

Cosentyx® (Secukinumab)

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[Instructions for Use](#)

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Related Commercial Policy

- [Provider Administered Drugs – Site of Care](#)

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.

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, Stelara (ustekinumab), Skyrizi (risankizumab), Tremfya (guselkumab), Cimzia (certolizumab pegol), Taltz (ixekizumab), Xeljanz (tofacitinib), Olumiant (baricitinib), Rinvoq (upadacitinib), Otezla (apremilast)]; **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, Stelara (ustekinumab), Skyrizi (risankizumab), Tremfya (guselkumab), Cimzia (certolizumab pegol), Taltz (ixekizumab), Xeljanz (tofacitinib), Olumiant (baricitinib), Rinvoq (upadacitinib), Otezla (apremilast)]; **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), Stelara (ustekinumab), Tremfya (guselkumab), Xeljanz/Xeljanz XR (tofacitinib), Otezla (apremilast), Skyrizi (risankizumab), Rinvoq (upadacitinib), Enbrel (etanercept)]

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, Stelara (ustekinumab), Skyrizi (risankizumab), Tremfya (guselkumab), Cimzia (certolizumab pegol), Taltz (ixekizumab), Xeljanz (tofacitinib), Olumiant (baricitinib), Rinvoq (upadacitinib), Otezla (apremilast)]; **and**
- Prescribed by or in consultation with **one** of the following:
 - Rheumatologist
 - 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, Stelara (ustekinumab), Skyrizi (risankizumab), Tremfya (guselkumab), Cimzia (certolizumab pegol), Taltz (ixekizumab), Xeljanz (tofacitinib), Olumiant (baricitinib), Rinvoq (upadacitinib), Otezla (apremilast)]; **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)]; **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)]; **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)]

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)]; **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)]; **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 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 |
| 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 |

| Diagnosis Code | Description |
|----------------|--|
| 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.

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.
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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 |
|------------|---|
| 07/01/2024 | <p>Coverage Rationale</p> <ul style="list-style-type: none">Removed instruction to refer to the Medical Benefit Drug Policy titled <i>Review at Launch for New to Market Medications</i> <p>Applicable Codes</p> <ul style="list-style-type: none">Updated list of applicable HCPCS codes to reflect quarterly edits:<ul style="list-style-type: none">Removed C9166Replaced J3490 and J3590 with J3247 <p>Supporting Information</p> <ul style="list-style-type: none">Archived previous policy version 2024D0132A |

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.