Taltz (ixekizumab)

NOTICE

This policy contains information which is clinical in nature. The policy is not medical advice. The information in this policy is used by Wellmark to make determinations whether medical treatment is covered under the terms of a Wellmark member's health benefit plan. Physicians and other health care providers are responsible for medical advice and treatment. If you have specific health care needs, you should consult an appropriate health care professional. If you would like to request an accessible version of this document, please contact customer service at 800-524-9242.

BENEFIT APPLICATION

Benefit determinations are based on the applicable contract language in effect at the time the services were rendered. Exclusions, limitations or exceptions may apply. Benefits may vary based on contract, and individual member benefits must be verified. Wellmark determines medical necessity only if the benefit exists and no contract exclusions are applicable. This medical policy may not apply to FEP. Benefits are determined by the Federal Employee Program.

DESCRIPTION

The intent of the Taltz drug policy is to ensure appropriate selection of patients for therapy based on product labeling, clinical guidelines and clinical studies while steering utilization to the most cost-effective medication within the therapeutic class. For this program, Humira, Enbrel, Cosentyx, Otezla, Rinvoq, Skyrizi, Stelara, Tremfya, and Xeljanz/Xeljanz XR are the preferred products and will apply to members requesting treatment for an indication that is FDA-approved for the preferred product. The criteria will require the use of two of the health plan's preferred products before the use of non-preferred products unless there are clinical circumstances that exclude the use of all the preferred products, the patient is currently receiving treatment with the non-preferred drug and experience a positive therapeutic outcome, or there is only one preferred product for an indication.

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 in patients aged 6 years and older who are candidates for systemic therapy or phototherapy
2. Adult patients with active psoriatic arthritis
3. Adult patients with active ankylosing spondylitis
4. Adult patients with active non-radiographic axial spondyloarthritis (nr-axSpA) with objective signs of inflammation

POLICY

Required Documentation

Submission of the following information is necessary to initiate the prior authorization review:

A) Plaque psoriasis
1. Initial requests:
    i. Chart notes or medical record documentation of affected area(s) and body surface area (BSA) affected.
    ii. Chart notes, medical record documentation, or claims history supporting previous medications tried (if applicable), including response to therapy. If therapy is not advisable, documentation of clinical reason to avoid therapy.
2. Continuation requests: Chart notes or medical record documentation of decreased body surface area (BSA) affected and/or improvement in signs and symptoms.

B) Psoriatic arthritis: For continuation requests: Chart notes or medical record documentation supporting positive clinical response.

C) Ankylosing spondylitis and axial spondyloarthritis:
1. Initial requests: Chart notes, medical record documentation, or claims history supporting previous medications tried (if applicable), including response to therapy. If therapy is if not advisable, documentation of clinical reason to avoid therapy.
2. Continuation requests: Chart notes or medical record documentation supporting positive clinical response.

Must meet BOTH the Preferred Drug Plan Design and Criteria for Initial Approval/Continuation of Therapy when both are applicable.

Preferred Drug Plan Design

A) Moderate to severe psoriatic arthritis
1. Criteria for initial approval on moderate to severe plaque psoriasis will only apply when at least ONE of the following criteria are met:
    a) Member has had an inadequate response to treatment or intolerable adverse event with Cosentyx and another of the preferred products (Enbrel, Humira, Rinvoq, Stelara, Otezla, Tremfya, and Xeljanz/Xeljanz XR)
    b) Member has a clinical reason to avoid Enbrel and Humira (See Appendix A) AND has had an inadequate response to treatment or intolerable adverse event with Cosentyx and another of the preferred products (Stelara, Otezla, Tremfya, Rinvoq and Xeljanz/Xeljanz XR)
    c) Member is currently receiving treatment with the requested product through insurance (excludes obtainment as samples or via manufacturer's patient assistance programs) and experiencing a positive therapeutic outcome

B) Moderate to severe plaque psoriasis (adults)
1. Criteria for initial approval on moderate to severe plaque psoriasis in adults will only apply when at least ONE of the following criteria are met:
    a) Member has had an inadequate response to treatment or intolerable adverse event with Cosentyx and another of the preferred products (Humira, Enbrel, Otezla, Skyrizi, Stelara, and Tremfya)
    b) Member has a clinical reason to avoid Enbrel and Humira (See Appendix A) AND has had an inadequate response to treatment or intolerable adverse event with Cosentyx and another of the preferred products (Otezla, Skyrizi, Stelara, and Tremfya)
    c) Member is currently receiving treatment with the requested product through insurance (excludes obtainment as samples or via manufacturer's patient assistance programs) and experiencing a positive therapeutic outcome

C) Moderate to severe plaque psoriasis (pediatrics)

1. Criteria for initial approval on moderate to severe plaque psoriasis in pediatrics will only apply when at least ONE of the following criteria are met:
    a) Member has had an inadequate response to treatment or intolerable adverse event with Cosentyx and another of the preferred products (Enbrel and Stelara)
    b) Member is currently receiving treatment with the requested product through insurance (excludes obtainment as samples or via manufacturer's patient assistance programs) and experiencing a positive therapeutic outcome

D) Active ankylosing spondylitis

1. Criteria for initial approval on moderate to active ankylosing spondylitis will only apply when at least ONE of the following criteria are met:
    a) Member has had an inadequate response to treatment or intolerable adverse event with Cosentyx and another of the preferred products (Enbrel, Humira, Rinvoq, and Xeljanz/Xeljanz XR)
    b) Member has a clinical reason to avoid Enbrel and Humira (See Appendix A) AND has had an inadequate response to treatment or intolerable adverse event with both of the preferred products (Cosentyx and Xeljanz)
    c) Member is currently receiving treatment with the requested product through insurance (excludes obtainment as samples or via manufacturer's patient assistance programs) and experiencing a positive therapeutic outcome

E) Non-radiographic axial spondyloarthritis

1. Criteria for initial approval on non-radiographic axial spondyloarthritis will only apply when at least ONE of the following criteria are met:
    a) Member has had an inadequate response to treatment or intolerable adverse event with the preferred product, Cosentyx
    b) Member is currently receiving treatment with the requested product through insurance (excludes obtainment as samples or via manufacturer's patient assistance programs) and experiencing a positive therapeutic outcome

Note: Submission of chart notes detailing the outcomes of treatment, intolerable adverse event(s) experienced, contraindication(s), or exclusion(s) to treatment with preferred product(s) is required (where applicable).

<u>Criteria for Initial Approval</u>

A) Moderate to severe plaque psoriasis

1. Authorization of 12 months may be granted for members who have previously received Otezla or a biologic indicated for the treatment of moderate to severe plaque psoriasis.
2. Authorization of 12 months may be granted for treatment of moderate to severe plaque psoriasis when all of the following criteria are met:
    a) 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.
    b) Member meets any of the following criteria:
        i.) Member has had an inadequate response or intolerance to either phototherapy (e.g., UVB, PUVA) or pharmacologic treatment with methotrexate, cyclosporine or acitretin.
        ii.) Member has a clinical reason to avoid pharmacologic treatment with methotrexate, cyclosporine and acitretin (see Appendix B).
        iii.) Member has severe psoriasis that warrants a biologic DMARD as first-line therapy(i.e. at least 10% of the body surface area (BSA) or crucial body areas (e.g., hands, feet, face, neck, scalp, genitals/groin, intertriginous areas) are affected).

B) Active psoriatic arthritis (PsA)

1. Authorization of 12 months may be granted for treatment of active psoriatic arthritis.

C) Active ankylosing spondylitis (AS) and active non-radiographic axial spondyloarthritis (nr-axSpA)

1. Authorization of 12 months may be granted for members who have previously received a biologic indicated for active ankylosing spondylitis.
2. Authorization of 12 months may be granted for treatment of active ankylosing spondylitis when either of the following criteria is met:
   a. Member has experienced an inadequate response to at least two non-steroidal anti-inflammatory drugs (NSAIDs).
   b. Member has an intolerance or contraindication to two or more NSAIDs.

Continuation of Therapy

A) Moderate to severe plaque psoriasis (PsO)

Authorization of 12 months may be granted for all members (including new members) who are using the requested medication for moderate to severe plaque psoriasis and who achieve or maintain positive clinical response as evidenced by low disease activity or improvement in signs and symptoms of the condition when any of the following is met:

1. Reduction in body surface area (BSA) affected from baseline
2. Improvement in signs and symptoms from baseline (e.g., itching, redness, flaking, scaling, burning, cracking, pain)

B) Active psoriatic arthritis (PsA)

Authorization of 12 months may be granted for all members (including new members) who are using the requested medication for active psoriatic arthritis and who achieve or maintain positive clinical response as evidenced by low disease activity or improvement in signs and symptoms of the condition when there is improvement in any of the following from baseline:

1. Number of swollen joints
2. Number of tender joints
3. Dactylitis
4. Enthesitis
5. Skin and/or nail involvement

C) Active ankylosing spondylitis (AS) and active non-radiographic axial spondyloarthritis

Authorization of 12 months may be granted for all members (including new members) who are using the requested medication for active ankylosing spondylitis or active non-radiographic axial spondyloarthritis and who achieve or maintain positive clinical response with the requested medication as evidenced by low disease activity or improvement in signs and symptoms of the condition when there is improvement in any of the following from baseline:

1. Functional status
2. Total spinal pain
3. Inflammation (e.g., morning stiffness)

Other

For all indications: Member has had a documented negative TB test (which can include a tuberculosis skin test [PPD], an interferon-release assay [IGRA], or a chest x-ray)* within 6 months of initiating therapy for persons who are naïve to biologic DMARDs or targeted synthetic DMARDs associated with an increased risk of TB.

* If the screening testing for TB is positive, there must be further testing to confirm there is no active disease. Do not administer the requested medication to members with active TB infection. If there is latent disease, TB treatment must be started before initiation of the requested medication.

For all indications: Member cannot use the requested medication concomitantly with any other biologic DMARD or targeted synthetic DMARD.

Taltz is considered **not medically necessary** for members who do not meet the criteria set forth above.

Dosage and Administration

Approvals may be subject to dosing limits in accordance with FDA-approved labeling, accepted compendia, and/or evidence-based practice guidelines.

Quantity Limits

Trade Name	Generic Name	Quantity Limit
Taltz®	Ixekizumab	**Plaque Psoriasis** Initiation of therapy (adults): 8 syringes or auto-injectors per first 84 days (12 weeks) Maintenance (adults): 1 syringe or auto-injector per 28 days Initiation of therapy (pediatrics): 2 syringes or auto-injectors per first 28 days (4 weeks) if body weight > 50kg, 1 syringe or auto-injector per first 28 days (4 weeks) if body weight ≤ 50kg Maintenance (pediatrics): 1 syringe or auto-injector per 28 days **Psoriatic Arthritis and Ankylosing Spondylitis** Initiation of therapy: 2 syringes or auto-injectors per first 28 days (4 weeks) Maintenance: 1 syringe or auto-injector per 28 days **Active Non-Radiographic Axial Spondyloarthritis** Initiation & Maintenance: 1 syringe or auto-injector per 28 days

Appendix

Appendix A: Clinical reasons to avoid TNF-inhibitors

1. History of demyelinating disorder
2. History of congestive heart failure
3. History of hepatitis B infection
4. Autoantibody formation/lupus-like syndrome
5. Risk of lymphoma

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

1. Clinical diagnosis of alcohol use disorder, 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 currently planning pregnancy
6. Significant comorbidity prohibits use of systemic agents (examples include liver or kidney disease, blood dyscrasias, uncontrolled hypertension)

PROCEDURES AND BILLING CODES

To report provider services, use appropriate CPT* codes, Alpha Numeric (HCPCS level 2) codes, Revenue codes, and/or ICD diagnostic codes.

- N/A

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*Some content reprinted from CVSHealth

POLICY HISTORY

Policy #: 05.02.15
Reviewed: October 2022
Revised: October 2022
Current Effective Date: November 30, 2022