UnitedHealthcare Pharmacy
Clinical Pharmacy Programs

Program Number	2019 P 3052-7
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
Effective Date	3/15/2019; Oxford only: 5/1/2019

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 or two preferred self-administered injectable products, depending on the prescribed indication, 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.

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 adult patients 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.

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 psoriatic arthritis

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:

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

-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 Covered Until You Are Covered 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*

***** 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 Covered Until You Are Covered Program **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 **two** of the following preferred biologic products:

(1) Humira (adalimumab)
(2) Stelara (ustekinumab)
(3) Cimzia (certolizumab)
(4) 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 Covered Until You Are Covered 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*

***** 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 Covered Until You Are Covered Program **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 **two** of the following preferred biologic products:

(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 Covered Until You Are Covered 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*

***** 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 Covered Until You Are Covered

Program **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.; December 2018
2. Stelara [package insert]. Horsham, PA: Janssen Biotech Inc.; June 2018.
3. Cosentyx [package insert]. East Hanover, NJ. Novartis Pharmaceuticals Corp.; January 2018.
4. Cimzia [package Insert]. Smyrna, GA: UCB, Inc; May 2018.
5. Simponi [package Insert]. Horsham, PA: Janssen Biotech Inc.; March 2018.
6. Tremfya [package insert]. Horsham, PA: Janssen Biotech Inc.; July 2017.

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.