

Applicable Drugs: Kineret (anakinra)

Preferred: N/A

Non-preferred: N/A

Date of Origin: 2/1/2013

Date Last Reviewed / Revised: 7/30/2026

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 (RA)
 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, etc).
 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, etc)
 - e. Chronic aseptic meningitis
 - f. Skeletal abnormalities (eg, epiphyseal and/or patellar overgrowth on radiographs, etc)
 - 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. Request is for a medication with the appropriate FDA labeling, or its use is supported by current clinical practice guidelines.

- 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 systemic targeted immune modulator (TIM). Refer to posted TIMs MP for systemic examples.

OTHER CRITERIA

- N/A

QUANTITY / DAYS SUPPLY RESTRICTIONS

- RA: Twenty-eight 100mg syringes (four 1 x 7 syringe dispensing packs) per 28 days.
- CAPS/DIRA: Sufficient quantity for recommended dose of 1-2 mg/kg/day up to max 8mg/kg/day 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. Swedish Orphan Biovitrum; October 2025. Accessed July 30, 2026. <https://www.kineretrx.com/pdf/Full-Prescribing-Information-English.pdf><http://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
4. Romano M, Arici ZS, Piskin D, et al. The 2021 EULAR/American College of Rheumatology points to consider for diagnosis, management and monitoring of the interleukin-1 mediated

autoinflammatory diseases: cryopyrin-associated periodic syndromes, tumour necrosis factor receptor-associated periodic syndrome, mevalonate kinase deficiency, and deficiency of the interleukin-1 receptor antagonist. *Ann Rheum Dis.* 2022;81(7):907-921. doi: 10.1136/annrheumdis-2021-221801

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.