CareSource Rxinnovations

PHARMACY POLICY STATEMENT
Marketplace

DRUG NAME	Cosentyx (secukinumab)
BILLING CODE	Must use valid NDC code
BENEFIT TYPE	Pharmacy
SITE OF SERVICE ALLOWED	Home
STATUS	Prior Authorization Required

Cosentyx is a human interleukin-17A antagonist initially approved by the FDA in 2015 for moderate-to-severe plaque psoriasis. Since then, it has also been granted approval for psoriatic arthritis, ankylosing spondylitis, non-radiographic axial spondylitis and enthesitis-related arthritis. This humanized IgG1 monoclonal antibody works by selectively binding to the IL-17 cytokine, inhibiting its interaction with the IL-17 receptor. IL-17 is a naturally occurring cytokine that is involved in inflammatory and immune responses.

Cosentyx (secukinumab) will be considered for coverage when the following criteria are met:

ANKYLOSING SPONDYLITIS (AS), NON-RADIOGRAPHIC AXIAL SPONDYLOARTHRITIS (nr-axSpA), or ENTHESITIS-RELATED ARTHRITIS (ERA)

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. Enthesitis-related arthritis: Member must be at least 4 years of age;
   Ankylosing spondylitis and non-radiographic axial spondylitis: Member must be at least 18 years of age; AND
2. Member has a documented diagnosis of active ankylosing spondylitis (AS), active non-radiographic axial spondyloarthritis (nr-axSpA) or active enthesitis-related arthritis; 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/Quantity limit:**
   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.

ERA: Based on body weight as shown below. Subcutaneous injection at weeks 0, 1, 2, 3, and 4 followed by every 4 weeks.

Body Weight at Time of Dosing	Recommended Dose
≥ 15 kg and less than 50 kg	75 mg
Greater than or equal to 50 kg	150 mg

If all the above requirements are met, the medication will be approved for 12 months.

For **reauthorization**:
1. Chart notes must show improvement or stabilized signs and symptoms of disease, demonstrated by improvement in joint pain, inflammation, morning stiffness, etc.

If all the above requirements are met, the medication will be approved for an additional 12 months.

PLAQUE PSORIASIS (PsO)

For **initial** authorization:
1. Member must be 6 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/Quantity limit:**
   Adult: 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.
   Pediatric: Based on body weight as shown below. Subcutaneous injection at weeks 0, 1, 2, 3, and 4 followed by every 4 weeks.

Body Weight at Time of Dosing	Recommended Dose
Less than 50 kg	75 mg
Greater than or equal to 50 kg	150 mg

If all the above requirements are met, the medication will be approved for 12 months.

For **reauthorization**:
1. Chart notes must show improvement or stabilized signs and symptoms of disease, demonstrated by BSA improvement, etc.

If all the above requirements are met, the medication will be approved for an additional 12 months.

PSORIATIC ARTHRITIS (PsA)

For **initial** authorization:
1. Member must be 2 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 conventional DMARD agent (e.g., methotrexate, sulfasalazine, cyclosporine, etc.) unless **one** of the following situations is met:
   a) Conventional DMARD is not required for:
      i) Concomitant axial disease (i.e., involving sacroiliac joint and spine) or enthesitis; OR
   b) NSAID and conventional 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/Quantity limit:**
   Adult: 150 mg by subcutaneous injection at weeks 0, 1, 2, 3, and 4 and every 4 weeks thereafter (with loading dose) OR 150 mg every 4 weeks (without loading dose). May increase to 300 mg every 4 weeks if PsA is still active
   Pediatric: Based on body weight as shown below. Subcutaneous injection at weeks 0, 1, 2, 3, and 4 followed by every 4 weeks.

Body Weight at Time of Dosing	Recommended Dose
≥ 15 kg and less than 50 kg	75 mg
Greater than or equal to 50 kg	150 mg

If all the above requirements are met, the medication will be approved for 12 months.

For **reauthorization**:
1. Chart notes must show improvement or stabilized signs and symptoms of disease, as demonstrated by improvement in joint pain, inflammation, skin lesions, etc.

If all the above requirements are met, the medication will be approved for an additional 12 months.

CareSource considers Cosentyx (secukinumab) not medically necessary for the treatment of conditions that are not listed in this document. For any other indication, please refer to the Off-Label policy.

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	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.
07/26/2021	Plaque psoriasis: Age indication expanded to include patients as young as 6 years.
02/04/2022	Transferred to new format. Lowered PsA age to 2 years and updated pediatric dosing. Lowered enthesitis-related arthritis to 4 years and updated pediatric dosing. Changed the wording of “non-biologic” DMARD to “conventional” DMARD. Clarified reauthorization criteria. Updated references.

References:

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Effective date: 04/01/2022
Revised date: 02/04/2022