UnitedHealthcare Pharmacy
Clinical Pharmacy Programs

Program Number	2025 P 2104-19
Program	Prior Authorization/Medical Necessity
Medication	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, 5/2020, 7/2020, 11/2020, 6/2021, 12/2021, 3/2022, 6/2022, 11/2022, 1/2023, 4/2023, 7/2023, 10/2024, 4/2025
Effective Date	6/1/2025

1. Background:

Taltz (ixekizumab) is a humanized interleukin-17A antagonist 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]

2. Coverage Criteria[a]:

A. <u>Plaque Psoriasis (PsO)</u>

a. **Taltz** will be approved based on **<u>all</u>** of the following criteria:

(1) Submission of medical records (e.g., chart notes, laboratory values) documenting **<u>all</u>** of the following:

(a) **<u>One</u>** of the following:

i. **<u>All</u>** of the following:

a. Diagnosis of chronic moderate to severe plaque psoriasis

-AND-

b. **<u>One</u>** of the following:

1. **<u>All</u>** 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-rzaa), ustekinumab, Tremfya (guselkumab), Enbrel (etanercept)].

-AND-

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

- One of the preferred adalimumab products[c]
- Cimzia (certolizumab)
- Cosentyx (secukinumab)
- Enbrel (etanercept)
- Skyrizi (risankizumab)
- Sotyktu (deucravacitinib)
- One of the preferred ustekinumab products[c]
- Tremfya (guselkumab)

-OR-

ii. **All** of the following:

a. Diagnosis of chronic moderate to severe plaque psoriasis

-AND-

b. Patient is less than 18 years of age

-AND-

c. History of failure, contraindication, or intolerance to Cosentyx (secukinumab), Enbrel (etanercept), or one of the preferred ustekinumab products[c](document date and duration of trial)

-AND-

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

-AND-

(c) Prescribed by or in consultation with a dermatologist

Authorization will be issued for 12 months.

B. <u>Psoriatic Arthritis (PsA)</u>

a. Taltz will be approved based on the following criteria:

(1) Submission of medical records (e.g., chart notes, laboratory values) documenting **<u>all</u>** of the following:

(a) Diagnosis of active psoriatic arthritis

-AND-

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

i. 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-

ii. 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), Cosentyx (secukinumab), adalimumab, Simponi (golimumab), ustekinumab, Tremfya (guselkumab), Xeljanz/Xeljanz XR (tofacitinib), Otezla (apremilast), Skyrizi (risankizumab), Rinvoq (upadacitinib), Enbrel (etanercept)]

-AND-

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

i. One of the preferred adalimumab products[c]
ii. Cimzia (certolizumab)
iii. Cosentyx (secukinumab)
iv. Enbrel (etanercept)
v. Simponi (golimumab)
vi. Skyrizi (risankizumab)
vii. One of the preferred ustekinumab products[c]
viii. Tremfya (guselkumab)

-AND-

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

i. Orencia (abatacept)
ii. Xeljanz/Xeljanz XR (tofacitinib)
iii. Rinvoq (upadacitinib)

-AND-

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

-AND-

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

i. Rheumatologist
ii. Dermatologist

Authorization will be issued for 12 months.

C. Ankylosing Spondylitis (AS)

a. Taltz will be approved based on the following criteria:

(1) Submission of medical records (e.g., chart notes, laboratory values) documenting **all** of the following:

(a) Diagnosis of active ankylosing spondylitis

-AND-

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

i. 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-

ii. 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), Rinvoq (upadacitinib), Xeljanz/Xeljanz XR (tofacitinib), Enbrel (etanercept)].

-AND-

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

i. One of the preferred adalimumab products[c]
ii. Cimzia (certolizumab)
iii. Cosentyx (secukinumab)
iv. Enbrel (etanercept)
v. Simponi (golimumab)

-AND-

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

i. Xeljanz/Xeljanz XR (tofacitinib)
ii. Rinvoq (upadacitinib)

-AND-

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

-AND-

(f) Prescribed by or in consultation with a rheumatologist

Authorization will be issued for 12 months.

D. Non-radiographic Axial Spondyloarthritis

a. Taltz will be approved based on the following criteria:

(1) Submission of medical records (e.g., chart notes, laboratory values) documenting **all** of the following:

(a) Diagnosis of active non-radiographic axial spondyloarthritis

-AND-

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

i. 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-

ii. 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), Cosentyx (secukinumab), Rinvoq (upadacitinib)].

-AND-

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

i. Cimzia (certolizumab)
ii. Cosentyx (secukinumab)
iii. Rinvoq (upadacitinib)

-AND-

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

-AND-

(e) Prescribed by or in consultation with a rheumatologist

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 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.
- Exclusion: Taltz is excluded from coverage for the majority of our benefits
- Supply limits may be in place.

4. References:

1. Taltz [package insert]. Indianapolis, IN: Eli Lilly and Company; September 2022.
2. 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.
3. 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.
4. 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.
5. 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.
6. 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.
7. 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.
8. 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.
9. 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.

10. Ward MM, Deodhar A, Dubreuil M, 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 Rheumatol. 2019; Aug 22. doi: 10.1002/art.41042.
11. 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.

Program	Prior Authorization/Medical Necessity-Taltz (ixekizumab)
Change Control	
Date	Change
8/2016	New Program.
11/2016	Administrative change. Added California coverage information.
5/2017	Updated disease severity criteria to include facial, genital area psoriasis, decreased to 5% of body surface area. Added criteria for patients already receiving Taltz. Updated references. Updated State Mandate Reference
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 formatting without changes to clinical intent. Updated references.
2/2019	Annual review. Updated background and criteria adding Cimzia to list of preferred products for the treatment of plaque psoriasis. Updated reference.
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.
5/2020	Updated program to include new indication in pediatric patients with plaque psoriasis. Updated criteria for psoriatic arthritis and ankylosing spondylitis pertaining to nonbiologic therapies. Updated references.
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 formatting for psoriasis section to match other sections. Modified psoriasis step requirement due to expanded indication for Stelara.
6/2021	Added coverage criteria for patients previously treated with a biologic DMARD.
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.
3/2022	Added Skyrizi as a preferred drug for active psoriatic arthritis.
6/2022	Added Rinvoq and Xeljanz to step therapy medication for ankylosing spondylitis and Rinvoq to 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 PsO, PsA, and AS. Added Enbrel as an example where appropriate. Added Rinvoq as a step option for non-radiographic axial spondyloarthritis. Updated reference. 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.
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. Updated state mandate footnote.
4/2025	Removed examples for adalimumab in step therapy. Changed Stelara step therapy to "One of the preferred ustekinumab products[c]". Changed Stelara example to Ustekinumab. Added the footnote "For a list of preferred products please reference drug coverage tools."