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:

<table>
<thead>
<tr>
<th>Kevzara pen 150 mg/1.14 mL</th>
<th>1 pack (2 x 150 mg pen) per 4 weeks</th>
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</thead>
<tbody>
<tr>
<td>Kevzara pen 200 mg/1.14 mL</td>
<td>1 pack (2 x 200 mg pen) per 4 weeks</td>
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</table>

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

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

Disclaimer
AllWays Health Partners complies with applicable federal civil rights laws and does not discriminate or exclude people on the basis of race, color, national origin, age, disability, or sex.