Mass General Brigham
Health Plan

Taltz (ixekizumab)
Effective 11/01/2024

Plan	☐ MassHealth UPPL ☒Commercial/Exchange	**Program Type**	☒ Prior Authorization ☐ Quantity Limit ☐ Step Therapy
Benefit	☒ Pharmacy Benefit ☐ Medical Benefit		
Specialty Limitations	This medication has been designated specialty and must be filled at a contracted specialty pharmacy.		
Contact Information	**Medical and Specialty Medications** All Plans | Phone: 877-519-1908 | Fax: 855-540-3693		
	Non-Specialty Medications All Plans | Phone: 800-711-4555 | Fax: 844-403-1029		
Exceptions	N/A		

Overview

Taltz (ixekizumab) is a humanized interleukin-17A antagonist insisted for the treatment of:

- Patients 6 years of age and older with moderate-to-severe plaque psoriasis who are candidates for systemic therapy or phototherapy
- Adults with active ankylosing spondylitis
- Adults with active non-radiographic axial spondyloarthritis with objective signs of inflammation

Coverage Guidelines

Authorization may be granted for members new to the plan within the past 90 days who are currently receiving treatment with the requested medication, 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::

Moderate to severe plaque psoriasis

1. At least 3% of body surface area (BSA) is affected OR crucial body areas (e.g., hands, feet, face, neck, scalp, genitals/groin, intertriginous areas) are affected.
2. The member meets ONE of the following criteria:
    a. Minimum duration of 4-week trial and failure, intolerance, or contraindication to ONE of the following topical therapies
        1. Corticosteroids (e.g., betamethasone, clobetasol)
        2. Vitamin D analogs (e.g., calcitriol, calcipotriene)
        3. Tazarotene
        4. Calcineurin inhibitors (e.g., tacrolimus, pimecrolimus)
        5. Anthralin
        6. Coal tar
    b. The member has severe psoriasis that warrants a biologic DMARD as first-line therapy

3. Trial and failure, intolerance, or contraindication to THREE of the following:
    a. Cimzia
    b. Enbrel
    c. Humira, Hadlima, Adalimumab-adaz, Adalimumab-fkjp
    d. Skyrizi
    e. Stelara
    f. Tremfya
4. Trial and failure, intolerance, or contraindication to Cosentyx

Active psoriatic arthritis (PsA)

1. Member has a diagnosis of active psoriatic arthritis
2. Trial and failure, intolerance, or contraindication to TWO of the following:
    a. Cimzia
    b. Enbrel
    c. Humira, Hadlima, Adalimumab-adaz, Adalimumab-fkjp
    d. Rinvoq/Rinvoq LQ
    e. Simponi
    f. Skyrizi
    g. Stelara
    h. Tremfya
    i. Xeljanz/XR
3. Trial and failure, intolerance, or contraindication to BOTH of the following:
    a. Cosentyx
    b. Orencia
4. The member has ONE of the following:
    a. Actively inflamed joints
    b. Dactylitis
    c. Enthesitis
    d. Axial disease
    e. Active skin and/or nail involvement

Active ankylosing spondylitis

1. The member has a diagnosis of ankylosing spondylitis
2. The member has experienced trial and failure, contraindication or intolerance to at least two non-steroidal anti-inflammatory drugs (NSAIDs) (e.g., ibuprofen, naproxen) at maximally tolerated doses.
3. Trial and failure, intolerance, or contraindication to TWO of the following:
    f. Cimzia
    b. Enbrel
    c. Humira, Hadlima, Adalimumab-adaz, Adalimumab-fkjp
    d. Rinvoq
    e. Simponi
    f. Xeljanz/XR
4. Trial and failure, intolerance, or contraindication to Cosentyx

Non-Radiographic axial spondyloarthritis (nr-axSpa)

1. Member has a diagnosis of non-radiographical axial spondyloarthritis

2. Member has objective signs of inflammation (e.g., C-reactive protein [CRP] levels above the upper limit of normal and/or sacroiliitis on magnetic resonance imaging [MRI], indicative of inflammatory disease, but without definitive radiographic evidence of structural damage on sacroiliac joints)
3. The member has experienced trial and failure, contraindication or intolerance to at least two non-steroidal anti-inflammatory drugs (NSAIDs) (e.g., ibuprofen, naproxen) at maximally tolerated doses.
4. Trial and failure, intolerance, or contraindication to BOTH of the following:
    a. Cimzia
    b. Rinvoq
5. Trial and failure, intolerance, or contraindication to Cosentyx

Continuation of Therapy

Reauthorization of Taltz for all FDA-approved indications will be granted for who 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 24 months
2. The following quantity limit applies:

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

References

1. 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.
2. 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
3. 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
4. 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
5. 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.
6. Taltz (ixekizumab) [prescribing information]. Indianapolis, IN: Eli Lilly and Co; February 2024.
7. Weber U, Jurik AG, Lambert RG, Maksymowych WP. Imaging in Spondyloarthritis: Controversies in Recognition of Early Disease. Curr Rheumatol Rep 2016; 18:58

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.

11/15/2023 – Reviewed and Updated at Nov P&T; For Psoriatic Arthritis: 5% BSA changed to at least 3%. Removed TB requirement. Updated preferred agents to prior use with 3 of the following agents: Cimzia, Enbrel, Humira or biosimilars, Skyrizi, Stelara, Tremfya, AND Cosentyx. Updated topical therapies. For Psoriatic arthritis: Updated preferred agents to require previous use of TWO of the following: Cimzia**,** Enbrel, Humira or biosimilars, Rinvoq, Simponi, Skyrizi, Stelara, Tremfya, Xeljanz/XR, AND Cosentyx, Orencia. Removed requirement of traditional DMARD. Separated out ankylosing spondylitis and non-radiographical axial spondyloarthritis criteria. Removed appendix. Effective 1/1/20240
9/11/2024 – Reviewed and updated at September P&T. Added Rinvoq LQ as a step through treatment option for psoriatic arthritis. Effective 11/1/2024.
10/09/2024 – Reviewed and updated at October P&T. Effective 11/1/2024: updated plaque psoriasis criteria to remove requirement of documentation for conventional therapies. Effective 1/1/2025: added Amjevita (Nuvaila) as a preferred adalimumab product for all indications. Removed biologic step requirements for all indications. Updated reauthorization criteria to require documentation of clinical improvement.