

**Generic Name:** Anakinra

**Therapeutic Class or Brand Name:** Kineret

**Applicable Drugs (if Therapeutic Class):** N/A

**Preferred:** N/A

**Non-preferred:** N/A

**Date of Origin:** 2/1/2013

**Date Last Reviewed / Revised:** 12/2/2023

## PRIOR AUTHORIZATION CRITERIA

(May be considered medically necessary when criteria I through V 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
    1. Meets all specified criteria outlined in the Targeted Immune Modulator policy.
  - B. Cryopyrin-associated periodic syndromes (CAPS)
    1. Documentation of pathogenic or likely pathogenic genetic mutation in the NLR family pyrin domain containing 3 (NLRP-3) gene.
    2. Documentation of elevated inflammatory markers (eg, serum levels of amyloid A, C-reactive protein, erythrocyte sedimentation rate).
    3. Documentation of at least 2 of the typical signs and symptoms of CAPS a through f:
      - a. Urticaria-like rash
      - b. Cold and/or stress-triggered episodes
      - c. Sensorineural hearing loss
      - d. Musculoskeletal symptoms (eg, arthralgia, arthritis, myalgia)
      - e. Chronic aseptic meningitis
      - f. Skeletal abnormalities (ie, epiphyseal and/or patellar overgrowth on radiographs)
  - C. Deficiency of interleukin-1 receptor antagonist (DIRA)
    1. Documentation of genetic homozygous mutations in interleukin 1-receptor antagonist (IL-1RN).
- II. Treatment must be prescribed by or in consultation with a rheumatologist, geneticist, dermatologist, or physician specializing in the treatment of autoinflammatory disorders.
- III. Absence of active serious infection or sepsis.
- IV. Negative TB skin test within the previous 12 months or history of treatment for latent TB infection.

- V. Refer to the plan document for the list of preferred products. If the 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 (TIM). Examples of TIM include, but are not limited to, Actemra (tocilizumab), Cimzia (certolizumab pegol), Cosentyx (secukinumab), Dupixent (dupilumab), Enbrel (etanercept), Entyvio (vedolizumab), Humira (adalimumab), Inflectra (infliximab-dyyb), Kevzara (sarilumab), Olumiant (baricitinib), Orencia (abatacept), Otezla (apremilast), Rinvoq (upadacitinib), Rituxan (rituximab), Siliq (brodalumab), Stelara (ustekinumab), Taltz (Ixekizumab), Remicade (infliximab), Renflexis (infliximab-abda), Simponi/Simponi Aria (golimumab)], Tremfya (guselkumab), Tysabri (natalizumab), Xeljanz/XR (tofacitinib), etc.

## OTHER CRITERIA

- N/A

## QUANTITY / DAYS SUPPLY RESTRICTIONS

- 28 syringes (one 4 x 7 syringe dispensing pack) per 28 days.

## APPROVAL LENGTH

- **Authorization:** 4 months.
- **Re-Authorization:** 1 year, with an updated letter of medical necessity or progress notes showing improvement or maintenance with medication.

## APPENDIX

- N/A

## REFERENCES

1. Kineret. Prescribing information. Sobi; 2020. Accessed December 2, 2023. <https://www.kineretrx.com/pdf/Full-Prescribing-Information-English.pdf>
2. Kuemmerle-Deschner JB, Ozen S, Tyrrell PN, et al. Diagnostic criteria for cryopyrin-associated periodic syndrome (CAPS). *Ann Rheum Dis*. 2017;76(6):942-947. doi:10.1136/annrheumdis-2016-209686
3. Aksentijevich I, Masters SL, Ferguson PJ, et al. An autoinflammatory disease with deficiency of the interleukin-1-receptor antagonist. *N Engl J Med*. 2009;360(23):2426-2437. doi:10.1056/NEJMoa0807865

**MEDICATION POLICY:**

Kineret®



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**DISCLAIMER:** Medication Policies are developed to help ensure safe, effective and appropriate use of selected medications. They offer a guide to coverage and are not intended to dictate to providers how to practice medicine. Refer to Plan for individual adoption of specific Medication Policies. Providers are expected to exercise their medical judgement in providing the most appropriate care for their patients.