UnitedHealthcare Community Plan

Clinical Pharmacy Program Guidelines for Kineret - OHIO

Program	Prior Authorization
Medication	Kineret (anakinra)
Markets In Scope	Ohio

1. Background:

Indicated for the reduction in signs and symptoms and slowing the progression of structural damage in moderately to severely active rheumatoid arthritis, in patients 18 years of age or older who have failed 1 or more disease modifying anti-rheumatic drugs (DMARDs). Kineret can be used alone or in combination with DMARDs other than Tumor Necrosis Factor (TNF) blocking agents.

Indicated for the treatment of Neonatal-Onset Multisystem Inflammatory Disease (NOMID).

Off Label Uses
Systemic Juvenile Idiopathic Arthritis
Has been used for the treatment of systemic juvenile idiopathic arthritis.

2. Coverage Criteria:

A. Rheumatoid Arthritis (RA)

1. Initial Authorization

a. Diagnosis of moderately to severely active RA

-AND-

b. Prescribed or recommended by a rheumatologist

-AND-

c. History of failure, contraindication, or intolerance to one non-biologic disease modifying anti-rheumatic drug (DMARD) [eg, methotrexate, leflunomide, sulfasalazine, hydroxychloroquine]

-AND-

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

(1) Biologic DMARD [eg, Enbrel (etanercept), Humira (adalimumab),

Cimzia (certolizumab), Simponi (golimumab)]
(2) Janus kinase inhibitor [eg, Xeljanz (tofacitinib)]
(3) Phosphodiesterase 4 (PDE4) inhibitor [e.g. Otezla (apremilast)]

-AND-

e. **One** of the following:

(1) History of failure, contraindication, or intolerance to **two** of the following:

- Cimzia (certolizumab)
- Humira (adalimumab)
- Enbrel (etanercept)

-OR-

(2) For continuation of prior Kineret therapy

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

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. Diagnosis of NOMID has been confirmed by one of the following:

(1) NLRP-3 (nucleotide-binding domain, leucine rich family (NLR), pyrin domain containing 3] gene (also known as Cold- Induced Auto-inflammatory Syndrome-1 [CIAS1]) mutation

-OR-

(2) Evidence of active inflammation which includes both of the following:
(a) Clinical symptoms (eg, rash, fever, arthralgia)
(b) Elevated acute phase reactants (eg, ESR, CRP)

-AND-

c. Prescribed or recommended by one of the following:
(1) Allergist/Immunologist
(2) Rheumatologist

-AND-

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

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

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

Authorization will be issued for 12 months.

C. Systemic Juvenile Idiopathic Arthritis (SJIA) (off-label)

1. Initial Authorization

a. Diagnosis of active systemic juvenile idiopathic arthritis

-AND-

b. Prescribed or recommended by a rheumatologist

-AND-

c. History of failure, contraindication, or intolerance to one of the following:

(1) Non-steroidal anti-inflammatory drugs (NSAIDs) [e.g., Motrin (ibuprofen), Naprosyn (naproxen)]
(2) Corticosteroids (e.g., prednisone)

-AND-

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

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

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

Authorization will be issued for 12 months.

3. References:

1. Kineret Prescribing Information. Swedish Orphan Biovitrum. November 2013.
2. Bresnihan B, et al. Treatment of rheumatoid arthritis with recombinant human interleukin-1 receptor antagonist. Arthritis Rheum.1998;41(12):2196-2204.
3. Jiang Y, et al. A multicenter, double-blind, dose-ranging, randomized, placebo-controlled study of recombinant human interleukin-1 receptor antagonist in patients with rheumatoid arthritis: radiologic progression and correlation of Genant and Larsen scores. Arthritis Rheum.2000;43(5):1001-1009.
4. Schiff MH, et al. Safety of combination therapy with anakinra and etanercept in patients with rheumatoid arthritis. Arthritis Rheum.2001;44:S79.
5. Singh JA, Furst DE, Bharat A, et al. 2012 update of the 2008 American College of Rheumatology recommendations for the use of disease-modifying antirheumatic drugs and biologic agents in the treatment of rheumatoid arthritis. Arthritis Care & Research. 2012;64(5):625-639.
6. 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.
7. Felson DT, Anderson JJ, Boers M, et al. American College of Rheumatology preliminary definition of improvement in rheumatoid arthritis. Arthritis Rheum. 1995; 38(6):727-735.
8. Felson D, Anderson JJ, Boers M, et al. The American College of Rheumatology preliminary core sets of disease activity measures for rheumatoid arthritis clinical trials. Arthritis Rheum. 1993;36(6): 729-740.
9. Ringold S, Weiss PF, Beukelman T, 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;65(10):2499-2512.
10. 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.
11. Per clinical consult with pediatric rheumatologist, August 2, 2011.
12. Per clinical consult with rheumatologist, June 30, 2011.
13. Furst DE, Keystone EC, Braun J, et al. Updated consensus statement on biological agents for the treatment of rheumatic diseases, 2011. Ann Rheum Dis. 2012 ;71(Suppl II):i2- i45 .
14. Nigrovic PA. Cryopyrin-associated periodic syndromes and related disorders. UpToDate Web Site. Updated August 8, 2012. http:www.uptodate.com. Accessed October 17, 2013.
15. Xeljanz Prescribing Information. Pfizer. March 2014.

Program	Program type – Prior Authorization
Change Control	
Date	Change
2/2018	Ohio specific policy created for 4/1/18 since Ohio will be moving to a Single PDL later in 2018.