UnitedHealthcare Community Plan

Clinical Pharmacy Program Guidelines for Kineret

Program	Prior Authorization
Medication	Kineret (anakinra)
Markets in Scope	California, Hawaii, Maryland, Nevada, New Jersey, New York, Pennsylvania CHIP, Rhode Island, South Carolina
Issue Date	3/2013
Pharmacy and Therapeutics Approval Date	5/2020
Effective Date	7/2020

1. Background:

Kineret is an interleukin-1 receptor antagonist indicated for the reduction in signs and symptoms and slowing the progression of structural damage in moderately to severely active rheumatoid arthritis (RA) in patients 18 years of age or older who have failed 1 or more disease modifying antirheumatic drugs (DMARDs). Kineret is also indicated for the treatment of neonatal-onset multisystem inflammatory disease (NOMID). Kineret has also been used for the treatment of active systemic juvenile idiopathic arthritis and adult onset Still's Disease.

2. Coverage Criteria:

A. Rheumatoid Arthritis (RA)

1. Initial Authorization

One of the following:

(1) **All** of the following:

a. Diagnosis of moderately to severely active RA

-AND-

b. History of failure to a 3 month trial of **one** non-biologic disease modifying anti-rheumatic drug (DMARD) [e.g., methotrexate, leflunomide, sulfasalazine, hydroxychloroquine] at maximally indicated doses within the last 6 months, unless contraindicated or clinically significant adverse effects are experienced (document drug, date, and duration of trial)

-AND-

c. Patient is not receiving Kineret in combination with **any** of the following:

(1) Biologic DMARD [e.g., Enbrel (etanercept), Humira (adalimumab), Cimzia (certolizumab), Simponi (golimumab)]
(2) Janus kinase inhibitor [e.g., Xeljanz (tofacitinib)]
(3) Phosphodiesterase 4 (PDE4) inhibitor [e.g. Otezla (apremilast)]

-AND-

d. History of failure, contraindication, or intolerance to **three** of the following:

- Cimzia (certolizumab)
- Humira (adalimumab)
- Enbrel (etanercept)
- Kevzara (sarilumab)
- Olumiant (baricitinib)

-AND-

e. Prescribed by or in consultation with a rheumatologist

-OR-

(2) **All** of the following:

a. Patient is currently on Kineret therapy as documented by claims history or medical records (document drug, date, and duration of therapy)

-AND-

b. Diagnosis of moderately to severely active RA

-AND-

c. Patient is not receiving Actemra in combination with **any** of the following:

(1) Biologic DMARD [e.g., Enbrel (etanercept), Humira (adalimumab), Cimzia (certolizumab), Simponi (golimumab)]
(2) Janus kinase inhibitor [e.g., Xeljanz (tofacitinib)]
(3) Phosphodiesterase 4 (PDE4) inhibitor [e.g. Otezla (apremilast)]

-AND-

d. Prescribed by or in consultation with a rheumatologist

Authorization will be issued for 12 months.

2. Reauthorization

a. Documentation of positive clinical response to Kineret therapy

-AND-

b. Patient is not receiving Kineret in combination with **any** of the following:

(1) Biologic DMARD [e.g., Enbrel (etanercept), Humira (adalimumab), Cimzia (certolizumab), Simponi (golimumab)]
(2) Janus kinase inhibitor [e.g., Xeljanz (tofacitinib)]
(3) Phosphodiesterase 4 (PDE4) inhibitor [e.g. Otezla (apremilast)]

-AND-

c. Prescribed by or in consultation with a rheumatologist

Authorization will be issued for 12 months.

B. Neonatal-Onset Multisystem Inflammatory Disease (NOMID)

1. Initial Authorization

a. Diagnosis of neonatal-onset multisystem inflammatory disease (NOMID)

-AND-

b. Patient is not receiving Kineret in combination with **any** of the following:

(1) Biologic DMARD [e.g., Enbrel (etanercept), Humira (adalimumab), Cimzia (certolizumab), Simponi (golimumab)]
(2) Janus kinase inhibitor [e.g., Xeljanz (tofacitinib)]
(3) Phosphodiesterase 4 (PDE4) inhibitor [e.g. Otezla (apremilast)]

-AND-

c. Prescribed by or in consultation with a rheumatologist

Authorization will be issued for 12 months.

2. Reauthorization

a. Documentation of positive clinical response to Kineret therapy

-AND-

b. Patient is not receiving Kineret in combination with **any** of the following:

(1) Biologic DMARD [e.g., Enbrel (etanercept), Humira (adalimumab), Cimzia (certolizumab), Simponi (golimumab)]
(2) Janus kinase inhibitor [e.g., Xeljanz (tofacitinib)]
(3) Phosphodiesterase 4 (PDE4) inhibitor [e.g. Otezla (apremilast)]

-AND-

c. Prescribed by or in consultation with a rheumatologist

Authorization will be issued for 12 months.

C. Systemic Juvenile Idiopathic Arthritis (SJIA)

1. Initial Authorization

a. Diagnosis of active systemic juvenile idiopathic arthritis (formerly Still's Disease)

-AND-

b. Patient is not receiving Kineret in combination with **any** of the following:

(1) Biologic DMARD [e.g., Enbrel (etanercept), Humira (adalimumab), Cimzia (certolizumab), Simponi (golimumab)]
(2) Janus kinase inhibitor [e.g., Xeljanz (tofacitinib)]
(3) Phosphodiesterase 4 (PDE4) inhibitor [e.g. Otezla (apremilast)]

-AND-

c. Prescribed by or in consultation with a rheumatologist

Authorization will be issued for 12 months.

2. Reauthorization

a. Documentation of positive clinical response to Kineret therapy

-AND-

b. Patient is not receiving Kineret in combination with **any** of the following:

(1) Biologic DMARD [e.g., Enbrel (etanercept), Humira (adalimumab), Cimzia (certolizumab), Simponi (golimumab)]
(2) Janus kinase inhibitor [e.g., Xeljanz (tofacitinib)]
(3) Phosphodiesterase 4 (PDE4) inhibitor [e.g. Otezla (apremilast)]

-AND-

c. Prescribed by or in consultation with a rheumatologist

Authorization will be issued for 12 months.

D. Adult Onset Still's Disease

1. Initial Authorization

a. Diagnosis of adult onset Still's Disease

-AND-

b. Patient is not receiving Kineret in combination with **any** of the following:

(1) Biologic DMARD [e.g., Enbrel (etanercept), Humira (adalimumab), Cimzia (certolizumab), Simponi (golimumab)]
(2) Janus kinase inhibitor [e.g., Xeljanz (tofacitinib)]
(3) Phosphodiesterase 4 (PDE4) inhibitor [e.g. Otezla (apremilast)]

-AND-

c. Prescribed by or in consultation with a rheumatologist

Authorization will be issued for 12 months.

2. Reauthorization

a. Documentation of positive clinical response to Kineret therapy

-AND-

b. Patient is not receiving Kineret in combination with **any** of the following:

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

(3) Phosphodiesterase 4 (PDE4) inhibitor [e.g. Otezla (apremilast)]

-AND-

c. Prescribed by or in consultation with a rheumatologist

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]. Thousand Oaks, CA: Amgen, Inc.; June 2018.
2. 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.
3. Kimura, Y. Systemic juvenile idiopathic arthritis: Treatment. UpToDate. Updated July 27, 2018. Accessed January 10, 2019.
4. Nigrovic PA. Cryopyrin-associated periodic syndromes and related disorders. UpToDate. Updated June 6, 2017. Accessed January 10, 2019.
5. Mandel, LA. Treatment of adult Still's Disease. UpToDate. Updated June 11, 2019. Accessed February 4, 2020.

Program	Program type – Prior Authorization
Change Control	
Date	Change
3/2013	New Guideline
2/2015	• Removed age requirement for RA and SJIA criteria • Changed requirement of one TNF trial to two TNF trials unless the request is for a continuation of therapy. Preferred TNFs were Enbrel and Humira and are now Cimzia and Humira. • Added requirement that the patient is not receiving a biologic DMARD or JAK inhibitor for the NOMID and SJIA

	reauthorization criteria. This was only present previously in the initial criteria for NOMID and SJIA.
3/2016	• Added Enbrel to list of prerequisite therapy for Rheumatoid Arthritis section, initial therapy • Added diagnosis confirmation requirements and prescriber requirement to NOMID section, initial therapy • Updated policy template
10/2016	• Annual Review – no change
2/2017	• Changed Enbrel to Kineret in rheumatoid arthritis section.
3/2017	• Added Otezla to list of medications that should not be used with Kineret
4/2017	• Added hydroxychloroquine to example list of non-biologic DMARDs
2/2018	• Updated step therapy medications in the rheumatoid arthritis section to a trial of two TNF inhibitors and Kevzara due to PDL changes effective 4/1/18.
3/2019	• Formatted background. Removed prescriber check to align with other programs. Revised step therapy medications for RA. Removed additional diagnostic criteria for NOMID. Updated references.
12/2019	• Revised non-biologic requirement for RA indication. Separated continuation of therapy requirements for current users. Updated background and references.
1/2020	• Revised RA step therapy medications due to PDL changes.
3/2020	• Added review criteria for adult onset Still's Disease. Updated background and references.
5/2020	• Added prescriber check to align with other programs.