Commercial PA Criteria

Effective: March 2004

Prior Authorization: Kineret

Products Affected: Kineret (anakinra) subcutaneous solution

Medication Description: Anakinra blocks the biologic activity of interleukin-1 (IL-1) by competitively inhibiting IL-1 binding to the IL-1 type I receptor. Produced in response to inflammatory stimuli, IL-1 mediates various inflammatory and immunological responses, and has activity involving cartilage degradation and stimulation of bone resorption. In rheumatoid arthritis patients, the levels of endogenous IL-1 receptor antagonist in synovium and synovial fluid are insufficient to compete with the elevated amount of locally produced IL-1. Patients with neonatal-onset multisystem inflammatory disease may have spontaneous gene mutations that lead to IL-1 beta secretion and increased systemic inflammation.

Covered Uses:

1. Rheumatoid arthritis – to reduce the signs and symptoms an slow the progression of structural damage in adult patients with moderately to severe active disease who have failed one or more disease modifying antirheumatic drugs (DMARDs) given DMARDs other than tumor necrosis factor inhibitors (TNFs)
2. Cryopyrin-associated periodic syndromes (CAPS) for treatment of neonatal-onset multisystem inflammatory disease (NOMID)
3. Deficiency of interleukin-1 receptor antagonist (DIRA) – treatment

Exclusion Criteria:

1. Ankylosing Spondylitis
2. Concurrent use with a biologic or with a DMARD
3. Lupus Arthritis
4. Osteoarthritis

Required Medical Information:

1. Diagnosis
2. Previous medications tried/failed

Age Restrictions:

Rheumatoid arthritis: 18 years of age or older

Prescriber Restrictions:

Rheumatoid arthritis: prescribed by or in consultation with a rheumatologist.
Neonatal-Onset Multisystem Inflammatory Disease & Deficiency of Interleukin-1 Receptor Antagonist: prescribed by or in consultation with a rheumatologist, geneticist, or a dermatologist.

Coverage Duration:
Initiation: 6 months
Continuation: 1 year

Other Criteria:
Initiation:

1. **Rheumatoid Arthritis**
   Initial Therapy: Approve if the patient meets the following criteria
   A. Patient has documented failure or intolerance to an adequate trial (at least 3 months) of a biologic **OR** DMARD, **AND**
   Note: This is a 3-month trial of at least one biologic other than the requested drug. A biosimilar of the requested biologic does not count. Refer to Appendix for examples of biologics and targeted synthetic DMARDs used for rheumatoid arthritis. Conventional synthetic DMARDs such as methotrexate, leflunomide, hydroxychloroquine, and sulfasalazine do not count.
   B. Patient has a documented failure of, or intolerance to, TWO of the following medications

Rheumatoid Arthritis (TWO of the following)
Enbrel
Adalimumab Product
Actemra SC
Xeljanz/XR
Rinvoq

2. **Cryopyrin-Associated Periodic Syndrome (CAPS):**
   Initial Therapy: Approve if the patient meets the following criteria
   A. Patient has a diagnosis of Neonatal Onset Multisystem Inflammatory Disease (NOMID), Familial Cold Autoinflammatory Syndrome (FCAS), Muckle-Wells Syndrome (MWS), and/or chronic infantile neurological cutaneous and articular (CINCA) syndrome; **AND**
   B. Kineret is prescribed by or in consultation with a rheumatologist, geneticist, or a dermatologist.

3. **Deficiency of Interleukin-1 Receptor Antagonist**
   Initial Therapy: Approve if the patient meets the following criteria
   A. Genetic testing has confirmed a mutation in the IL1RN gene; AND
   B. The medication is prescribed by or in consultation with a rheumatologist, geneticist, dermatologist, or a physician specializing in the treatment of autoinflammatory disorders.

Continuation:

A. Patient meets all initial authorization criteria; **AND**
B. Patient achieves or maintains a positive clinical response after at least 6 months of therapy with Kineret as evidenced by low disease activity or improvement in signs and symptoms of the condition

References:

1. Kineret® subcutaneous injection [prescribing information]. Stockholm, Sweden: Swedish Orphan Biovitrum; December 2020

Policy Revision history

Rev #	Type of Change	Summary of Change	Sections Affected	Date
1	New Policy	New Policy	All	01/01/2019
2	Update	Update	Coverage Duration: Continuation	07/01/2019
3	Update	Added Rinvoq as a preferred product for RA	Other Criteria	10/18/2019
4	Policy Update	Removed Actemra SQ as a preferred product for RA	Other Criteria	1/1/2021
5	Policy Update	Added Actemra SQ as a preferred product for RA	Other Criteria	02/22/2022
6	Policy Update	Other Criteria: changed "Humira" to "adalimumab"	Other Criteria	05/11/2023
7	Update	Addition to covered uses Deficiency of interleukin-1 receptor antagonist (DIRA) treatment. Addition to exclusion criteria; Ankylosing Spondylitis, Concurrent use with a biologic or with a DMARD, Lupus Arthritis, Osteoarthritis. Removed RA criteria and revised select criteria to implement to label coverage. Addition of Deficiency of Interleukin-1 Receptor Antagonist and criteria	Covered uses Other Criteria	12/20/2023