I. Medication Description

Anakinra blocks the biologic activity of interleukin-1 (IL-1) alpha and beta by competitively inhibiting IL-1 binding to the interleukin-1 type I receptor which is expressed in a wide variety of tissues and organs. IL-1 production is induced in response to inflammatory stimuli and mediates various physiologic responses including inflammatory and immunological responses. IL-1 has a broad range of activities including cartilage degradation as well as stimulation of bone resorption. Also, spontaneous mutations in the CIAS1/NLRP3 gene have been identified in a majority of patients with cryopyrin-associated periodic syndromes (such as NOMID). This gene encodes for cryopyrin, a component of the inflammasome. The activated inflammasome results in proteolytic maturation and secretion of IL-1beta, which has an important role in the systemic inflammation and manifestations of NOMID.

II. Position Statement

Coverage is determined through a prior authorization process with supporting clinical documentation for every request.

III. Policy

Coverage of Kineret is provided for the following conditions:

- Treatment of moderately to severely active rheumatoid arthritis (RA) in members ≥ 18 years of age when:
  - The member is under the care or referral of a rheumatologist AND
  - Inadequate results seen (failure after 12 weeks or intolerance) with at least one non-biologic DMARD AND
  - The member has tried at least two of the plan-preferred medications first (Actemra, Humira, Enbrel, Xeljanz/Xeljanz XR) OR the following criteria have been met:
    - When requesting coverage of a brand medication for which an A/B rated generic is available, there is sufficient evidence that the use of the A/B rated generic equivalent has resulted in inadequate results AND
    - At least one of the following is met:
      - The plan-preferred medications are contraindicated or will likely cause an adverse reaction by or physical or mental harm to the member.
      - The plan-preferred medications are expected to be ineffective based on the known clinical history and conditions of the member and the member’s prescription drug regimen.
- The member has tried the plan-preferred medications or another prescription drug in the same pharmacologic class or with the same mechanism of action and such prescription drug was discontinued due to lack of efficacy or effectiveness, diminished effect, or an adverse event.

- The member is stable on the medication selected by their healthcare professional for the medical condition under consideration (where “stable” is defined as receiving the medication for an adequate period of time, have achieved optimal response, and continued favorable outcomes are expected UNLESS the medication was initially selected due to the availability of a drug sample or a coupon card).

- The plan-preferred medication is not in the best interest of the member because it will likely cause a significant barrier to the member’s adherence or to compliance with the member’s plan of care, will likely worsen a comorbid condition of the member, or will likely decrease the member’s ability to achieve or maintain reasonable functional ability in performing daily activities.

  - Treatment of Neonatal-Onset Multisystem Inflammatory Disease (NOMID)

IV. **Quantity Limitations**

- Up to 30 of the 100mg syringes will be covered per each 30 days.

- Additional quantities may be covered for the treatment of NOMID (up to a maximum dose of 8mg/kg/day can be considered) upon request.

V. **Coverage Duration**

Coverage is provided for 12 months and may be renewed.

VI. **Coverage Renewal Criteria**

Coverage can be renewed based upon the following criteria:
- Stabilization of disease or in absence of disease progression AND
- Absence of unacceptable toxicity from the drug

VII. **Billing/Coding Information**

Product: Kineret 100mg / 0.67 ml single use, prefilled glass syringes

VIII. **Summary of Policy Changes**

- 3/1/11: Policy reformatted
- 6/15/12: no policy changes
- 3/15/13: clarified that prior authorization is required for all pharmacy claims
- 6/2013: New FDA indication for NOMID added to coverage
Kineret® (anakinra)

- 7/1/13: Medicaid/FHP criteria differentiated
- 3/15/14: increased quantities available for NOMID treatment
- 3/15/15: no policy changes
- 7/1/15: formulary distinctions made
- 3/15/16: broadened requirement for previous trial with methotrexate to include any non-biologic DMARD
- 1/1/17: step criteria specified for coverage in RA
- 5/1/17: step therapy criteria added
- 1/1/18: no policy changes

IX. References


*The Plan fully expects that only appropriate and medically necessary services will be rendered. The Plan reserves the right to conduct pre-payment and post-payment reviews to assess the medical appropriateness of the above-referenced therapies.*

*The preceding policy applies only to members for whom the above named pharmacy benefit medications are included on their covered formulary. Members with closed formulary benefits are subject to trying all appropriate formulary alternatives before a coverage exception for a non-formulary medication will be considered.*

*The preceding policy is a guideline to allow for coverage of the pertinent medication/product, and is not meant to serve as a clinical practice guideline.*