Pharmacy Medical Necessity Guidelines: Kevzara® (sarilumab)

Effective: January 1, 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

Note: For Tufts Health Plan Medicare Preferred members, please refer to the Tufts Health Plan Medicare Preferred Prior Authorization Criteria. Background, applicable product and disclaimer information can be found on the last page.

OVERVIEW

FOOD AND DRUG ADMINISTRATION-APPROVED INDICATIONS

Kevzara (sarilumab) is an interleukin-6 receptor antagonist indicated for treatment of adult patients with moderately to severely active rheumatoid arthritis who have had an inadequate response or intolerance to one or more disease-modifying antirheumatic drugs.

COVERAGE GUIDELINES

The plan may authorize coverage for Kevzara (sarilumab) for members when the following criteria are met:

1. The member has a documented diagnosis of rheumatoid arthritis

AND

2. The prescribing physician is a rheumatologist

AND

3. Member is over 18 years of age

AND

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

LIMITATIONS

1. Samples, free goods or similar offerings of Kevzara (sarilumab) do not qualify for an established clinical response and will not be considered for prior authorization.
2. Initial authorization will be for one (1) year. Subsequent authorizations may be given in 12-month intervals based on submission of current progress notes from physician documenting efficacy.
3. Coverage will be limited to a 28-day supply as follows:
   - Kevzara (sarilumab) 200 mg syringe –2 syringes per 28 days

CODES

Medical billing codes may not be used for these medications. These medications must be obtained via the member's pharmacy benefit.

REFERENCES

1. American College of Rheumatology. Rheumatoid Arthritis. http://www.rheumatology.org. 2017 March. Available from Internet. Accessed 2017 October 2.
2. Asquith DL, McInnes IB. Emerging cytokine targets in rheumatoid arthritis: IL-6. Curr Opin Rheumatol. 2007; 19(3):246-51.
3. Burmester G, Lin Y, Patel R et al. Efficacy and safety of sarilumab monotherapy versus adalimumab monotherapy for the treatment of patients with active rheumatoid arthritis (MONARCH): a randomized, double-blind, parallel-group, phase III trial. Ann Rheum Dis. 2017; 76:840-847.

4. Fleischmann R, Adelsberg J, Lin Y et al. Sarilumab and nonbiologic disease-modifying antirheumatic drugs in patients with active rheumatoid arthritis and inadequate response or intolerance to tumor necrosis factor inhibitors. Arthritis & Rheumatology. 2017; 69(2):277-90.
5. Genovese M, Fleischmann R, Kivitz A et al. Sarilumab plus methotrexate in patients with active rheumatoid arthritis and inadequate response to methotrexate: results of a phase III study. Arthritis & Rheumatology 2015; 67:1424-37.
6. Hennigan S, Kavanaugh A. Interleukin-6 inhibitor in the treatment of rheumatoid arthritis. Ther Clin Risk Manag. 2008; 4(4):767-75.
7. Kevzara (sarilumab) [package insert]. Bridgewater, NJ: sanofi-aventis U.S. LLC; May 2017.

APPROVAL HISTORY

October 17, 2017: Reviewed by Pharmacy & Therapeutics Committee.

Subsequent endorsement date(s) and changes made:

- December 12, 2017: Effective January 1, 2018, removed criteria allowing members new to the plan stable on Kevzara (sarilumab) to be authorized due to new state requirements.

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.