UnitedHealthcare Community Plan

Clinical Pharmacy Program Guidelines for Taltz

Program	Prior Authorization
Medication	Taltz (ixekizumab)
Markets in Scope	California, Florida-CHIP, Hawaii, Maryland, Nevada, New Mexico, New York, Ohio, Rhode Island
Issue Date	5/2016
Pharmacy and Therapeutics Approval Date	2/2018
Effective Date	4/2018

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.[1]

2. Coverage Criteria:

A. Plaque Psoriasis

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 chronic moderate to severe plaque psoriasis

-AND-

(b) Greater than or equal to 5% body surface area involvement, palmoplantar, facial, or genital involvement, or severe scalp psoriasis

-AND-

(c) **Both** of the following:

i. History of failure, contraindication, or intolerance to **one** of

the following topical therapies:

- 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, contraindication, or intolerance to a 3 month trial of methotrexate (document drug, date, and duration of trial)

-AND-

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

i. Humira (adalimumab)
ii. Enbrel (etanercept)

-AND-

(e) **One** of the following (document drug, 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)]

-OR-

(2) Both of the following:

(a) Patient is currently on Taltz therapy

-AND-

(b) 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)]

Authorization will be issued for 12 months.

2. **Reauthorization**

a. **Taltz** will be approved based on **both** 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)]

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, contraindication, or intolerance to a 3 month trial to methotrexate (document drug, 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 drug, 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)]

-OR-

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

(a) Patient is currently on Taltz therapy

-AND-

(b) 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)]

Authorization will be issued for 12 months.

2. **Reauthorization**

a. **Taltz** will be approved based on **both** 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)]

Reauthorization will be issued for 12 months

3. References:

1. Taltz Prescribing Information. Indianapolis, IN: Eli Lilly and Company; December 2017.
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. 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.

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.