Pharmacy Medical Necessity Guidelines: Taltz® (ixekizumab)

Effective: January 15, 2018

Prior Authorization Required	√	Type of Review – Care Management	
Not Covered		Type of Review – Clinical Review	√
Pharmacy (RX) or Medical (MED) Benefit	RX	Department to Review	RXUM

This Pharmacy Medical Necessity Guideline applies to the following:

Tufts Health Plan Commercial Plans

☐ Tufts Health Plan Commercial Plans – large group plans
☐ Tufts Health Plan Commercial Plans – small group and individual plans

Tufts Health Public Plans

☐ Tufts Health Direct – Health Connector
☐ Tufts Health Together – A MassHealth Plan
☒ Tufts Health RITogether – A RIte Care + Rhody Health Partners Plan

Tufts Health Freedom Plan products

☐ Tufts Health Freedom Plan - large group plans
☐ Tufts Health Freedom Plan - small group plans

Fax Numbers:

RXUM: 617.673.0988

OVERVIEW

FDA-APPROVED INDICATIONS

Taltz (ixekizumab) is a humanized interleukin-17A antagonist indicated for:

- **Psoriatic arthritis:**
  Taltz (ixekizumab) is indicated for the treatment of adults with active psoriatic arthritis.
- **Plaque psoriasis:**
  Taltz (ixekizumab) is indicated for the treatment of adults with moderate to severe plaque psoriasis who are candidates for systemic therapy or phototherapy.

COVERAGE GUIDELINES

The plan may authorize coverage of Taltz (ixekizumab) for Members when all of the following criteria for a particular regimen are met:

Psoriatic Arthritis

1. The Member has a documented definitive diagnosis from a rheumatologist of active psoriatic arthritis

AND

2. The Member is 18 years of age or older

AND

3. The Member has tried and failed treatment with, has a contraindication to or the provider has indicated clinical inappropriateness of treatment with Enbrel (etanercept) and Humira (adalimumab)

OR

4. The Member is new to the plan and has stable on Taltz (ixekizumab) prior to enrollment

Plaque Psoriasis

1. The Member has a documented definitive diagnosis from a dermatologist of moderate to severe chronic plaque psoriasis

AND

2. The Member is 18 years of age or older

AND

3. The Member has tried and failed treatment with, or the Member has a contraindication to, at least 2 of the preferred therapies, such as PUVA or UVB phototherapy, acitretin, cyclosporine or methotrexate

AND

4. The Member has tried and failed treatment with, or the provider has indicated clinical inappropriateness of treatment with Humira and Enbrel

OR

5. The Member is new to the plan and has been stable on Taltz (ixekizumab) prior to enrollment

LIMITATIONS

1. Samples, free goods or similar offerings of Taltz (ixekizumab) do not qualify for an established clinical response and will not be considered for prior authorization.

2. Coverage of Taltz (ixekizumab) for the diagnosis of psoriatic arthritis will be limited to a 28-day supply
   - One 80 mg autoinjector or syringe per 28-days
3. Coverage for Taltz (ixekizumab) for the diagnosis of plaque psoriasis will be limited to 28-day supplies as follows:
   - Initial dose - four 80 mg autoinjectors or syringes for the initial prescription per 28 days for 1 month
   - Followed by - two 80 mg autoinjectors or syringes per 28 days for 2 months (months 2 and 3)
   - Followed by - one 80 mg autoinjector or syringe per 28 days for maintenance dosing

CODES

Medical billing codes may not be used for this medication. This medication must be obtained via the Member's pharmacy benefit.

REFERENCES

1. Armstrong AW, Lynde CW, McBride SR et al. Effect of Ixekizumab Treatment on Work Productivity for Patients With Moderate-to-Severe Plaque Psoriasis: Analysis of Results From 3 Randomized Phase 3 Clinical Trials. *JAMA Dermatol*. 2016 Mar 7.
2. Bhosle M, Kulkarni A, Feldman SR et al. Quality of life in patients with psoriasis. Health Qual Life Outcomes. 2006;4:35.
3. Callen JP, Krueger GG, Lebwohl M et al. AAD consensus statement on psoriasis therapies. *J Am Acad Dermatol*. 2003; 49:897-9.
4. Enbrel prescribing information. Thousand Oaks, CA: Amgen Inc. and Pfizer Inc.; 2015 March.
5. Farahnik B, Beroukhim K, Zhu TH et al. Ixekizumab for the Treatment of Psoriasis: A Review of Phase III Trials. *Dermatol Ther*. 2016 Mar;6(1):25-37.
6. Food and Drug Administration. Drugs@FDA. URL: accessdata.fda.gov/scripts/cder/drugsatfda. Available from Internet. Accessed 2016 August 5.
7. Gisondi P, Fantin F, Del Giglio M et al. Chronic plaque psoriasis is associated with increased arterial stiffness. *Dermatology*. 2009; 218(2):110-3.
8. Gisondi P, Galvan A, Idolazzi L et al. Management of moderate to severe psoriasis in patients with metabolic comorbidities. *Front Med*. 2015 ;2:1.
9. Gordon KB. Ixekizumab for treatment of moderate-to-severe plaque psoriasis: 60-week results from a double-blind phase 3 induction and randomized withdrawal study (UNCOVER-1). Presented at: 73rd Annual Meeting of the American Academy of Dermatology; San Francisco; 2015.
10. 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 Aug 8;386(9993):541-51.
11. Humira prescribing information. North Chicago, IL: AbbVie Inc.; 2016 June.
12. Krueger G, Ellis CN. Psoriasis-recent advances in understanding its pathogenesis and treatment. *J Am Acad Dermatol*. 2005; 53(1 Suppl 1):S94-100.
13. Lebwohl M. Psoriasis. *Lancet*. 2003; 361(9364):1197-204.
14. Lowes MA, Suárez-Fariñas M, Krueger JG. Immunology of psoriasis. *Annu Rev Immunol*. 2014;32:227-55.
15. Mason J, Mason AR, Cork MJ. Topical preparations for the treatment of psoriasis: a systematic review. *Br J Dermatol*. 2002; 146(3):351-64.
16. Menter A, Korman N, 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):137-74.
17. National Psoriasis Foundation. About psoriasis. URL: psoriasis.org/about-psoriasis. Available from Internet. Accessed 2016 August 5.
18. Taltz (ixekizumab) [prescribing information]. Indianapolis, Indiana: Eli Lilly and Company; 2017 December.

APPROVAL HISTORY

Reviewed by Pharmacy & Therapeutics Committee.

Subsequent endorsement date(s) and changes made:

- April 11, 2017: Administrative update, Adding Tufts Health RITogether to the template.
- July 11, 2017: July 11, 2017: Administrative update to add the following Limitation: Samples, free goods or similar offerings of Taltz (ixekizumab) do not qualify for an established clinical response and will not be considered for prior authorization.

- January 9, 2015: Added coverage criteria for the new indication of psoriatic arthritis to the Medical Necessity Guideline. Removed the limitation that authorizations will be approved for a duration of 12 months.

BACKGROUND, PRODUCT AND DISCLAIMER INFORMATION

Pharmacy Medical Necessity Guidelines have been developed for determining coverage for plan benefits and are published to provide a better understanding of the basis upon which coverage decisions are made. They are used in conjunction with a Member's benefit document and in coordination with the Member's physician(s). The plan makes coverage decisions on a case-by-case basis considering the individual Member's health care needs. Pharmacy Medical Necessity Guidelines are developed for selected therapeutic classes or drugs found to be safe, but proven to be effective in a limited, defined population of patients or clinical circumstances. They include concise clinical coverage criteria based on current literature review, consultation with practicing physicians in the service area who are medical experts in the particular field, FDA and other government agency policies, and standards adopted by national accreditation organizations. The plan revises and updates Pharmacy Medical Necessity Guidelines annually, or more frequently if new evidence becomes available that suggests needed revisions.

This Pharmacy Medical Necessity Guideline does not apply to Uniformed Services Family Health Plan Members or to certain delegated service arrangements. Unless otherwise noted in the Member's benefit document or applicable Pharmacy Medical Necessity Guideline, Pharmacy Medical Necessity Guidelines do not apply to CareLink^{SM} Members. For self-insured plans, drug coverage may vary depending on the terms of the benefit document. If a discrepancy exists between a coverage guideline and a self-insured Member's benefit document, the provisions of the benefit document will govern. Applicable state or federal mandates will take precedence.

For Tufts Health Plan Medicare Preferred, please refer to Tufts Health Plan Medicare Preferred Prior Authorization Criteria.

Treating providers are solely responsible for the medical advice and treatment of Members. The use of this policy is not a guarantee of payment or a final prediction of how specific claim(s) will be adjudicated. Claims payment is subject to Member eligibility and benefits on the date of service, coordination of benefits, referral/authorization and utilization management guidelines when applicable, and adherence to plan policies and procedures and claims editing logic.

Provider Services