CareSource Rxinnovations

PHARMACY POLICY STATEMENT
Georgia Medicaid

DRUG NAME	Cosentyx (secukinumab)
BENEFIT TYPE	Pharmacy or Medical
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, enthesitis-related arthritis and hidradenitis suppurativa. 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) 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 at least 18 years of age; AND
2. Member has a documented diagnosis of active AS, nr-axSpA or axSpA; AND
3. Medication must be prescribed by or in consultation with a rheumatologist; AND
4. Member shows **ONE** of the following signs or symptoms of inflammation:
   a) Elevated serum C-reactive protein (CRP);
   b) Sacroiliitis on magnetic resonance imaging (MRI); AND
5. Member has had a trial and failure of **TWO** NSAIDs for 14 days each, taken at the maximum recommended dosages; AND
6. Member has had a negative tuberculosis test within the past 12 months.
7. **Dosage allowed/Quantity limit:**
   a) Administer 150 mg subcutaneously at week 0, 1, 2, 3, and 4 and every 4 weeks thereafter; OR
   b) Administer 150 mg subcutaneously every 4 weeks. If member has diagnosis of AS, may consider a dosage of 300 mg subcutaneously every 4 weeks; OR
   c) Administer 6 mg/kg by IV infusion at week 0 followed by 1.75 mg/kg every 4 weeks thereafter (max maintenance dose 300 mg per infusion); OR
   d) Administer 1.75 mg/kg by IV infusion every 4 weeks (max maintenance dose 300 mg per infusion).

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. 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
5. Member has tried and failed, or unable to tolerate a systemic conventional DMARD (i.e., cyclosporine, methotrexate, acitretin) for at least 12 weeks; AND
6. Member has had a negative tuberculosis test within the past 12 months.
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: weight-based dosage (see below) is administered by subcutaneous injection at Weeks 0, 1, 2, 3, and 4 and every 4 weeks thereafter.

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) or or Enthesitis-related Arthritis (ERA)

For **initial** authorization:

1. For PsA, member must be at least 2 years of age; OR
2. For ERA, member must be at least 4 years of age; AND
3. Medication must be prescribed by or in consultation with a rheumatologist or a dermatologist; AND
4. Member has a documented diagnosis of active PsA or active ERA ; 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); AND
6. Member has had a negative tuberculosis test within the past 12 months.
7. **Dosage allowed/Quantity limit:**
   Adult:

a) Administer 150 mg by subcutaneous injection at weeks 0, 1, 2, 3, and 4 and every 4 weeks thereafter. May increase to 300 mg every 4 weeks if PsA is still active; OR
b) Administer 150 mg by subcutaneous injection every 4 weeks. May increase to 300 mg every 4 weeks if PsA is still active; OR
c) Administer 6 mg/kg by IV infusion at week 0 followed by 1.75 mg/kg every 4 weeks thereafter (max maintenance dose 300 mg per infusion); OR
d) Administer 1.75 mg/kg by IV infusion every 4 weeks (max maintenance dose 300 mg per infusion).

Pediatric:

a) Administer weight-based dosage (see below) is administered by 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.

Hidradenitis Suppurativa (HS)

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 a documented diagnosis of moderate to severe HS with Hurley stage II or III disease; AND
4. Member has been counseled on weight loss if they are overweight or obese; AND
5. Member is a non-smoker or has been counseled on smoking cessation and advised to quit; AND
6. Member has tried and failed at least **ONE** of the following:
   a. Topical clindamycin x 12 weeks and an oral tetracycline x 12 weeks (sequential or concomitant);
   b. Oral clindamycin plus rifampicin x 8-12 weeks; AND
7. Member has had a negative tuberculosis test within the past 12 months.
8. **Dosage allowed/Quantity limit:** Recommended dosage is 300 mg administered by subcutaneous injection at weeks 0, 1, 2, 3 and 4 and every 4 weeks thereafter. If a patient does not adequately respond, consider increasing the dosage to 300 mg every 2 weeks.

If all the above requirements are met, the medication will be approved for 6 months.

For **reauthorization**:

1. Chart notes must include documentation of a positive clinical response such as reduced count of total abscesses and inflammatory nodules or reduction of skin pain.

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.
11/08/2023	Added HS diagnosis; added/updated references; added IV dosing to applicable dx; simplified TB test requirement wording; added medical benefit option.
08/15/2024	Moved ERA into section with PsA. PsO: Changed the wording of “non-biologic” DMARD to “conventional” DMARD. AS/nr-axSpA: changed trial of each NSAID from 4 weeks to 2 weeks for a total of 4 weeks of treatment per EULAR 22 guidelines; removed criteria requiring back pain for 3 or more months before the age of 50; added that member must have elevated CRP or sacroiliitis on MRI per EULAR 22 guidelines; removed Positive HLA-B27 test from signs/symptoms of spondyloarthritis and changed to signs/symptoms inflammation; added axSpA to diagnosis list; removed duplicate dosing for AS and nr-axSpA.

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