Cosentyx® (Secukinumab)

Policy Number: 2025D0132C
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➲ Instructions for Use

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Related Commercial Policy

- Provider Administered Drugs – Site of Care

Coverage Rationale

➲ See Benefit Considerations

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

General Requirements (Applicable to all Medical Necessity Requests/Reviews)

- 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 is proven 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**
  - Cosentyx is initiated and titrated according to U.S. FDA labeled dosing for PsA; **and**
  - Patient is not receiving Cosentyx in combination with a targeted immunomodulator [e.g., Enbrel (etanercept), Simponi (golimumab), Orencia (abatacept), adalimumab, ustekinumab, Skyrizi (risankizumab), Tremfya (guselkumab), Cimzia (certolizumab pegol), Taltz (ixekizumab), Xeljanz (tofacitinib), Olumiant (baricitinib), Rinvoq (upadacitinib), Otezla (apremilast), Bimzelx (bimekizumab-bkzx)]; **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 U.S. FDA labeled dosing for PsA; **and**
  - Patient is not receiving Cosentyx in combination with a targeted immunomodulator [e.g., Enbrel (etanercept), Simponi (golimumab), Orencia (abatacept), adalimumab, ustekinumab, Skyrizi (risankizumab), Tremfya (guselkumab), Cimzia (certolizumab pegol), Taltz (ixekizumab), Xeljanz (tofacitinib), Olumiant (baricitinib), Rinvoq (upadacitinib), Otezla (apremilast), Bimzelx (bimekizumab-bkzx)]; **and**
  - Authorization will be issued for 12 months

Cosentyx is 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), ustekinumab, Tremfya (guselkumab), Xeljanz/Xeljanz XR (tofacitinib), Otezla (apremilast), Skyrizi (risankizumab), Rinvoq (upadacitinib), Enbrel (etanercept), Bimzelx (bimekizumab-bkzx)]

    and
  - Cosentyx is initiated and titrated according to U.S. FDA labeled dosing for PsA; **and**
  - Patient is not receiving Cosentyx in combination with a targeted immunomodulator [e.g., Enbrel (etanercept), Simponi (golimumab), Orencia (abatacept), adalimumab, ustekinumab, Skyrizi (risankizumab), Tremfya (guselkumab), Cimzia (certolizumab pegol), Taltz (ixekizumab), Xeljanz (tofacitinib), Olumiant (baricitinib), Rinvoq (upadacitinib), Otezla (apremilast), Bimzelx (bimekizumab-bkzx)]; **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 U.S. FDA labeled dosing for PsA; **and**
  - Patient is not receiving Cosentyx in combination with a targeted immunomodulator [e.g., Enbrel (etanercept), Simponi (golimumab), Orencia (abatacept), adalimumab, ustekinumab, Skyrizi (risankizumab), Tremfya (guselkumab), Cimzia (certolizumab pegol), Taltz (ixekizumab), Xeljanz (tofacitinib), Olumiant (baricitinib), Rinvoq (upadacitinib), Otezla (apremilast), Bimzelx (bimekizumab-bkzx)]; **and**
  - Authorization will be issued for 12 months

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

Cosentyx is proven 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**
  - Cosentyx is initiated and titrated according to U.S. FDA labeled dosing for AS or nr-axSpA; **and**
  - Patient is not receiving Cosentyx in combination with a targeted immunomodulator [e.g., Enbrel (etanercept), Simponi (golimumab), Orencia (abatacept), adalimumab, Cimzia (certolizumab pegol), Xeljanz (tofacitinib), Olumiant (baricitinib), Rinvoq (upadacitinib), Bimzelx (bimekizumab-bkzx)]; **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 U.S. FDA labeled dosing for AS or nr-axSpA; **and**
  - Patient is not receiving Cosentyx in combination with a targeted immunomodulator [e.g., Enbrel (etanercept), Simponi (golimumab), Orencia (abatacept), adalimumab, Cimzia (certolizumab pegol), Xeljanz (tofacitinib), Olumiant (baricitinib), Rinvoq (upadacitinib), Bimzelx (bimekizumab-bkzx)]; **and**
  - Authorization will be issued for 12 months

Cosentyx is 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), Bimzelx (bimekizumab-bkzx)]

      and
    - Cosentyx is initiated and titrated according to U.S. FDA labeled dosing for AS or nr-axSpA; **and**
    - Patient is not receiving Cosentyx in combination with a targeted immunomodulator [e.g., Enbrel (etanercept), Simponi (golimumab), Orencia (abatacept), adalimumab, Cimzia (certolizumab pegol), Xeljanz (tofacitinib), Olumiant (baricitinib), Rinvoq (upadacitinib), Bimzelx (bimekizumab-bkzx)]; **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 U.S. FDA labeled dosing for AS or nr-axSpA; **and**
    - Patient is not receiving Cosentyx in combination a targeted immunomodulator [e.g., Enbrel (etanercept), Simponi (golimumab), Orencia (abatacept), adalimumab, Cimzia (certolizumab pegol), Xeljanz (tofacitinib), Olumiant (baricitinib), Rinvoq (upadacitinib), Bimzelx (bimekizumab-bkzx)]; **and**
    - Authorization will be issued for 12 months

Cosentyx (secukinumab) for intraveneous 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 the member specific benefit plan document 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
J3247	Injection, secukinumab, IV, 1 mg

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

Diagnosis Code	Description
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

Background

Cosentyx 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.

Benefit Considerations

Some Certificates of Coverage allow for coverage of experimental/investigational/unproven treatments for life-threatening illnesses when certain conditions are met. The member specific benefit plan document must be consulted to make coverage decisions for this service. Some states mandate benefit coverage for off-label use of medications for some diagnoses or under some circumstances when certain conditions are met. Where such mandates apply, they supersede language in the benefit document or in the medical or drug policy.

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 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.
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 & Rheumatology. 2019; 71(10): 1599-1613.
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
07/01/2025	**Template Updated** • Added *Benefit Considerations* section
05/01/2025	**Coverage Rationale** • Updated list of examples of targeted immunomodulators with which the patient received previous treatment and/or the patient must not be receiving in combination with Cosentyx: ***Psoriatic Arthritis (PsA)*** ○ Added Bimzelx (bimekizumab-bkzx) ○ Replaced "*Stelara* (ustekinumab)" with "ustekinumab" ***Ankylosing Spondylitis (AS) and Non-Radiographic Axial Spondyloarthritis (nr-axSpA)*** ○ Added Bimzelx (bimekizumab-bkzx) **Supporting Information** • Archived previous policy version 2024D0132B

Instructions for Use

This Medical Benefit Drug Policy provides assistance in interpreting UnitedHealthcare standard benefit plans. When deciding coverage, the member specific benefit plan document must be referenced as the terms of the member specific benefit plan may differ from the standard plan. In the event of a conflict, the member specific benefit plan document governs. Before using this policy, please check the member specific benefit plan document and any applicable federal or state mandates. 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.

This Medical Benefit Drug Policy may also be applied to Medicare Advantage plans in certain instances. In the absence of a Medicare National Coverage Determination (NCD), Local Coverage Determination (LCD), or other Medicare coverage guidance, CMS allows a Medicare Advantage Organization (MAO) to create its own coverage determinations, using objective evidence-based rationale relying on authoritative evidence (Medicare IOM Pub. No. 100-16, Ch. 4, §90.5).

UnitedHealthcare may also use tools developed by third parties, such as the InterQual® criteria, to assist us in administering health benefits. 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.