Effective Date: 2/2020
Reviewed: 12/2019, 7/2020, 12/2020, 5/2021 Scope: Medicaid

SPECIALTY GUIDELINE MANAGEMENT

TALTZ (ixekizumab)

POLICY

I. INDICATIONS

The indications below including FDA-approved indications and compendial uses are considered a covered benefit provided that all the approval criteria are met and the member has no exclusions to the prescribed therapy.

FDA-Approved Indications

1. Moderate to severe plaque psoriasis
2. Active psoriatic arthritis
3. Active ankylosing spondylitis
4. Active non-radiographic axial spondyloarthritis (nr-axSpA)

All other indications are considered experimental/investigational and are not a covered benefit.

II. CRITERIA FOR INITIAL AND CONTINUATION OF THERAPY

For all indications:

- Prior Authorization Request is submitted by the Provider's office; AND
- Prior Authorization Request is not submitted by a pharmacy or another third party; AND
- Submission of the member's chart or medical record is required, documenting medical necessity based on the criteria corresponding to the applicable indication.

III. CRITERIA FOR INITIAL APPROVAL

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). *[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.]**;*** AND

A. Moderate to severe plaque psoriasis (PsO)

Authorization of 6 months may be granted for treatment of moderate to severe plaque psoriasis in members who are 18 years of age and older when all of the following criteria are met:

1. Taltz is prescribed by, or in consultation with, a specialist in dermatology or rheumatology.
2. At least 10% of body surface area (BSA) is affected OR crucial body areas (e.g., hands, feet, face, neck, scalp, genitals/groin, intertriginous areas) are affected.
3. Member meets either of the following criteria:
   a. Member has had an inadequate response to at least a 3 month trial of methotrexate, cyclosporine or acitretin, or experienced clinically significant adverse effects from methotrexate, cyclosporine or acitretin
   b. Member has had an inadequate response to at least a 3 month trial of phototherapy (e.g., UVB, PUVA), unless intolerance experienced

4. Taltz will not be used concomitantly with any other biologic DMARD (e.g. adalimumab, infliximab) or targeted synthetic DMARD (e.g. apremilast, tofacitinib).

B. Active psoriatic arthritis (PsA)

Authorization of 6 months may be granted for treatment of active psoriatic arthritis in members who are 18 years of age or older when all of the following criteria are met:

1. Taltz is prescribed by, or in consultation with, a specialist in dermatology or rheumatology.
2. Documented moderate to severe active disease and member meets either of the following criteria:
   a. If member has predominantly axial disease or active enthesitis and/or dactylitis, member has experienced an inadequate response or intolerance to at least two non-steroidal anti-inflammatory drugs (NSAIDs), unless use is contraindicated
   b. If member has peripheral arthritis, member has experienced an inadequate response to a ≥ 3 consecutive month trial a trial of one oral disease-modifying anti-rheumatic agent (DMARD) such as methotrexate, azathioprine, sulfasalazine, or hydroxychloroquine, unless intolerance experienced

C. Active ankylosing spondylitis (AS) and active axial spondyloarthritis

Authorization of 6 months may be granted for treatment of active ankylosing spondylitis and active axial spondyloarthritis in members who are 18 years of age or older when both of the following criteria are met:

1. Taltz is prescribed by, or in consultation with, a specialist in rheumatology.
2. Member has experienced an inadequate response or intolerance to at least two non-steroidal anti-inflammatory drugs (NSAIDs), unless use is contraindicated.

IV. CONTINUATION OF THERAPY

Authorization of 12 months may be granted for all members (including new members) 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.

V. QUANTITY LIMIT

Taltz has a quantity limit of 80mg (1ml) per 28 days, with post-limit for loading dose of 160mg (2ml) per 28 days for PsA and AS and 640mg (8ml) per 84 days for PsO and PsA with comorbid moderate-to-severe PsO.

Indication	Dosing (subcutaneous)
Plaque Psoriasis	160mg (two 80 mg injections) at Week 0, followed by 80 mg at Weeks 2, 4, 6, 8, 10, and 12, then 80 mg every 4 weeks.
Psoriatic Arthritis	160 mg (two 80 mg injections) at Week 0, followed by 80 mg every 4 weeks.
Ankylosing Spondylitis	160 mg (two 80 mg injections) at Week 0, followed by 80 mg every 4 weeks.
Non-radiographic Axial Spondyloarthritis	80 mg every 4 weeks.

VI. REFERENCES

1. Taltz [package insert]. Indianapolis, IN: Eli Lilly and Company; March 2021.
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