Kansas City

An Independent Licensee of the Blue Cross and Blue Shield Association

Taltz (ixekizumab for subcutaneous injection)

Policy Number: 5.01.613
Origination: 4/2016
Last Review: 4/2023
Next Review: 4/2024

Policy

Blue Cross and Blue Shield of Kansas City (Blue KC) will provide coverage for Taltz (ixekizumab) when it is determined to be medically necessary because the criteria shown below are met.

When Policy Topic is covered

Taltz requires prior authorization through the pharmacy services area.

Taltz is considered medically necessary for moderate to severe **plaque psoriasis** in adults who are candidates for systemic therapy or phototherapy after at least a 12-week treatment course of **ONE** first line agent (Cimzia, Enbrel, Humira, Stelara, Skyrizi, or Tremfya) has not been effective.

Taltz is considered medically necessary for moderate to severe **psoriatic arthritis** in adults after at least a 12-week treatment course of **ONE** first line agent (Cimzia, Enbrel, Humira, Simponi, Tremfya, Skyrizi, Rinvoq, Xeljanz/XR or Stelara) has not been effective.

Taltz is considered medically necessary for moderate to severe **ankylosing spondylitis** in adults after at least a 12-week treatment course of **ONE** first line agent (Cimzia, Enbrel, Humira, Rinvoq, Xeljanz/XR, or Simponi) has not been effective.

Taltz is considered medically necessary for **nonradiographic axial spondyloarthritis** in adults after at least a 12-week treatment course of Cimzia OR Rinvoq has not been effective.

This drug is considered a **pharmacy benefit**.

When Policy Topic is not covered

BlueKC may impose administrative limits on the quantity or frequency by which a drug may be dispensed. These limits will be based on recommendations of the drug manufacturer or by community physicians and pharmacists.

Taltz® is considered not medically necessary if the criteria above are not met and investigational for the conditions listed below.

Conditions Not Recommended for Approval

Taltz has not been shown to be effective, or there are limited or preliminary data or potential safety concerns that are not supportive of general approval for the following conditions. Rationale for non-coverage for these specific conditions is provided below. (Note: This is not an exhaustive list of Conditions Not Recommended for Approval.)

1. **Concurrent Use with other Biologics or Targeted Synthetic Disease-Modifying Antirheumatic Drugs (DMARDs).** Taltz should not be administered in combination with another biologic agent for an inflammatory condition (e.g., Cosentyx, Enbrel, Humira, Remicade, Stelara). Combination therapy with two biologic agents is generally not recommended due to a higher rate of adverse

effects with combinations and lack of additive efficacy.[4] Targeted synthetic DMARDs such as Otezla® (apremilast tablets) should not be used in combination with a biologic such as Taltz.[5] Note: This does NOT exclude the use of MTX (a conventional synthetic DMARD used to treat psoriasis) in combination with Taltz.

2. **Inflammatory Bowel Disease (i.e., Crohn's disease, ulcerative colitis).** Exacerbations of inflammatory bowel disease, in some cases serious, occurred in clinical trials with Tatlz-treated patients.[1]

3. **Patients < 18 Years of Age.** Taltz is indicated in adults ≥ 18 years of age. Safety and efficacy in pediatric patients have not been established.[1]

Description of Procedure or Service

Taltz is a humanized immunoglobulin G (IgG) subclass 4 monoclonal antibody with neutralizing activity against interleukin (IL)-17A.[1] IL-17A is a naturally occurring cytokine involved in normal inflammatory and immune responses; therefore, Taltz inhibits the release of proinflammatory cytokines and chemokines. Taltz is indicated for treatment of adults with moderate to severe plaque psoriasis who are candidates for systemic therapy or phototherapy. **In plaque psoriasis, the recommended dose is 160 mg (administered as two 80-mg subcutaneous [SC] injections) at Week 0 followed by 80 mg SC at Weeks 2, 4, 6, 8, 10 and 12, then 80 mg every 4 weeks (Q4W).** Taltz is intended for use under the guidance and supervision of a physician. Those trained in SC injection technique using the pen or prefilled syringe may self-inject when deemed appropriate.

Rationale

References

1. Taltz® injection [prescribing information]. Indianapolis, IN: Eli Lilly and Company; March 2016.
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 phase 3 randomised trials. *Lancet*. 2015;386(9993):541-551.
3. Hsu S, Papp KA, Lebwohl MG, et al. Consensus guidelines for the management of plaque psoriasis. *Arch Dermatol*. 2012;148(1):95-102.
4. Furst DE, Keystone EC, So AK, et al. Updated consensus statement on biological agents for the treatment of rheumatic diseases, 2012. *Ann Rheum Dis*. 2013;72 Suppl 2:ii2-34.
5. Otezla® tablets [prescribing information]. Summit, NJ: Celgene Corporation; December 2015.

Warnings and Precautions

• Antibody formation: Formation of neutralizing anti-drug antibodies may occur with ixekizumab and may be associated with loss of efficacy (AAD/NPF [Menter 2019]).

• Hypersensitivity reactions: Serious hypersensitivity reactions, including urticaria, angioedema, and anaphylaxis (which may lead to hospitalization), have been reported; discontinue immediately if signs/symptoms of a serious hypersensitivity reaction develop and initiate appropriate treatment.

• Infections: May increase the risk of infections. A higher rate of infections was observed with ixekizumab treatment in clinical trials, including upper respiratory tract infection, oral candidiasis, conjunctivitis, and tinea infections. Use with caution in patients with a chronic infection or a history of recurrent infection. In patients who develop a serious infection, monitor closely and discontinue use until the infection resolves.

• Tuberculosis: Patients should be evaluated for tuberculosis (TB) infection prior to initiating therapy; do not initiate therapy in patients with an active TB infection. Consider antituberculosis therapy if an adequate course of treatment cannot be confirmed in patients with a history of latent or active TB. Monitor all patients for signs and symptoms of active TB during and after treatment.

Billing Coding/Physician Documentation Information

NA	Pharmacy benefit; specialty

Policy Implementation/Update Information

04/2016	New policy
03/2017	Updated prerequisite requirements to include preferred agents
03/2018	Reviewed – no changes
06/2019	Step criteria updated to 2 for PsA and 3 for PsO
01/2020	Added ankylosing spondlylitis indication and updated step criteria to be consistent with Optum recommendations.
04/2020	Annual review - no changes made
08/2020	Added new indication and step for noradiographic axial spondyloarthritis
04/2021	Annual review, no changes made
04/2022	Added Tremyfa to the list of T/F meds for diagnosis of PsA
06/2022	Added Rinvoq and Xeljanz/XR to preferred step options for AS
01/2023	Added Enbrel as a preferred step for PsA, PsO, and AS and Rinvoq as a preferred agents for NRX-SPA
04/2023	Added Warnings and Precautions