UnitedHealthcare Pharmacy
Clinical Pharmacy Programs

Program Number	2020 P 3052-10
Program	Step Therapy
Medications	Cosentyx™ (secukinumab) prefilled syringe or Sensoready pen
P&T Approval Date	2/2015, 3/2016, 8/2016, 5/2017, 2/2018, 2/2019, 9/2019, 7/2020, 11/2020
Effective Date	1/1/2021; Oxford only: N/A

1. Background:

Step therapy programs are utilized to encourage use of lower cost alternatives for certain therapeutic classes. This program requires a member to try one preferred self-administered injectable product before providing coverage for Cosentyx™ (secukinumab). Infused medications for any of the conditions referenced in this document are not part of the criteria.

Cosentyx (secukinumab) is 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 or for treatment of adults with active ankylosing spondylitis. It is also indicated for the treatment of adult patients with active non-radiographic axial spondyloarthritis with objective signs of inflammation.

Humira® (adalimumab) is also indicated for the treatment of adult patients with moderate to severe plaque psoriasis who are candidates for systemic therapy or phototherapy, for reducing signs and symptoms, inhibiting the progression of structural damage, and improving physical function in adult patients with active psoriatic arthritis, or for reducing signs and symptoms in adult patients with active ankylosing spondylitis.

Stelara® (ustekinumab) is indicated for the treatment of patients 6 years or older with moderate to severe plaque psoriasis who are candidates for systemic therapy or phototherapy or for treatment of adult patients with active psoriatic arthritis.

Tremfya® (guselkumab) is indicated for the treatment of adult patients with moderate-to-severe plaque psoriasis who are candidates for systemic therapy or phototherapy. Tremfya is also indicated for the treatment of adult patients with active psoriatic arthritis.

Simponi (golimumab) and Cimzia (certolizumab) are both indicated for the treatment of adult patients with active psoriatic arthritis and for treatment of adult patients with active ankylosing spondylitis. Cimzia is also indicated for the treatment of adult patients with moderate to severe plaque psoriasis who are candidates for systemic therapy or phototherapy or for treatment of adult patients with active non-radiographic axial spondyloarthritis with objective signs of inflammation.

Skyrizi™ (risankizumab) is indicated for the treatment of moderate-to-severe plaque psoriasis in adults who are candidates for systemic therapy or phototherapy.

Members currently on Cosentyx therapy as documented in claims history will be allowed to continue on their current therapy. Members new to therapy will be required to meet the coverage criteria below.

2. Coverage Criteria [a]:

A. Plaque Psoriasis

1. Cosentyx will be approved based on **one** of the following criteria:

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

(1) Humira (adalimumab)
(2) Stelara (ustekinumab)
(3) Tremfya (guselkumab)
(4) Cimzia (certolizumab)
(5) Skyrizi (risankizumab)

-OR-

b. **Both** of the following:

(1) Patient is 6 years to less than 18 years of age

-AND-

(2) History of failure, contraindication, or intolerance to Stelara (ustekinumab) (document date and duration of trial)

-OR-

c. **Both** of the following:

(1) Patient is currently on Cosentyx therapy

-AND-

(2) 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*

***** 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.

B. Psoriatic Arthritis

1. **Cosentyx** will be approved based on **one** of the following criteria:

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

      (1) Humira (adalimumab)
      (2) Stelara (ustekinumab)
      (3) Cimzia (certolizumab)
      (4) Simponi (golimumab)
      (5) Tremfya (guselkumab)

      -OR-

   b. **Both** of the following:

      (1) Patient is currently on Cosentyx therapy

      -AND-

      (2) 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*

      ***** 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.

C. Ankylosing Spondylitis

1. **Cosentyx** will be approved based on **one** of the following criteria:

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

      (1) Humira (adalimumab)
      (2) Cimzia (certolizumab)
      (3) Simponi (golimumab)

      -OR-

   b. **Both** of the following:

      (1) Patient is currently on Cosentyx therapy

-AND-

(2) 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*

***** 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.

D. Non-radiographic Axial Spondyloarthritis

1. Cosentyx will be approved based on **one** of the following criteria:

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

-OR-

b. **Both** of the following:

(1) Patient is currently on Cosentyx therapy

-AND-

(2) 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*

***** 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.

[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.

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 and/or Notification may be in place.

4. References:

1. Humira [package insert]. North Chicago, IL: AbbVie Inc.; March 2020.
2. Stelara [package insert]. Horsham, PA: Janssen Biotech Inc.; July 2020.
3. Cosentyx [package insert]. East Hanover, NJ. Novartis Pharmaceuticals Corp.; June 2020.
4. Cimzia [package Insert]. Smyrna, GA: UCB, Inc; September 2019.
5. Simponi [package Insert]. Horsham, PA: Janssen Biotech Inc.; September 2019.
6. Tremfya [package insert]. Horsham, PA: Janssen Biotech Inc.; July 2020.
7. Skyrizi [package Insert]. North Chicago, IL: AbbVie Inc.; March 2020.

Program	Step Therapy - Cosentyx (secukinumab)
Change Control	
2/2015	New program.
3/2016	Annual review. Updated background information with 2 new indications for Cosentyx (active psoriatic arthritis and ankylosing spondylitis) and updated the indications for Stelara and Humira if they had the same indications. Updated clinical criteria so the step therapy would apply for the two new indications. Added Maryland Continuation of Care. Updated references.
8/2016	Updated criteria requiring trial of only 1 preferred alternative in plaque psoriasis. Added IN, WV coverage information. Updated references.
11/2016	Administrative change. Added California coverage information.
5/2017	Updated criteria for patients already receiving Cosentyx. Updated reference. Updated state mandate reference.
2/2018	Updated criteria adding Tremfya as an additional preferred agent for plaque psoriasis.
2/2019	Annual review. Updated background and criteria adding Cimzia to list of preferred products for the treatment of plaque psoriasis. Updated references.
9/2019	Updated criteria for psoriasis, adding Skyrizi as preferred medication. Updated criteria for psoriatic arthritis and ankylosing spondylitis requiring trial of one preferred product prior to coverage for Cosentyx. Updated references.
7/2020	Updated background and criteria to include new indication for non-radiographic axial spondylarthritis. Added review criteria for psoriasis patients 12-18 years. Clarified documentation requirements. Updated references.
11/2020	Added Tremfya as a step therapy medication for psoriatic arthritis. Revised age requirements for psoriasis section due to expanded indication for Stelara. Updated background and references.