Cosentyx® (Secukinumab)

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Instructions for Use

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Commercial Policy

- Cosentyx® (Secukinumab)

Application

This Medical Benefit Drug Policy does not apply to the states listed below; refer to the state-specific policy/guideline, if noted:

State	Policy/Guideline
Arizona	Refer to the state's Medicaid clinical policy
Indiana	Refer to the state's Medicaid clinical policy
Kansas	Refer to the state's Medicaid clinical policy
Louisiana	Refer to the state's Medicaid clinical policy
Mississippi	None
North Carolina	None
Ohio	None
Pennsylvania	Refer to the state's Medicaid clinical policy
Texas	Refer to drug specific criteria found within the Texas Medicaid Provider Procedures Manual
Washington	Refer to the state's Medicaid clinical policy

Coverage Rationale

This policy refers to Cosentyx (secukinumab) for intravenous (IV) injection. Cosentyx (secukinumab) for self-administered subcutaneous injection is obtained under the pharmacy benefit.

The Following Information Pertains to All Medical Necessity Reviews

General Requirements (Applicable to All Medical Necessity Requests)

- All requests for IV Cosentyx must include justification as to why the IV route is medically reasonable and necessary
- Prescriber must attest that the patient or caregiver are not able to be trained or are physically unable to administer Cosentyx FDA labeled for self-administration and the prescriber must submit medical records and/or justification explanation

Psoriatic Arthritis (PsA)

Cosentyx (secukinumab) is proven and medically necessary for the treatment of psoriatic arthritis (PsA) when all of the following criteria are met:

- For **initial therapy**, all of the following:
  - Diagnosis of active psoriatic arthritis; **and**
  - One of the following:
    - History of failure to a 3 month trial of methotrexate at the maximally indicated dose, unless contraindicated or clinically significant adverse effects are experienced; **or**
    - Patient has been previously treated with a targeted immunomodulator FDA-approved for the treatment of psoriatic arthritis as documented by claims history or submission of medical records (document drug, date, and duration of therapy) [e.g., Cimzia (certolizumab), adalimumab, Simponi (golimumab), Stelara (ustekinumab), Tremfya (guselkumab), Xeljanz/Xeljanz XR (tofacitinib), Otezla (apremilast), Skyrizi (risankizumab), Rinvoq (upadacitinib), Enbrel (etanercept)]

    and
  - Cosentyx is initiated and titrated according to the U.S. FDA labeled dosing for PsA; **and**
  - Patient is not receiving Cosentyx in combination with any of the following:
    - Biologic DMARD [e.g., adalimumab, Cimzia (certolizumab), Simponi (golimumab), Taltz (ixekizumab), Orencia (abatacept), Skyrizi (risankizumab-rzaa)]; **or**
    - Janus kinase inhibitor [e.g., Xeljanz (tofacitinib)]; **or**
    - Phosphodiesterase 4 (PDE4) inhibitor [e.g., Otezla (apremilast)]

    and
  - Prescribed by, or in consultation with, one of the following:
    - Rheumatologist; **or**
    - Dermatologist

    and
  - Initial authorization will be issued for 12 months
- For **continuation of therapy**, all of the following:
  - Documentation of positive clinical response; **and**
  - Cosentyx is initiated and titrated according to the U.S. FDA labeled dosing for PsA; **and**
  - Patient is not receiving Cosentyx in combination with any of the following:
    - Biologic DMARD [e.g., adalimumab, Cimzia (certolizumab), Simponi (golimumab), Taltz (ixekizumab), Orencia (abatacept), Skyrizi (risankizumab-rzaa)]; **or**
    - Janus kinase inhibitor [e.g., Xeljanz (tofacitinib)]; **or**
    - Phosphodiesterase 4 (PDE4) inhibitor [e.g., Otezla (apremilast)]

    and
  - Authorization will be issued for 12 months

Ankylosing Spondylitis (AS) and Non-Radiographic Axial Spondyloarthritis (nr-axSpA)

Cosentyx (secukinumab) is proven and medically necessary for the treatment of ankylosing spondylitis (AS) and non-radiographic axial spondyloarthritis (nr-axSpA) when all of the following criteria are met:

- For **initial therapy**, all of the following:
  - Diagnosis of active ankylosing spondylitis or non-radiographic axial spondyloarthritis; **and**
  - One of the following:
    - History of failure to **two** NSAIDs (e.g., ibuprofen, naproxen) at the maximally indicated doses, each used for at least 4 weeks, unless contraindicated or clinically significant adverse effects are experienced; **or**
    - Patient has been previously treated with a targeted immunomodulator FDA-approved for the treatment of ankylosing spondylitis or nr-axSpA [e.g., adalimumab, Simponi (golimumab), Rinvoq (upadacitinib), Xeljanz/Xeljanz XR (tofacitinib)]

    and
  - Cosentyx is initiated and titrated according to the U.S. FDA labeled dosing for AS or nr-axSpA; **and**
  - Patient is not receiving Cosentyx in combination with any of the following:
    - Biologic DMARD [e.g., adalimumab, Cimzia (certolizumab), Simponi (golimumab), Taltz (ixekizumab), Orencia (abatacept)]; **or**
    - Janus kinase inhibitor [e.g., Xeljanz (tofacitinib)]; **or**
    - Phosphodiesterase 4 (PDE4) inhibitor [e.g., Otezla (apremilast)]

    and
  - Prescribed by, or in consultation with, a rheumatologist; **and**
  - Initial authorization will be issued for 12 months
- For **continuation of therapy**, all of the following:
  - Documentation of positive clinical response; **and**
  - Cosentyx is initiated and titrated according to US FDA labeled dosing for AS or nr-axSpA; **and**
  - Patient is not receiving Cosentyx in combination with any of the following:

- Biologic DMARD [e.g., adalimumab, Cimzia (certolizumab), Simponi (golimumab), Taltz (ixekizumab), Orencia (abatacept)]; **or**
- Janus kinase inhibitor [e.g., Xeljanz (tofacitinib)]; **or**
- Phosphodiesterase 4 (PDE4) inhibitor [e.g., Otezla (apremilast)]

and

- Authorization will be issued for 12 months

Cosentyx (secukinumab) for intravenous injection is unproven and not medically necessary for the following (Cosentyx for self-administered subcutaneous injection is obtained under the pharmacy benefit):

- Plaque psoriasis
- Enthesitis-related arthritis
- Hidradenitis suppurativa

Applicable Codes

The following list(s) of procedure and/or diagnosis codes is provided for reference purposes only and may not be all inclusive. Listing of a code in this policy does not imply that the service described by the code is a covered or non-covered health service. Benefit coverage for health services is determined by federal, state, or contractual requirements and applicable laws that may require coverage for a specific service. The inclusion of a code does not imply any right to reimbursement or guarantee claim payment. Other Policies and Guidelines may apply.

HCPCS Code	Description
C9166	Injection, secukinumab, intravenous, 1 mg
J3490	Unclassified drugs
J3590	Unclassified biologics

Diagnosis Code	Description
L40.50	Arthropathic psoriasis, unspecified
L40.51	Distal interphalangeal psoriatic arthropathy
L40.52	Psoriatic arthritis mutilans
L40.53	Psoriatic spondylitis
L40.54	Psoriatic juvenile arthropathy
L40.59	Other psoriatic arthropathy
M08.1	Juvenile ankylosing spondylitis
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

Diagnosis Code	Description
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

Background

Cosentyx (secukinumab) is a human IgG1 monoclonal antibody that selectively binds to the interleukin-17A (IL-17A) cytokine and inhibits its interaction with the IL-17 receptor. IL-17A is a naturally occurring cytokine that is involved in normal inflammatory and immune responses. Cosentyx inhibits the release of proinflammatory cytokines and chemokines.

Clinical Evidence

The effectiveness of intravenous Cosentyx in the treatment of adult patients with active PsA, AS, and nr-axSpA was extrapolated from the established effectiveness of subcutaneous Cosentyx in adult patients with PsA, AS, and nr-axSpA based on pharmacokinetic exposure.

U.S. Food and Drug Administration (FDA)

This section is to be used for informational purposes only. FDA approval alone is not a basis for coverage.

Cosentyx (secukinumab) is a human interleukin-17A antagonist. Cosentyx (secukinumab) for IV injection 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

References

1. Cosentyx [package insert]. East Hanover, NJ. Novartis Pharmaceuticals Corp.; October 2023.
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3. Yu, DT, van Tubergen A. Treatment of axial spondyloarthritis (ankylosing spondylitis and nonradiographic axial spondyloarthritis) in adults. Sieper, J (Ed). UpToDate. Waltham, MA: UpToDate Inc. http://www.uptodate.com. Accessed on February 21, 2024.
4. Singh, JA, Guyatt, G, et al. 2018 American College of Rheumatology/National Psoriasis Foundation Guideline for the Treatment of Psoriatic Arthritis. Arthritis & Rheumatology. 2019; 71(1): 5-32.
5. Menter A, Gottlieb A, Feldman SR, et al. Guidelines of care for the management of psoriasis and psoriatic arthritis: Section 1. Overview of psoriasis and guidelines of care for the treatment of psoriasis with biologics. J Am Acad Dermatol 2008; 58(5):826-50.
6. Gottlieb A, Korman NJ, Gordon KB, et al. Guidelines of care for the management of psoriasis and psoriatic arthritis. Psoriatic arthritis: Overview and guidelines of care for treatment with an emphasis on the biologics. J Am Acad Dermatol 2008;58(5):851-64.

Policy History/Revision Information

Date	Summary of Changes
06/01/2024	• New Medical Benefit Drug Policy

Instructions for Use

This Medical Benefit Drug Policy provides assistance in interpreting UnitedHealthcare standard benefit plans. When deciding coverage, the federal, state or contractual requirements for benefit plan coverage must be referenced as the terms of the federal, state or contractual requirements for benefit plan coverage may differ from the standard benefit plan. In the event of a conflict, the federal, state or contractual requirements for benefit plan coverage govern. Before using this policy, please check the federal, state or contractual requirements for benefit plan coverage. UnitedHealthcare reserves the right to modify its Policies and Guidelines as necessary. This Medical Benefit Drug Policy is provided for informational purposes. It does not constitute medical advice.

UnitedHealthcare may also use tools developed by third parties, such as the InterQual® criteria, to assist us in administering health benefits. The UnitedHealthcare Medical Benefit Drug Policies are intended to be used in connection with the independent professional medical judgment of a qualified health care provider and do not constitute the practice of medicine or medical advice.