UnitedHealthcare Pharmacy
Clinical Pharmacy Programs

Program Number	2025 P 1055-15
Program	Prior Authorization/Notification
Medication	Kineret® (anakinra)
P&T Approval Date	1/2007, 6/2008 , 4/2009, 6/2009, 12/2009, 7/2010, 11/2010, 7/2011, 11/2011, 7/2012, 11/2012, 2/2013, 2/2014, 2/2015, 3/2016, 3/2017, 3/2018, 3/2019, 3/2020, 3/2021, 3/2022, 3/2023, 7/2023, 10/2024, 10/2025
Effective Date	1/17/2026

1. Background:

Kineret (anakinra) is an interleukin-1 receptor antagonist indicated for moderately to severely active rheumatoid arthritis in patients 18 years of age or older who have failed one or more disease-modifying anti-rheumatic drugs (DMARDs).[1] Examples of DMARDs commonly used in the treatment of rheumatoid arthritis include methotrexate, leflunomide, and sulfasalazine.[2,6] Kineret is also indicated for the treatment of Neonatal-Onset Multisystem Inflammatory Disease (NOMID) and the treatment of deficiency of interleukin-1 receptor antagonist (DIRA).[1] Clinical evidence also supports the use of Kineret to treat active systemic juvenile idiopathic arthritis and adult onset Still's disease.[3,4,7,8]

2. Coverage Criteria[a]:

A. Rheumatoid Arthritis (RA)

1. **Initial Authorization**

a. **Kineret** will be approved based on **all** of the following criteria:

(1) Diagnosis of moderately to severely active rheumatoid arthritis

-AND-

(2) Patient has had an inadequate response to one or more disease-modifying anti-rheumatic drugs (DMARDs) (e.g., methotrexate, leflunomide, and sulfasalazine)

-AND-

(3) Patient is not receiving Kineret in combination with another systemic targeted immunomodulator. [e.g., adalimumab, Cimzia (certolizumab), Enbrel (etanercept), Olumiant (baricitinib), Orencia (abatacept), Rinvoq (upadacitinib), Simponi (golimumab), Xeljanz/Xeljanz XR (tofacitinib)] for treatment of the same indication.

Authorization will be issued for 12 months.

2. **Reauthorization**

a. **Kineret** will be approved based on **both** of the following criteria:

(1) Documentation of positive clinical response to Kineret therapy

-AND-

(2) Patient is not receiving Kineret in combination with another systemic targeted immunomodulator [e.g., adalimumab, Cimzia (certolizumab), Enbrel (etanercept), Olumiant (baricitinib), Orencia (abatacept), Rinvoq (upadacitinib), Simponi (golimumab), Xeljanz/Xeljanz XR (tofacitinib)] for treatment of the same indication.

Authorization will be issued for 12 months.

B. Neonatal-Onset Multisystem Inflammatory Disease (NOMID)

1. **Initial Authorization**

a. **Kineret** will be approved based on **both** of the following criteria:

(1) Diagnosis of neonatal-onset multisystem inflammatory disease (NOMID)

-AND-

(2) Patient is not receiving Kineret in combination with another systemic targeted immunomodulator [e.g., Enbrel (etanercept), Cimzia (certolizumab), Simponi (golimumab), Orencia (abatacept), Xeljanz (tofacitinib), Olumiant (baricitinib), Rinvoq (upadacitinib)] for treatment of the same indication.

Authorization will be issued for 12 months.

2. **Reauthorization**

a. **Kineret** will be approved based on **both** of the following criteria:

(1) Documentation of positive clinical response to Kineret therapy

-AND-

(2) Patient is not receiving Kineret in combination with another systemic targeted immunomodulator [e.g., Enbrel (etanercept), Cimzia (certolizumab), Simponi (golimumab), Orencia (abatacept), Xeljanz (tofacitinib), Olumiant (baricitinib), Rinvoq (upadacitinib)] for treatment of the same indication.

Authorization will be issued for 12 months.

C. Systemic Juvenile Idiopathic Arthritis

1. **Initial Authorization**

   a. **Kineret** will be approved based on **both** of the following criteria:

      (1) Diagnosis of active systemic juvenile idiopathic arthritis (formerly Still's disease)

      -AND-

      (2) Patient is not receiving Kineret in combination with another systemic targeted immunomodulator [e.g., adalimumab, Cimzia (certolizumab), Enbrel (etanercept), Olumiant (baricitinib), Orencia (abatacept), Rinvoq (upadacitinib), Simponi (golimumab), Xeljanz/Xeljanz XR (tofacitinib)] for treatment of the same indication.

      Authorization will be issued for 12 months.

2. **Reauthorization**

   a. **Kineret** will be approved based on **both** of the following criteria:

      (1) Documentation of positive clinical response to Kineret therapy

      -AND-

      (2) Patient is not receiving Kineret in combination with another systemic targeted immunomodulator [e.g., adalimumab, Cimzia (certolizumab), Enbrel (etanercept), Olumiant (baricitinib), Orencia (abatacept), Rinvoq (upadacitinib), Simponi (golimumab), Xeljanz/Xeljanz XR (tofacitinib)] for treatment of the same indication.

      Authorization will be issued for 12 months.

D. Adult Onset Still's Disease

1. **Initial Authorization**

   a. **Kineret** will be approved based on **both** of the following criteria:

      (1) Diagnosis of adult onset Still's Disease

      -AND-

      (2) Patient is not receiving Kineret in combination with another systemic targeted immunomodulator [e.g., Enbrel (etanercept), Cimzia (certolizumab), Simponi (golimumab), Orencia (abatacept), Xeljanz (tofacitinib), Olumiant (baricitinib), Rinvoq (upadacitinib)] for treatment of the same indication.

      Authorization will be issued for 12 months.

2. **Reauthorization**

a. **Kineret** will be approved based on **both** of the following criteria:

(1) Documentation of positive clinical response to Kineret therapy

-AND-

(3) Patient is not receiving Kineret in combination with another systemic targeted immunomodulator [e.g., Enbrel (etanercept), Cimzia (certolizumab), Simponi (golimumab), Orencia (abatacept), Xeljanz (tofacitinib), Olumiant (baricitinib), Rinvoq (upadacitinib)] for treatment of the same indication.

Authorization will be issued for 12 months.

E. Deficiency of Interleukin-1 Receptor Antagonist (DIRA)

1. **Initial Authorization**

a. **Kineret** will be approved based on **both** of the following criteria:

(1) Diagnosis of deficiency of Interleukin-1 Receptor Antagonist (DIRA)

-AND-

(2) Patient is not receiving Kineret in combination with another systemic targeted immunomodulator [e.g., Enbrel (etanercept), Cimzia (certolizumab), Simponi (golimumab), Orencia (abatacept), Xeljanz (tofacitinib), Olumiant (baricitinib), Rinvoq (upadacitinib)] for treatment of the same indication.

Authorization will be issued for 12 months.

2. **Reauthorization**

a. **Kineret** will be approved based on **both** of the following criteria:

(1) Documentation of positive clinical response to Kineret therapy

-AND-

(2) Patient is not receiving Kineret in combination with another systemic targeted immunomodulator [e.g., Enbrel (etanercept), Cimzia (certolizumab), Simponi (golimumab), Orencia (abatacept), Xeljanz (tofacitinib), Olumiant (baricitinib), Rinvoq (upadacitinib)] for treatment of the same indication.

Authorization will be issued for 12 months.

[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

3. Additional Clinical Rules:

- Notwithstanding Coverage Criteria, UnitedHealthcare may approve initial and re-authorization based solely on previous claim/medication history, diagnosis codes (ICD-10) and/or claim logic. Use of automated approval and re-approval processes varies by program and/or therapeutic class.
- Supply limits may be in place.

4. References:

1. Kineret [package insert]. Waltham, MA: Sobi; September 2024.
2. Pavy S. Constantin A, Pham T, et al. Methotrexate therapy for rheumatoid arthritis: clinical practice guidelines based on published evidence and expert opinions. Joint Bone Spine 2006;73(4):388-95.
3. Beukelman T, Patkar NM, Saag KG, et al. 2011 American College of Rheumatology recommendations for the treatment of juvenile idiopathic arthritis: initiation and safety monitoring of therapeutic agents for the treatment of arthritis and systemic features. Arthritis Care Res. 2011 Apr;63(4):465-82.
4. Quartier P, Allantaz, Cimaz R, et al. A multicenter, randomized, double-blind, placebo-controlled trial with the interleukin-1 receptor antagonist anakinra in patients with systemic-onset juvenile idiopathic arthritis (ANAJIS trial). Ann Rheum Dis. 2011 May;70(5):747-54.
5. Yu JR and Leslie KS. Cryopyrin-associated periodic syndrome: an update on diagnosis and treatment response. Curr Allergy Asthma Rep. 2011;11(1):12-20.
6. 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):934-939.
7. Ringold S, et al. 2013 update of the 2011 American College of Rheumatology recommendations for the treatment of juvenile idiopathic arthritis: recommendations for the medical therapy of children with systemic juvenile idiopathic arthritis and tuberculosis screening among children receiving biologic medications. Arthritis Rheum. 2013 Oct;65(10):2499-512.
8. Mandl LA. Treatment of adult-onset Still's disease. In: UpToDate, Waltham, MA, August 2021.

Program	Prior Authorization/Notification - Kineret
Change Control	
2/2014	Reauthorization criteria revised to include concomitant therapy criterion. Extended reauthorization duration to 24 months.
9/2014	Administrative change - Tried/Failed exemption for State of New Jersey removed.
2/2015	Annual reviewed. Updated NOMID criteria to align with other CAPS programs. Minor reformatting. Updated references.
3/2016	Annual review. Updated criteria for NOMID to match section 1 of packet insert. Updated reference.
3/2017	Annual review with no changes to clinical criteria. Updated background and references.
3/2018	Annual review with no changes to clinical criteria. Updated references.
3/2019	Annual review. Added Olumiant (baricitinib) to list of medications that patient should not be receiving while on Kineret therapy for rheumatoid arthritis. Updated references.

3/2020	Annual review. Added criteria for adult onset Still's disease. Updated reference.
3/2021	Annual review. Updated background information to reflect package insert. Added coverage criteria for the treatment of Deficiency of Interleukin-1 Receptor Antagonist (DIRA). Updated reauthorization to 12 months to reflect other programs. Updated references.
3/2022	Annual review. Updated references.
3/2023	Annual review with no update to coverage criteria. Changed Humira examples to adalimumab and added Rinvoq as a JAKI example Added state mandate footnote.
7/2023	Updated not receiving in combination language to targeted immunomodulator and updated examples.
10/2024	Annual review with no change to coverage criteria.
10/2025	Annual review. Updated combination examples and language with no change to clinical intent.