

**Taltz® (ixekizumab)  
Effective 08/01/2022**

<b>Plan</b>	<input type="checkbox"/> MassHealth <input checked="" type="checkbox"/> MassHealth (PUF) <input type="checkbox"/> Commercial/Exchange	<b>Program Type</b>	<input checked="" type="checkbox"/> Prior Authorization <input checked="" type="checkbox"/> Quantity Limit <input type="checkbox"/> Step Therapy
<b>Benefit</b>	<input checked="" type="checkbox"/> Pharmacy Benefit <input type="checkbox"/> Medical Benefit (NLX)		
<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:

- Moderate-to-severe plaque psoriasis (PsO)
- Active psoriatic arthritis (PsA)
- Active ankylosing spondylitis (AS)
- Non-radiographic axial spondyloarthritis

**Coverage Guidelines**

Authorization may be reviewed on a case by case basis for members new to AllWays Health Partners 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:

Moderate to Severe Plaque Psoriasis

Prescriber provides documentation of ALL of the following:

1. Appropriate diagnosis
2. **ONE** of the following:
  - a. Paid claims or physician documented inadequate response or adverse reaction to **ONE** conventional therapy (see appendix B)
    - i. topical agent
    - ii. phototherapy
    - iii. systemic agent



- b. Contraindication to **ALL** conventional therapies:
    - i. topical agents
    - ii. phototherapy
    - iii. systemic agents
  - c. Paid claims or physician documented inadequate response or adverse reaction to **ONE** biologic DMARD that is FDA-approved for plaque psoriasis
3. Appropriate dosing

**Psoriatic Arthritis (PsA)**

Prescriber provides documentation of **ALL** of the following:

- 1. Appropriate diagnosis
- 2. **ONE** of the following:
  - a. Paid claims or physician documented inadequate response or adverse reaction to **ONE** anti-TNF agent that is FDA-approved for the requested indication
  - b. Contraindication to **ALL** anti-TNF agents that are FDA-approved for the requested indication
- 3. Appropriate dosing

**Ankylosing spondylitis (AS) and Non-radiographic axial spondyloarthritis**

Prescriber provides documentation of **ALL** of the following:

- 1. Appropriate diagnosis
- 2. Paid claims or physician documented inadequate response or adverse reaction to **TWO** NSAIDs or contraindication to **ALL** NSAIDs
- 3. **ONE** of the following:
  - a. Paid claims or physician documented inadequate response or adverse reaction to **ONE** anti-TNF agent that is FDA-approved for the requested indication
  - b. Contraindication to **ALL** anti-TNF agents that are FDA-approved for the requested indication
- 4. Appropriate dosing (see appendix A)

**Continuation of Therapy**

Resubmission by prescriber for any of the following FDA-approved diagnoses will infer a positive response to therapy and request can be recertified if dosing is appropriate.

**Limitations**

- 1. Initial approvals will be granted for:
  - a. Plaque Psoriasis: 3 months.
  - b. All other diagnosis: 6 months.
- 2. Reauthorizations will be granted for 12 months
- 3. The following quantity limits apply:

Taltz Inj 80mg/mL	80mg (1mL) per 28 days
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**Appendices**

**Appendix A: Dosing**

Taltz® (ixekizumab)	<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></p>
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	<p><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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Appendix B. Conventional Therapies for Plaque Psoriasis	
Conventional Treatment Lines	Agents Used
Topical Agents	emollients, keratolytics, corticosteroids, coal tar, anthralin, calcipotriene, tazarotene, calcitriol, calcineurin inhibitors
Systemic Agents	Traditional DMARDs: methotrexate, apremilast, acitretin,
Phototherapy	ultraviolet A and topical psoralens (topical PUVA), ultraviolet A and oral psoralens (systemic PUVA), narrow band UV-B (NUVB)

### Appendix C: More Frequent/High Doses

Requests for more frequent or higher doses of injectable biologics may be approved if **ALL** of the following is provided:

1. Documentation of severe disease
2. Documentation partial response to FDA-approved dosing of current biologic therapy
3. Documentation of specialist consult for the requested indication

### References

1. Taltz (ixekizumab) [prescribing information]. Indianapolis, IN: Eli Lilly and Co; November 2021.
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

4/15/2020 – 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.



10/21/2020 – Reviewed and Updated; separated out Comm/Exch vs. MassHealth. Matched MassHealth Preferred Unified Formulary for implementation 1/1/2021

11/17/2021 – Reviewed and Updated for Nov P&T; matched MH UPPL; updated to reflect criteria changes based on literature; added appendix with higher dose/more frequent dosing

11/17/2021 – Updated per MH UPPL: criteria for Taltz revised for psoriatic arthritis, ankylosing spondylitis and non-radiographic axial spondyloarthritis based on contract. Additionally, recertification criteria regarding Cosentyx requests approved for ankylosing spondylitis or non-radiographic axial spondyloarthritis prior to Taltz require was removed as this is no longer a requirement in the criteria. Effective 01/01/2022.

05/18/2022 – Reviewed and Updated for May P&T; Guideline updated to remove the step requirement through Stelara for requests for Taltz in psoriasis and psoriatic arthritis, as per MassHealth request.

06/22/2022 – Reviewed and Updated for June P&T; matched MH UPPL. Continuation of therapy language was updated. Appendix C: More Frequent/High Doses was updated to allow requests for Taltz to be approved without documentation of a trial with another injectable biologic. Updated References. Effective 08/01/2022

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