

Clinical Pharmacy Program Guidelines for Taltz- ARIZONA

Program	Prior Authorization
Medication	Taltz (ixekizumab)
Issue Date	1/2018

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:

<p>A. <u>Plaque Psoriasis</u></p> <p>1. <u>Initial Authorization</u></p> <p>a. Taltz will be approved based on <u>one</u> of the following criteria:</p> <p>(1) Submission of medical records (e.g., chart notes, laboratory values) documenting <u>all</u> of the following:</p> <p>(a) Diagnosis of chronic moderate to severe plaque psoriasis</p> <p style="text-align: center;">-AND-</p> <p>(b) Greater than or equal to 5 % body surface area involvement, palmoplantar, facial, or genital involvement, or severe scalp psoriasis</p> <p style="text-align: center;">-AND-</p> <p>(c) History of failure, contraindication, or intolerance to <u>Both</u> of the following conventional therapies:</p> <p>i. History of failure, contraindication, or intolerance to Topical therapy with <u>one</u> of the following <u>topical therapies</u>:</p> <ul style="list-style-type: none"> ▪ Corticosteroids (e.g., betamethasone, clobetasol, desonide) ▪ Vitamin D analogs (e.g., calcitriol, calcipotriene) ▪ Tazarotene ▪ Calcineurin inhibitors (e.g., tacrolimus, pimecrolimus) ▪ Anthralin
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- Coal tar

-AND-

- ii. History of failure, contraindication, or intolerance to a 3 month trial of methotrexate (document drug, date, and duration of trial)
~~Systemic therapy of at least 3 months duration with methotrexate~~

-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) 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) **All** 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:¹

- 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.

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

~~i. Cimzia (certolizumab)~~

i. Humira (adalimumab)

ii. Enbrel (etanercept)

-AND-

(d) 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. 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.

Program	Prior Authorization – Taltz (ixekizumab)
Change Control	

Date	Change
1/2018	New Program specific to Arizona (different preferred products)