Commercial PA Criteria

Effective: January 1, 2019

Prior Authorization: Cosentyx

Products Affected: Cosentyx (secukinumab) subcutaneous solution

Medication Description: Cosentyx is a human IgG1 monoclonal antibody that selectively binds to the interleukin-17A (IL-17A) cytokine and inhibits its interaction with the IL-17 receptor. IL-17A is a naturally occurring cytokine that is involved in normal inflammatory and immune responses. Cosentyx inhibits the release of proinflammatory cytokines and chemokines.

Covered Uses:

1. **Enthesitis-related arthritis**, in patients ≥ 4 years of age with active disease.
2. **Hidradenitis suppurativa**, in adults with moderate to severe disease.
3. **Plaque psoriasis**, in patients ≥ 6 years of age with moderate to severe disease who are candidates for systemic therapy or phototherapy.
4. **Psoriatic arthritis**, in patients ≥ 2 years of age with active disease.
5. **Ankylosing spondylitis**, in adults with active disease.
6. **Non-radiographic axial spondyloarthritis**, in adults with active disease and objective signs of inflammation.

Exclusion Criteria:

1. Concurrent use with other Biologics or DMARDs
2. Crohn's Disease
3. Rheumatoid Arthritis
4. Uveitis

Required Medical Information:

1. Diagnosis
2. Previous medications tried/failed

Age Restrictions:

1. Psoriatic Arthritis: 2 years of age or older
2. Ankylosing Spondylitis: 18 years of age or older
3. Plaque Psoriasis: 6 years of age or older
4. Non-radiographic Axial Spondyloarthritis: 18 years of age or older
5. Enthesitis-Related Arthritis: 4 years of age or older
6. Hidradenitis suppurativa: 18 years of age or older

Prescriber Restrictions:

Psoriatic Arthritis: Must be prescribed by or in consultation with a rheumatologist or dermatologist

Enthesitis-Related Arthritis, Ankylosing Spondylitis & Non-radiographical Axial Spondyloarthritis: Must be prescribed by, or in consultation with, a rheumatologist.
Plaque Psoriasis, Hidradentis Suppurativa: Must be prescribed by or in consultation with a dermatologist.

Coverage Duration:
Initial: 3 months, 6 months (as per criteria)
Continuation: 1 year

Other Criteria:

1. **Ankylosing Spondylitis**
   Initial therapy: Approve for 6 months if the patient meets the following criteria;
   A. Patient has clinically diagnosed ankylosing spondylitis **AND**
   B. Prescribed by or in consultation with a rheumatologist **AND**
   C. Patient must have a trail and documented failure of, or intolerance to, **TWO** of the following medications
   Note: Examples of adalimumab products include Humira, Abrilada, adalimumab-adaz, adalimumab-adbm, adalimumab-fkjp, adalimumab-aaty, adalimumab-ryvk, Simlandi, Amjevita, Cyltezo, Hadlima, Hulio, Hyrimoz, Idacio, Yuflyma, and Yusimry. A trial of multiple adalimumab products counts as ONE product. A trial of either or both Xeljanz products (Xeljanz and Xeljanz XR) collectively counts as ONE product. A trial of Cimzia, an infliximab product (e.g. Remicade, biosimilars), or Simponi (Aria or subcutaneous) also counts [documentation required].

Ankylosing Spondylitis
Enbrel
Adalimumab Product
Taltz
Rinvoq
Xeljanz/XR

2. **Enthesitis-Related Arthritis**
   Initial therapy: Approve for 6 months if the patient meets the following criteria;
   A. Patient has clinically diagnosed enthesis-related arthritis **AND**
   B. Prescribed by or in consultation with a rheumatologist

3. **Hidradenitis Suppurativa**
   Initial therapy: Approve for 3 months if the patient meets the following criteria;
   A. Patient has tried at least one other therapy; **AND**
   Note: Examples include intralesional or oral corticosteroids (e.g., triamcinolone, prednisone), systemic antibiotics (e.g., clindamycin, dicloxacillin, erythromycin), and isotretinoin.
   B. The medication is prescribed by or in consultation with a dermatologist.

4. **Non-Radiographic Axial Spondyloarthritis**
   Initial therapy: Approve for 6 months if the patient meets the following criteria;
   A. Patient has objective signs of inflammation, defined as at least ONE of the following (i **OR** ii):

i. C-reactive protein elevated beyond the upper limit of normal for the reporting laboratory; **OR**
ii. Sacroiliitis reported on magnetic resonance imaging; **AND**

B. Patient must have a trail and documented failure of, or intolerance to, **TWO** of the following medications
Note: A trial of Enbrel, an adalimumab product (e.g., Humira, Abrilada, adalimumab-adaz, adalimumab-adbm, adalimumab-fkjp, adalimumab-aaty, adalimumab-ryvk, Simlandi, Amjevita, Cyltezo, Hadlima, Hulio, Hyrimoz, Idacio, Yuflyma, and Yusimry), an infliximab product (e.g., Remicade, biosimilars), or Simponi (Aria or subcutaneous) also counts [documentation required]. A trial of multiple adalimumab products counts as ONE product.

Non-Radiographic Spondyloarthritis (nr-axSpA)
Cimzia
Taltz
Rinvoq

5. Plaque Psoriasis
Initial therapy: Approve for 3 months if the patient meets the following criteria;

A. Patient has a documented failure of, or intolerance to, or contraindication to at least one traditional systemic agent for at least 3 months **AND**
Note: Examples include methotrexate, cyclosporine, acitretin, or psoralen plus ultraviolet A light (PUVA). An exception to the requirement for a trial of one traditional systemic agent for psoriasis can be made if the patient has already had a 3-month trial or previous intolerance to at least one biologic other than Cosentyx. A biosimilar of Cosentyx does not count. A patient who has already tried a biologic for psoriasis is not required to "step back" and try a traditional systemic agent for psoriasis.

B. Patient has a contraindication to methotrexate, as determined by the prescriber; **AND**

C. Patient must have a trial and documented failure of, or intolerance to, **TWO** of the following medications
Note: Examples of adalimumab products include Humira, Abrilada, adalimumab-adaz, adalimumab-adbm, adalimumab-fkjp, adalimumab-aaty, adalimumab-ryvk, Simlandi, Amjevita, Cyltezo, Hadlima, Hulio, Hyrimoz, Idacio, Yuflyma, and Yusimry. A trial of multiple adalimumab products counts as ONE product.

Plaque Psoriasis
Enbrel
Adalimumab Product
Otezla
Skyrizi SQ
Sotyktu
Stelara SQ
Taltz
Tremfya

6. <u>Psoriatic Arthritis</u>

Initial Therapy: Approve for 6 months if the patient meets the following criteria

A. Patient has clinically diagnosed psoriatic arthritis **AND**

B. Prescribed by or in consultation with a rheumatologist or dermatologist **AND**

C. Patient meets one of the following (i **OR** ii)

i. Patient is ≥ 18 years of age **AND** must have a trail and documented failure of, or intolerance to, **TWO** of the following medications **OR**

Note: Examples of adalimumab products include Humira, Abrilada, adalimumab-adaz, adalimumab-adbm, adalimumab-fkjp, adalimumab-aaty, adalimumab-ryvk, Simlandi, Amjevita, Cyltezo, Hadlima, Hulio, Hyrimoz, Idacio, Yuflyma, and Yusimry. A trial of multiple adalimumab products counts as ONE product. A trial of Cimzia, an infliximab product (e.g., Remicade, biosimilars), or Simponi (subcutaneous or Aria) also counts toward a trial of a TNFi [documentation required]. For a patient < 18 years of age, a trial of another TNFi counts towards a trial of Enbrel [documentation required]. A trial of either or both Xeljanz products (Xeljanz and Xeljanz XR) collectively counts as ONE product. A trial of either or both Rinvoq products (Rinvoq and Rinvoq LQ) collectively counts as ONE product.

Psoriatic Arthritis
Enbrel
Adalimumab product
Otezla
Stelara SC
Taltz
Tremfya
Skyrizi SQ
Rinvoq / Rinvoq LQ
Xeljanz/XR

ii. Patient is < 18 years of age AND must have a trail and documented failure of, or intolerance to ONE of the following medications

Psoriatic Arthritis
Enbrel
Rinvoq / Rinvoq LQ
Stelara SC

<u>Continuation</u>

A. Patient has been established on therapy for at least 3-6 months; **AND**

Note: A patient who has received < 3-6 months of therapy or who is restarting therapy is reviewed under Initial Therapy criteria.

B. When assessed by at least one objective measure, patient experienced a beneficial clinical response from baseline (prior to initiating Cosentyx)

References:

1. COSENTYX® subcutaneous injection, secukinumab subcutaneous injection. Novartis Pharmaceuticals Corporation (per FDA), East Hanover, NJ, 2018.

Policy Revision history

Rev #	Type of Change	Summary of Change	Sections Affected	Date
1	New Policy	New Policy	All	01/01/2019
2	Update	Update	Coverage Duration: Continuation Update to 3 years	07/01/2019
3	Update	Removal of DMARD use for Ankylosing Spondylitis	Other Criteria	07/19/2019
4	Update	Added Dosing Limitations according to FDA label	Other Criteria	5/4/2020
5	Update	Added new indication: Non-radiographical Axial Spondyloarthritis Updated prescriber restrictions for Non-radiographical Axial Spondyloarthritis Added clinical criteria for Non-radiographical Axial Spondyloarthritis	Covered uses Prescriber restrictions Other criteria	6/23/2020
6	Update	Added criteria to require the use of TWO preferred products prior to Cosentyx for PsA, Ankylosing Spondylitis, and Non-radiographic Axial Spondyloarthritis Added criteria to require the use of THREE preferred products prior to Cosentyx for Psoriasis Removed Patient has chronic (greater than or equal to 1 year) plaque psoriasis	Other criteria	1/1/2021
7	Update	Added Enthesitis-Related Arthritis to Covered Uses Updated Age restriction of Psoriatic Arthritis to 2 years old and older Added ERA to Age restrictions and Prescriber restrictions Added dosing for ERA Added pediatric dosing for Psoriatic Arthritis Added Criteria for ERA Updated Criteria for plaque psoriasis to require use of FOUR preferred agents Updated criteria for PsA to require use of THREE preferred agents	Covered Uses Age Restriction Prescriber Restriction Dosing Limits Other Criteria	2/23/22
8	Update	Added Rinvoq as preferred option for Ankylosing Spondylitis	Other Criteria	5/20/2022
9	Update	Added Rinvoq as a preferred option for Non-radiographic Axial Spondyloarthritis	Other Criteria	11/2022
10	Update	Other Criteria: replaced “Humira” with “adalimumab”	Other Criteria	5/16/2023

11	Update	Addition of Hidradenitis suppurativa, in adults with moderate to severe disease. Addition to Exclusion Criteria - Concurrent use with other Biologics or DMARDs, Crohn's Disease, Rheumatoid Arthritis, Uveitis Removal of dosing limitations Removed Ankylosing Spondylitis/ Enthesitis-Related Arthritis/ Non-Radiographic Axial Spondyloarthritis/ Plaque Psoriasis criteria and revised select criteria to implement to label coverage. Removal of ConnectiCare does not consider alcohol use to be a clinical reason to use Cosentyx over methotrexate.	Covered uses Exclusion Criteria Prescriber Restrictions	12/21/2023
12	Update	Clarification for initial timeframe for approval based on indication. Notes added into step requirements for Ankylosing Spondylitis, Plaque Psoriasis, Psoriatic Arthritis and Non-Radiographic Spondyloarthritis (nr-axSpA) – Initial Therapy.	Other Criteria	5/22/2024
13	Update Policy	For Plaque Psoriasis, Cosentyx subcutaneous was moved from Step 3c to Step 3a. A trial of two Step 1 or Step 2 Products is required (previously was two Step 1 Products). Sotyktu was added as a Step 1 Product that may have been tried prior to Cosentyx subcutaneous. For Psoriatic Arthritis, Rinvoq LQ was added as a Step 2 Product that may have been tried prior to Cosentyx subcutaneous. For Ankylosing Spondylitis, Psoriatic Arthritis, and Plaque Psoriasis, Simlandi and adalimumab-ryvk were added to the list of Preferred adalimumab products that may have been tried prior to Cosentyx subcutaneous.	Other Criteria	6/11/2024