

Market Applicability															
Market	DC	FL & FHK	FL MMA	FL LTC	GA	KS	KY	LA	MD	NJ	NV	NY	TN	TX	WA
Applicable	X	X	NA	NA	X	NA	X	X	X	X	X	X	NA	NA	NA

*FHK- Florida Healthy Kids

Kineret (anakinra)

Override(s)	Approval Duration
Prior Authorization Quantity Limit	1 year

Medications	Quantity Limit
Kineret (anakinra)	May be subject to quantity limit

APPROVAL CRITERIA

Requests for Kineret (anakinra) may be approved if the following criteria are met:

- I. Individual has a diagnosis of Rheumatoid Arthritis (RA) when each of the following criteria are met:
 - A. Individual is 18 years of age or older with moderately to severely active RA; **AND**
 - B. Agent is used for any of the following reasons:
 1. To reduce signs or symptoms; **OR**
 2. To induce or maintain clinical response; **OR**
 3. To inhibit the progression of structural damage; **OR**
 4. To improve physical function;
- AND**
- C. Individual has had an inadequate response to, is intolerant of, or has a contraindication to one or more disease modifying anti-rheumatic agents (DMARDs); **AND**
 - D. Individual has had trial (medication samples/coupons/discount cards are excluded from consideration as a trial) and inadequate response or intolerance to TWO (2) preferred biologic agents [Current preferred biologics include – Enbrel (etanercept), Humira (adalimumab)] unless the following criteria is met:
 1. Individual has been receiving and is maintained on a stable dose of Kineret (anakinra); **OR**
 2. The preferred agents are not acceptable due to concomitant clinical conditions, such as but not limited to any of the following:
 - a. Known hypersensitivity to any active or inactive component which is not also associated with Kineret (anakinra); **OR**
 - b. Individual's age; **OR**

This policy does not apply to health plans or member categories that do not have pharmacy benefits, nor does it apply to Medicare. Note that market specific restrictions or transition-of-care benefit limitations may apply.

Market Applicability															
Market	DC	FL & FHK	FL MMA	FL LTC	GA	KS	KY	LA	MD	NJ	NV	NY	TN	TX	WA
Applicable	X	X	NA	NA	X	NA	X	X	X	X	X	X	NA	NA	NA

*FHK- Florida Healthy Kids

- c. Pregnant or planning on becoming pregnant; **OR**
- d. Serious infections or concurrent sepsis;
- 3. The preferred agent(s) do not have activity against a concomitant clinical condition and Kineret (anakinra) does. An example includes but may not be limited to the following:
 - a. Concomitant Crohn's disease: TNFi (agents FDA-approved for both indications) are preferred;

OR

- II. Individual has a diagnosis of treatment-naïve or refractory (DrugPoints B II a) neonatal-onset multisystem inflammatory disease (NOMID), also known as chronic infantile neurological cutaneous and articular (CINCA syndrome);

OR

- III. Individual has a diagnosis of relapsed/refractory or progressive multicentric Castleman's Disease (MCD) (NCCN 2A);

OR

- IV. Systemic Juvenile Idiopathic Arthritis (SJIA) when each of the following criteria is met (Quartier et al, 2011; ACR 2013):

- A. Individual is 2 years of age or older with active SJIA; **AND**

- B. Agent is used for any of the following reasons:

- 1. To reduce signs or symptoms; **OR**
- 2. To induce or maintain clinical response;

AND

- C. Individual has had an inadequate response to, is intolerant of, or has a contraindication to one or more corticosteroids or nonsteroidal anti-inflammatory drugs (NSAIDs).

Kineret (anakinra) may **not** be approved for the following:

- I. In combination with tumor necrosis factor (TNF) antagonists; **OR**
- II. In combination with tofacitinib (Xeljanz); **OR**
- III. In combination with non-TNF immunomodulatory drugs [such as but not limited to, Actemra (tocilizumab) or Orencia (abatacept)]; **OR**
- IV. Tuberculosis or other active serious infections or a history of recurrent infections; **OR**

This policy does not apply to health plans or member categories that do not have pharmacy benefits, nor does it apply to Medicare. Note that market specific restrictions or transition-of-care benefit limitations may apply.

Market Applicability															
Market	DC	FL & FHK	FL MMA	FL LTC	GA	KS	KY	LA	MD	NJ	NV	NY	TN	TX	WA
Applicable	X	X	NA	NA	X	NA	X	X	X	X	X	X	NA	NA	NA

*FHK- Florida Healthy Kids

- V. Individual has not had a tuberculin skin test (TST) or Centers for Disease Control (CDC) and Prevention - recommended equivalent to evaluate for latent tuberculosis prior to initiating Kineret.

State Specific Mandates		
State name	Date effective	Mandate details (including specific bill if applicable)
N/A	N/A	N/A

Key References:

Clinical Pharmacology [database online]. Tampa, FL: Gold Standard, Inc.: 2016. URL: <http://www.clinicalpharmacology.com>. Updated periodically.

DailyMed. Package inserts. U.S. National Library of Medicine, National Institutes of Health website. <http://dailymed.nlm.nih.gov/dailymed/about.cfm>.

DrugPoints® System (electronic version). Truven Health Analytics, Greenwood Village, CO. Updated periodically.

Lexi-Comp ONLINE™ with AHFS™, Hudson, Ohio: Lexi-Comp, Inc.; 2016; Updated periodically.

This policy does not apply to health plans or member categories that do not have pharmacy benefits, nor does it apply to Medicare. Note that market specific restrictions or transition-of-care benefit limitations may apply.