional coding guidance prior to the submission of claims for reimbursement of covered services.

HCPCS Codes	Description
J3247	Injection, secukinumab, intravenous, 1 mg

Revision Log

Reviews, Revisions, and Approvals	Revision Date	Approval Date
RT2: Added newly FDA-approved indication for Cosentyx for nr-axSpA to the policy, including requiring redirection only to Cosentyx based on contracting (no redirection to Humira and Enbrel as these are off-label for nr-axSpA), while allowing for redirection to Cosentyx, Humira, and Enbrel when the diagnosis is AS; added new FDA indication for Tremfya to policy: PsA; RT4: updated Enbrel new dosage form: single-dose vial AND updated Stelara PsO criteria and dosing information in response to pediatric extension to be used in patients 6yo+; references reviewed and updated.	08.25.20	11.20
2Q 2022 annual review: added newly FDA-approved indications: pediatric use extension down to 2 years and older for PsA for Cosentyx.	05.02.22	05.22
RT4: for Cosentyx, added new dosage form single-dose vial 125 mg/5 mL for intravenous infusion, added IV specific dosing for AS, nr-axSpA and PsA.	09.19.23	
2Q 2024 annual review: for Cosentyx added “maximum dose escalation allowed per prescriber information with documentation of inadequate response” in criteria and section V	03.25.24	05.24
For Cosentyx dosing in table V, updated maximum dose escalation to allow “300 mg every 4 weeks, if documentation supports inadequate response to a ≥ 3 consecutive month trial of 150 mg every 4 weeks” for AS indication.	05.09.24	06.24

Important Reminder

This clinical policy has been developed by appropriately experienced and licensed healthcare professionals based on a review and consideration of currently available generally accepted standards of medical practice; peer-reviewed medical literature; government agency/program approval status; evidence-based guidelines and positions of leading national health professional organizations; views of physicians practicing in relevant clinical areas affected by this clinical policy; and other available clinical information. The Health Plan makes no representations and accepts no liability with respect to the content of any external information used or relied upon in developing this clinical policy. This clinical policy is consistent with standards of medical practice current at the time that this clinical policy was approved. "Health Plan" means a health plan that has adopted this clinical policy and that is operated or administered, in whole or in part, by Centene Management Company, LLC, or any of such health plan's affiliates, as applicable.

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