

**Taltz® (ixekizumab)**  
**Effective 06/22/20**

<b>Plan</b>	<input checked="" type="checkbox"/> MassHealth <input type="checkbox"/> Commercial/Exchange	<b>Program Type</b>	<input checked="" type="checkbox"/> Prior Authorization
<b>Benefit</b>	<input checked="" type="checkbox"/> Pharmacy Benefit <input type="checkbox"/> Medical Benefit (NLX)		<input type="checkbox"/> Quantity Limit <input type="checkbox"/> Step Therapy
<b>Specialty Limitations</b>	This medication has been designated specialty and must be filled at a contracted specialty pharmacy.		
<b>Contact Information</b>	<b>Specialty Medications</b>		
	All Plans	Phone: 866-814-5506	Fax: 866-249-6155
	<b>Non-Specialty Medications</b>		
	MassHealth	Phone: 877-433-7643	Fax: 866-255-7569
	Commercial	Phone: 800-294-5979	Fax: 888-836-0730
	Exchange	Phone: 855-582-2022	Fax: 855-245-2134
	<b>Medical Specialty Medications (NLX)</b>		
	All Plans	Phone: 844-345-2803	Fax: 844-851-0882
<b>Exceptions</b>	N/A		

### Overview

Taltz® (ixekizumab) is a humanized interleukin-17A antagonist indicated for the treatment of adults with:

1. Moderate-to-severe plaque psoriasis who are candidates for systemic therapy or phototherapy
2. Active psoriatic arthritis
3. Active ankylosing spondylitis

### Coverage Guidelines

Approval will be granted if the member meets the following diagnosis specific criteria:

#### Moderate to severe plaque psoriasis

Authorization may be granted for members who are currently receiving treatment with Taltz excluding when the product is obtained as samples or via manufacturer's patient assistance programs.

#### OR

Authorization may be granted for members when all the following criteria are met, and documentation is provided:

1. Member has a diagnosis of moderate-severe plaque psoriasis
2. Member is at least 6 years of age
3. Dosing is appropriate (see appendix)
4. Prescriber has provided documentation of ONE of the following:
  - a. Inadequate response or adverse reaction to at least TWO conventional therapies in any one of the following combinations (combinations DO NOT have to be used concurrently):
    - i. 1 topical agent + 1 systemic agent
    - ii. 1 topical agent + 1 phototherapy (required for diagnosis of guttate psoriasis)
    - iii. 1 systemic agent + 1 phototherapy



- iv. 2 systemic agents
- b. Contraindication to ALL conventional therapies (topical agents, phototherapy, and systemic agents)
- c. Inadequate response or adverse reaction to either Humira OR Enbrel

### **Psoriatic arthritis**

Authorization may be granted for members who are currently receiving treatment with Taltz excluding when the product is obtained as samples or via manufacturer's patient assistance programs.

#### **OR**

Authorization may be granted for members when all the following criteria are met, and documentation is provided:

1. Member has a diagnosis of psoriatic arthritis **AND**
  2. Member is at least 18 years of age **AND**
  3. Prescriber has provided documentation of ONE of the following:
    - a. Inadequate response, adverse reaction, or contraindication to at least ONE traditional DMARD (hydroxychloroquine, methotrexate, sulfasalazine)
    - b. Inadequate response or adverse reaction to Enbrel OR Humira
- AND**
4. Dosing is appropriate (see appendix)

### **Ankylosing Spondylitis**

Authorization may be granted for members who are currently receiving treatment with Taltz excluding when the product is obtained as samples or via manufacturer's patient assistance programs.

#### **OR**

Authorization may be granted for members when all the following criteria are met, and documentation is provided:

1. Member has a diagnosis of ankylosing spondylitis **AND**
  2. Member is at least 18 years of age **AND**
  3. Prescriber has provided documentation of ONE of the following:
    - a. Inadequate response or adverse reaction to two non-steroidal anti-inflammatory drug (NSAID)
    - b. Contraindication to ALL NSAIDs
  4. Inadequate response or adverse reaction to either Humira OR Enbrel
- AND**
5. Dosing is appropriate (see appendix)

### **Continuation of Therapy**

Reauthorization requires physician documentation indicating a positive response to therapy.

### **Limitations**

1. Initial approvals will be varied based on the treatment:
  - a. For moderate to severe plaque psoriasis, approvals will be granted for 3 months.
  - b. For psoriatic arthritis and ankylosing spondylitis, approvals will be granted for 6 months.
2. Reauthorizations will be granted for 12 months.

## Appendices

### Dosing

<p>Taltz® (ixekizumab)</p>	<p><b>Plaque Psoriasis:</b> <u>SQ:</u> 160 mg initially at week 0, followed by 80 mg at weeks 2, 4, 6, 8, 10 and 12; followed by 80 mg every four weeks</p> <p><b>Psoriatic Arthritis and Ankylosing Spondylitis:</b> <u>SQ:</u> 160 mg initially at week 0, followed by 80 mg every 4 weeks.</p> <p>For psoriatic arthritis patients with coexistent moderate-to-severe plaque psoriasis, use the dosing regimen for plaque psoriasis</p>
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### References

1. Taltz (ixekizumab) [prescribing information]. Indianapolis, IN: Eli Lilly and Co; May 2018
2. Nash P, Kirkham B, Okada M, et al. Ixekizumab for the treatment of patients with active psoriatic arthritis and an inadequate response to tumour necrosis factor inhibitors: results from the 24-week randomised, double-blind, placebo-controlled period of the SPIRIT-P2 phase 3 trial. *Lancet* 2017; 389:2317.
3. Menter A, Korman NJ, Elmets CA, et al. Guidelines of care for the management of psoriasis and psoriatic arthritis. Section 4: Guidelines of care for the management and treatment of psoriasis with traditional systemic agents. *J Am Acad Dermatol.* 2009; 61:451-485.
4. Griffiths CE, Reich K, Lebwohl M, et al. Comparison of ixekizumab with etanercept or placebo in moderate-to-severe psoriasis (UNCOVER-2 and UNCOVER-3): results from two phases 3 randomised trials. *Lancet.* 2015;386(9993):541-51.
5. Gossec L, Smolen JS, Ramiro S, et al. European League Against Rheumatism (EULAR) recommendations for the management of psoriatic arthritis with pharmacological therapies: 2015 update. *Ann Rheum Dis.* 2016;75(3):499-510.
6. McInnes IB, Mease PJ, Kirkham B, et al. Secukinumab, a human anti-interleukin-17A monoclonal antibody, in patients with psoriatic arthritis (FUTURE 2): a randomised, double-blind, placebo-controlled, phase 3 trial. *Lancet.* 2015;386(9999):1137-46.

### Review History

11/28/16 – Reviewed

02/27/17 – Adopted SGM & ST

03/20/17 – Effective

03/01/18 – Adopted MH RS

02/20/19 – Reviewed in P&T Meeting

4/15/20 – MH unified drug list to prefer Taltz; change previous use of ONE biologic DMARD to inadequate response to Enbrel OR Humira; added indication of ankylosing spondylitis; updated age requirement of plaque psoriasis to  $\geq 6$  years. Change effective 6/22/20.

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