Policy Number	**RX501.169**
Policy Effective Date	**11/01/2025**

Secukinumab

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Related Policies (if applicable)
None

Disclaimer

Medical policies are a set of written guidelines that support current standards of practice. They are based on current generally accepted standards of and developed by nonprofit professional association(s) for the relevant clinical specialty, third-party entities that develop treatment criteria, or other federal or state governmental agencies. A requested therapy must be proven effective for the relevant diagnosis or procedure. For drug therapy, the proposed dose, frequency and duration of therapy must be consistent with recommendations in at least one authoritative source. This medical policy is supported by FDA-approved labeling and/or nationally recognized authoritative references to major drug compendia, peer reviewed scientific literature and generally accepted standards of medical care. These references include, but are not limited to: MCG care guidelines, DrugDex (IIa level of evidence or higher), NCCN Guidelines (IIb level of evidence or higher), NCCN Compendia (IIb level of evidence or higher), professional society guidelines, and CMS coverage policy.

Carefully check state regulations and/or the member contract.

Each benefit plan, summary plan description or contract defines which services are covered, which services are excluded, and which services are subject to dollar caps or other limitations, conditions or exclusions. Members and their providers have the responsibility for consulting the member's benefit plan, summary plan description or contract to determine if there are any exclusions or other benefit limitations applicable to this service or supply. **If there is a discrepancy between a Medical Policy and a member's benefit plan, summary plan description or contract, the benefit plan, summary plan description or contract will govern.**

Legislative Mandates

EXCEPTION: For HCSC members residing in the state of Ohio, § 3923.60 requires any group or individual policy (Small, Mid-Market, Large Groups, Municipalities/Counties/Schools, State Employees, Fully-Insured, PPO, HMO, POS, EPO) that covers prescription drugs to provide for the coverage of any drug approved by the U. S. Food and Drug Administration (FDA) when it is prescribed for a use recognized as safe and effective for the treatment of a given indication in one or more of the standard medical reference compendia adopted by the United States Department of Health and Human Services or in medical literature even if the FDA has not approved the drug for that indication. Medical literature support is only satisfied when safety and efficacy has been confirmed in two articles from major peer-reviewed professional medical journals that present data supporting the proposed off-label use or uses as generally safe and effective. Examples of accepted journals include, but are not limited to, Journal of

American Medical Association (JAMA), New England Journal of Medicine (NEJM), and Lancet. Accepted study designs may include, but are not limited to, randomized, double blind, placebo controlled clinical trials. Evidence limited to case studies or case series is not sufficient to meet the standard of this criterion. Coverage is never required where the FDA has recognized a use to be contraindicated and coverage is not required for non-formulary drugs.

Coverage

NOTE 1: Secukinumab (Cosentyx®) may be self-administered. Refer to the applicable pharmacy benefit plan when self-administered.

Secukinumab (Cosentyx®) **may be considered medically necessary** when administered intravenously (IV) for the following indications:

- Treatment of adults with active psoriatic arthritis (PsA), despite non-steroidal anti-inflammatory drug (NSAID), corticosteroid, or disease modifying anti-rheumatic drug (DMARD) therapy;
- Treatment of adults with active ankylosing spondylitis (AS), despite nonsteroidal anti-inflammatory drug (NSAID), corticosteroid OR disease modifying anti-rheumatic drug (DMARD) therapy; OR
- Treatment of adults with active non-radiographic axial spondylarthritis (nr-axSpA) despite NSAID therapy, corticosteroid OR disease modifying anti-rheumatic drug (DMARD) therapy.

Intravenous administration of secukinumab (Cosentyx®) **is considered experimental, investigational and/or unproven** for all other non-Food and Drug Administration approved indications.

Policy Guidelines

None.

Description

Psoriatic Arthritis

Psoriatic arthritis (PsA) is a musculoskeletal condition involving joint inflammation (arthritis) that usually occurs in conjunction with psoriasis, a skin disorder characterized by patches of red, irritated skin that are often covered by flaky white scales. Psoriasis may cause changes to fingernails and toenails, causing pitting, ridges, crumbling of the nail or separation of the nail from the nail bed. PsA causes stiff, painful joints with redness, heat and swelling in the surrounding tissues. Inflammation at the site of the insertion of tendons, ligaments, and synovium into bone (enthesitis) may be present. Swelling and redness may result in a sausage-like appearance of the fingers or toes when the hands or feet are affected. Ocular inflammation (e.g., uveitis and conjunctivitis) occurs in some individuals with PsA, as it does with other chronic inflammatory joint disorders. Psoriasis appears before joint problems develop in most

people. Both conditions may occur at any age; and in a small number of cases, PsA develops without any noticeable skin changes. (2)

Ankylosing Spondylitis
Ankylosing spondylitis (AS) is a form of arthritis affecting the spine. It often involves redness, heat, swelling and pain in the spine or in the joint where the bottom of the spine (sacrum) joins the pelvic bone (ilium). It can also affect the shoulders, ribs, hips, knees, and feet, as well as areas where the tendons and ligaments attach to the bones. Sometimes it can affect the eyes, bowel and very rarely, the heart and lungs. AS is more than twice as likely to affect men as it is women. (3)

Non-Radiographic Axial Spondylarthritis
Non-radiographic axial spondylarthritis (nr-axSpA) is closely associated with ankylosing spondylitis. Both are sub-types of axial spondyloarthritis. The difference is that in nr-axSpA, the sacroiliac (SI) joints does not show definitive changes on xrays, as seen in AS. Nr-axSpA can also cause inflammation, pain, and stiffness in the neck, shoulders, hips, ribs, heels, and joints of the arms and legs. Inflammation can also impact the eyes (causing iritis or uveitis), the skin (causing psoriasis), and the gut (causing intestinal pain and other problems). (3, 4)

Secukinumab (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. Elevated levels of IL-17A have been found in psoriatic plaques, and increased numbers of IL-17A producing lymphocytes and innate immune cells, and increased levels of IL-17A have been found in the blood of individuals with PsA and AS. Increased numbers of IL-17A producing lymphocytes have been found in individuals with nr-axSpA. Secukinumab inhibits the release of proinflammatory cytokines and chemokines. (1)

Regulatory Status
The U.S. Food and Drug Administration (FDA) approved secukinumab (Cosentyx®) for the following indications (1):

FDA Approved Condition	Route Of Administration
Moderate to severe plaque psoriasis (PsO) in individuals 6 years of age and older who are candidates for systemic therapy or phototherapy;	Subcutaneous administration (refer to the applicable pharmacy benefit plan)
Active psoriatic arthritis (PsA) in individuals 2 years of age and older;	Intravenous or subcutaneous administration. (Refer to the applicable pharmacy benefit plan for subcutaneous administration)
Adults with active ankylosing spondylitis (AS);	Intravenous or subcutaneous administration. (Refer to the applicable pharmacy benefit plan for subcutaneous administration).

Adults with active non-radiographic axial spondyloarthritis (nr-axSpA) with objective signs of inflammation;	Intravenous administration.
Active enthesitis-related arthritis (ERA) in pediatric individuals 4 years of age and older;	Subcutaneous administration (refer to the applicable pharmacy benefit plan).
Adults with moderate to severe hidradenitis suppurativa (HS).	Subcutaneous administration (refer to the applicable pharmacy benefit plan).

NOTE 2: Secukinumab (Cosentyx®) may be self-administered. Refer to the applicable pharmacy benefit plan when self-administered.

Rationale

This medical policy is based on the U.S. Food and Drug Administration (FDA) studies for the labeled indications for Secukinumab (Cosentyx®).

Secukinumab (Cosentyx®) (1)

Adult Psoriatic Arthritis (PsA)

The safety and efficacy of Cosentyx were assessed in 1,999 patients, in 3 randomized, double-blind, placebo-controlled trials (PsA1, PsA2, and PsA3) in adult patients, age 18 years and older with active PsA (greater than or equal to 3 swollen and greater than or equal to 3 tender joints) despite non-steroidal anti-inflammatory drug (NSAID), corticosteroid or disease modifying anti-rheumatic drug (DMARD) therapy. Patients in these trials had a diagnosis of PsA of at least 5 years across all trials.

- PsA1 Study (NCT01752634) evaluated 397 patients, who were treated with 75 mg, 150 mg or 300 mg of Cosentyx (administered as two subcutaneous injections of 150 mg) at Weeks 0, 1, 2, 3, and 4, followed by the same subcutaneous dose every 4 weeks. Patients who received placebo were re-randomized to receive subcutaneous Cosentyx (either 150 mg or 300 mg every 4 weeks) at Week 16 or Week 24 based on responder status. The primary endpoint was the percentage of patients achieving an American College of Rheumatology (ACR20) response at Week 24.
- PsA2 Study (NCT01392326) evaluated 606 patients, who were treated with intravenous secukinumab 10 mg/kg, or placebo at Weeks 0, 2, and 4, followed by either 75 mg or 150 mg of subcutaneous Cosentyx treatment (or placebo) every 4 weeks. Patients who received placebo were re-randomized to receive subcutaneous Cosentyx (either 75 mg or 150 mg every 4 weeks) at Week 16 or Week 24 based on responder status.
- PsA3 Study (NCT02404350) evaluated 996 patients, who were treated with 150 mg or 300 mg of Cosentyx (administered as two subcutaneous injections of 150 mg) at Weeks 0, 1, 2, 3, and 4 followed by the same subcutaneous dose every 4 weeks, or once every 4 weeks of Cosentyx 150 mg. Patients treated with placebo received subcutaneous Cosentyx, either 150 mg or 300 mg, per baseline randomization, at Week 16 or Week 24 based upon responder status. The primary endpoint was ACR20 response at Week 16 with the key

secondary endpoint the change from baseline in modified Total Sharp Score (mTSS) at Week 24.

Baseline Disease Characteristics
At baseline, over 61% and 42% of the patients had enthesitis (inflammation of the attachment site of tendons, ligaments, or joint capsules to bone) and dactylitis ("sausage digits"), respectively. Overall, 31% of patients discontinued previous treatment with anti-TNFα (tumor necrosis factor alpha) agents due to either lack of efficacy or intolerance. In addition, approximately 53% of patients from both studies had concomitant methotrexate (MTX) use. Patients with different subtypes of PsA were enrolled, including polyarticular arthritis with no evidence of rheumatoid nodules (80%), asymmetric peripheral arthritis (63%), distal interphalangeal involvement (58%), spondylitis with peripheral arthritis (20%), and arthritis mutilans (7%).

Clinical Response
In PsA1, patients treated with 150 mg or 300 mg Cosentyx demonstrated a greater clinical response, including ACR20, ACR50, and ACR70 compared to patients treated with placebo at Week 24 (Table 1). Responses were similar in patients regardless of concomitant MTX treatment. Responses were seen regardless of prior anti-TNFα exposure.

In patients with coexistent plaque psoriasis (PsO) receiving Cosentyx (n = 99), the skin lesions of psoriasis improved with treatment, relative to placebo, as measured by the Psoriasis Area Severity Index (PASI).

Table 1. Responses[a] In PsA1 Study at Week 16 and Week 24 (Subcutaneous Treatment)

	Cosentyx 150 mg (N=100)	**Cosentyx 300 mg (N=100)**	**Placebo (N=98)**	**Difference from placebo (95% CI)**	
				Cosentyx 150 mg	**Cosentyx 300 mg**
ACR20 Response					
Week 16 (%)	60	57	18	42 (30, 54)	38 (26, 51)
Week 24 (%)	51	54	15	36 (24, 48)	39 (27, 51)
ACR50 Response					
Week 16 (%)	37	35	6	31 (21, 42)	28 (18, 39)
Week 24 (%)	35	35	7	28 (18, 38)	28 (17, 38)
ACR70 Response					
Week 16 (%)	17	15	2	15 (7, 23)	13 (5, 20)
Week 24 (%)	21	20	1	20 (12, 28)	19 (11, 27)

ACR: American College of Rheumatology; CI: confidence interval; mg: milligram; PsA: psoriatic arthritis.
[a] Patients who met escape criteria (less than 20% improvement in tender or swollen joint counts) at Week 16 were considered non-responders.

The improvements in the components of the ACR response criteria in the PsA1 study are shown in Table 2.

Table 2. Mean Change from Baseline in ACR Components at Week 16[a] (PsA1 Study) (Subcutaneous Treatment)

	Cosentyx 150 mg (N=100)	Cosentyx 300 mg (N=100)	Placebo (N=98)
Number of swollen joints			
Baseline	12.0	11.2	12.1
Mean change at Week 16	-4.86	-5.83	-3.22
Number of tender joints			
Baseline	24.1	20.2	23.5
Mean change at Week 16	-10.70	-10.01	-1.77
Patient's assessment of pain			
Baseline	58.9	57.7	55.4
Mean change at Week 16	-22.91	-23.97	-7.98
Patient global assessment			
Baseline	62.0	60.7	57.6
Mean change at Week 16	-25.47	-25.40	-8.25
Physician global assessment			
Baseline	56.7	55.0	55.0
Mean change at Week 16	-29.24	-34.71	-14.95
Disability index (HAQ)			
Baseline	1.2200	1.2828	1.1684
Mean change at Week 16	-0.45	-0.55	-0.23
CRP (mg/L)			
Baseline	14.15	10.88	7.87
Mean change at Week 16[b]	-8.41	-7.21	0.79

CRP: C-reactive protein; HAQ: Health Assessment Questionnaire; mg/L: milligrams per milliliter; PsA: psoriatic arthritis.

[a] Week 16 rather than Week 24 data are displayed to provide comparison between arms prior to placebo escape to Cosentyx.

[b] Mean change based upon observed data.

Improvements in enthesitis and dactylitis scores were observed in each Cosentyx group compared to placebo at Week 24.

Radiographic Response

In PsA3 Study, inhibition of progression of structural damage was assessed radiographically and expressed by the modified mTSS and its components, the Erosion Score (ES) and Joint Space Narrowing Score (JSN), at Week 24 compared to baseline. Radiographs of hands, wrists, and feet were obtained at baseline, Week 16 and/or Week 24 and scored independently by at least two readers who were blinded to treatment group and visit number. Treatment with

subcutaneous Cosentyx 150 mg without a loading dose, 150 mg with a loading dose and 300 mg with a loading dose significantly inhibited progression of peripheral joint damage compared with treatment with placebo as measured by change from baseline in mTSS at Week 24. The percentage of patients with no disease progression (defined as a change from baseline in mTSS of less than or equal to 0.0) from randomization to Week 24 was 75.7%, 70.9%, and 76.5% for Cosentyx 150 mg without a loading dose, 150 mg, 300 mg, respectively versus 68.2% for placebo.

Table 3. Rate of Change per 24 Weeks in Modified Total Sharp Score (Subcutaneous Treatment)

Treatment	N	Rate of change per 24 weeks	Difference from placebo (95% CI)
Cosentyx 150 mg without a loading dose	210	-0.10	-0.61 (-0.95, -0.26)
Cosentyx 150 mg with a loading dose	213	0.14	-0.37 (-0.71, -0.03)
Cosentyx 300 mg with a loading dose	217	0.03	-0.48 (-0.82, -0.14)
Placebo	296	0.51	-

CI: confidence interval; mg: milligram.
Results from a linear mixed effects model that excluded data after escape for placebo subjects who received escape therapy at Week 16. The model assumes approximately linear progression over time and estimates a difference in rates (slopes) of progression over 24 weeks to compare treatment arms.

Physical Function
Improvement in physical function as assessed by Health Assessment Questionnaire-Disability Index (HAQ-DI) demonstrated that the proportion of patients who achieved at least -0.3 improvement in HAQ-DI score from baseline was greater in the subcutaneous Cosentyx 150 mg and 300 mg groups compared to the placebo group at Weeks 16 and 24.

At Week 16 in PsA1 study, estimated mean change from baseline was -0.23 in the placebo group compared with -0.45 in the Cosentyx 150 mg group and -0.55 in the Cosentyx 300 mg group.

Treatment of Adult Patients with Active Psoriatic Arthritis with Intravenous Cosentyx
The effectiveness of intravenous Cosentyx in the treatment of adult patients with active PsA was extrapolated from the established effectiveness of subcutaneous Cosentyx in adult patients with active PsA based on pharmacokinetic exposure. Following an intravenous administration of 1.75 mg/kg maintenance dose every four weeks, with or without a loading dose of 6 mg/kg at Day 0, the secukinumab concentrations [steady state trough secukinumab concentrations ($C_{min,ss}$), mean secukinumab concentrations ($C_{avg,ss}$), and maximum secukinumab concentrations ($C_{max,ss}$)] are estimated to be within the range of the steady state concentrations following subcutaneous administration of 150 mg and 300 mg doses of Cosentyx administered every four weeks.

Ankylosing Spondylitis (AS)

The safety and efficacy of subcutaneous Cosentyx were assessed in 816 adult patients (18 years of age and older) with active AS in three randomized, double-blind, placebo-controlled trials (AS1, AS2, and AS3). Patients had active disease as defined by the Bath Ankylosing Spondylitis Disease Activity Index (BASDAI) greater or equal to 4 despite nonsteroidal anti-inflammatory drug (NSAID), corticosteroid or disease modifying anti-rheumatic drug (DMARD) therapy.

- AS1 Study (NCT01649375) evaluated 219 patients, who were treated with 75 mg or 150 mg of subcutaneous Cosentyx treatment at Weeks 0, 1, 2, 3, and 4, followed by the same dose every 4 weeks. At Week 16, patients who received placebo were re-randomized to either 75 mg or 150 mg of subcutaneous Cosentyx every 4 weeks. The primary endpoint was the percentage of patients who achieved an Assessment in Ankylosing Spondylitis (ASAS20) response at Week 16.
- AS2 Study (NCT01358175) evaluated 371 patients, who were treated with intravenous secukinumab 10 mg/kg at Weeks 0, 2, and 4 (for both treatment arms) or placebo, followed by either 75 mg or 150 mg subcutaneous Cosentyx treatment every 4 weeks or placebo. Patients who received placebo were re-randomized to receive subcutaneous Cosentyx (either 75 mg or 150 mg every 4 weeks) at Week 16 or Week 24 based on responder status.
- AS3 Study (NCT02008916) evaluated 226 patients, who were treated with intravenous secukinumab 10 mg/kg at Weeks 0, 2, and 4 (for both treatment arms) or placebo, followed by either 150 mg or 300 mg subcutaneous Cosentyx treatment every 4 weeks or placebo. Patients who received placebo were re-randomized to receive subcutaneous Cosentyx (either 150 mg or 300 mg every 4 weeks) at Week 16. The primary endpoint was the percentage of patients who achieved an ASAS20 response at Week 16. Patients were blinded to the treatment regimen up to Week 52, and the trial continued to Week 156. In this study, each 300 mg dose was administered as two injections of 150 mg.

Baseline Disease Characteristics

At baseline, approximately 13% and 25% used concomitant methotrexate (MTX) or sulfasalazine, respectively. Overall, 29% of patients discontinued previous treatment with anti-TNFα agents due to either lack of efficacy or intolerance.

Clinical Response

In AS1, patients treated with 150 mg Cosentyx demonstrated greater improvements in ASAS20 and ASAS40 responses compared to patients treated with placebo at Week 16 (Table 4). Responses were similar in patients regardless of concomitant therapies.

Table 4. ASAS20 and ASAS40 Responses in All AS Patients at Week 16 in Study AS1 (Subcutaneous Treatment)

	Cosentyx 150 mg (n=72)	**Placebo (n=74)**	**Difference from Placebo (95% CI)**
ASAS20 Response, %	61	28	33 (18, 48)
ASAS40 Response, %	36	11	25 (12, 38)

AS: ankylosing spondylitis; ASAS: Assessment in ankylosing spondylitis; CI: confidence interval; mg: milligram.

The improvements in the main components of the ASAS20 response criteria and other measures of disease activity are shown in Table 5.

Table 5. ASAS20 Components and Other Measures of Disease Activity at Week 16 (AS1 Study) (Subcutaneous Treatment)

	Cosentyx 150 mg (N=72)		Placebo (N=74)	
	Baseline	**Week 16 change from baseline**	**Baseline**	**Week 16 change from baseline**
ASAS20 response criteria				
Patient Global Assessment of Disease Activity (0-100 mm)[1]	67.5	-27.7	70.5	-12.9
Total spinal pain (0-100 mm)	66.2	-28.5	69.2	-10.9
BASFI (0-10) [2]	6.2	-2.2	6.1	-0.7
Inflammation (0-10)[3]	6.5	-2.5	6.5	-0.8
BASDAI score[4]	6.6	-2.2	6.8	-0.9
BASMI[5]	3.6	-0.51	3.9	-0.22
hsCRP[6] (mg/L) mean change at Week 16	27.0	-17.2	15.9	0.8

ASAS: Assessment of Ankylosing Spondylitis score; BASFI: Bath Ankylosing Spondylitis Functional Index; BASDAI: Bath Ankylosing Spondylitis Disease Activity Index; BASMI: Bath Ankylosing Spondylitis Metrology Index; hsCRP: high-sensitivity C-reactive protein; mg: milligram; mm: millimeter; mg/L: milligrams per liter.

[1] Percent of subjects with at least a 20%- and 10-unit improvement measured on a Visual Analog Scale (VAS) with 0 = none, 100 = severe.

[2] Bath Ankylosing Spondylitis Functional Index.

[3] Inflammation is the mean of two patient-reported stiffness self-assessments in BASDAI.

[4] Bath Ankylosing Spondylitis Disease Activity Index.

[5] Bath Ankylosing Spondylitis Metrology Index.

[6] High sensitivity C-reactive protein/mean change based upon observed data.

In AS3 Study, patients treated with subcutaneous Cosentyx (150 mg and 300 mg) demonstrated improved signs and symptoms, and had comparable efficacy responses, regardless of dose, that were superior to placebo at Week 16 for the primary and most secondary endpoints. At Week 16, the ASAS20 and ASAS40 responses were 58.1% and 40.5% for 150 mg and 60.5% and 42.1% for 300 mg, respectively. Cosentyx treated patients showed improvement compared to placebo-treated patients in health-related quality of life as assessed by ASQoL at Week 16.

Treatment of Adult Patients with Active Ankylosing Spondylitis with Intravenous Cosentyx

The effectiveness of intravenous Cosentyx in the treatment of adult patients with active AS was extrapolated from the established effectiveness of subcutaneous Cosentyx in adult patients with active AS based on pharmacokinetic exposure.

Non-Radiographic Axial Spondyloarthritis (nr-axSpA)

The safety and efficacy of Cosentyx were assessed in 555 adult patients (18 years of age and older) with active nr-axSpA in one randomized, double-blind, placebo-controlled Phase 3 study (nr-axSpA1, NCT02696031). Patients met ASAS criteria for axSpA with objective signs of inflammation and had active disease as defined by a BASDAI greater or equal to 4, a Visual Analogue Scale (VAS) for total back pain greater or equal to 40 (on a scale of 0-100 mm) despite NSAID therapy and no evidence of radiographic changes in the sacroiliac joints that would meet the modified New York criteria for AS. Patients also had to have objective signs of inflammation with a C-reactive protein (CRP) level above the upper limit of normal and/or evidence of sacroiliitis on Magnetic Resonance Imaging (MRI).

Patients were treated with 150 mg of subcutaneous Cosentyx treatment with a loading dosage (Weeks 0, 1, 2, 3, and 4) or without a loading dosage (Weeks 0 and 4) followed by the same dose every 4 weeks or placebo. In the double-blind period, patients (n = 555) received either placebo or Cosentyx for 52 weeks. Starting Week 16, dosage adjustment or addition of concomitant NSAIDs and DMARDs was permitted. Starting at Week 20, patients were allowed to switch to open-label 150 mg of subcutaneous Cosentyx monthly or other biologic at the discretion of the investigator and patient. The primary endpoint was at least 40% improvement in Assessment of Spondyloarthritis International Society (ASAS40) at Week 52.

Baseline Disease Characteristics

Approximately 10% and 15% of patients used concomitant MTX or sulfasalazine, respectively. Overall, 10% of patients had received previous treatment with anti-TNFα agents and discontinued these due to either lack of efficacy or intolerance.

Clinical Response

In nr-axSpA1 Study, treatment with Cosentyx 150 mg resulted in significant improvements in the measure of disease activity compared to treatment with placebo at Week 16 and Week 52 (Table 6).

Table 6. Clinical Response in the nr-axSpA1 Study at Week 16 and Week 52 (Subcutaneous Treatment)

Number of subjects with ASAS40 responses (%)	Cosentyx 150 mg without load (n=184)	Cosentyx 150 mg with load (n=185)	Placebo (N=186)	Difference from Placebo (95% CI)	
				Cosentyx 150 mg without load	Cosentyx 150 mg with load
Week 16	75 (41)	74 (40)	52 (28)	13 (3 ,22)	12 (2, 22)
Week 52	40 (38)	62 (34)	39 (19)	19 (10, 28)	14 (5, 23)

ASAS: Assessment of Ankylosing Spondylitis; CI: confidence interval; nr-axSpA: Non-Radiographic Axial Spondylarthritis.
Differences in proportions with 95% CI based on normal approximation.

The results of the main components of the ASAS40 response criteria in the nr-axSpA1 Study are shown in Table 7.

Table 7. Main Components of the ASAS40 Response Criteria and Other Measures of Disease Activity in nr-axSpA Patients at Baseline and Week 16 in the nr-axSpA1 Study (Subcutaneous Treatment)

	Cosentyx 150 mg without loading dose (N=184)		**Cosentyx 150 mg with a loading dose (N=185)**		**Placebo (N=186)**	
	Baseline	**Week 16 change from baseline**	**Baseline**	**Week 16 change from baseline**	**Baseline**	**Week 16 change from baseline**
ASAS40 response criteria						
Patient global assessment of disease activity (0-100 mm)	71.0	-26.2	72.6	-24.1	68.8	-13.8
Total back pain (0-100 mm)	72.0	-25.5	73.3	-25.0	70.9	-15.6
BASFI (0-10)	5.9	-1.6	6.2	-1.8	5.9	-1.0
Inflammation (0-10)	6.8	-2.8	7.2	-2.8	6.6	-1.7
hsCRP (mg/L) mean change at week 16	9.8	-4.7	13.4	-7.9	9.2	-2.4
BASDAI (0-10) Spinal pain Peripheral pain and swelling (0-10)	6.9 7.6 6.6	-2.4 -3.0 -2.4	7.1 7.8 6.3	-2.4 -3.0 -2.3	6.8 7.5 6.1	-1.5 -2.0 -1.6
BASMI	2.8	-0.3	2.9	-0.3	2.8	-0.1

ASAS: Assessment of Ankylosing Spondylitis score; BASFI: Bath Ankylosing Spondylitis Functional Index; BASDAI: Bath Ankylosing Spondylitis Disease Activity Index; BASMI: Bath Ankylosing Spondylitis Metrology Index; hsCRP: high-sensitivity C-reactive protein; mg: milligram; mm: millimeter; mg/L: milligrams per liter.

Health-Related Quality of Life
Cosentyx treated patients showed improvement in both loading and without loading dosage arms compared to placebo-treated patients at Week 16 in health-related quality of life measured by ASQoL. (LS mean change: Week 16: -3.5 and -3.6 versus -1.8, respectively).

Treatment of Adult Patients with Active Non-radiography Axial Spondyloarthritis with Intravenous Cosentyx
The effectiveness of intravenous Cosentyx in the treatment of adult patients with active nr-axSpA was extrapolated from the established effectiveness of subcutaneous Cosentyx in adult patients with active nr-axSpA based on pharmacokinetic exposure.

Summary of Evidence
Secukinumab (Cosentyx®) may be considered medically necessary when administered intravenously (IV) for the treatment of adults with active psoriatic arthritis (PsA), active ankylosing spondylitis (AS), and active non-radiographic axial spondylarthritis (nr-axSpA) despite use of NSAID therapy, corticosteroid or disease modifying anti-rheumatic drug (DMARD) therapy. Intravenous administration of secukinumab (Cosentyx®) is considered experimental, investigational and/or unproven for all other non-Food and Drug Administration (FDA) approved indications.

Coding

Procedure codes on Medical Policy documents are included **only** as a general reference tool for each policy. **They may not be all-inclusive.**

The presence or absence of procedure, service, supply, or device codes in a Medical Policy document has no relevance for determination of benefit coverage for members or reimbursement for providers. **Only the written coverage position in a Medical Policy should be used for such determinations.**

Benefit coverage determinations based on written Medical Policy coverage positions must include review of the member's benefit contract or Summary Plan Description (SPD) for defined coverage vs. non-coverage, benefit exclusions, and benefit limitations such as dollar or duration caps.

CPT Codes	None
HCPCS Codes	J3247

*Current Procedural Terminology (CPT®) ©2024 American Medical Association: Chicago, IL.

References

U.S. Food and Drug Administration Label:
1. U.S. Food and Drug Administration (FDA). Highlights of prescribing information: Cosentyx® (secukinumab). Revised 9/2024. Available at <https://www.accessdata.fda.gov> (accessed June 5, 2025).

Other:
2. Gladman DD, Ritchlin C. Clinical manifestations and diagnosis of psoriatic arthritis. In: UpToDate, Sieper J (Ed), UpToDate. Waltham, MA: UpToDate Inc. Available at <https://www.uptodate.com> (accessed June 6, 2025).
3. van Tubergen A. Clinical manifestations of axial spondyloarthritis (ankylosing spondylitis and nonradiographic axial spondyloarthritis) in adults. In: UpToDate, Sieper J (Ed), UpToDate.

Waltham, MA: UpToDate Inc. Available at <https://www.uptodate.com> (accessed June 27, 2025).
4. Overview of non-radiography axial spondyloarthritis (nr-axSpA). 2025. Available at <https://www.spondylitis.org> (accessed June 27, 2025).

Centers for Medicare and Medicaid Services (CMS)

The information contained in this section is for informational purposes only. HCSC makes no representation as to the accuracy of this information. It is not to be used for claims adjudication for HCSC Plans.

The Centers for Medicare and Medicaid Services (CMS) does not have a national Medicare coverage position. Coverage may be subject to local carrier discretion.

A national coverage position for Medicare may have been developed since this medical policy document was written. See Medicare's National Coverage at <https://www.cms.hhs.gov>.

Policy History/Revision

Date	Description of Change
11/01/2025	Document updated with literature review. The following changes were made in Coverage: 1) Modified the conditional coverage criteria statements for the treatment of adults with active psoriatic arthritis (PsA), active ankylosing spondylitis (AS), and active non-radiographic axial spondylarthritis (nr-axSpA); 2) Added “non-Food and Drug Administration approved” to the existing experimental, investigational and/or unproven statement. No new references; others updated.
08/15/2024	New medical document. Secukinumab (Cosentyx® may be considered medically necessary when administered intravenously (IV) for the following indications: treatment of adults with moderately to severely active psoriatic arthritis (PsA); treatment of adults with moderately to severely active ankylosing spondylitis (AS); or treatment of adults with active non-radiographic axial spondylarthritis (nr-axSpA) and with objective signs of inflammation. Intravenous administration of Secukinumab (Cosentyx®) is considered experimental, investigational and/or unproven for all other indications.