Mass General Brigham
Health Plan

Taltz (ixekizumab)
Effective 03/01/2023

Plan	☐ MassHealth UPPL ☒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
Ixekizumab is a humanized IgG4 monoclonal antibody that selectively binds with the interleukin 17A (IL-17A) cytokine and inhibits its interaction with the IL-17 receptor. IL-17A is a naturally occurring cytokine that is involved in normal inflammatory and immune responses. Ixekizumab inhibits the release of proinflammatory cytokines and chemokines.

Coverage Guidelines
Authorization may be granted for members new to the plan who are currently receiving treatment with Taltz, excluding when the product is obtained as samples or via manufacturer's patient assistance program
OR
Authorization may be granted if the member meets all the following diagnosis-specific criteria and documentation has been submitted:

Moderate to severe plaque psoriasis

1. The member has had a documented inadequate response or intolerable adverse event with ALL the preferred products (Cosentyx, Enbrel, Humira, Otezla, Skyrizi and Stelara) unless there is a documented clinical reason to avoid the products
2. The member has at least 5% of body surface area (BSA) affected OR crucial body areas (e.g., hands, feet, face, neck, scalp, genitals/groin, intertriginous areas) are affected.
3. The member meets any of the following criteria:
4. The member has experienced an inadequate response or adverse reaction to TWO conventional therapies in any one of the following combinations:
    - 1 topical agent + 1 systemic agent
    - 1 topical agent + 1 phototherapy (e.g., UVB, PUVA)

- 1 systemic agent + 1 phototherapy (e.g., UVB, PUVA)
- 2 systemic agents

5. The member has a clinical reason to avoid ALL conventional therapies (topical agents, phototherapy and systemic agents). See Appendix A.
6. The member has severe psoriasis that warrants a biologic DMARD as first-line therapy

Active psoriatic arthritis (PsA)

ONE of the following:

1. The member has had a documented inadequate response or intolerable adverse event with ALL the preferred products (Cosentyx, Enbrel, Humira, Otezla, Stelara, Rinvoq, and Skyrizi).
2. The member has a contraindication to all the preferred agents and BOTH of the following criteria is met:
    a. One of the following:
        i. The member has had an inadequate response to at least a 3-month trial of at least one TNF inhibitor indicated for PsA (see Appendix B).
        ii. The member has experienced an intolerance to a trial of at least one TNF inhibitor indicated for PsA.
        iii. All TNF inhibitors indicated for PsA are not appropriate for the member (e.g., due to comorbidities or a history of infections)
    b. One of the following:
        i. The member has had an intolerance to or inadequate response (after at least 3 months of treatment) with methotrexate OR leflunomide.
        ii. The member has a contraindication to BOTH methotrexate and leflunomide AND has experienced an inadequate response, intolerance, or contraindication to sulfasalazine.

Active ankylosing spondylitis or Radiographic axial spondyloarthritis (AS)

1. The member has had a documented inadequate response or intolerable adverse event with BOTH preferred products (Cosentyx, Enbrel, Rinvoq and Humira).

   AND
2. The member has experienced an inadequate response to at least two non-steroidal anti-inflammatory drugs (NSAIDs).

   OR
3. The prescriber has submitted rationale why Cosentyx, Enbrel, Rinvoq and Humira and NSAIDs are not appropriate therapies.

<u>Continuation of Therapy</u>

Reauthorization of Taltz for all FDA-approved indications will be granted for members (including new members) who meet all initial authorization criteria and achieve or maintain positive clinical response after at least 3 months of therapy with Taltz as evidenced by low disease activity or improvement in signs and symptoms of the condition.

Limitations

1. Approvals will be granted for 12 months
2. For all indications: Member has a pretreatment tuberculosis (TB) screening with a TB skin test or an interferon gamma release assay (e.g., QFT-GIT, T-SPOT.TB).
    a. Note: Members who have received Taltz or any other biologic DMARD or targeted synthetic DMARD (e.g., Xeljanz) are exempt from requirements related to TB screening in this Policy.
3. The following quantity limit applies:

Taltz 80MG/ML	80 mg (1 ml) per 28 days

Appendices

Appendix A
Examples of Clinical Reasons to Avoid Pharmacologic Treatment with Methotrexate, Cyclosporine or Acitretin

1. Alcoholism, alcoholic liver disease or other chronic liver disease
2. Breastfeeding
3. Cannot be used due to risk of treatment-related toxicity
4. Drug interaction
5. Pregnancy or planning pregnancy (male or female)
6. Significant comorbidity prohibits use of systemic agents (examples include liver or kidney disease, blood dyscrasias, uncontrolled hypertension)

Appendix B
TNF Inhibitors Indicated for Psoriatic Arthritis

1. Cimzia (certolizumab pegol)
2. Enbrel (etanercept)
3. Humira (adalimumab)
4. Inflectra (infliximab-dyyb)
5. Renflexis (infliximab-abda)
6. Remicade (infliximab)
7. Simponi (golimumab)

References

1. Taltz (ixekizumab) [prescribing information]. Indianapolis, IN: Eli Lilly and Co; August 2019
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. 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
4. Deodhar A, Strand V, Kay J, Braun J. The term 'non-radiographic axial spondyloarthritis' is much more important to classify than to diagnose patients with axial spondyloarthritis. Ann Rheum Dis 2016; 75:791.
5. Weber U, Jurik AG, Lambert RG, Maksymowych WP. Imaging in Spondyloarthritis: Controversies in Recognition of Early Disease. Curr Rheumatol Rep 2016; 18:58
6. Kimball AB, Luger T, Gottlieb A, et al. Impact of ixekizumab on psoriasis itch severity and other psoriasis symptoms: Results from 3 phase III psoriasis clinical trials. J Am Acad Dermatol 2016; 75:1156
7. Leonardi C, Maari C, Philipp S, et al. Maintenance of skin clearance with ixekizumab treatment of psoriasis: Three-year results from the UNCOVER-3 study. J Am Acad Dermatol 2018; 79:824
8. 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

Review History

02/20/19 – Reviewed
09/18/19 - Added new indication of AS and updated references
11/20/19 – Added Skyrizi as preferred trial for PS
03/16/2022 – Reviewed and Updated for March P&T; Added Rinvoq and Skyrizi as preferred trial for PsA. Effective 05/01/2022
9/21/2022 – Reviewed and Updated for Sept P&T. added Rinvoq as preferred agent for ankylosing spondylitis. Effective 11/1/22.
02/08/2023 – Reviewed and Updated for Feb P&T. Reduces approval duration from 24 months to 12 months. Effective 3/1/2023