UnitedHealthcare Pharmacy
Clinical Pharmacy Programs

Program Number	2024 P 2196-14
Program	Prior Authorization/Medical Necessity
Medication	Cosentyx® (secukinumab) prefilled syringe or Sensoready pen
P&T Approval Date	5/2020, 7/2020, 11/2020, 6/2021, 7/2021, 12/2021, 2/2022, 3/2022, 6/2022, 11/2022, 1/2023, 4/2023, 7/2023, 1/2024
Effective Date	4/1/2024

1. Background:
Cosentyx (secukinumab) is a human interleukin-17A antagonist indicated for the treatment of moderate to severe plaque psoriasis in patients 6 years and older who are candidates for systemic therapy or phototherapy, active psoriatic arthritis (PsA) in patients 2 years of age and older, adults with active ankylosing spondylitis (AS) or active non-radiographic axial spondyloarthritis (nr-axSpA) with objective signs of inflammation, active enthesitis-related arthritis (ERA) in patients 4 years of age and older, and adults with moderate to severe hidradenitis (HS).

2. Coverage Criteria[a]:

A. Plaque Psoriasis

1. **Initial Authorization**

a. **Cosentyx** will be approved based on **all** of the following criteria:

(1) Diagnosis of moderate to severe plaque psoriasis

-AND-

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

(a) **Both** of the following:

i. **One** of the following:

1. **All** of the following:

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

-AND-

b. 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-

c. History of failure to a 3 month trial of methotrexate at maximally indicated dose, unless contraindicated or clinically significant adverse effects are experienced (document date and duration of trial)[b]

-OR-

2. Patient has been previously treated with a targeted immunomodulator FDA-approved for the treatment of plaque psoriasis as documented by claims history or submission of medical records (Document drug, date, and duration of therapy) [e.g., Cimzia (certolizumab), adalimumab, Otezla (apremilast), Skyrizi (risankizumab), Stelara (ustekinumab), Tremfya (guselkumab), Enbrel (etanercept)].

-AND-

ii. History of failure, contraindication, or intolerance to **<u>one</u>** of the following preferred products: (document drug, date, and duration of trial)

a. One of the preferred adalimumab products[c]
b. Stelara (ustekinumab)
c. Tremfya (guselkumab)
d. Cimzia (certolizumab)
e. Skyrizi (risankizumab)
f. Enbrel (etanercept)

-OR-

(b) **<u>Both</u>** of the following:

i. Patient is currently on Cosentyx therapy as documented by claims history or submission of medical records (Document date and duration of therapy):

-AND-

ii. Patient has **<u>not</u>** received a manufacturer supplied sample at no cost in prescriber office, or any form of assistance from the Novartis sponsored Cosentyx Connect (e.g., sample card which can be redeemed at a pharmacy for a free supply of medication) as a means to establish as a current user of Cosentyx*

-OR-

(c) **<u>Both</u>** of the following:

i. Patient is less than 18 years of age

-AND-

ii. History of failure, contraindication, or intolerance to Stelara (ustekinumab) or Enbrel (etanercept) (document date and duration of trial)

-AND-

(3) Patient is not receiving Cosentyx in combination with another targeted immunomodulator [e.g., Enbrel (etanercept), Cimzia (certolizumab), Simponi (golimumab), Orencia (abatacept), adalimumab, Stelara (ustekinumab), Skyrizi (risankizumab), Tremfya (guselkumab), Taltz (ixekizumab), Siliq (brodalumab), Ilumya (tildrakizumab), Xeljanz (tofacitinib), Olumiant (baricitinib), Rinvoq (upadacitinib), Otezla (apremilast)]

-AND-

(4) Prescribed by or in consultation with a dermatologist

***** Patients requesting initial authorization who were established on therapy via the receipt of a manufacturer supplied sample at no cost in the prescriber's office or any form of assistance from the Novartis sponsored Cosentyx Connect **shall be required** to meet initial authorization criteria as if patient were new to therapy.

Authorization will be issued for 12 months.

2. **Reauthorization**

a. **Cosentyx** will be approved based on **all** of the following criteria:

(1) Documentation of positive clinical response to Cosentyx therapy

-AND-

(2) Patient is not receiving Cosentyx in combination with another targeted immunomodulator [e.g., Enbrel (etanercept), Cimzia (certolizumab), Simponi (golimumab), Orencia (abatacept), adalimumab, Stelara (ustekinumab), Skyrizi (risankizumab), Tremfya (guselkumab), Taltz (ixekizumab), Siliq (brodalumab), Ilumya (tildrakizumab), Xeljanz (tofacitinib), Olumiant (baricitinib), Rinvoq (upadacitinib), Otezla (apremilast)]

Authorization will be issued for 12 months.

B. Psoriatic Arthritis (PsA)

1. **Initial Authorization**

a. **Cosentyx** will be approved based on **all** of the following criteria:

(1) Diagnosis of active psoriatic arthritis

-AND-

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

(a) **Both** of the following:

i. **One** of the following:

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

-OR-

b. Patient has been previously treated with a targeted immunomodulator FDA-approved for the treatment of psoriatic arthritis as documented by claims history or submission of medical records (Document drug, date, and duration of therapy) [e.g., Cimzia (certolizumab), adalimumab, Simponi (golimumab), Stelara (ustekinumab), Tremfya (guselkumab), Xeljanz/Xeljanz XR (tofacitinib), Otezla (apremilast), Skyrizi (risankizumab), Rinvoq (upadacitinib), Enbrel (etanercept)]

-AND-

ii. History of failure, contraindication, or intolerance to **one** of the following preferred products (document drug, date, and duration of trial)

a. One of the preferred adalimumab products[c]
b. Stelara (ustekinumab)
c. Cimzia (certolizumab)
d. Simponi (golimumab)
e. Tremfya (guselkumab)
f. Skyrizi (risankizumab-rzaa)
g. Rinvoq (upadacitinib)
h. Xeljanz/Xeljanz XR (tofacitinib)
i. Enbrel (etanercept)

-OR-

(b) **Both** of the following:

i. Patient is currently on Cosentyx therapy as documented by claims history or submission of medical records (Document date and duration of therapy)

-AND-

ii. Patient has **not** received a manufacturer supplied sample at no cost in prescriber office, or any form of assistance from the Novartis sponsored Cosentyx Connect (e.g., sample card which can be redeemed at a pharmacy for a free supply of medication) as a means to establish as a current user of Cosentyx*

-AND-

(3) Patient is not receiving Cosentyx in combination with another targeted immunomodulator [e.g., Enbrel (etanercept), Cimzia (certolizumab), Simponi (golimumab), Orencia (abatacept), adalimumab, Stelara (ustekinumab), Skyrizi (risankizumab), Tremfya (guselkumab), Taltz (ixekizumab), Xeljanz (tofacitinib), Olumiant (baricitinib), Rinvoq (upadacitinib), Otezla (apremilast)]

-AND-

(4) Prescribed by or in consultation with **one** of the following:

(a) Rheumatologist
(b) Dermatologist

* Patients requesting initial authorization who were established on therapy via the receipt of a manufacturer supplied sample at no cost in the prescriber's office or any form of assistance from the Novartis sponsored Cosentyx Connect **shall be required** to meet initial authorization criteria as if patient were new to therapy.

Authorization will be issued for 12 months.

2. **Reauthorization**

a. **Cosentyx** will be approved based on **all** of the following criteria:

(1) Documentation of positive clinical response to Cosentyx therapy

-AND-

(2) Patient is not receiving Cosentyx in combination with another targeted immunomodulator [e.g., Enbrel (etanercept), Cimzia (certolizumab), Simponi (golimumab), Orencia (abatacept), adalimumab, Stelara (ustekinumab), Skyrizi (risankizumab), Tremfya (guselkumab), Taltz (ixekizumab), Xeljanz (tofacitinib), Olumiant (baricitinib), Rinvoq (upadacitinib), Otezla (apremilast)]

Authorization will be issued for 12 months.

C. Ankylosing Spondylitis (AS)

1. **Initial Authorization**

a. **Cosentyx** will be approved based on **all** of the following criteria:

(1) Diagnosis of active ankylosing spondylitis

-AND-

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

(a) **Both** of the following:

i. **One** of the following:

a. 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)

-OR-

b. Patient has been previously treated with a targeted immunomodulator FDA-approved for the treatment of ankylosing spondylitis as documented by claims history or submission of medical records (Document drug, date, and duration of therapy) [e.g., adalimumab, Simponi (golimumab), Xeljanz/Xeljanz XR (tofacitinib), Rinvoq (upadacitinib), Enbrel (etanercept)].

-AND-

ii. History of failure, contraindication, or intolerance to **one** of the following preferred products:(document drug, date, and duration of trial)

a. One of the preferred adalimumab products[c]
b. Cimzia (certolizumab)
c. Simponi (golimumab)
d. Rinvoq (upadacitinib)
e. Xeljanz/Xeljanz XR (tofacitinib)
f. Enbrel (etanercept)

-OR-

(b) **Both** of the following:

i. Patient is currently on Cosentyx therapy as documented by claims history or submission medical records (Document date and duration of therapy):

-AND-

ii. Patient has **not** received a manufacturer supplied sample at no cost in prescriber office, or any form of assistance from the Novartis sponsored Cosentyx Connect (e.g., sample card which can be redeemed at a pharmacy for a free supply of medication) as a means to establish as a current user of Cosentyx*

-AND-

(3) Patient is not receiving Cosentyx in combination with another targeted immunomodulator [e.g., Enbrel (etanercept), Cimzia (certolizumab), Simponi (golimumab), Orencia (abatacept), adalimumab, Xeljanz (tofacitinib), Olumiant (baricitinib), Rinvoq (upadacitinib)]

-AND-

(4) Prescribed by or in consultation with a rheumatologist

* Patients requesting initial authorization who were established on therapy via the receipt of a manufacturer supplied sample at no cost in the prescriber's office or any form of assistance from the Novartis sponsored Cosentyx Connect **shall be required** to meet initial authorization criteria as if patient were new to therapy.

Authorization will be issued for 12 months.

2. **Reauthorization**

a. **Cosentyx** will be approved based on **all** of the following criteria:

(1) Documentation of positive clinical response to Cosentyx therapy

-AND-

(2) Patient is not receiving Cosentyx in combination with another targeted immunomodulator [e.g., Enbrel (etanercept), Cimzia (certolizumab), Simponi (golimumab), Orencia (abatacept), adalimumab, Xeljanz (tofacitinib), Olumiant (baricitinib), Rinvoq (upadacitinib)]

Authorization will be issued for 12 months.

D. Non-radiographic Axial Spondyloarthritis

1. **Initial Authorization**

a. **Cosentyx** will be approved based on **all** of the following criteria:

(1) Diagnosis of active non-radiographic axial spondyloarthritis

-AND-

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

(a) **Both** of the following:

i. **One** of the following:

a. 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)

-OR-

b. Patient has been previously treated with a targeted immunomodulator FDA-approved for the treatment of non-radiographic axial spondyloarthritis as documented by claims history or submission of medical records (Document drug, date, and duration of therapy) [e.g., Cimzia (certolizumab), Rinvoq (upadacitinib)]

-AND-

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

-OR-

(b) **Both** of the following:

i. Patient is currently on Cosentyx therapy as documented by claims history or submission of medical records (Document date and duration of therapy)

-AND-

ii. Patient has **not** received a manufacturer supplied sample at no cost in prescriber office, or any form of assistance from the Novartis sponsored Cosentyx Connect (e.g., sample card which can be redeemed at a pharmacy for a free supply of medication) as a means to establish as a current user of Cosentyx*

-AND-

(3) Patient is not receiving Cosentyx in combination with another targeted immunomodulator [e.g., Enbrel (etanercept), Cimzia (certolizumab),

Simponi (golimumab), Orencia (abatacept), adalimumab, Xeljanz (tofacitinib), Olumiant (baricitinib), Rinvoq (upadacitinib)]

-AND-

(4) Prescribed by or in consultation with a rheumatologist

***** Patients requesting initial authorization who were established on therapy via the receipt of a manufacturer supplied sample at no cost in the prescriber's office or any form of assistance from the Novartis sponsored Cosentyx Connect **shall be required** to meet initial authorization criteria as if patient were new to therapy.

Authorization will be issued for 12 months.

2. **Reauthorization**

a. **Cosentyx** will be approved based on **all** of the following criteria:

(1) Documentation of positive clinical response to Cosentyx therapy

-AND-

(2) Patient is not receiving Cosentyx in combination with another targeted immunomodulator [e.g., Enbrel (etanercept), Cimzia (certolizumab), Simponi (golimumab), Orencia (abatacept), adalimumab, Xeljanz (tofacitinib), Olumiant (baricitinib), Rinvoq (upadacitinib)]

Authorization will be issued for 12 months.

E. Enthesitis-Related Arthritis

1. **Initial Authorization**

a. **Cosentyx** will be approved based on **all** of the following criteria:

(1) Diagnosis of active enthesitis-related arthritis

-AND-

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

(a) 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)

-OR-

(b) **Both** of the following:

i. Patient is currently on Cosentyx therapy as documented by claims history or submission of medical records (Document date and duration of therapy)

-AND-

ii. Patient has **not** received a manufacturer supplied sample at no cost in prescriber office, or any form of assistance from the Novartis sponsored Cosentyx Connect (e.g., sample card which can be redeemed at a pharmacy for a free supply of medication) as a means to establish as a current user of Cosentyx*

-AND-

(3) Patient is not receiving Cosentyx in combination with another targeted immunomodulator [e.g., Enbrel (etanercept), adalimumab, Cimzia (certolizumab), Simponi (golimumab), Xeljanz (tofacitinib), Rinvoq (upadacitinib)]

-AND-

(4) Prescribed by or in consultation with a rheumatologist

* Patients requesting initial authorization who were established on therapy via the receipt of a manufacturer supplied sample at no cost in the prescriber's office or any form of assistance from the Novartis sponsored Cosentyx Connect **shall be required** to meet initial authorization criteria as if patient were new to therapy.

Authorization will be issued for 12 months.

2. **Reauthorization**

a. **Cosentyx** will be approved based on **all** of the following criteria:

(1) Documentation of positive clinical response to Cosentyx therapy

-AND-

(2) Patient is not receiving Cosentyx in combination with another targeted immunomodulator [e.g., Enbrel (etanercept), adalimumab, Cimzia (certolizumab), Simponi (golimumab), Xeljanz (tofacitinib), Rinvoq (upadacitinib)]

Authorization will be issued for 12 months.

F. Hidradenitis Suppurativa (HS)

1. **Initial Authorization**

a. **Cosentyx** will be approved based on **all** of the following criteria:

(1) Diagnosis of moderate to severe hidradenitis suppurativa (i.e., Hurley Stage II or III)

-AND-

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

(a) History of failure to at least **one** oral antibiotic (e.g., doxycycline, clindamycin, rifampin) at maximally indicated doses, unless contraindicated or clinically significant adverse effects are experienced (document drug, date, and duration of trial)

-OR-

(b) **Both** of the following:

i. Patient is currently on Cosentyx therapy as documented by claims history or submission of medical records (Document date and duration of therapy):

-AND-

ii. Patient has **not** received a manufacturer supplied sample at no cost in the prescriber's office, or any form of assistance from a Novartis sponsored program (e.g., sample card which can be redeemed at a pharmacy for a free supply of medication) as a means to establish as a current user of Cosentyx*

-AND-

(3) Patient is not receiving Cosentyx in combination with another targeted immunomodulator [e.g., adalimumab, Enbrel (etanercept), Cimzia (certolizumab), Simponi (golimumab), Orencia (abatacept), Xeljanz (tofacitinib), Olumiant (baricitinib), Rinvoq (upadacitinib)]

-AND-

(4) Prescribed by or in consultation with a dermatologist

* Patients requesting initial authorization who were established on therapy via the receipt of a manufacturer supplied sample at no cost in the prescriber's office or any form of assistance from a Novartis sponsored program **shall be required** to meet initial authorization criteria as if patient were new to therapy.

Authorization will be issued for 12 months.

2. **Reauthorization**

a. **Cosentyx** will be approved based on **all** of the following criteria:

(1) Documentation of positive clinical response to Cosentyx therapy.

-AND-

(2) Patient is not receiving Cosentyx in combination with another targeted immunomodulator [e.g., adalimumab, Enbrel (etanercept), Cimzia (certolizumab), Simponi (golimumab), Orencia (abatacept), Xeljanz (tofacitinib), Olumiant (baricitinib), Rinvoq (upadacitinib)]

Authorization will be issued for 12 months.

[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.
[b] For Connecticut, Kentucky and Mississippi business only a 30-day trial will be required.
[c] For a list of preferred adalimumab products please reference drug coverage tools.

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. Reference:

1. Cosentyx [package insert]. East Hanover, NJ: Novartis Pharmaceuticals Corp.; October 2023.
2. Ward MM, Deodhar, A, Gensler, LS, et al. 2019 Update of the American College of Rheumatology/Spondylitis Association of America/Spondyloarthritis Research and Treatment Network Recommendations for the Treatment of Ankylosing Spondylitis and Nonradiographic Axial Spondyloarthritis. Arthritis & Rheumatology. 2019; 71(10): 1599-1613.
3. Yu, DT, van Tubergen A. Treatment of axial spondyloarthritis (ankylosing spondylitis and nonradiographic axial spondyloarthritis) in adults. Sieper, J (Ed). UpToDate. Waltham, MA: UpToDate Inc. http://www.uptodate.com (Accessed on October 10, 2019.)
4. Singh, JA, Guyatt, G, et al. 2018 American College of Rheumatology/National Psoriasis Foundation Guideline for the Treatment of Psoriatic Arthritis. Arthritis & Rheumatology. 2019; 71(1): 5-32.
5. Menter A, Gottlieb A, Feldman SR, et al. Guidelines of care for the management of psoriasis and psoriatic arthritis: Section 1. Overview of psoriasis and guidelines of care for the treatment of psoriasis with biologics. J Am Acad Dermatol 2008; 58(5):826-50.
6. Gottlieb A, Korman NJ, Gordon KB, et al. Guidelines of care for the management of psoriasis and psoriatic arthritis. Psoriatic arthritis: Overview and guidelines of care for treatment with an emphasis on the biologics. J Am Acad Dermatol 2008;58(5):851-64.
7. Menter A, Korman NJ, Elmets CA, et al. Guidelines of care for the management of psoriasis and psoriatic arthritis. Section 3. Guidelines of care for the management and treatment of psoriasis with topical therapies. J Am Acad Dermatol 2009;60(4):643-59.
8. Menter A, Korman NJ, Elmets CA, et al. Guidelines of care for the management of psoriasis and psoriatic arthritis. Guidelines of care for the treatment of psoriasis with phototherapy and photochemotherapy. J Am Acad Dermatol 2010;62(1):114-35.

9. Menter A, Korman NJ, Elmets CA, et al. Guidelines of care for the management of psoriasis and psoriatic arthritis. Guidelines of care for the management and treatment of psoriasis with traditional systemic agents. J Am Acad Dermatol 2009;61(3):451-85.
10. Nast A, et al; European S3-Guidelines on the systemic treatment of psoriasis vulgaris – update 2015 – short version – EFF in cooperation with EADV and IPC, J Eur Acad Derm Venereol 2015;29:2277-94.
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.
12. Gossec L, et al; European League Against Rheumatism (EULAR) recommendations for the management of psoriatic arthritis with pharmacological therapies: 2015 update, Ann Rheum Dis 2016;75:499-510.
13. Menter A, Strober BE, Kaplan DH, et al. Joint AAD-NPF guidelines of care for the management and treatment of psoriasis with biologics. J Am Acad Dermatol. 2019;80:1029-72.
14. Bodemer C, Kaszuba A, Kingo K, et al. Secukinumab demonstrates high efficacy and a favourable safety profile in paediatric patients with severe chronic plaque psoriasis: 52-week results from a Phase 3 double-blind randomized, controlled trial. J Eur Acad Dermatol Venereol. 2021;35(4):938-947. doi:10.1111/jdv.17002

Program	Prior Authorization/Medical Necessity - Cosentyx (secukinumab)
Change Control	
5/2020	New program.
7/2020	Updated background and criteria to include new indication for non-radiographic axial spondyloarthritis. Clarified documentation requirements. Updated references.
11/2020	Added Tremfya as a step therapy medication for psoriatic arthritis. Revised psoriasis step therapy medications due to expanded indication for use of Stelara in patients 6 years and older.
6/2021	Removed prescriber requirement from reauthorization criteria. Added coverage criteria for patients previously treated with a biologic DMARD. Added clarification that submission of medical records is required documenting current therapy with Cosenyx in order to bypass step if claim history not available.
7/2021	Updated background to include expanded indication for moderate to severe plaque psoriasis to pediatric patients 6 years and older. Updated references.
12/2021	Updated the following with no change to clinical intent: updated conventional DMARD bypass language for psoriatic arthritis and psoriasis, removed “biologic” from required preferred product criteria language, updated age requirement language and updated CT/KY footnote.
2/2022	Updated background and clinical criteria with new indication for ERA. Updated formatting of clinical criteria for nr-axSpA. Updated reference.
3/2022	Added Skyrizi as a preferred drug for active psoriatic arthritis. Clarified criteria for non-radiographic axial spondyloarthritis that patient must still have a history of failure, contraindication, or

	intolerance to Cimzia (certolizumab) whether they were previously treated with a DMARD or have failed two NSAIDs.
6/2022	Added Rinvoq and Xeljanz to step therapy medication for ankylosing spondylitis and psoriatic arthritis. Added Rinvoq and/or Xeljanz to examples where appropriate. Added Mississippi to state mandate footnote.
11/2022	Added Enbrel as a preferred product step option for AS, PsO, and PsA. Added Enbrel as an example where appropriate. Added Rinvoq as a step option for non-radiographic axial spondyloarthritis. Added targeted synthetic to DMARD bypass for non-radiographic axial spondyloarthritis.
1/2023	Updated step therapy requirements to Humira or Amjevita. Updated listed examples from Humira to adalimumab.
4/2023	Updated step therapy requirement from Humira or Amjevita to one of the preferred adalimumab products and added the footnote "For a list of preferred adalimumab products please reference drug coverage tools."
7/2023	Updated not receiving in combination language to targeted immunomodulator and updated examples.
1/2024	Added coverage criteria for new indication for Hidradenitis Suppurativa (HS). Updated state mandate footnote. Updated background and reference.