



Effective Date: 02/01/2013  
Last P&T Approval/Version: 01/26/2022  
Next Review Due By: 11/2023  
Policy Number: C10410-A

## Cosentyx (secukinumab)

### PRODUCTS AFFECTED

Cosentyx (secukinumab)

### COVERAGE POLICY

*Coverage for services, procedures, medical devices, and drugs are dependent upon benefit eligibility as outlined in the member's specific benefit plan. This Coverage Guideline must be read in its entirety to determine coverage eligibility, if any. This Coverage Guideline provides information related to coverage determinations only and does not imply that a service or treatment is clinically appropriate or inappropriate. The provider and the member are responsible for all decisions regarding the appropriateness of care. Providers should provide Molina Healthcare complete medical rationale when requesting any exceptions to these guidelines*

#### **Documentation Requirements:**

*Molina Healthcare reserves the right to require that additional documentation be made available as part of its coverage determination; quality improvement; and fraud; waste and abuse prevention processes. Documentation required may include, but is not limited to, patient records, test results and credentials of the provider ordering or performing a drug or service. Molina Healthcare may deny reimbursement or take additional appropriate action if the documentation provided does not support the initial determination that the drugs or services were medically necessary, not investigational, or experimental, and otherwise within the scope of benefits afforded to the member, and/or the documentation demonstrates a pattern of billing or other practice that is inappropriate or excessive*

#### **DIAGNOSIS:**

moderate to severe plaque psoriasis, active psoriatic arthritis (PsA), ankylosing spondylitis (AS), non-radiographic axial spondyloarthritis

#### **REQUIRED MEDICAL INFORMATION:**

*This clinical policy is consistent with standards of medical practice current at the time that this clinical policy was approved. If a drug within this policy receives an updated FDA label within the last 180 days, medical necessity for the member will be reviewed using the updated FDA label information along with state and federal requirements, benefit being administered and formulary preferencing. Coverage will be determined on a case-by-case basis until the criteria can be updated through Molina Healthcare, Inc. clinical governance. Additional information may be required on a case-by-case basis to allow for adequate review*

#### **FOR ALL INDICATIONS:**

1. (a) Prescriber attests member has had a negative TB screening or TB test result within the last 12 months for initial and continuation of therapy requests  
OR  
(b) For members who have a positive test for latent TB, provider documents member has completed a treatment course (a negative chest x-ray is also required every 12 months) OR that member has been cleared by an infectious disease specialist to begin treatment

## Drug and Biologic Coverage Criteria

AND

2. Member is not on concurrent treatment or will be used in combination with other TNF- inhibitor, biologic response modifier or other biologic DMARDs, Janus kinase Inhibitors, or Phosphodiesterase 4 inhibitor (i.e., apremilast, tofacitinib, baricitinib) as verified by prescriber attestation, member medication fill history, or submitted documentation

AND

3. IF THIS IS A NON-FORMULARY/NON-PREFERRED PRODUCT: Documentation of trial/failure of or intolerance to a majority (not more than 3) of the preferred formulary/PDL alternatives for the given diagnosis. If yes, please submit documentation including medication(s) tried, dates of trial(s) and reason for treatment failure(s) [DOCUMENTATION REQUIRED]

### A. PSORIATIC ARTHRITIS (PsA):

1. Documentation of active psoriatic arthritis

AND

2. (a) Documented treatment failure with or FDA labeled contraindication to a minimum 3-month trial of ONE of the following DMARDs: Leflunomide, Methotrexate, Sulfasalazine, Cyclosporine

OR

(b) Documentation member has severe psoriatic arthritis [erosive disease, elevated markers of inflammation, long term damage that interferes with function, highly active disease that causes a major impairment in quality of life, active PsA at many sites including dactylitis, enthesitis, function-limiting PsA at a few sites or rapidly progressive disease]

OR

(c) Documentation member has severe psoriasis [PASI  $\geq$  12, BSA of >5-10%, significant involvement in specific areas (e.g., face, hands or feet, nails, intertriginous areas, scalp), impairment of physical or mental functioning with lower amount of surface area of skin involved]

AND

3. Documentation of prescriber baseline disease activity evaluation and goals for treatment to be used to evaluate efficacy of therapy at renewal

### B. CHRONIC PLAQUE PSORIASIS:

1. Documented diagnosis of moderate to severe psoriasis (BSA 3%-10%-moderate, >10%-severe) OR  $\leq$ 10% body surface area with plaque psoriasis that involves sensitive areas of the body or areas that would significantly impact daily function (ex. face, neck, hands, feet, genitals)

AND

2. (a) Documentation of treatment failure with or a clinical contraindication to TWO of the following systemic therapies for  $\geq$ 3 months: Methotrexate (oral or IM at a minimum dose of 15 mg/week), cyclosporine, acitretin, azathioprine, hydroxyurea, leflunomide, mycophenolate mofetil, sulfasalazine, or tacrolimus

OR

(b) Documentation of treatment failure to Phototherapy for  $\geq$ 3 months with either psoralens with ultraviolet A (PUVA) or ultraviolet B (UVB) radiation (provider to submit documentation of duration of treatment, dates of treatment, and number of sessions; contraindications include type 1 or type 2 skin, history of photosensitivity, treatment of facial lesions, presence of premalignant lesions, history of melanoma or squamous cell carcinoma, or physical inability to stand for the required exposure time)

AND

3. Documentation of prescriber baseline disease activity evaluation and goals for treatment to be used to evaluate efficacy of therapy at renewal

## Drug and Biologic Coverage Criteria

### C. MODERATE TO SEVERE ANKYLOSING SPONDYLITIS:

1. Documentation of moderate to severe ankylosing spondylitis diagnosis  
AND
2. Prescriber attestation of member having an inadequate response or FDA labeled contraindication to TWO NSAIDs (e.g., ibuprofen, naproxen, etodolac, meloxicam, indomethacin) for  $\geq 3$  consecutive months at maximal recommended or tolerated anti-inflammatory doses  
AND
3. FOR THOSE MEMBERS WITH PROMINENT PERIPHERAL ARTHRITIS: Documentation of trial ( $\geq 3$  consecutive months) or FDA labeled contraindication to methotrexate OR sulfasalazine  
AND
4. Documentation of prescriber baseline disease activity evaluation and goals for treatment to be used to evaluate efficacy of therapy at renewal

### D. NON-RADIOGRAPHIC AXIAL SPONDYLOARTHRITIS:

1. Prescriber attests to diagnosis of adult-onset active axial spondylarthritis  
AND
2. Documentation that C-reactive protein (CRP) levels are above the upper limit of normal and/or sacroiliitis on magnetic resonance imaging (MRI), indicative of inflammatory disease  
AND
3. Documentation that there is no definitive radiographic evidence of structural damage on sacroiliac joints.  
AND
4. Documentation member has active disease and prescriber provides baseline disease activity evaluation and goals for treatment to be used to evaluate efficacy of therapy at renewal  
AND
5. Prescriber attestation of member having an inadequate response or FDA labeled contraindication to TWO NSAIDs (e.g., ibuprofen, naproxen, etodolac, meloxicam, indomethacin) for  $\geq 3$  consecutive months at maximal recommended or tolerated anti-inflammatory doses

### E. ENTHESITIS RELATED ARTHRITIS:

1. Documented diagnosis of Enthesitis related arthritis  
AND
2. Documentation of member trial (4 weeks) and failure of preferred formulary Nonsteroidal anti-inflammatory drugs (NSAIDs)  
AND
3. Documentation of member weight (within the last 30 days)

## CONTINUATION OF THERAPY:

### A. ALL INDICATIONS

1. Adherence to therapy at least 85% of the time as verified by the prescriber or member medication fill history OR adherence less than 85% of the time due to the need for surgery or treatment of an infection, causing temporary discontinuation (documentation required)  
AND
2. Documentation of no intolerable adverse effects or drug toxicity  
AND
3. Documentation of positive clinical response as demonstrated by low disease activity and/or improvements in the condition's signs and symptoms.  
AND
4. (a) Prescriber attests member has had a negative TB screening or TB test result within the last 12 months for initial and continuation of therapy requests  
OR

## Drug and Biologic Coverage Criteria

(b) For members who have a positive test for latent TB, provider documents member has completed a treatment course (a negative chest x-ray is also required every 12 months) OR that member has been cleared by an infectious disease specialist to begin treatment

### **DURATION OF APPROVAL:**

Initial authorization: 6 months, Continuation of therapy: 12 months

### **PRESCRIBER REQUIREMENTS:**

PSORIATIC ARTHRITIS (PsA): Prescribed by or in consultation with a board-certified rheumatologist or dermatologist

CHRONIC PLAQUE PSORIASIS: Prescribed by or in consultation with a board-certified dermatologist

MODERATE TO SEVERE ANKYLOSING SPONDYLITIS and NON-RADIOGRAPHIC AXIAL SPONDYLOARTHRITIS, ENTHSITIS RELATED ARTHRITIS: Prescribed by or in consultation with a board-certified rheumatologist

[If prescribed in consultation, consultation notes must be submitted within initial request and reauthorization requests]

### **AGE RESTRICTIONS:**

Moderate to severe plaque psoriasis: 6 years of age or older

Active psoriatic arthritis (PsA): 2 years of age and older

Ankylosing spondylitis (AS), Non-Radiographic Axial Spondyloarthritis: 18 years of age or older

Enthesitis related arthritis: 4 years of age and older

### **QUANTITY:**

Plaque Psoriasis:

Adults ( $\geq 18$  years of age) - Recommended dosage is 300 mg by subcutaneous injection at Weeks 0, 1, 2, 3, and 4 followed by 300 mg every 4 weeks. For some patients, a dose of 150 mg may be acceptable. Pediatric patients (6 years to  $< 18$  years of age) - based on body weight and is administered at weeks 0, 1, 2, 3, and 4, followed by dosing every 4 weeks [Less than 50kg - 75mg; Greater than or equal to 50 kg - 150mg]

Psoriatic Arthritis:

For adult psoriatic arthritis patients with coexistent moderate to severe plaque psoriasis use the dosage and administration for plaque psoriasis

For other psoriatic arthritis patients, administer with or without a loading dosage.

With a loading dosage: 150 mg at Weeks 0, 1, 2, 3, and 4 and every 4 weeks thereafter;

Without a loading dosage: 150 mg every 4 weeks. If a member continues to have active psoriatic arthritis, consider a dosage of 300 mg every 4 weeks.

2 years of age and older- Recommended dosage is administered by subcutaneous injection at Weeks 0, 1, 2, 3, and 4 and every 4 weeks thereafter. For patients weighing  $\geq 15$  kg and  $< 50$  kg the dose is 75 mg, For patients weighing  $\geq 50$  kg the dose is 150 mg.

Ankylosing Spondylitis:

With a loading dosage: 150 mg at Weeks 0, 1, 2, 3, and 4 and every 4 weeks thereafter.

Without a loading dosage: 150 mg every 4 weeks, if a member continues to have active ankylosing spondylitis, consider a dosage of 300 mg every 4 weeks.

Non-radiographic Axial Spondyloarthritis:

With a loading dosage: 150 mg at weeks 0, 1, 2, 3, and 4 and every 4 weeks thereafter Without a loading dosage: 150 mg every 4 weeks

Enthesitis related arthritis:

For patients weighing  $\geq 15$  kg and  $< 50$  kg the dose is 75 mg at Weeks 0, 1, 2, 3, and 4 and

Drug and Biologic Coverage Criteria

every 4 weeks  
For patients weighing ≥ 50 kg the dose is 150 mg at Weeks 0, 1, 2, 3, and 4 and every 4 weeks

PLACE OF ADMINISTRATION:

The recommendation is that injectable medications in this policy will be for pharmacy benefit coverage and patient self-administered.

DRUG INFORMATION

ROUTE OF ADMINISTRATION:

Subcutaneous

DRUG CLASS:

Antipsoriatics – Systemic

FDA-APPROVED USES:

Indicated for the treatment of:

- moderate to severe plaque psoriasis in patients 6 years and older who are candidates for systemic therapy or phototherapy
- active psoriatic arthritis(PsA) in patients 2 years of age and older
- adults with active ankylosing spondylitis (AS)
- adults with active non-radiographic axial spondyloarthritis (nr-axSpA) with objective signs of inflammation
- active enthesitis-related arthritis (ERA) in patients 4 years of age and older

COMPENDIAL APPROVED OFF-LABELED USES:

None

APPENDIX

APPENDIX:

To meet the CASPAR criteria, a patient must have inflammatory articular disease (joint, spine, or enthesal) with ≥3 points from any of the following five categories:

- |    |  |
|----|--|
| 1. | Evidence of current psoriasis, <sup>b,c</sup> a personal history of psoriasis, or a family history of psoriasis <sup>d</sup> |
| 2. | Typical psoriatic nail dystrophy <sup>e</sup> observed on current physical examination                                       |
| 3. | A negative test result for rheumatoid factor   |
| 4. | Either current dactylitis or a history of dactylitis recorded by a rheumatologist  |
| 5. | Radiographic evidence of juxtaarticular new bone information <sup>g</sup> in the hand or foot                                |

<sup>a</sup> Specificity of 99% and sensitivity of 91%. <sup>b</sup> Current psoriasis is assigned 2 points; all other features assigned 1 point. Psoriatic skin or scalp disease at the time of examination, as judged by a rheumatologist or dermatologist. <sup>c</sup> H

hyperkeratosis. <sup>f</sup> Swelling of an entire digit. <sup>g</sup> Ill-defined ossification near joint margins, excluding osteophyte formation.  
Source: From W Taylor et al: Arthritis Rheum, 54:2665,2006.

Psoriatic Arthritis

An estimated 1% of the U.S. adult population harbors cutaneous evidence of psoriasis, characterized by well-demarcated erythematous scaly plaques, some of whom develop a related arthritis. In fact, there are several distinct subsets of psoriatic arthritis, including (a) an asymmetric oligoarthritis affecting lower extremity joints; (b) a symmetric polyarthritis affecting upper and lower extremity joints; (c) monoarticular involvement of a distal interphalangeal joint alone; (d) a destructive finger joint arthritis that produces “telescoping,” a shortening of the digit as a consequence of aggressive bone destruction and resorption (arthritis mutilans); and (e) axial skeleton involvement (spondylitis, sacroiliitis).

### BACKGROUND AND OTHER CONSIDERATIONS

#### BACKGROUND:

Cosentyx, a human interleukin (IL)-17A antagonist, is indicated for moderate to severe plaque psoriasis, active psoriatic arthritis (PsA), and ankylosing spondylitis (AS) in adults. It is a recombinant human monoclonal Immunoglobulin G (IgG)1/k antibody binds specifically to the IL-17A cytokine and inhibits its interaction with the IL-17 receptor. IL-17A is a naturally occurring cytokine involved in normal inflammatory and immune responses; therefore, Cosentyx inhibits the release of proinflammatory cytokines and chemokines. The recommended dose for plaque psoriasis is 300 mg by subcutaneous (SC) injection at every week for five doses followed by 300 mg every 4 weeks thereafter. For some patients, a dose of 150 mg may be acceptable. Recommended dosing for active psoriatic arthritis (PsA) and ankylosing spondylitis (AS) is either: a loading dose of 150 mg at weeks 0, 1, 2, 3, and 4 and 150 mg every four weeks thereafter or 150 mg every four weeks without a loading dose. For PsA the dose can be increased to 300 mg. Cosentyx is intended for use under the guidance and supervision of a physician. Those trained in SC injection technique using the pen or prefilled syringe may self-inject when deemed appropriate.

Cosentyx is indicated for moderate to severe plaque psoriasis in adults who are candidates for systemic therapy or phototherapy. Guidelines developed by the National Psoriasis Foundation Medical Board (2012), prior to the availability of Cosentyx, note that Stelara, Humira, and Enbrel are appropriate first-line biologics for treatment of psoriasis. It is also stated that oral agents for psoriasis (i.e., acitretin, cyclosporine, and MTX) may be used first line in various clinical situations. For example, acitretin is a first-line systemic drug for palmoplantar or pustular psoriasis and is especially useful in those with severely sun damaged skin, in which it may suppress actinic keratosis and even invasive malignant neoplasms. Cyclosporine may be effective long-term but is normally reserved for intermittent use (up to 12 weeks) to control a flare so the member can transition to another drug for long-term maintenance. When used intermittently, a course of cyclosporine can induce an average decrease of > 75% in psoriasis severity. MTX is considered a first-line systemic agent for plaque psoriasis that may be used continuously for many years or decades with durable benefits. Cosentyx is also indicated for active psoriatic arthritis (PsA) and ankylosing spondylitis (AS). Guidelines have yet to be updated to address Cosentyx for these indications. Initial therapy for moderate or severe active PsA currently recommends methotrexate and/or TNF blockade. For ankylosing spondylitis, guidelines strongly recommend use of nonsteroidal anti-inflammatory drugs (NSAIDs) and use of tumor necrosis factor inhibitors (TNFi) if activity persists despite NSAID treatment. For patients with active nonradiographic axial SpA despite treatment with NSAIDs, guidelines conditionally recommend treatment with TNFi.

#### CONTRAINDICATIONS/EXCLUSIONS/DISCONTINUATION:

All other uses of Cosentyx (secukinumab) are considered experimental/investigational and therefore, will follow Molina's Off-Label policy. Contraindications include: Serious hypersensitivity to secukinumab or any component of the formulation, Inflammatory bowel disease, Chronic infection, other active serious infections or a history of recurrent infections.

#### OTHER SPECIAL CONSIDERATIONS:

None

### CODING/BILLING INFORMATION

*Note: 1) This list of codes may not be all-inclusive. 2) Deleted codes and codes which are not effective at the time the service is rendered may not be eligible for reimbursement*

## Drug and Biologic Coverage Criteria

HPCCS CODE	DESCRIPTION
N/A	N/A

### AVAILABLE DOSAGE FORMS:

Cosentyx Sensoready Pen SOAJ 150MG/ML  
 Cosentyx Sensoready 300 Dose SOAJ 150MG/ML  
 Cosentyx SOSY 150MG/ML  
 Cosentyx 300 Dose SOSY 150MG/ML  
 Cosentyx SOSY 75MG/0.5 ML

### REFERENCES

1. Cosentyx™[prescribing information]. East Hanover, NJ: Novartis Pharmaceuticals; December 2021.
2. Novartis. Secukinumab (AIN457) Advisory Committee briefing material. Release date September 12, 2014. Available at: <http://www.fda.gov/downloads/AdvisoryCommittees/CommitteesMeetingMaterials/Drugs/DermatologicandOphthalmicDrugsAdvisoryCommittee/UCM419023.pdf>.
3. Langley RG, Elewski BE, Lebwohl M, et al. Secukinumab in plaque psoriasis—results of two phase 3 trials. N Engl J Med. 2014;371(4):326-338.
4. Blauvelt A, Prinz JC, Gottlieb AB, et al. Secukinumab Administration by Pre-filled Syringe: Efficacy, Safety, and Usability Results from a Randomized Controlled Trial in Psoriasis (FEATURE). Br J Dermatol. 2014 Aug 16. [Epub ahead of print].
5. Paul C, Lacour JP, Tedremets L, et al. Efficacy, safety and usability of secukinumab administration by autoinjector/pen in psoriasis: a randomized, controlled trial (JUNCTURE). J Eur Acad Dermatol Venereol. 2014 Sep 22. [Epub ahead of print].
6. Hsu S, Papp KA, Lebwohl MG, et al. Consensus guidelines for the management of plaque psoriasis. Arch Dermatol. 2012;148(1):95-102.
7. Baeten D, Baraliakos X, Braun J, et al. Anti-interleukin-17A monoclonal antibody secukinumab in treatment of ankylosing spondylitis: a 4 randomized, double-blind, placebo-controlled trial. Lancet. 2013;382(9906):1705-1713.
8. Furst DE, Keystone EC, So AK, et al. Updated consensus statement on biological agents for the treatment of rheumatic diseases, 2012. Ann Rheum Dis. 2013;72 Suppl 2:ii2-34.
9. Otezla® tablets [prescribing information]. Summit, NJ: Celgene Corporation; March 2014.
10. Hueber W, Sands BE, Lewitzky S, et al. Secukinumab, a human anti-IL-17A monoclonal antibody, for moderate to severe Crohn's disease: unexpected results of a 4 randomized, double-blind placebo-controlled trial. Gut. 2012;61(12):1693-1700.
11. McInnes IB, Sieper J, Braun J, et al. Efficacy and safety of secukinumab, a fully human anti-interleukin-17A monoclonal antibody, in patients with moderate-to-severe psoriatic arthritis: a 24-week, 4 randomized, double-blind, placebo-controlled, phase II proof-of-concept trial. Ann Rheum Dis. 2014;73(2):349-356.
12. Genovese MC, Durez P, Richards HB, et al. One-year efficacy and safety results of secukinumab in patients with rheumatoid arthritis: phase II, dose-finding, double-blind, randomized, placebo-controlled study. J Rheumatol. 2014 Mar;41(3):414-21.
13. Genovese MC, Durez P, Richards HB, et al. Efficacy and safety of secukinumab in patients with rheumatoid arthritis: a phase II, dose-finding, double-blind, 4 randomized, placebo-controlled study. Ann Rheum Dis. 2013;72(6):863-869.
14. Strand V, Kosinski M, Gnanasakthy A, et al. Secukinumab treatment in rheumatoid arthritis associated with incremental benefit in the clinical outcomes and HRQoL improvements that exceed minimally important thresholds. Health Qual Life Outcomes. 2014;12:31.

## Drug and Biologic Coverage Criteria

15. Dick AD, Tugal-Tutkun I, Foster S, et al. Secukinumab in the treatment of noninfectiousuveitis: results of three randomized, controlled clinical trials. *Ophthalmology*. 2013;120(4):777-787.
16. Flatø B, Hoffmann-Vold AM, Reiff A, et al. Long-term outcome and prognostic factors in enthesitis-related arthritis: a case-control study. *Arthritis Rheum* 2006; 54:3573
17. Weiss PF, Beukelman T, Schanberg LE, et al. Enthesitis-related arthritis is associated with higher pain intensity and poorer health status in comparison with other categories of juvenile idiopathic arthritis: the Childhood Arthritis and Rheumatology Research Alliance Registry. *J Rheumatol* 2012; 39:2341.