Commercial/Healthcare Exchange 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. Treatment of moderate to severe rheumatoid arthritis in patients who have failed 1 or more disease modifying antirheumatic drugs (DMARDs).
2. Treatment of Neonatal-Onset Multisystem Inflammatory Disease (NOMID)

Exclusion Criteria: N/A

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: prescribed by or in consultation with a rheumatologist, geneticist, or a dermatologist

Coverage Duration:

Initiation: 3 months
Continuation: 3 years

Other Criteria:

Initiation:

Rheumatoid Arthritis:

A. The patient has a diagnosis of rheumatoid arthritis; AND
B. Patient has documented failure or intolerance to an adequate trial of NSAID/COX-2 or steroid therapy; **AND**

C. Patient has documented failure or intolerance to an adequate trial (at least 3 months) of ONE DMARD (e.g., methotrexate [oral or injectable], leflunomide, and sulfasalazine); A**ND**
D. Patient must have a trail and documented failure of, or intolerance to, **TWO** of the following medications [documentation required]:

Rheumatoid Arthritis
Actemra
Enbrel
Humira
Xeljanz/Xeljanz XR
Rinvoq

Cryopyrin-Associated Periodic Syndrome (CAPS):

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.

Continuation:

A. Patient meets all initial authorization criteria; **AND**
B. Patient achieves or maintains a positive clinical response after at least 3 months of therapy with Kineret as evidenced by low disease activity or improvement in signs and symptoms of the condition

References:

1. Kineret full prescribing Information. Stockholm, Sweden: Swedish Orphan Biovitrum.

Policy Revision history

Rev #	Type of Change	Summary of Change	Sections Affected	Date
1	New Policy	CCI adopted EH template; CCI P&T Review History:3/04, 6/07, 6/08, 9/09, 9/10, 12/11, 10/12, 10/13, 10/14, 11/15, 11/16, 11/17, 11/18 CCI Revision Record: 9/13, 9/14, 11/16	All	06/28/2019

2	Policy Update	Changed continuation approval length from 1 year to 3 years	Coverage Duration	7/1/2019
3	Policy Update	Added Rinvoq as a preferred product for RA	Other Criteria	10/18/2019