UnitedHealthcare Pharmacy
Clinical Pharmacy Programs

Program Number	2024 P 3073-18
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, 11/2021, 3/2022, 6/2022, 11/2022, 1/2023, 4/2023, 4/2024, 10/2024
Effective Date	1/1/2025

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 (PsO) 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 (PsA), active ankylosing spondylitis (AS) and active non-radiographic axial spondyloarthritis with objective signs of inflammation.

Adalimumab is indicated for reducing signs and symptoms, inhibiting the progression of structural damage, and improving physical function in adult patients with active PsA, reducing signs and symptoms in adult patients with active AS, and the treatment of adult patients with moderate to severe chronic plaque psoriasis who are candidates for systemic therapy or phototherapy, and when other systemic therapies are medically less appropriate.

Cimzia® (certolizumab) is indicated for the treatment of adult patients with active PsA, treatment of adults with active ankylosing spondylitis (SpA), treatment of adults with moderate to severe PsO who are candidates for systemic therapy or phototherapy, and for the treatment of adults with non-radiographic axial spondyloarthritis (nr-axSpA), with objective signs of inflammation.

Simponi® (golimumab) is indicated for the treatment of adult patients with active PsA, alone or in combination with methotrexate and the treatment of adult patients with active AS.

Rinvoq® (upadacitinib) is indicated for the treatment of adults with active PsA who have an inadequate response or intolerance to one or more TNF blockers, adults with active ankylosing spondylitis who have had an inadequate response or intolerance to one or more TNF blockers, and adults with active non-radiographic axial spondyloarthritis with objective signs of inflammation who have had an inadequate response or intolerance to TNF blocker therapy. Use of Rinvoq in combination with other JAK inhibitors, biologic DMARDs, biologic therapies for UC, or with potent immunosuppressants such as azathioprine and cyclosporine is not recommended.

Xeljanz/Xeljanz XR® (tofacitinib) is indicated for the treatment of adult patients with active PsA and AS who have had an inadequate response or intolerance to one or more TNF blockers. The use of Xeljanz/Xeljanz XR/Xeljanz Oral Solution in combination with biologic DMARDs, biologic therapies for UC or potent immunosuppressants such as azathioprine and cyclosporine is not recommended.

Stelara® (ustekinumab) is indicated for the treatment of patients 6 years of age or older with moderate to severe PsO who are candidates for phototherapy or systemic therapy and adult patients with active PsA, alone or in combination with methotrexate.

Tremfya® (guselkumab) is indicated for the treatment of adult patients with moderate-to-severe PsO who are candidates for systemic therapy or phototherapy and for the treatment of adult patients with active PsA.

Skyrizi® (risankizumab-rzaa) is indicated for the treatment of moderate to severe PsO in adults who are candidates for systemic therapy or phototherapy and active PsA in adults.

Cosentyx® (secukinumab) is indicated for the treatment of moderate to severe PsO in patients 6 years and older who are candidates for systemic therapy or phototherapy. It is also indicated for the treatment of active PsA in patients 2 years of age and older, adults with active AS or non-radiographic axial spondyloarthritis (nr-axSpA) with objective signs of inflammation.

Orencia® (abatacept) is indicated for the treatment of adult patients with active PsA. Concomitant use of Orencia with other immunosuppressives [e.g., biologic disease-modifying antirheumatic drugs (bDMARDS), Janus kinase (JAK) inhibitors] is not recommended.

Enbrel (etanercept) is indicated for the treatment of psoriatic arthritis (PsA), ankylosing spondylitis (AS), and plaque psoriasis (PsO) in patients 4 years or older.

Sotyktu (deucravacitinib) is indicated for the treatment of adults with moderate to severe plaque psoriasis who are candidates for systemic therapy or phototherapy.

Members will be required to meet the coverage criteria below.

2. Coverage Criteria[a]:

A. <u>Plaque Psoriasis</u>

1. **Taltz** will be approved based on **<u>one</u>** of the following criterion:

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

      (1) One of the preferred adalimumab products (i.e. Adalimumab-adaz (unbranded Hyrimoz), Amjevita for Nuvaila, Humira)
      (2) Cimzia (certolizumab)
      (3) Cosentyx (secukinumab)
      (4) Enbrel (etanercept)

(5) Skyrizi (risankizumab)
(6) Sotyktu (deucravacitinib)
(7) Stelara (ustekinumab)
(8) Tremfya (guselkumab)

-OR-

b. **Both** of the following:

(1) Patient is less than 18 years of age

-AND-

(2) History of failure, contraindication, or intolerance to Cosentyx (secukinumab), Enbrel (etanercept), or 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 **both** of the following criteria:

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

(1) One of the preferred adalimumab products (i.e. Adalimumab-adaz (unbranded Hyrimoz), Amjevita for Nuvaila, Humira)
(2) Cimzia (certolizumab)
(3) Cosentyx (secukinumab)
(4) Enbrel (etanercept)
(5) Simponi (golimumab)
(6) Skyrizi (risankizumab)
(7) Stelara (ustekinumab)
(8) Tremfya (guselkumab)

-AND-

b. 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)
(3) Rinvoq (upadacitinib)

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 **three** of the following preferred products (document drug, date, and duration of trial):

(1) One of the preferred adalimumab products (i.e. Adalimumab-adaz (unbranded Hyrimoz), Amjevita for Nuvaila, Humira)
(2) Cimzia (certolizumab)
(3) Cosentyx (secukinumab)
(4) Enbrel (etanercept)
(5) Simponi (golimumab)

-AND-

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

(1) Xeljanz/Xeljanz XR (tofacitinib)
(2) Rinvoq (upadacitinib)

Authorization will be issued for 12 months.

D. Non-radiographic Axial Spondyloarthritis

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

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

(1) Cimzia (certolizumab)
(2) Cosentyx (secukinumab)
(3) Rinvoq (upadacitinib)

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; February 2022.
2. Humira [package insert]. North Chicago, IL: AbbVie Inc.; February 2024.
3. Stelara [package insert]. Horsham, PA: Janssen Biotech Inc.; August 2022.
4. Cosentyx [package insert]. East Hanover, NJ. Novartis Pharmaceuticals Corp.; December 2023.
5. Tremfya [package insert]. Horsham, PA: Janssen Biotech Inc.; November 2023.
6. Cimzia [package Insert]. Smyrna, GA: UCB, Inc; September 2022.
7. Simponi [package Insert]. Horsham, PA: Janssen Biotech Inc.; September 2019.
8. Skyrizi [package Insert]. North Chicago, IL: AbbVie Inc.; January 2024.
9. Orencia [package insert]. Princeton, NJ: Bristol-Myers Squibb Company; October 2023.
10. Xeljanz/Xeljanz XR/Xeljanz Oral Solution [package insert]. New York, NY: Pfizer Labs; January 2022.
11. Rinvoq [package insert]. North Chicago, IL: AbbVie Inc.; November 2023.
12. Enbrel [package insert]. Thousand Oaks, CA: Immunex Corp.; October 2023.
13. Sotyktu [package insert]. Princeton, NJ: Bristol-Myers Squibb Company; September 2022

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.
11/2021	Annual review with no changes to step therapy requirements. Updated background and references.

3/2022	Added Skyrizi as a preferred drug for active psoriatic arthritis. Updated conventional DMARD bypass language removing "biologic" from required preferred product criteria language. For plaque psoriasis, updated criteria from 6 to 18 years of age to less than 18 years of age. Updated reference.
6/2022	Updated background. Added Rinvoq and Xeljanz to step therapy for ankylosing spondylitis and Rinvoq to psoriatic arthritis. Updated references.
11/2022	Added Enbrel as a preferred product step option for PsO, PsA, and AS. Added Rinvoq as a step option for non-radiographic axial spondyloarthritis. Updated background and references.
1/2023	Updated step therapy requirements to Humira or Amjevita.Updated background and references.
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." Updated references.
4/2024	Annual review with no change to coverage criteria. Updated background and references.
10/2024	Updated step requirement noting Adalimumab-adaz (unbranded Hyrimoz), Amjevita for Nuvaila, and Humira as preferred adalimumab products with no change to clinical intent. Removed preferred adalimumab footnote. Added Sotyktu as step therapy agent for PsO. Moved Cosentyx to preferred step agent.