Kineret (anakinra)

Override(s)	Approval Duration
Prior Authorization Quantity Limit	1 year

Medications	Quantity Limit/Dosing Limit*
Kineret (anakinra) 100 mg/0.67 mL prefilled syringe	1 prefilled syringe per day

*For the treatment of neonatal-onset multisystem inflammatory disease (NOMID) or deficiency of interleukin-1 receptor antagonist (DIRA): May approve up to 8 mg/kg/day.

APPROVAL CRITERIA

Initial requests for Kineret (anakinra) may be approved for the following:

I. Rheumatoid Arthritis (RA) when each of the following criteria is met:
   A. Individual is 18 years of age or older with moderate to severe RA; **AND**
   B. Documentation is provided that individual has had an inadequate response to methotrexate titrated to maximally tolerated dose (ACR 2021); **OR**
   C. Documentation is provided that if methotrexate is not tolerated, individual has had an inadequate response to or is intolerant of other conventional therapy (sulfasalazine, leflunomide, or hydroxychloroquine); **OR**
   D. Documentation is provided that individual has a contraindication to methotrexate, sulfasalazine, leflunomide, and hydroxychloroquine;

   AND
   E. Documentation is provided that individual has had trial and inadequate response or intolerance to TWO (2) preferred biologic agents [Current preferred biologics include – adalimumab-adbm, Enbrel (etanercept), Humira (adalimumab), or Simponi (golimumab)]. Medication samples/coupons/discount cards are excluded from consideration as a trial.;
      AND
      1. Documentation is provided describing the nature of the inadequate response or intolerance for each product tried;
         OR
      2. Documentation is provided that a completed FDA MedWatch Adverse Event Reporting Form has been submitted to the FDA for each product tried;

   OR
   F. Documentation is provided that individual has been receiving and is maintained on a stable dose of Kineret (anakinra). Medication samples/coupons/discount cards are excluded from consideration as a trial; **OR**

*Note: Rinvoq is the preferred Janus Kinase (JAK) inhibitor. JAK inhibitor clinical criteria require a trial and inadequate response or intolerance to one or more tumor necrosis factor (TNF) antagonist agents**.**

OR

II. Individual has a diagnosis of deficiency of interleukin-1 receptor antagonist (DIRA), confirmed through IL1RN mutations;

OR

III. Individual has a diagnosis of treatment-naïve or refractory (DP B II-a) neonatal-onset multisystem inflammatory disease (NOMID), also known as chronic infantile neurological cutaneous and articular (CINCA) syndrome;

OR

IV. Individual has a diagnosis of multicentric Castleman's Disease (MCD) (NCCN 2A); **AND**
V. Disease has progressed following treatment of relapsed/refractory or progressive disease;

OR

VI. Individual has a diagnosis of Chimeric antigen receptor (CAR) T cell-induced cytokine release syndrome CRS (NCCN 2A); **AND**
VII. CRS is refractory to steroids and anti-IL-6 therapy.

OR

VIII. Individual has a diagnosis of Erdheim-Chester Disease (NCCN 2A); **AND**
IX. Individual is using anakinra as a single agent;

OR

X. Still's disease (Adult-onset Still's Disease [AOSD] or Systemic Juvenile Idiopathic Arthritis (SJIA) when the following is met (ACR 2021):
A. Individual is 2 years of age or older with Still's Disease as either AOSD or SJIA.

Continuation requests for Kineret (anakinra) may be approved if the following criteria are met:

I. Documentation is provided that individual has been receiving and is maintained on a stable dose of Kineret. Medication samples/coupons/discount cards are excluded from consideration as a trial.; **AND**
II. There is confirmation of clinically significant improvement or stabilization in clinical signs and symptoms of disease.

Requests for Kineret (anakinra) may **not** be approved for the following:

I. In combination with topical or oral JAK inhibitors, ozanimod, etrasimod, deucravacitinib, or any of the following biologic immunomodulators: TNF antagonists, IL-23 inhibitors, IL-17 inhibitors, vedolizumab, ustekinumab, abatacept, other IL-1 inhibitors, IL-6 inhibitors, rituximab, or natalizumab; **OR**
II. Tuberculosis or other active serious infections or a history of recurrent infections [repeat TB testing not required for ongoing therapy]; **OR**
III. If initiating therapy, individual has not had a tuberculin skin test (TST) or Centers for Disease Control (CDC) and Prevention-recommended equivalent to evaluate for latent tuberculosis (unless switching therapy from another targeted immune modulator and no new risk factors); **OR**
IV. When the above criteria are not met and for all other indications.

Key References:

1. DailyMed. Package inserts. U.S. National Library of Medicine, National Institutes of Health website. http://dailymed.nlm.nih.gov/dailymed/about.cfm. Accessed: September 7, 2023.
2. DrugPoints® System [electronic version]. Truven Health Analytics, Greenwood Village, CO. Updated periodically.
3. Lexi-Comp ONLINE™ with AHFS™, Hudson, Ohio: Lexi-Comp, Inc.; 2022; Updated periodically.
4. NCCN Drugs & Biologics Compendium (NCCN Compendium®) 2022 National Comprehensive Cancer Network, Inc. Available at: NCCN.org. Updated periodically. Accessed on: October 4, 2022.
5. Fraenkel L, Bathon JM, England BR et al. 2021 American College of Rheumatology Guideline for the Treatment of Rheumatoid Arthritis. Arthritis Care & Research. 2021;73(7):924-939.
6. Onel KB, Horton DB, Lovell DJ, et al. 2021 American College of Rheumatology Guideline for the Treatment of Juvenile Idiopathic Arthritis: Therapeutic Approaches for Oligoarthritis, Temporomandibular Joint Arthritis, and Systemic Juvenile Idiopathic Arthritis. Arthritis Rheum. 2022; 74(4):553-569
7. Ringold S, Angeles-Han ST, Beukelman T, et al. 2019 American College of Rheumatology/Arthritis Foundation Guideline for the Treatment of Juvenile Idiopathic Arthritis: Therapeutic Approaches for Non-Systemic Polyarthritis, Sacroiliitis, and Enthesitis. Arthritis Rheum. 2019; 71(6):846-863.
8. Centers for Disease Control and Prevention (CDC). Tuberculosis (TB). Available at: https://www.cdc.gov/tb/topic/basics/risk.htm. Last updated: March 18, 2016. Accessed October 4, 2022.
9. FitzGerald JD, Dalbeth N, Mikuls T, et al. 2020 American College of Rheumatology Guideline for the Management of Gout. Arthritis Rheumatol. 2020;72(6):879-895.
10. NCCN Clinical Practice Guidelines in Oncology™. © 2023 National Comprehensive Cancer Network, Inc. For additional information visit the NCCN website: http://www.nccn.org/index.asp. Accessed on October 13, 2023.
    a. Management of Immunotherapy-related Toxicities. V3.2023. Revised October 11, 2023.
    b. Histiocytic Neoplasms. V1.2023. Revised August 11, 2023.
    c. B-cell Lymphomas. V6.2023. Revised October 10, 2023.

Federal and state laws or requirements, contract language, and Plan utilization management programs or polices may take precedence over the application of this clinical criteria.