

The following policy is for medication that falls under the Medicare Part D benefit only.

Prior Authorization Group: KINERET Policy

Drug(s): KINERET (anakinra)

Covered Uses: Kineret is indicated for the reduction in signs and symptoms and slowing the progression of structural damage in moderately to severely active rheumatoid arthritis, inpatients 18 years of age or older who have failed one or more disease modifying anti-rheumatic drugs (DMARDs). All criteria in "other criteria" section must be met for coverage.

Required Medical Information: Chart notes including physical exam findings, number of swollen or tender joints, duration of morning stiffness, other symptoms, requested dose and frequency and expected duration of therapy.

Age Restrictions: Restricted to 18 years of age and older.

Prescriber Restrictions: Restricted to rheumatologists and immunologists.

Other Criteria: For the treatment of moderate to severe active adult **rheumatoid arthritis** as defined by persistent or recurrent symptoms with documented synovitis and morning stiffness of significant duration to inhibit activities of daily living (ADLs), the following criteria must be met:

- Failed to respond to other DMARDs including a 2 month trial of methotrexate before Kineret is covered. (American College of Rheumatology (ACR) response of less than 20 after 7.5-20mg of methotrexate for 2 months).
- In the event the member has contraindications or intolerance to methotrexate, the member must have failed to respond to other DMARDs.
- Kineret may be used without prior methotrexate trial if the member has an acute, aggressive, very rapidly progressive intense inflammatory symmetrical arthritis disease as defined by their rheumatologist.

Exclusion Criteria:

- ulcerative colitis,
- **Ankylosing spondylitis**
- osteoarthritis.
- Coverage is excluded if member has a history of or currently has Lupus, malignancy, clinically significant chronic or recurrent infections.
- Should not be used for members at risk for infections or who have active infections including chronic or localized infections
- Kineret is contraindicated in members with known hypersensitivity to E-coli derived proteins.
- Concomitant therapy with other DMARDs or biologic therapies other than methotrexate.
- Doses exceeding FDA approved dosage are not covered.

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Coverage Duration: Initial approval for 3 months with extensions of up to 6 months intervals.