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 and Stelara are the preferred products. 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, or the patient is currently receiving treatment with the non-preferred drug and experience a positive therapeutic outcome.

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
2. Active psoriatic arthritis
3. Active ankylosing spondylitis
4. Active non-radiographic axial spondylorarthritis

POLICY

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

Preferred Drug Plan Design

Wellmark Blue Cross and Blue Shield is an independent licensee of the Blue Cross and Blue Shield Association.
© 2020 Wellmark Inc.

A) Moderate to severe plaque psoriasis and psoriatic arthritis (adults)

1. Criteria for initial approval on moderate to severe plaque psoriasis and psoriatic arthritis 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 at least TWO of the preferred products (Humira, Enbrel, Cosentyx, Otezla and Stelara)
    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 at least TWO of the preferred products (Cosentyx, Otezla and Stelara)
    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 (pediatrics)

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 at least TWO of the preferred products (Humira, Enbrel, and Stelara)
    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 the preferred product (Stelara).
    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) Active ankylosing spondylitis

1. Criteria for initial approval on moderate to severe plaque psoriasis and psoriatic arthritis 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 at least TWO of the preferred products (Humira, Enbrel, and Cosentyx)
    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 the preferred product, Cosentyx
    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

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).

Wellmark Blue Cross and Blue Shield is an independent licensee of the Blue Cross and Blue Shield Association.
© 2020 Wellmark Inc.

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)

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.

D) 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 non-radiographic axial spondyloarthritis (nr-axSpA).
2. Authorization of 12 months may be granted for treatment of active non-radiographic axial spondyloarthritis (nr-axSpA) 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

Authorization of 12 months may be granted for all members (including new members) who are using Taltz for an indication outlined in the Criteria for Initial Approval and who achieve or maintain positive clinical response with Taltz as evidenced by low disease activity or improvement in signs and symptoms of the condition.

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 (e.g., Xeljanz), and repeated yearly for members with risk factors** for TB that are continuing therapy with biologics.

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

** Risk factors for TB include: Persons with close contact to people with infectious TB disease; persons who have recently immigrated from areas of the world with high rates of TB (e.g., Africa, Asia, Eastern Europe, Latin America, Russia); children less than 5 years of age who have a positive TB test; groups with high rates of TB transmission (e.g., homeless persons, injection drug users, persons with HIV infection); persons who work or reside with people who are at an increased risk for active TB (e.g., hospitals, long-term care facilities, correctional facilities, homeless shelters).

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

Wellmark Blue Cross and Blue Shield is an independent licensee of the Blue Cross and Blue Shield Association.
© 2020 Wellmark Inc.

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.

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.

Wellmark Blue Cross and Blue Shield is an independent licensee of the Blue Cross and Blue Shield Association.
© 2020 Wellmark Inc.

- N/A

REFERENCES

- Taltz [package insert]. Indianapolis, IN: Eli Lilly and Company; August 2019.
- Menter A, Korman NJ, Elmets CA, et al. Guidelines of care for the management of psoriasis and psoriatic arthritis. Section 6: Guidelines of care for the treatment of psoriasis and psoriatic arthritis: case-based presentations and evidence-based conclusions. *J Am Acad Dermatol*. 2011;65(1):137-174.
- 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.
- 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 phase 3 randomised trials. *Lancet.* 2015;386(9993):541-51.
- 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.
- 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.
- Menter A, Strober BE, Kaplan DH, et al. Joint AAD-NPF guidelines of care for the management and treatment of psoriasis with biologics. J Am Acad Dermatol. 2019;80(4):1029-1072.
- Tuberculosis (TB). TB risk factors. Centers for Disease Control and Prevention. Retrieved on 21 June 2019 from: https://www.cdc.gov/tb/topic/basics/risk.htm.
- Braun J, van den Berg R, Baraliakos X, et al. 2010 update of the ASAS/EULAR recommendations for the management of ankylosing spondylitis. *Ann Rheum Dis* 2011;70:896–904.
- Ward MM, Deodhar A, Akl EA, et al. American College of Rheumatology/Spondylitis Association of America/Spondyloarthritis Research and Treatment Network 2015 recommendations for the treatment of ankylosing spondylitis and nonradiographic axial spondyloarthritis. *Arthritis Rheumatol*. 2015: 10.1002/art.39298.
- Ward MM et al. 2019 Update of the American College of Rheumatology/Spondylitis Association of America/Spondyloarthritis Research and Treatment Network Recommendations for the Treatment of Ankylosing Spondylitis and Nonradiographic Axial Spondyloarthritis. *Arthritis Rheumatol*. 2019;71(10):1599-1613.
- Menter A et al. Joint American Academy of Dermatology – National Psoriasis Foundation guidelines of care for the management and treatment of psoriasis in pediatric patients. *J Am Acad Dermatol*. 2020;82(1):161-201.

*Some content reprinted from CVSHealth

Wellmark Blue Cross and Blue Shield is an independent licensee of the Blue Cross and Blue Shield Association.
© 2020 Wellmark Inc.

POLICY HISTORY

Policy #: 05.02.15
Reviewed: July 2020
Revised: July 2020
Current Effective Date: September 4, 2020

Wellmark Blue Cross and Blue Shield is an independent licensee of the Blue Cross and Blue Shield Association.
© 2020 Wellmark Inc.