UnitedHealthcare Community Plan

Clinical Pharmacy Program Guidelines for Cosentyx

Program	Prior Authorization
Medication	Cosentyx (secukinumab)
Markets in Scope	Colorado, California, Hawaii, Maryland, Nevada, New Jersey, New York, Pennsylvania- CHIP, Rhode Island, South Carolina
Issue Date	3/2015
Pharmacy and Therapeutics Approval Date	11/2020
Effective Date	12/2020

1. Background:

Cosentyx (secukinumab) is a human interleukin-17A antagonist indicated for the treatment of moderate to severe plaque psoriasis in adult patients who are candidates for systemic therapy or phototherapy. It is also indicated for the treatment of adult patients with active psoriatic arthritis, active non-radiographic axial spondyloarthritis with objective signs of inflammation, or active ankylosing spondylitis.

2. Coverage Criteria:

A. Plaque Psoriasis

1. Initial Authorization

One of the following:

(1) **All** of the following:

a. Diagnosis of moderate to severe plaque psoriasis

-AND-

b. Greater than or equal to 3% body surface area involvement, palmoplantar, facial, or genital involvement, or severe scalp psoriasis

-AND-

c. **Both** of the following:

(1) History of failure to one of the following topical therapies, unless contraindicated or clinically significant adverse effects are experienced (document drug, date, and duration of trial):

- Corticosteroids (e.g., betamethasone, clobetasol, desonide)
- Vitamin D analogs (e.g., calcitriol, calcipotriene)
- Tazarotene
- Calcineurin inhibitors (e.g., tacrolimus, pimecrolimus)
- Anthralin
- Coal tar

-AND-

(2) History of failure to a 3 month trial of methotrexate at the maximally indicated dose within the last 6 months, unless contraindicated or clinically significant adverse effects are experienced (document date, and duration of trial)

-AND-

d. Patient is not receiving Cosentyx in combination with **any** of the following:

i. Biologic DMARD [e.g., Humira (adalimumab), Cimzia (certolizumab), Simponi (golimumab), Taltz (ixekizumab), Orencia (abatacept)]
ii. Janus kinase inhibitor [e.g., Xeljanz (tofacitinib)]
iii. Phosphodiesterase 4 (PDE4) inhibitor [e.g. Otezla (apremilast)]

-AND-

e. History of failure, contraindication, or intolerance to **one** of the following:

(a) Humira (adalimumab)
(b) Enbrel (etanercept)
(c) Cimzia (certolizumb)
(d) Ilumya (tildrakizumab)

-AND-

f. Prescribed by or in consultation with a dermatologist

-OR-

(2) **All** of the following:

a. Patient is currently on Cosentyx therapy as documented by claims history or medical records (document date, and duration of therapy)

-AND-

b. Diagnosis of moderate to severe plaque psoriasis

-AND-

c. Patient is not receiving Cosentyx in combination with **any** of the following:

i. Biologic DMARD [e.g., Humira (adalimumab), Cimzia (certolizumab), Simponi (golimumab), Taltz (ixekizumab), Orencia (abatacept)]
ii. Janus kinase inhibitor [e.g., Xeljanz (tofacitinib)]
iii. Phosphodiesterase 4 (PDE4) inhibitor [e.g. Otezla (apremilast)]

-AND-

d. Prescribed by or in consultation with a dermatologist

Authorization will be issued for 12 months.

2. Reauthorization

a. Documentation of positive clinical response to Cosentyx therapy

-AND-

b. Patient is not receiving Cosentyx in combination with **any** of the following:

i. Biologic DMARD [e.g., Humira (adalimumab), Cimzia (certolizumab), Simponi (golimumab), Taltz (ixekizumab), Orencia (abatacept)]
ii. Janus kinase inhibitor [e.g., Xeljanz (tofacitinib)]
iii. Phosphodiesterase 4 (PDE4) inhibitor [e.g. Otezla (apremilast)]

-AND-

c. Prescribed by or in consultation with a dermatologist

Authorization will be issued for 12 months.

B. Ankylosing Spondylitis

1. Initial Authorization

One of the following:

(1) **All** of the following:

a. Diagnosis of active ankylosing spondylitis

-AND-

b. History of failure to two NSAIDs (e.g., ibuprofen, naproxen) at maximally indicated doses, each used for at least 4 weeks within the last 3 months, unless contraindicated or clinically significant adverse effects are experienced (document drug, date, and duration of trials)

-AND-

c. Patient is not receiving Cosentyx in combination with **any** of the following:

i. Biologic DMARD [e.g., Humira (adalimumab), Cimzia (certolizumab), Simponi (golimumab), Taltz (ixekizumab), Orencia (abatacept)]
ii. Janus kinase inhibitor [e.g., Xeljanz (tofacitinib)]
iii. Phosphodiesterase 4 (PDE4) inhibitor [e.g. Otezla (apremilast)]

-AND-

d. History of failure, contraindication, or intolerance to **two** of the following:

(a) Humira (adalimumab)
(b) Enbrel (etanercept)
(c) Cimzia (certolizumab pegol)

-AND-

e. Prescribed by or in consultation with a rheumatologist

-OR-

(2) **All** of the following:

a. Patient is currently on Cosentyx therapy as documented by claims history or medical records (document date, and duration of therapy)

-AND-

b. Diagnosis of active ankylosing spondylitis

-AND-

c. Patient is not receiving Cosentyx in combination with **any** of the following:

i. Biologic DMARD [e.g., Humira (adalimumab), Cimzia (certolizumab), Simponi (golimumab), Taltz (ixekizumab), Orencia (abatacept)]
ii. Janus kinase inhibitor [e.g., Xeljanz (tofacitinib)]
iii. Phosphodiesterase 4 (PDE4) inhibitor [e.g. Otezla (apremilast)]

-AND-

d. Prescribed by or in consultation with a rheumatologist

Authorization will be issued for 12 months.

2. Reauthorization

a. Documentation of positive clinical response to Cosentyx therapy

-AND-

b. Patient is not receiving Cosentyx in combination with **any** of the following:

i. Biologic DMARD [e.g., Humira (adalimumab), Cimzia (certolizumab), Simponi (golimumab), Taltz (ixekizumab), Orencia (abatacept)]
ii. Janus kinase inhibitor [e.g., Xeljanz (tofacitinib)]
iii. Phosphodiesterase 4 (PDE4) inhibitor [e.g. Otezla (apremilast)]

-AND-

c. Prescribed by or in consultation with a rheumatologist

Authorization will be issued for 12 months.

C. Psoriatic Arthritis

1. Initial Authorization

One of the following:

(1) **All** of the following:

a. Diagnosis of active psoriatic arthritis

-AND-

b. History of failure to a 3 month trial of methotrexate at the maximally indicated dose within the last 6 months, unless contraindicated or clinically significant adverse effects are experienced (document date, and duration of trial)

-AND-

c. Patient is not receiving Cosentyx in combination with **any** of the following:

i. Biologic DMARD [e.g., Humira (adalimumab), Cimzia (certolizumab), Simponi (golimumab), Taltz (ixekizumab), Orencia (abatacept)]
ii. Janus kinase inhibitor [e.g., Xeljanz (tofacitinib)]
iii. Phosphodiesterase 4 (PDE4) inhibitor [e.g. Otezla (apremilast)]

-AND-

d. History of failure, contraindication, or intolerance to **two** of the following:

(a) Humira (adalimumab)
(b) Enbrel (etanercept)
(c) Cimzia (certolizumab pegol)

-AND-

e. Prescribed by or in consultation with **one** of the following:

(1) Rheumatologist
(2) Dermatologist

-OR-

(2) **All** of the following:

a. Patient is currently on Cosentyx therapy as documented by claims history or medical records (document date, and duration of therapy)

-AND-

b. Diagnosis of active psoriatic arthritis

-AND-

c. Patient is not receiving Cosentyx in combination with **any** of the following:

i. Biologic DMARD [e.g., Humira (adalimumab), Cimzia (certolizumab), Simponi (golimumab), Taltz (ixekizumab), Orencia (abatacept)]
ii. Janus kinase inhibitor [e.g., Xeljanz (tofacitinib)]
iii. Phosphodiesterase 4 (PDE4) inhibitor [e.g. Otezla (apremilast)]

-AND-

d. Prescribed by or in consultation with **one** of the following:

(1) Rheumatologist
(2) Dermatologist

Authorization will be issued for 12 months.

2. Reauthorization

a. Documentation of positive clinical response to Cosentyx therapy

-AND-

b. Patient is not receiving Cosentyx in combination with **any** of the following:

i. Biologic DMARD [e.g., Humira (adalimumab), Cimzia (certolizumab), Simponi (golimumab), Taltz (ixekizumab), Orencia (abatacept)]
ii. Janus kinase inhibitor [e.g., Xeljanz (tofacitinib)]
iii. Phosphodiesterase 4 (PDE4) inhibitor [e.g. Otezla (apremilast)]

-AND-

c. Prescribed by or in consultation with **one** of the following:

(1) Rheumatologist
(2) Dermatologist

Authorization will be issued for 12 months.

D. Non-radiographic Axial Spondyloarthritis

1. Initial Authorization

One of the following:

(1) **All** of the following:

a. Diagnosis of active non-radiographic axial spondyloarthritis

-AND-

b. History of failure to **two** NSAIDs (e.g., ibuprofen, naproxen) at maximally indicated doses, each used for at least 4 weeks, unless contraindicated or clinically significant adverse effects are experienced (document drug, date, and duration of trials)

-AND-

c. History of failure, contraindication, or intolerance to Cimzia (certolizumab) (document date and duration of trial)

-AND-

d. Patient is not receiving Cosentyx in combination with **any** of the following:

i. Biologic DMARD [e.g., Humira (adalimumab), Cimzia (certolizumab), Simponi (golimumab), Taltz (ixekizumab), Orencia (abatacept)]
ii. Janus kinase inhibitor [e.g., Xeljanz (tofacitinib)]

-AND-

e. Prescribed by or in consultation with a rheumatologist

-OR-

(2) **All** of the following:

a. Patient is currently on Cosentyx therapy as documented by claims history or medical records (document date, and duration of therapy)

-AND-

b. Diagnosis of active non-radiographic axial spondyloarthritis

-AND-

c. Patient is not receiving Cosentyx in combination with **any** of the following:

i. Biologic DMARD [e.g., Humira (adalimumab), Cimzia (certolizumab), Simponi (golimumab), Taltz (ixekizumab), Orencia (abatacept)]
ii. Janus kinase inhibitor [e.g., Xeljanz (tofacitinib)]

-AND-

d. Prescribed by or in consultation with a rheumatologist

Authorization will be issued for 12 months.

2. Reauthorization

a. Documentation of positive clinical response to Cosentyx therapy

-AND-

b. Patient is not receiving Cosentyx in combination with **any** of the following:

i. Biologic DMARD [e.g., Humira (adalimumab), Cimzia (certolizumab), Simponi (golimumab), Taltz (ixekizumab), Orencia (abatacept)]
ii. Janus kinase inhibitor [e.g., Xeljanz (tofacitinib)]

-AND-

c. Prescribed by or in consultation with a rheumatologist

Authorization will be issued for 12 months.

3. Additional Clinical Rules:

- Notwithstanding Coverage Criteria, UnitedHealthcare may approve initial and re-authorization based solely on previous claim/medication history, diagnosis codes (ICD-10) and/or claim logic. Use of automated approval and re-approval processes varies by program and/or therapeutic class.
- Supply limits may be in place.

4. References:

1. Cosentyx Prescribing Information. East Hanover, NJ: Novartis Pharmaceuticals Corp, June2020.
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11. 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.
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Program	Prior Authorization - Cosentyx (secukinumab)
Change Control	
Date	Change
3/2015	New Guideline
3/2016	Initial therapy section: Added Enbrel to list of preferred drugs that require history of failure, contraindication, or intolerance Added technician note indicating Actemra as a non-preferred drug Annual Review- Updated policy template
5/2016	Added criteria sections for ankylosing spondylitis and psoriatic arthritis. Added Phosphodiesterase 4 (PDE4) inhibitor [e.g., Otezla (apremilast)] to Section C in Plaque Psoriasis.
7/2016	Added Phosphodiesterase 4 (PDE4) inhibitor [e.g., Otezla (apremilast)] to Ankylosing Spondylitis (initial and reauthorization) and Plaque Psoriasis (reauthorization).
9/2016	Updated background. Removed prescriber check from all sections. Removed trial and failure of NSAIDs from Ankylosing Spondylitis section. Changed trial and failure requirements from “all” to “two” biologics in Ankylosing Spondylitis and Psoriatic Arthritis sections and from “both” to “one” for Plaque Psoriasis.
3/2017	Updated template. No changes to clinical criteria.
9/2017	Updated preferred products for plaque psoriasis and psoriatic arthritis to include Otezla
2/2018	Removed Otezla as a step therapy medication and updated number of trial/fail medications in the psoriasis and psoriatic arthritis sections.
2/2019	Added Cimzia as a step therapy medication for psoriasis. Updated references.
11/2019	Revised prerequisite therapies for psoriasis, psoriatic arthritis, and ankylosing spondylitis. Added body surface requirement for use in psoriasis. Updated references.
12/2019	Revised prerequisite therapies and added documentation of drug, date, and duration of trials. Separated continuation of therapy requirements for current users.

1/2020	Revised step therapy medications for psoriasis due to PDL changes.
5/2020	Added prescriber requirement. Minor revisions to prerequisite therapy requirements. Changed BSA requirement to 3% to align with current psoriasis guidelines.
7/2020	Updated background and criteria to include new indication for non-radiographic axial spondyloarthritis. Clarified documentation requirements. Updated references.
11/2020	Minor formatting revisions.