Medical Policy Bulletin

Title:
Secukinumab (Cosentyx®) for Intravenous Use
Policy #:
MA08.174

The Company makes decisions on coverage based on the Centers for Medicare and Medicaid Services (CMS) regulations and guidance, benefit plan documents and contracts, and the member's medical history and condition. If CMS does not have a position addressing a service, the Company makes decisions based on Company Policy Bulletins. Benefits may vary based on contract, and individual member benefits must be verified. The Company determines medical necessity only if the benefit exists and no contract exclusions are applicable. Although the Medicare Advantage Policy Bulletin is consistent with Medicare's regulations and guidance, the Company's payment methodology may differ from Medicare.

When services can be administered in various settings, the Company reserves the right to reimburse only those services that are furnished in the most appropriate and cost-effective setting that is appropriate to the member's medical needs and condition. This decision is based on the member's current medical condition and any required monitoring or additional services that may coincide with the delivery of this service.

This Policy Bulletin document describes the status of CMS coverage, medical terminology, and/or benefit plan documents and contracts at the time the document was developed. This Policy Bulletin will be reviewed regularly and be updated as Medicare changes their regulations and guidance, scientific and medical literature becomes available, and/or the benefit plan documents and/or contracts are changed.

Policy

Coverage is subject to the terms, conditions, and limitations of the member's Evidence of Coverage.

The Company reserves the right to reimburse only those services that are furnished in the most appropriate and cost-effective setting that is appropriate to the member's medical needs and condition.

MEDICALLY NECESSARY

INITIAL THERAPY
Secukinumab (Cosentyx) for intravenous infusion is considered medically necessary and, therefore, covered for the following indications when, for each individual indication, all of the associated criteria are met:

Psoriatic Arthritis (PsA)

Secukinumab (Cosentyx) for intravenous infusion may be covered as monotherapy or concomitantly with nonbiologic disease-modifying antirheumatic drugs (DMARDs) when **all** of the following criteria are met:

- Active or latent tuberculosis (TB) has been ruled out.
- The individual has had an inadequate response after at least 3 months of one or more DMARDs (e.g., methotrexate, hydroxychloroquine, leflunomide, azathioprine, sulfasalazine), or the use of all DMARDs is contraindicated in the individual.
- The individual is 18 years of age or older.
- Secukinumab (Cosentyx) will not be used in combination with other biologic DMARDs or Janus kinase inhibitor (JAK) inhibitors.

Ankylosing Spondylitis (AS)

- The individual is at least 18 years old.
- Documentation of failure, contraindication to, or intolerance of either of the following:
    - At least a 4-week trial of two nonsteroidal anti-inflammatory drugs (NSAIDs) at maximum recommended or tolerated anti-inflammatory dose
    - At least a 3-month trial of one DMARD (e.g., sulfasalazine, methotrexate, hydroxychloroquine)
- Active or TB has been ruled out.

Axial spondyloarthritis (nonradiographic)

- When all of the following criteria are met:
  - Individual is at least 18 years of age
  - Documentation of evidence of active disease (increasing inflammation, pain, disability, and decreased function)
  - Documentation of an adequate therapeutic trial* of at least two NSAIDs that have failed to control symptoms
  -

*An adequate therapeutic trial is defined as: Treatment with NSAIDs for at least 3 months at maximum recommended or tolerated anti-inflammatory dose unless treatment is discontinued due to lack of response, intolerance, toxicity or contraindication.

- If the above criteria are not met, there must be documentation, both of very severe disease and that the clinician considers infliximab or related biosimilars the best initial drug of choice with appropriate justification (severe pain, disability, and inability to perform activities of daily living [ADLs], or severe impact on quality of life).

CONTINUATION THERAPY

Secukinumab (Cosentyx) for intravenous infusion is considered medically necessary and, therefore, covered for continuation therapy when the individual meets all of the following criteria:

- The individual has met the medical necessity criteria for initial therapy.
- There is documentation of a positive clinical response or stabilization to therapy (e.g., improvement in total active [swollen and tender] joint count from baseline, improvement in symptoms [e.g., pain, stiffness, inflammation, body surface area] from baseline).

EXPERIMENTAL/INVESTIGATIONAL

All other uses for secukinumab (Cosentyx) for intravenous use are considered experimental/investigational and, therefore, not covered unless the indication is supported as an accepted off-label use, as defined in the Company medical policy on off-label coverage for prescription drugs and biologics.

REQUIRED DOCUMENTATION

The individual's medical record must reflect the medical necessity for the care provided. These medical records may include, but are not limited to: records from the professional provider's office, hospital, nursing home, home health agencies, therapies, and test reports.

The Company may conduct reviews and audits of services to our members, regardless of the participation status of the provider. All documentation is to be available to the Company upon request. Failure to produce the requested information may result in a denial for the service.

Guidelines

BLACK BOX WARNINGS

Refer to the specific manufacturer's prescribing information for any applicable Black Box Warnings.

BENEFIT APPLICATION

Subject to the applicable Evidence of Coverage, secukinumab (Cosentyx) is covered under the medical benefits of the Company's Medicare Advantage products when the medical necessity criteria listed in this medical policy are met.

Certain drugs are available through either the member's medical benefit (Part B benefit) or pharmacy benefit (Part D benefit), depending on how the drug is prescribed, dispensed, or administered. This medical policy only addresses instances when secukinumab (Cosentyx) is covered under a member's medical benefit (Part B benefit). It does not address instances when secukinumab (Cosentyx) is covered under a member's pharmacy benefit (Part D benefit).

US FOOD AND DRUG ADMINISTRATION (FDA) STATUS

Secukinumab (Cosentyx) for intravenous use was approved by the US Food and Drug Administration (FDA) on October 6, 2023, for the treatment of adults with with active psoriatic arthritis (PsA)**,** active ankylosing spondylitis (AS), and active nonradiographic axial spondyloarthritis (nr-axSpA), and it is infused once a month.

PEDIATRIC USE
The safety and effectiveness in pediatric individuals have not been established.

Description

ANKYLOSING SPONDYLITIS (AS) AND NONRADIOGRAPHIC AXIAL SPONDYLOARTHRITIS (nraxSpA)

AS and nraxSpA is a chronic immune-mediated inflammatory disease characterized by spinal inflammation, progressive spinal rigidity, and peripheral arthritis. Interleukin-17 (IL-17) is thought to be a key inflammatory cytokine in the development of ankylosing spondylitis, the prototypical form of spondyloarthritis. Secukinumab is an anti-interleukin-17A monoclonal antibody that has been shown to control the symptoms of AS and nraxSpA.

PSORIATIC ARTHRISTIS (PsA)

PsA is a chronic inflammatory musculoskeletal disease associated with psoriasis, manifesting most commonly with peripheral arthritis, dactylitis, enthesitis, and spondylitis. Nail lesions, including pitting and onycholyisis, occur in approximately 80% to 90% of patients with PsA. About 30% of patients with psoriasis will eventually develop PsA within an average of 7 to 10 years, but there is significant variability in this timeframe.

SECUKINUMAB (COSENTYX)

Secukinumab (Cosentyx) is a humanized immunoglobulin G1 (IgG1) monoclonal antibody that selectively targets IL-17A. IL-17A is a naturally occurring cytokine that is involved in normal inflammatory and immune responses. Secukinumab inhibits the release of proinflammatory cytokines and chemokines.

The recommended intravenous (IV) dosage regimen is as follows:

- 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).

Total doses exceeding 300 mg per infusion are not recommended for the 1.75-mg/kg maintenance dose in adults with PsA, AS, and nr-axSPA.

PEER-REVIEWED LITERATURE

The approval of the IV formulation of secukinumab (Cosentyx) was extrapolated from the established safety and effectiveness of the subcutaneous formulation of secukinumab (Cosentyx) in adult patients with active nr-axSpA, PsA, and AS based on pharmacokinetic exposure.

OFF-LABEL INDICATION

There may be additional indications contained in the Policy section of this document due to evaluation of criteria highlighted in the Company's off-label policy, and/or review of clinical guidelines issued by leading professional organizations and government entities.

References

American Hospital Formulary Service–Drug Information (AHFS-DI). Secukinumab. [LexiComp Web site]. 04/18/2024. Available at: http://online.lexi.com/lco/action/home [via subscription only]. Accessed April 22, 2024.

Baeten D, Baraliakos X, Braun J, et al. Anti-interleukin-17A monoclonal antibody secukinumab in treatment of ankylosing spondylitis: A randomised, double-blind, placebo-controlled trial. *Lancet.* 2013;382(9906):1705-1713.

Baeten D, Sieper J, Braun J, et al.; MEASURE 1 Study Group; MEASURE 2 Study Group. Secukinumab, an interleukin-17A inhibitor, in ankylosing spondylitis. *N Engl J Med*. 2015;373(26):2534-2548.

Braun J, van den Berg R, Baraliakos X, et al. 2010 update of the ASAS/EULAR recommendations for the management of ankylosing spondylitis. *Ann Rheum Dis.* 2011;70:896-904.

Centers for Medicare & Medicaid Services (CMS). Guidance for Prior Authorization and Step Therapy for Part B Drugs in Medicare Advantage. 08/07/2018. Available at: https://www.cms.gov/Medicare/Health-Plans/HealthPlansGenInfo/Downloads/MA_Step_Therapy_HPMS_Memo_8_7_2018.pdf.

Coates LC, Soriano ER, Corp N, et al. Group for Research and Assessment of Psoriasis and Psoriatic Arthritis (GRAPPA): Updated treatment recommendations for psoriatic arthritis 2021. *Nat Rev Rheumatol.* 2022;18(8):465-479.

Elsevier's Clinical Pharmacology Compendium. Secukinumab. 04/01/2024. [Clinical Key Web site]. Available at: https://www.clinicalkey.com/pharmacology/ [via subscription only]. Accessed April 22, 2024.

Lexi-Drugs Compendium. Secukinumab. 04/23/24. [Lexicomp Online Web site]. Available at: ttp://online.lexi.com/lco/action/home [via subscription only]. Accessed April 23, 2024.

Novitas Solutions, Inc. Article (A53127): Self-Administered Drug Exclusion List. [Novitas Medicare Services Web site]. Original: 10/01/2015, Revised: 03/17/2024. Available at: Article - Self-Administered Drug Exclusion List: (A53127) (cms.gov). Accessed April 26, 2024.

Ramiro S, Nikiphorou E, Sepriano A, et al. ASAS-EULAR recommendations for the management of axial spondyloarthritis: 2022 update. *Ann Rheum Dis.* 2023;82:19-34.

Truven Health Analytics. Micromedex® DrugDex® Compendium. Secukinumab. 03/13/24. Greenwood Village, CO. [Micromedex® Solutions Web site]. Available at: http://www.micromedexsolutions.com/micromedex2/librarian [via subscription only]. Accessed April 22, 2024.

US Food and Drug Administration (FDA). Secukinumab [prescribing information]. [FDA Web site]. 11/2023. Available at: https://www.accessdata.fda.gov/drugsatfda_docs/label/2023/125504s066,761349s004lbl.pdf. Accessed April 22, 2024.

Coding

Inclusion of a code in this table does not imply reimbursement. Eligibility, benefits, limitations, exclusions, precertification/referral requirements, provider contracts, and Company policies apply.

The codes listed below are updated on a regular basis, in accordance with nationally accepted coding guidelines. Therefore, this policy applies to any and all future applicable coding changes, revisions, or updates.

In order to ensure optimal reimbursement, all health care services, devices, and pharmaceuticals should be reported using the billing codes and modifiers that most accurately represent the services rendered, unless otherwise directed by the Company.

The Coding Table lists any CPT, ICD-10, and HCPCS billing codes related only to the specific policy in which they appear.

CPT Procedure Code Number(s)

N/A

ICD - 10 Procedure Code Number(s)

N/A

ICD - 10 Diagnosis Code Number(s)

L40.50 Arthropathic psoriasis, unspecified

L40.51 Distal interphalangeal psoriatic arthropathy

L40.52 Psoriatic arthritis mutilans

L40.53 Psoriatic spondylitis

L40.59 Other psoriatic arthropathy

M45.0 Ankylosing spondylitis of multiple sites in spine

M45.1 Ankylosing spondylitis of occipito-atlanto-axial region

M45.2 Ankylosing spondylitis of cervical region

M45.3 Ankylosing spondylitis of cervicothoracic region

M45.4 Ankylosing spondylitis of thoracic region

M45.5 Ankylosing spondylitis of thoracolumbar region

M45.6 Ankylosing spondylitis lumbar region

M45.7 Ankylosing spondylitis of lumbosacral region

M45.8 Ankylosing spondylitis sacral and sacrococcygeal region

M45.9 Ankylosing spondylitis of unspecified sites in spine

M45.A0 Non-radiographic axial spondyloarthritis of unspecified sites in spine

M45.A1 Non-radiographic axial spondyloarthritis of occipito-atlanto-axial region

M45.A2 Non-radiographic axial spondyloarthritis of cervical region

M45.A3 Non-radiographic axial spondyloarthritis of cervicothoracic region

M45.A4 Non-radiographic axial spondyloarthritis of thoracic region

M45.A5 Non-radiographic axial spondyloarthritis of thoracolumbar region

M45.A6 Non-radiographic axial spondyloarthritis of lumbar region

M45.A7 Non-radiographic axial spondyloarthritis of lumbosacral region

M45.A8 Non-radiographic axial spondyloarthritis of sacral and sacrococcygeal region

M45.AB Non-radiographic axial spondyloarthritis of multiple sites in spine

HCPCS Level II Code Number(s)

J3247 Injection, secukinumab, intravenous, 1 mg

Revenue Code Number(s)

N/A

Policy History

Revisions From MA08.174:

12/15/2025	This policy has been reissued in accordance with the Company's annual review process.

12/16/2024	This version of the policy will become effective 12/16/2024. This new policy has been developed to communicate the Company's coverage criteria for secukinumab (Cosentyx) for intravenous use.

Version Effective Date:
12/15/2025
Version Issued Date:
12/15/2025
Version Reissued Date:
N/A