UnitedHealthcare Pharmacy
Clinical Pharmacy Programs

Program Number	2020 P 3073-10
Program	Step Therapy
Medications	Taltz (ixekizumab)* * Taltz is excluded from coverage for the majority of our benefits
P&T Approval Date	8/2016, 5/2017, 2/2018, 2/2019, 9/2019, 12/2019, 5/2020,7/2020, 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 preferred products before providing coverage for Taltz®. Infused medications for any of the conditions referenced in this document are not part of the criteria.

Taltz (ixekizumab) is indicated for the treatment of moderate to severe plaque psoriasis in patients aged 6 years or older 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.[1]

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.[2]

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.[3]

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. Cosentyx is also indicated for the treatment of adult patients with active non-radiographic axial spondyloarthritis with objective signs of inflammation.[4]

Tremfya® (guselkumab) is indicated for the treatment of adult patients with moderate-to-severe plaque psoriasis who are candidates for systemic therapy or phototherapy.[5] Tremfya is also indicated for the treatment of adult patients with active psoriatic arthritis.

Cimzia® (certolizumab) and Simponi® (golimumab) are both indicated for the treatment of adult patients with active psoriatic arthritis or 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 and for the treatment of adults with active non-radiographic axial spondyloarthritis with objective signs of inflammation.[6-7]

Skyrizi™ (risankizumab) is indicated for the treatment of moderate-to-severe plaque psoriasis in adults who are candidates for systemic therapy or phototherapy.[8]
Orencia® (abatacept) is indicated for the treatment of adult patients with active psoriatic arthritis.[9]

Xeljanz/Xeljanz XR® is indicated for the treatment of adult patients with active psoriatic arthritis who have had an inadequate response or intolerance to methotrexate or other DMARDs.[10]

Members will be required to meet the coverage criteria below.

2. Coverage Criteria [a]:

A. Plaque Psoriasis

1. Taltz will be approved based on **one** of the following criterion:

a. **Both** of the following

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

(a) Humira (adalimumab)
(b) Stelara (ustekinumab)
(c) Tremfya (guselkumab)
(d) Cimzia (certolizumab)
(e) Skyrizi (risankizumab)

-AND-

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

-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)

Authorization will be issued for 12 months.

B. Psoriatic Arthritis

1. Taltz will be approved based on **all** of the following criteria:

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

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

-AND-

b. History of failure, contraindication, or intolerance to Cosentyx (secukinumab) (document date and duration of trial)

-AND-

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

(1) Orencia (abatacept)
(2) Xeljanz/Xeljanz XR (tofacitinib)

Authorization will be issued for 12 months.

C. Ankylosing Spondylitis

1. Taltz will be approved based on **both** of the following criteria:

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

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

-AND-

b. History of failure, contraindication, or intolerance to Cosentyx (secukinumab) (document date and duration of trial)

Authorization will be issued for 12 months.

D. Non-radiographic Axial Spondyloarthritis

1. Taltz will be approved based on **both** of the following:

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

-AND-

b. History of failure, contraindication, or intolerance to Cosentyx (secukinumab) (document date and duration of trial)

Authorization will be issued for 12 months.

E. Other Diagnoses

1. Taltz will be approved

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.
- Exclusion: Taltz is excluded from coverage for the majority of our benefits
- Medical Necessity, Supply limits and/or Notification may be in place.

4. References:

1. Taltz [package insert]. Indianapolis, IN: Eli Lilly and Company; May 2020.
2. Humira [package insert]. North Chicago, IL: AbbVie Inc.; March 2020.
3. Stelara [package insert]. Horsham, PA: Janssen Biotech Inc.; July 2020.
4. Cosentyx [package insert]. East Hanover, NJ. Novartis Pharmaceuticals Corp.; January 2020.
5. Tremfya [package insert]. Horsham, PA: Janssen Biotech Inc.; July 2020.
6. Cimzia [package Insert]. Smyrna, GA: UCB, Inc; September 2019.
7. Simponi [package Insert]. Horsham, PA: Janssen Biotech Inc.; September 2019.
8. Skyrizi [package Insert]. North Chicago, IL: AbbVie Inc.; March 2020.
9. Orencia [package insert]. Princeton, NJ: Bristol-Myers Squibb Company; June 2020.
10. Xeljanz/Xeljanz XR/Xeljanz Oral Solution [package insert]. New York, NY: Pfizer Labs; September 2020.

Program	Step Therapy - Taltz (ixekizumab)
Change Control	
8/2016	New program.
11/2016	Administrative change. Added California coverage information.
5/2017	Updated criteria for patients already receiving Taltz. Updated reference. Updated state mandate reference language.
2/2018	Updated background and added criteria for new indication of psoriatic arthritis. Updated criteria adding Tremfya as additional preferred option for plaque psoriasis. Updated reference.

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 background and criteria to include new indication for active ankylosing spondylitis. Updated criteria for psoriasis and psoriatic arthritis. Added coverage exclusion statement. Updated references.
12/2019	Updated formatting without change to clinical intent.
5/2020	Updated program to include criteria for pediatric patients with plaque psoriasis.
7/2020	Updated background and criteria to include new indication for non-radiographic axial spondylarthritis. Added review criteria for psoriasis patients 6-12 years and 12-18 years. 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 age indication for Stelara. Updated background and references.