

PHARMACY POLICY STATEMENT

Indiana Medicaid

DRUG NAME	Cosentyx (secukinumab)
BILLING CODE	Must use valid NDC code
BENEFIT TYPE	Pharmacy
SITE OF SERVICE ALLOWED	Home
COVERAGE REQUIREMENTS	Prior Authorization Required (Preferred Product) QUANTITY LIMIT— 1 per 28 days (after loading dose)
LIST OF DIAGNOSES CONSIDERED NOT MEDICALLY NECESSARY	Click Here

Cosentyx (secukinumab) is a **preferred** product and will only be considered for coverage under the **pharmacy** benefit when the following criteria are met:

Members must be clinically diagnosed with one of the following disease states and meet their individual criteria as stated.

ANKYLOSING SPONDYLITIS (AS)

For **initial** authorization:

1. Member must be 18 years of age or older; AND
2. Must have a documented negative TB test (i.e., tuberculosis skin test (PPD), an interferon-release assay (IGRA)) within 12 months prior to starting therapy; AND
3. Medication must be prescribed by a rheumatologist; AND
4. Member has had back pain for 3 months or more that began before the age of 50; AND
5. Current imaging results show an inflammation of one or both of the sacroiliac joints; AND
6. Member shows at least **one** of the following signs or symptoms of Spondyloarthritis:
 - a) Arthritis;
 - b) Elevated serum C-reactive protein;
 - c) Inflammation at the tendon, ligament or joint capsule insertions;
 - d) Positive HLA-B27 test;
 - e) Limited chest expansion;
 - f) Morning stiffness for 1 hour or more; AND
7. Member meets at least **one** of the following scenarios:
 - a) Member has Axial (spinal) disease;
 - b) Member has peripheral arthritis without axial involvement and has tried and failed treatment with methotrexate or sulfasalazine. Treatment failure requires at least 3 months of therapy without an adequate response; AND
8. Member has tried and failed to respond to treatment with at least **two** prescription NSAIDs taken at the maximum recommended dosages. Treatment failure requires at least 4 weeks of therapy with each NSAID without an adequate response.
9. **Dosage allowed:** With a loading dosage is 150 mg at weeks 0, 1, 2, 3, and 4 and every 4 weeks thereafter; without a loading dosage is 150 mg every 4 weeks.

If member meets all the requirements listed above, the medication will be approved for 12 months.

For **reauthorization**:

1. Member must be retested for TB with a negative result within the past 12 months; AND
2. Member must be in compliance with all other initial criteria; AND
3. Chart notes have been provided that show the member has shown improvement of signs and symptoms of disease.

If member meets all the reauthorization requirements above, the medication will be approved for an additional 12 months.

PLAQUE PSORIASIS (PsO)

For **initial** authorization:

1. Member must be 18 years of age or older; AND
2. Must have a documented negative TB test (i.e., tuberculosis skin test (PPD), an interferon-release assay (IGRA)) within 12 months prior to starting therapy; AND
3. Medication must be prescribed by a rheumatologist or dermatologist; AND
4. Member has PsO involves 10% or more of the member's body surface area; AND
5. Member's Psoriasis Area and Severity Index (PASI) score is greater than or equal to 12; AND
6. Member has tried and failed to respond to treatment with at least **one** of the following:
 - a) At least 12 weeks of photochemotherapy (i.e., psoralen plus ultraviolet A therapy);
 - b) At least 12 weeks of phototherapy (i.e., UVB light therapy, Excimer laser treatments) (tanning beds emit mostly UVA light and therefore would not meet this criteria).
 - c) At least a 4 week trial with topical antipsoriatic agents (i.e., anthralin, calcipotriene, coal tar, corticosteroids, tazarotene); AND
7. Member has tried and failed to respond to treatment with traditional first-line oral/systemic therapies (i.e., cyclosporine, methotrexate, acitretin) for at least a 12 week trial.
8. **Dosage allowed:** 300 mg by subcutaneous injection at Weeks 0, 1, 2, 3, and 4 followed by 300 mg every 4 weeks.

If member meets all the requirements listed above, the medication will be approved for 12 months.

For **reauthorization**:

1. Must have been retested for TB with a negative result within the past 12 months; AND
2. Member must be in compliance with all other initial criteria; AND
3. Chart notes have been provided that show the member has shown improvement of signs and symptoms of disease (e.g., documented member's PASI score improvement, etc.).

If member meets all the reauthorization requirements above, the medication will be approved for an additional 12 months.

PSORIATIC ARTHRITIS (PsA)

For **initial** authorization:

1. Member must be 18 years of age or older; AND
2. Must have a documented negative TB test (i.e., tuberculosis skin test (PPD), an interferon-release assay (IGRA)) within 12 months prior to starting therapy; AND
3. Medication must be prescribed by a rheumatologist or dermatologist; AND
4. Member meets at least **one** of the following scenarios:
 - a) Member has predominantly axial disease (i.e., sacroiliitis or spondylitis) as indicated by radiographic evidence; OR
 - b) Member has shown symptoms of predominantly axial disease (i.e., sacroiliitis or spondylitis) for more than 3 months (i.e., limited spinal range of motion, spinal morning stiffness for more than 30 minutes) AND has tried and failed to respond to treatment with at least 2 prescription NSAIDs taken at the maximum recommended dosages. Treatment failure requires at least 4 weeks of therapy with each NSAID without an adequate response; OR

- c) Member has predominately non-axial disease (e.g., peripheral synovitis or dactylitis or nail involvement) and has tried and failed to respond to treatment with at least 8-week trial of methotrexate and NSAID taken at the maximum recommended dosages (if unable to tolerate or has contraindication to methotrexate than 8-week trial of sulfasalazine or azathioprine or cyclosporine).
5. **Dosage allowed:** With a loading dosage is 150 mg at weeks 0, 1, 2, 3, and 4 and every 4 weeks thereafter; without a loading dosage is 150 mg every 4 weeks.

If member meets all the requirements listed above, the medication will be approved for 12 months.

For **reauthorization**:

1. Must have been retested for TB with a negative result within the past 12 months; AND
2. Member must be in compliance with all other initial criteria; AND
3. Chart notes have been provided that show the member has shown improvement of signs and symptoms of disease.

If member meets all the reauthorization requirements above, the medication will be approved for an additional 12 months.

CareSource considers Cosentyx (secukinumab) not medically necessary for the treatment of the following disease states based on a lack of robust clinical controlled trials showing superior efficacy compared to currently available treatments:

- Active infections
- Asthma
- Cellulitis
- Crohn's Disease
- Dissecting scalp cellulitis
- For use in combination with other TNF-inhibitors (i.e., Humira, Kineret, Enbrel, Remicade)
- Giant-cell arteritis
- Infectious uveitis
- Lupus perino
- Osteoarthritis
- Recurrent pregnancy loss
- Relapsing polychondritis
- Sarcoidosis
- Sciatica
- Spondyloarthritis (other than ankylosing spondylitis)
- Takayasu's arteritis
- Vogt-Koyanagi

DATE	ACTION/DESCRIPTION
05/08/2017	New policy for Cosentyx created. Policies SRx-0043 achieved. New diagnoses of AS and PsA with criteria were added. For diagnosis of PsO: immunosuppressive criterion was separated from phototherapies and topical agents trials; TNF inhibitors Humira and Enbrel were listed as required trials; Psoriasis Area and Severity Index (PASI) score requirement was added. List of diagnoses considered not medically necessary was added.
02/26/2019	Status changed to preferred. Trials of Humira and Enbrel removed from criteria. Clarifications entered for AS and PsA on NSAIDs trial length. References updated. TB test allowed to be done within 12 months prior to initiation of therapy; chest x-ray option

removed. Symptoms of back pain for AS extended till before age of 50. Other drugs options allowed for PsA if there is an intolerance or contraindication to methotrexate. “Immunosuppressant therapies” changed to “treatment of traditional first-line oral/systemic” therapies. Reauthorization criteria on documented member’s PASI score improvement incorporated into general chart noted documentation requirements.

References:

1. Cosentyx [package insert]. East Hanover, NJ:Novartis Pharmaceuticals Corporation; 2015. Accessed on May 1, 2017.
2. 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 May;58(5):826-50.
3. Gottlieb A, Korman NJ, Gordon KB, et al. Guidelines of care for the management of psoriasis and psoriatic arthritis: Section 2. Psoriatic arthritis: overview and guidelines of care for treatment with an emphasis on the biologics. *J Am Acad Dermatol*. 2008 May;58(5):851-64.
4. Menter A, Korman NJ, Elmets CA, Feldman SR, Gelfand JM, Gordon KB, et al. Guidelines of care for the management of psoriasis and psoriatic arthritis. Section 3. Guidelines of care for the management and treatment of psoriasis with topical therapies. *J Am Acad Dermatol*. 2009 Apr;60(4):643-59.
5. Menter A, Korman NJ, Elmets CA, et al. Guidelines of care for the management of psoriasis and psoriatic arthritis: section 4. Guidelines of care for the management and treatment of psoriasis with traditional systemic agents. *J Am Acad Dermatol*. 2009 Sep;61(3):451-85.
6. Menter A, Korman NJ, Elmets CA, Feldman SR, Gelfand JM, Gordon KB, et al. Guidelines of care for the management of psoriasis and psoriatic arthritis: Section 5. Guidelines of care for the treatment of psoriasis with phototherapy and photochemotherapy. *J Am Acad Dermatol*. 2010 Jan;62(1):114-35.
7. Menter A, Korman NJ, Elmets CA, Feldman SR, Gelfand JM, Gordon KB, Guidelines of care for the management of psoriasis and psoriatic arthritis: section 6. Guidelines of care for the treatment of psoriasis and psoriatic arthritis: case-based presentations and evidence-based conclusions. *J Am Acad Dermatol*. 2011 Jul;65(1):137-74.
8. Hsu S, Papp KA, Lebwohl MG, et al. Consensus guidelines for the management of plaque psoriasis. *Arch Dermatol*. 2012 Jan;148(1):95-102.
9. Braun J, et al. Secukinumab shows sustained efficacy and low structural progression in ankylosing spondylitis: 4-year results from the MEASURE 1 study. *Rheum. Key375*.
10. Bissonnette R, et al. Secukinumab demonstrates high sustained efficacy and a favorable safety profile through 5 years of treatment in moderate to severe psoriasis. *J Eur Acad Dermatol Venereol*. 2018 Sep;32(9):1507-1514.
11. Mease PJ, et al. Secukinumab Provides Sustained Improvements in the Signs and Symptoms of Active Psoriatic Arthritis through 3 Years: Efficacy and Safety Results from a Phase 3 Trial. *Ann Rheum Dis*. 2017;76:952-953.
12. Baeten D, et al. Secukinumab, interleukin-17A inhibition in ankylosing spondylitis. *N Engl J Med*. 2015;373:2534-48.
13. McInnes IB, et al. Secukinumab, a human anti-interleukin-17A monoclonal antibody, in patients with psoriatic arthritis (FUTURE 2): a randomised, double-blind, placebo-controlled, phase 3 trial. *Lancet*. 2015;386(9999):1137-1146.
14. Reich K, et al. Secukinumab, a fully human anti-interleukin-17A monoclonal antibody, exhibits minimal immunogenicity in patients with moderate-to-severe plaque psoriasis. *Br J Dermatol*. 2017;176:752-58.

Effective date: 04/01/2019

Revised date: 02/26/2019