UnitedHealthcare Pharmacy
Clinical Pharmacy Programs

Program Number	2021 P 1055-10
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
Effective Date	6/1/2021; Oxford only: 6/1/2021

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. <u>Rheumatoid Arthritis (RA)</u>

1. <u>Initial Authorization</u>

a. **Kineret** will be approved based on **<u>all</u>** 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 either of the following:[1]

(a) Biologic DMARD [e.g., Enbrel (etanercept), Humira (adalimumab), Cimzia (certolizumab), Simponi (golimumab)]
(b) Janus kinase inhibitor [e.g., 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 either of the following:[1]

(a) Biologic DMARD [e.g., Enbrel (etanercept), Humira (adalimumab), Cimzia (certolizumab), Simponi (golimumab)]
(b) Janus kinase inhibitor [e.g., 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 either of the following:[1]

(a) Biologic DMARD [e.g., Enbrel (etanercept), Humira (adalimumab), Cimzia (certolizumab), Simponi (golimumab)]
(b) Janus kinase inhibitor [e.g., Xeljanz (tofacitinib)]

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 either of the following:[1]

(a) Biologic DMARD [e.g., Enbrel (etanercept), Humira (adalimumab), Cimzia (certolizumab), Simponi (golimumab)]
(b) Janus kinase inhibitor [e.g., Xeljanz (tofacitinib)]

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 either of the following:[1]

(a) Biologic DMARD [e.g., Enbrel (etanercept), Humira (adalimumab), Cimzia (certolizumab), Simponi (golimumab)]
(b) Janus kinase inhibitor [e.g., Xeljanz (tofacitinib)]

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 either of the following:[1]

(a) Biologic DMARD [e.g., Enbrel (etanercept), Humira (adalimumab), Cimzia (certolizumab), Simponi (golimumab)]
(b) Janus kinase inhibitor [e.g., Xeljanz (tofacitinib)]

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 either of the following:[1]

(a) Biologic DMARD [e.g., Enbrel (etanercept), Humira (adalimumab), Cimzia (certolizumab), Simponi (golimumab)]
(b) Janus kinase inhibitor [e.g., Xeljanz (tofacitinib)]

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 either of the following:[1]

(a) Biologic DMARD [e.g., Enbrel (etanercept), Humira (adalimumab), Cimzia (certolizumab), Simponi (golimumab)]
(b) Janus kinase inhibitor [e.g., Xeljanz (tofacitinib)]

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 either of the following:[1]

(a) Biologic DMARD [e.g., Enbrel (etanercept), Humira (adalimumab), Cimzia (certolizumab), Simponi (golimumab)]
(b) Janus kinase inhibitor [e.g., Xeljanz (tofacitinib)]

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 either of the following:[1]

(a) Biologic DMARD [e.g., Enbrel (etanercept), Humira (adalimumab), Cimzia (certolizumab), Simponi (golimumab)]
(b) Janus kinase inhibitor [e.g., Xeljanz (tofacitinib)]

Authorization will be issued for 12 months.

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 multicentre, randomised, 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. Singh JA, Saag KG, Bridges SL, et al. 2015 American College of Rheumatology Guideline for the Treatment of Rheumatoid Arthritis. Arthritis Care & Research. Arthritis Rheum. 2016; 68(1):1-26.
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 Still's disease. In: UpToDate, Waltham, MA, 2020

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.
3/2020	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.