Taltz® (ixekizumab)
Effective 01/01/2022

Plan	☐ MassHealth ☒ MassHealth (PUF) ☐Commercial/Exchange	**Program Type**	☒ Prior Authorization ☒ Quantity Limit ☐ Step Therapy
Benefit	☒ Pharmacy Benefit ☐ Medical Benefit (NLX)		
Specialty Limitations	This medication has been designated specialty and must be filled at a contracted specialty pharmacy.		
Contact Information	**Specialty Medications**		
	All Plans	Phone: 866-814-5506	Fax: 866-249-6155
	Non-Specialty Medications		
	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
	Medical Specialty Medications (NLX)		
	All Plans	Phone: 844-345-2803	Fax: 844-851-0882
Exceptions	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:

<u>Moderate to Severe Plaque Psoriasis</u>

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. Prescriber provides clinical rationale for use of the requested agent instead of Stelara
4. Appropriate dosing

Psoriatic Arthritis (PsA)
Prescriber provides documentation of **ALL** of the following:
1. Appropriate diagnosis
2. **BOTH** of the following:
    a. Paid claims or physician documented inadequate response, adverse reaction, or contraindication to Stelara
    b. **ONE** of the following:
        i. Paid claims or physician documented inadequate response or adverse reaction to **ONE** anti-TNF agent that is FDA-approved for the requested indication
        ii. Contraindication to **ALL** anti-TNF agents that are FDA-approved for the requested indication
3. Appropriate dosing

NOTE: Requests for Taltz® in non-radiographic axial spondylarthritis may be approved if all criteria are met.

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
Reauthorization requires physician documentation of continuation of therapy, positive response to therapy, FDA approved indication and appropriate dosing.

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

Appendices

Appendix A: Dosing

Taltz® (ixekizumab)	**Plaque Psoriasis:** SQ: 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 **Psoriatic Arthritis and Ankylosing Spondylitis:** SQ: 160 mg initially at week 0, followed by 80 mg every 4 weeks. For psoriatic arthritis patients with coexistent moderate-to-severe plaque psoriasis, use the dosing regimen for plaque psoriasis

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: Off-Label Indications

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. **ONE** of the following:
    a. Paid claims or physician documented inadequate response or adverse reaction to **ONE** other injectable biologic which is FDA-approved for the requested indication
    b. Contraindication to **ALL** other injectable biologics which are FDA-approved for the requested indication
3. Documented partial response to FDA-approved dosing of current biologic therapy
4. Documentation of specialist consult for the requested indication

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 ≥ 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.

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