

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— 2 injections per 28 days (after loading dose)
LIST OF DIAGNOSES CONSIDERED NOT MEDICALLY NECESSARY	Click Here

Cosentyx (secukinumab) is a **non-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) or NON-RADIOGRAPHIC AXIAL SPONDYLOARTHRITIS (nr-axSpA)

Note: Diagnosis of axial spondyloarthritis (axSpA) is also accepted. SpA comprises of 2 subtypes – ankylosing spondylitis (AS) and non-radiographic axial spondyloarthritis (nr-axSpA).

For **initial** authorization:

1. Member must be 18 years of age or older; AND
2. Member has a documented diagnosis of active ankylosing spondylitis (AS) or active non-radiographic axial spondyloarthritis (nr-axSpA); AND
3. Medication must be prescribed by or in consultation with a rheumatologist; AND
4. Must have a documented negative TB test (i.e., tuberculosis skin test (PPD), interferon-gamma release assay (IGRA)) within 12 months prior to starting therapy; AND
5. Member has had back pain for 3 months or more that began before the age of 50; AND
6. Member shows at least one of the following signs or symptoms of Spondyloarthritis:
 - a) Elevated serum C-reactive protein (CRP) or erythrocyte sedimentation rate (ESR);
 - b) Positive HLA-B27 test;
 - c) Sacroiliitis; AND
7. Member has tried and failed to respond to treatment with at least **two** NSAIDs taken at the maximum recommended dosages. Treatment failure requires at least 4 weeks of therapy with each NSAID without an adequate response.
8. **Dosage allowed:**
 - a) AS: 150 mg at Week 0, 1, 2, 3, and 4 and every 4 weeks thereafter (with loading dose) OR 150 mg every 4 weeks (no loading dose), may increase dose to 300 mg every 4 weeks if needed.
 - b) nr-axSpA: 150 mg at Week 0, 1, 2, 3, and 4 and every 4 weeks thereafter (with loading dose) OR 150 mg every 4 weeks (no loading dose). Max dose 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 in compliance with all other initial criteria; AND
2. Chart notes have been provided that show 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. Medication must be prescribed by or in consultation with a dermatologist; AND
3. Member has clinical documentation of moderate to severe plaque psoriasis characterized by 3% or more of body surface area (BSA) or disease affecting sensitive areas (e.g., hands, feet, face, genitals, etc.); AND
4. Must have a documented negative TB test (i.e., tuberculosis skin test (PPD), interferon-gamma release assay (IGRA)) within 12 months prior to starting therapy; AND
5. 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);
 - c) At least a 4 week trial with topical antipsoriatic agents (i.e., anthralin, calcipotriene, coal tar, corticosteroids, tazarotene, tacrolimus, pimecrolimus); AND
6. Member has tried and failed, or unable to tolerate a systemic non-biologic DMARD (i.e., cyclosporine, methotrexate, acitretin) for at least 12 weeks.
7. **Dosage allowed:** 300 mg (2 injections of 150 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. Member must be in compliance with all other initial criteria; AND
2. Chart notes have been provided that show the member has shown improvement of signs and symptoms of disease (e.g., documented member's BSA 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. Medication must be prescribed by or in consultation with a rheumatologist or a dermatologist; AND
3. Member has a documented diagnosis of active psoriatic arthritis (PsA); AND
4. Must have a documented negative TB test (i.e., tuberculosis skin test (PPD), interferon-gamma release assay (IGRA)) within 12 months prior to starting therapy; AND
5. Member has met a 4-week trial of an NSAID taken at maximally tolerated doses AND a 3-month trial of a non-biologic DMARD agent (e.g., methotrexate, sulfasalazine, cyclosporine, etc.) unless **one** of the following situations is met:
 - a) Non-biologic DMARD is not required for:
 - i) Concomitant axial disease (i.e., involving sacroiliac joint and spine) or enthesitis; OR
 - b) NSAID and non-biologic DMARD are not required for:

- i) Severe PsA (defined as having at least one of the following: erosive disease, active PsA at many sites including dactylitis or enthesitis, elevated levels of ESR or CRP, joint deformities, or major impairment in quality of life).
6. **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. May increase to 300 mg every 4 weeks if PsA is still active.

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

For **reauthorization**:

1. Member must be in compliance with all other initial criteria; AND
2. Chart notes have been provided that show 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 diseases that are not listed in this document.

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.
09/25/2020	For <u>AS</u> : Modified to include the new indication nr-axSpA. Modified signs/symptoms to only include inflammatory markers or sacroiliitis. Removed peripheral arthritis requirement – not relevant for this diagnosis. For <u>PsO</u> : Removed rheumatologist from prescriber. Changed BSA to 3% or sensitive area involvement. Removed PASI score requirement. For <u>PsA</u> : Added requirement of diagnosis of PsA. Changed the trial section to be 4 weeks of an NSAID AND 3 months of a DMARD unless other circumstances apply (e.g., concomitant axial disease, severe PsA, etc.). Removed repeat TB test for reauth for all diagnoses.
10/1/2021	Updated status to non-preferred

References:

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