Mass General Brigham
Health Plan

Kevzara (sarilumab)
Effective January 1, 2020

Plan	☐ MassHealth UPPL ☒Commercial/Exchange	**Program Type**	☒ Prior Authorization ☐ Quantity Limit ☐ Step Therapy
Benefit	☒ Pharmacy Benefit ☐ Medical Benefit (NLX)		
Specialty Limitations	This medication has been designated specialty and must be filled at a contracted specialty pharmacy.		
Contact Information	**Specialty Medications**		
	All Plans	Phone: 866-814-5506	Fax: 866-249-6155
	Non-Specialty Medications		
	MassHealth	Phone: 877-433-7643	Fax: 866-255-7569
	Commercial	Phone: 800-294-5979	Fax: 888-836-0730
	Exchange	Phone: 855-582-2022	Fax: 855-245-2134
	Medical Specialty Medications (NLX)		
	All Plans	Phone: 844-345-2803	Fax: 844-851-0882
Exceptions	N/A		

Overview
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 Indication
Kevzara is 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 (DMARDs)

All other indications are considered experimental/investigational and are not a covered benefit.

Coverage Guidelines

Moderately to severely active rheumatoid arthritis (RA)

1. Authorization may be granted for members who are currently receiving treatment with Kevzara, excluding when the product is obtained as samples or via manufacturer's patient assistance programs.
   OR
2. Authorization may be granted for treatment of moderately to severely active RA when one of the following criteria is met:
   a. Member has experienced an inadequate response or intolerance to ALL preferred products (Enbrel, Humira and Rinvoq).
   b. Member has a contraindication to Enbrel, Humira and Rinvoq and meets one of the following:

- Member has experienced an inadequate response to at least a 3-month trial of methotrexate despite adequate dosing (i.e., titrated to 20 mg/week).
- Member has an intolerance or contraindication to methotrexate (see Appendix).

Continuation of Therapy

Reauthorization may be granted for all members (including new members) who meet all initial authorization criteria and achieve or maintain positive clinical response after at least 3 months of therapy with Kevzara as evidenced by low disease activity or improvement in signs and symptoms of RA.

Limitations

1. Approvals will be granted for 24 months
2. For all indications: Member has a pretreatment tuberculosis (TB) screening with a TB skin test or an interferon gamma release assay (e.g., QFT-GIT, T-SPOT.TB).
    a. Note: Members who have received Kevzara or any other biologic DMARD or targeted synthetic DMARD (e.g., Xeljanz) are exempt from requirements related to TB screening in this Policy.
3. The following quantity limits apply:

Kevzara pen 150 mg/1.14 mL	1 pack (2 x 150 mg pen) per 4 weeks
Kevzara pen 200 mg/1.14 mL	1 pack (2 x 200 mg pen) per 4 weeks

Appendix

Examples of Contraindications to Methotrexate

1. Alcoholism, alcoholic liver disease or other chronic liver disease
2. Breastfeeding
3. Blood dyscrasias (e.g., thrombocytopenia, leukopenia, significant anemia)
4. Elevated liver transaminases
5. History of intolerance or adverse event
6. Hypersensitivity
7. Interstitial pneumonitis or clinically significant pulmonary fibrosis
8. Myelodysplasia
9. Pregnancy or planning pregnancy (male or female)
10. Renal impairment
11. Significant drug interaction

References

1. Kevzara (sarilumab) [prescribing information]. Bridgewater, NJ: Sanofi-Aventis; April 2018.
2. Genovese MC, Fleischmann R, Kivitz AJ, et al. Sarilumab plus methotrexate in patients with active rheumatoid arthritis and inadequate response to methotrexate: results of a phase III study. *Arthritis Rheumatol.* June 2015;67(6):1424-37.
3. Strand V, Reaney M, Chen C, et al. Sarilumab improves patient-reported outcomes in rheumatoid arthritis patients with inadequate response/intolerance to tumour necrosis factor inhibitors. *RMD Open.* 2017; 3**:** e000416. doi: 10.1136/rmdopen-2016-000416.

Review History

02/26/18 – Reviewed
06/01/18 – Implemented
02/20/19 – Updated

11/20/19 – Added Rinvoq as a preferred trial for RA.