UnitedHealthcare Community Plan

Clinical Pharmacy Program Guidelines for Taltz

Program	Prior Authorization
Medication	Taltz (ixekizumab)
Markets in Scope	California, Colorado, Hawaii, Maryland, Nevada, New Jersey, New York, Pennsylvania- CHIP, Rhode Island, South Carolina
Issue Date	5/2016
Pharmacy and Therapeutics Approval Date	11/2020
Effective Date	12/2020

1. Background:

Taltz (ixekizumab) is a humanized interleukin-17A antagonist 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, active non-radiographic axial spondyloarthritis with objective signs of inflammation, or active ankylosing spondylitis.[1]

2. Coverage Criteria:

A. <u>Plaque Psoriasis</u>

1. **<u>Initial Authorization</u>**

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

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

(a) Diagnosis of chronic moderate to severe plaque psoriasis

-AND-

(b) Greater than or equal to 3% body surface area involvement, palmoplantar, facial, or genital involvement, or severe scalp psoriasis

-AND-

(c) **<u>Both</u>** of the following:

i. 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-

ii. History of failure to a 3 month trial of methotrexate at maximally indicated dose within the last 6 months, unless contraindicated or clinically significant adverse effects are experienced (document date and duration of trial)

-AND-

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

i. Humira (adalimumab)
ii. Enbrel (etanercept)
iii. Cimzia (certolizumab)
iv. Ilumya (tildrakizumab)

-AND-

(e) **One** of the following (document date and duration of trial):

i. History of 6 month trial of Cosentyx (secukinumab) with moderate clinical response yet residual disease activity

-OR-

ii. **Both** of the following:

- History of intolerance or adverse event to Cosentyx
- Physician attests that in their clinical opinion the same intolerance or adverse event would not be expected to occur with Taltz

-AND-

(f) Patient is not receiving Taltz in combination with **any** of the following:

i. Biologic DMARD [e.g., Humira (adalimumab), Cimzia (certolizumab), Simponi (golimumab), Cosentyx (secukinumab), Orencia (abatacept)]
ii. Janus kinase inhibitor [e.g., Xeljanz (tofacitinib)]
iii. Phosphodiesterase 4 (PDE4) inhibitor [e.g. Otezla (apremilast)]

-AND-

(g) Prescribed by or in consultation with a dermatologist

-OR-

(2) **All** of the following:

(a) Patient is currently on Taltz therapy as documented by claims history or medical records (document date and duration of therapy)

-AND-

(b) Diagnosis of chronic moderate to severe plaque psoriasis

-AND-

(c) Patient is not receiving Taltz in combination with **any** of the following:

i. Biologic DMARD [e.g., Humira (adalimumab), Cimzia (certolizumab), Simponi (golimumab), Cosentyx (secukinumab), Orencia (abatacept)]
ii. Janus kinase inhibitor [e.g., Xeljanz (tofacitinib)]
iii. Phosphodiesterase 4 (PDE4) inhibitor [e.g. Otezla (apremilast)]

-AND-

(d) Prescribed by or in consultation with a dermatologist

Authorization will be issued for 12 months.

2. **Reauthorization**

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

(1) Documentation of positive clinical response to Taltz therapy

-AND-

(2) Patient is not receiving Taltz in combination with **any** of the following:

i. Biologic DMARD [e.g., Humira (adalimumab), Cimzia (certolizumab), Simponi (golimumab), Cosentyx (secukinumab), Orencia (abatacept)]
ii. Janus kinase inhibitor [e.g., Xeljanz (tofacitinib)]
iii. Phosphodiesterase 4 (PDE4) inhibitor [e.g. Otezla (apremilast)]

-AND-

(3) Prescribed by or in consultation with a dermatologist

Authorization will be issued for 12 months.

B. Psoriatic Arthritis (PsA)

1. **Initial Authorization**

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

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

(a) Diagnosis of active psoriatic arthritis

-AND-

(b) History of failure to a 3 month trial of methotrexate at maximally indicated dose within the last 6 months, unless contraindicated or clinically significant adverse effects are experienced (document date and duration of trial)

-AND-

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

i. Cimzia (certolizumab)
ii. Humira (adalimumab)
iii. Enbrel (etanercept)

-AND-

(d) **One** of the following (document date and duration of trial):

i. History of 6 month trial of Cosentyx (secukinumab) with moderate clinical response yet residual disease activity

-OR-

ii. **Both** of the following:

1. History of intolerance or adverse event to Cosentyx
2. Physician attests that in their clinical opinion the same intolerance or adverse event would not be expected to occur with Taltz

-AND-

(e) Patient is not receiving Taltz in combination with **any** of the following:

i. Biologic DMARD [e.g., Humira (adalimumab), Cimzia (certolizumab), Simponi (golimumab), Cosentyx (secukinumab), Orencia (abatacept)]
ii. Janus kinase inhibitor [e.g., Xeljanz (tofacitinib)]
iii. Phosphodiesterase 4 (PDE4) inhibitor [e.g. Otezla (apremilast)]

-AND-

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

i. Rheumatologist
ii. Dermatologist

-OR-

(2) **All** of the following:

(a) Patient is currently on Taltz therapy as documented by claims history or medical records (document date and duration of therapy)

-AND-

(b) Diagnosis of active psoriatic arthritis

-AND-

(c) Patient is not receiving Taltz in combination with **any** of the following:

i. Biologic DMARD [e.g., Humira (adalimumab), Cimzia (certolizumab), Simponi (golimumab), Cosentyx (secukinumab), Orencia (abatacept)]
ii. Janus kinase inhibitor [e.g., Xeljanz (tofacitinib)]
iii. Phosphodiesterase 4 (PDE4) inhibitor [e.g. Otezla (apremilast)]

-AND-

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

i. Rheumatologist
ii. Dermatologist

Authorization will be issued for 12 months.

2. **Reauthorization**

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

(1) Documentation of positive clinical response to Taltz therapy

-AND-

(2) Patient is not receiving Taltz in combination with **any** of the following:

i. Biologic DMARD [e.g., Humira (adalimumab), Cimzia (certolizumab), Simponi (golimumab), Cosentyx (secukinumab), Orencia (abatacept)]
ii. Janus kinase inhibitor [e.g., Xeljanz (tofacitinib)]
iii. Phosphodiesterase 4 (PDE4) inhibitor [e.g. Otezla (apremilast)]

-AND-

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

i. Rheumatologist
ii. Dermatologist

Reauthorization will be issued for 12 months.

C. Ankylosing Spondylitis

1. Initial Authorization

a. Taltz will be approved based on **one** of 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) History of failure to two NSAIDs (e.g., ibuprofen, naproxen) at maximally indicated doses, each used for at least 4 weeks within the last 3 months, unless contraindicated or clinically significant adverse effects are experienced (document drug, date, and duration of trials)

-AND-

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

i. Cimzia (certolizumab)
ii. Humira (adalimumab)
iii. Enbrel (etanercept)

-AND-

(d) **One** of the following (document date and duration of trial):

i. History of 6 month trial of Cosentyx (secukinumab) with moderate clinical response yet residual disease activity

-OR-

ii. **Both** of the following:

1. History of intolerance or adverse event to Cosentyx
2. Physician attests that in their clinical opinion the same intolerance or adverse event would not be expected to occur with Taltz

-AND-

(e) Patient is not receiving Taltz in combination with **any** of the following:

i. Biologic DMARD [e.g., Humira (adalimumab), Cimzia (certolizumab), Simponi (golimumab), Cosentyx (secukinumab), Orencia (abatacept)]
ii. Janus kinase inhibitor [e.g., Xeljanz (tofacitinib)]
iii. Phosphodiesterase 4 (PDE4) inhibitor [e.g. Otezla (apremilast)]

-AND-

(f) Prescribed by or in consultation with a rheumatologist

-OR-

(2) **All** of the following:

(a) Patient is currently on Taltz therapy as documented by claims history or medical records (document date and duration of therapy)

-AND-

(b) Diagnosis of active ankylosing spondylitis

-AND-

(c) Patient is not receiving Taltz in combination with **any** of the following:

i. Biologic DMARD [e.g., Humira (adalimumab), Cimzia (certolizumab), Simponi (golimumab), Cosentyx (secukinumab), Orencia (abatacept)]
ii. Janus kinase inhibitor [e.g., Xeljanz (tofacitinib)]
iii. Phosphodiesterase 4 (PDE4) inhibitor [e.g. Otezla (apremilast)]

-AND-

(d) Prescribed by or in consultation with a rheumatologist

Authorization will be issued for 12 months.

2. Reauthorization

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

(1) Documentation of positive clinical response to Taltz therapy

-AND-

(2) Patient is not receiving Taltz in combination with **any** of the following:

i. Biologic DMARD [e.g., Humira (adalimumab), Cimzia (certolizumab), Simponi (golimumab), Cosentyx (secukinumab), Orencia (abatacept)]
ii. Janus kinase inhibitor [e.g., Xeljanz (tofacitinib)]
iii. Phosphodiesterase 4 (PDE4) inhibitor [e.g. Otezla (apremilast)]

-AND-

(3) Prescribed by or in consultation with a rheumatologist

Reauthorization will be issued for 12 months.

D. Non-radiographic Axial Spondyloarthritis

1. Initial Authorization

a. Taltz will be approved based on **one** of 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) 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)

-AND-

(c) History of failure, contraindication, or intolerance to the following preferred biologic product (document date, and duration of trial):

i. Cimzia (certolizumab)

-AND-

(d) **One** of the following (document date and duration of trial):

i. History of 6 month trial of Cosentyx (secukinumab) with moderate clinical response yet residual disease activity

-OR-

ii. **Both** of the following:

1. History of intolerance or adverse event to Cosentyx
2. Physician attests that in their clinical opinion the same intolerance or adverse event would not be expected to occur with Taltz

(e) Patient is not receiving Taltz in combination with **any** of the following:

i. Biologic DMARD [e.g., Humira (adalimumab), Cimzia (certolizumab), Simponi (golimumab), Cosentyx (secukinumab), Orencia (abatacept)]
ii. Janus kinase inhibitor [e.g., Xeljanz (tofacitinib)]

-AND-

(f) Prescribed by or in consultation with a rheumatologist

OR-

(2) **All** of the following:

(a) Patient is currently on Taltz therapy as documented by claims history or medical records (document date, and duration of therapy)

-AND-

(b) Diagnosis of active non-radiographic axial spondyloarthritis

-AND-

(c) Patient is not receiving Taltz in combination with **any** of the following:

i. Biologic DMARD [e.g., Humira (adalimumab), Cimzia (certolizumab), Simponi (golimumab), Cosentyx (secukinumab), Orencia (abatacept)]
ii. Janus kinase inhibitor [e.g., Xeljanz (tofacitinib)]

-AND-

(d) Prescribed by or in consultation with a rheumatologist

Authorization will be issued for 12 months.

2. Reauthorization

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

(1) Documentation of positive clinical response to Taltz therapy

-AND-

(2) Patient is not receiving Taltz in combination with **any** of the following:
i. Biologic DMARD [e.g., Humira (adalimumab), Cimzia (certolizumab), Simponi (golimumab), Cosentyx (secukinumab), Orencia (abatacept)]
ii. Janus kinase inhibitor [e.g., Xeljanz (tofacitinib)]

-AND-

(3) Prescribed by or in consultation with a rheumatologist

Reauthorization will be issued for 12 months.

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 may be in place.

4. References:

1. Taltz [package insert]. Indianapolis, IN: Eli Lilly and Company; May 2020.
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.
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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.
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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. M enter 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 –Taltz (ixekizumab)
Change Control	
Date	Change
5/2016	New program
9/2016	Updated clinical criteria to align with Employer & Individual medical necessity policy except trial/failure of Enbrel instead of Stelara
2/2017	Changed BSA requirement from 10% to 5% to align with AAD guidelines
5/2017	Updated disease severity criteria to include facial and genital areas and specified that BSA is greater than or equal to 5%. Added criteria for patients already receiving Taltz. Updated references.
9/2017	Updated preferred biologic products to include Otezla
2/2018	Updated background and clinical criteria to account for new indication of psoriatic arthritis. Revised trial/fail products in psoriasis section. Updated references.
2/2019	Added Cimzia as a step therapy medication for psoriasis. Updated reference.
11/2019	Added review criteria for ankylosing spondylitis. Updated background and references.
12/2019	Revised additional prerequisite therapies and added documentation of drug, date, and duration of trials.
1/2020	Revised psoriasis step therapy medications due to PDL changes.
5/2020	Added prescriber requirement. Minor updates to prerequisite therapy requirements. Changed BSA requirement to 3% to align with current psoriasis guidelines.
7/2020	Updated background and criteria with new indication for non-radiographic axial spondyloarthritis (included bypass of ST if patient currently on therapy and reauth criteria) Updated references.
11/2020	Minor formatting revisions.