MEDICATION POLICY:

Kineret®

Generic Name: Anakinra

Therapeutic Class or Brand Name: Kineret®

Applicable Drugs (if Therapeutic Class): N/A

GPI Code: 6626001000

Preferred: N/A

Non-preferred: N/A

Date of Origin: 2/1/2013

Date Last Reviewed / Revised: 12/29/2020

PRIOR AUTHORIZATION CRITERIA

(May be considered medically necessary when criteria I through III are met)

I. Documented diagnosis of one of the following conditions A through C AND must meet criteria listed under applicable diagnosis:

A. Moderately to Severely Active Rheumatoid Arthritis and criteria 1 through 4 are met:

1. History of treatment failure, intolerance, or contraindication to Methotrexate, or one other DMARD or second line drug (azathioprine, sulfasalazine, leflunomide, penicillamine, hydroxychloroquine, etc.).
2. Documented failure, intolerance, or contraindication to two preferred biologic products (refer to plan document for the list of preferred products).
3. Diagnosis must be established by a rheumatologist.
4. Minimum age requirement: 18 years old.

B. Cryopyrin-Associated Periodic Syndromes (CAPS) (including Neonatal-Onset Multisystem Inflammatory Disease [NOMID]) and criteria 1 through 3 are met:

1. Diagnosis must be established by a rheumatologist.
2. Documentation of laboratory evidence of a genetic mutation in the Cold-Induced Auto-inflammatory Syndrome 1 (CIAS1 – sometimes referred to as the NLRP-3).
3. Documentation that the patient is experiencing the classic symptoms of CAPS, defined as meeting at least ONE of the following described in a through c:

a. NOMID – Urticaria-like rash, CNS involvement (papilledema, cerebrospinal fluid [CSF] pleocytosis, or sensorineural hearing loss), elevated C-reactive protein, or epiphyseal and/or patellar overgrowth on radiographs.

b. Familial Cold Auto-Inflammatory Syndrome (FCAS) – Recurrent intermittent episodes of fever and rash that primarily followed natural, artificial (e.g., air conditioning) or both types of generalized cold exposure.

c. Muckle-Wells Syndrome (MWS) – Syndrome of chronic fever and rash that may wax and wane in intensity; sometimes exacerbated by generalized cold exposure. This syndrome may be associated with deafness or amyloidosis.

C. Deficiency of Interleukin-1 Receptor Antagonist (DIRA) and criteria 1 through 2 are met:

1. Diagnosis established with laboratory evidence of genetic homozygous mutations in interleukin (IL) 1-receptor antagonist (IL-1RN).

2. Documentation of symptoms characteristic of DIRA including neonatal onset of sterile multifocal osteomyelitis, periostitis, and pustulosis.

II. Absence of active serious infection or sepsis.

III. Negative TB skin test within the previous 12 months or history of treatment for latent TB infection.

IV. Refer to plan document for the list of preferred products. If requested agent is not listed as a preferred product, must have a documented failure, intolerance, or contraindication to a preferred product(s).

EXCLUSION CRITERIA

- Coadministration of Kineret® with another targeted immune modulator. Examples of targeted immune modulators include the following:
  - Actemra® (tocilizumab)
  - Cosentyx® (secukinumab)
  - Entyvio® (vedolizumab)
  - Kevzara® (sarilumab)
  - Olumiant® (baricitinib)
  - Orencia® (abatacept)
  - Otezla® (apremilast)
  - Rinvoq™ (upadacitinib)
  - Rituxan® (rituximab)
  - Siliq™ (brodalumab)
  - Stelara® (ustekinumab)
  - Taltz® (Ixekizumab)
  - TNF inhibitors [Cimzia® (certolizumab pegol), Enbrel® (etanercept), Humira® (adalimumab), Inflectra® (infliximab-dyyb), Remicade® (infliximab), Renflexis™ (infliximab-abda), Simponi®/Simponi® Aria® (golimumab)]

- Tremfya™ (guselkumab)
- Tysabri® (natalizumab)
- Xeljanz®/XR (tofacitinib)

OTHER CRITERIA

- N/A.

QUANTITY / DAYS SUPPLY RESTRICTIONS

- 28 syringes (one 4x7 syringe dispensing pack) per 28 days.

APPROVAL LENGTH

- **Authorization:** 1 year.
- **Re-Authorization:** An updated letter of medical necessity or progress notes showing improvement or maintenance with medication.

APPENDIX

N/A.

REFERENCES

1. Jasvinder A. Singh, et. al., 2015 American College of Rheumatology Guideline for the Treatment of Rheumatoid Arthritis. Arthritis Care & Research. 2015. DOI 10.1002/acr.22783.
2. Aksentijevich, I. et. al., An Autoinflammatory Disease with Deficiency of the Interleukin-1–Receptor Antagonist. N Engl J Med. 2009 Jun 4; 360(23): 2426–2437. doi: 10.1056/NEJMoa0807865.
3. Medi-Span®.
4. Kineret® [Package Insert]. Stockholm, Sweden: Sobi. December 2020. Available at http://www.kineretrx.com/pdf/Full-Prescribing-Information-English.pdf.