

UnitedHealthcare Pharmacy  
Clinical Pharmacy Programs

Program Number	2024 P 1055-14
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
Effective Date	1/1/2025

**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).<sup>1</sup> Examples of DMARDs commonly used in the treatment of rheumatoid arthritis include methotrexate, leflunomide, and sulfasalazine.<sup>2,6</sup> 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).<sup>1</sup> Clinical evidence also supports the use of Kineret to treat active systemic juvenile idiopathic arthritis and adult onset Still's disease.<sup>3,4,7, 8</sup>

**2. Coverage Criteria<sup>a</sup>:**

**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 targeted immunomodulator. [e.g., Enbrel (etanercept), Cimzia (certolizumab), Simponi (golimumab), Orencia (abatacept), Xeljanz (tofacitinib), Olumiant (baricitinib), Rinvoq (upadacitinib)]

**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 targeted immunomodulator. [e.g., Enbrel (etanercept), Cimzia (certolizumab), Simponi (golimumab), Orencia (abatacept), Xeljanz (tofacitinib), Olumiant (baricitinib), Rinvoq (upadacitinib)]

**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 targeted immunomodulator. [e.g., Enbrel (etanercept), Cimzia (certolizumab), Simponi (golimumab), Orencia (abatacept), Xeljanz (tofacitinib), Olumiant (baricitinib), Rinvoq (upadacitinib)]

**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 targeted immunomodulator. [e.g., Enbrel (etanercept), Cimzia (certolizumab), Simponi (golimumab), Orencia (abatacept), Xeljanz (tofacitinib), Olumiant (baricitinib), Rinvoq (upadacitinib)]

**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 targeted immunomodulator [e.g., Enbrel (etanercept), Cimzia (certolizumab), Simponi (golimumab), Orencia (abatacept), Xeljanz (tofacitinib), Olumiant (baricitinib), Rinvoq (upadacitinib)]

**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 targeted immunomodulator [e.g., Enbrel (etanercept), Cimzia (certolizumab), Simponi (golimumab), Orencia (abatacept), Xeljanz (tofacitinib), Olumiant (baricitinib), Rinvoq (upadacitinib)]

**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 targeted immunomodulator [e.g., Enbrel (etanercept), Cimzia (certolizumab), Simponi (golimumab), Orencia (abatacept), Xeljanz (tofacitinib), Olumiant (baricitinib), Rinvoq (upadacitinib)]

**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 targeted immunomodulator [e.g., Enbrel (etanercept), Cimzia (certolizumab), Simponi (golimumab), Orencia (abatacept), Xeljanz (tofacitinib), Olumiant (baricitinib), Rinvoq (upadacitinib)]

**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 targeted immunomodulator [e.g., Enbrel (etanercept), Cimzia (certolizumab), Simponi (golimumab), Orencia (abatacept), Xeljanz (tofacitinib), Olumiant (baricitinib), Rinvoq (upadacitinib)]

**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 targeted immunomodulator [e.g., Enbrel (etanercept), Cimzia (certolizumab), Simponi (golimumab), Orencia (abatacept), Xeljanz (tofacitinib), Olumiant (baricitinib), Rinvoq (upadacitinib)]

**Authorization will be issued for 12 months.**

<sup>a</sup> 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; December 2020.
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
<b>Change Control</b>	
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.