

Market Applicability							
Market	DC	GA	KY	MD	NJ	NY	WA
Applicable	X	X	X	X	X	X	NA

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 for the following:

- I. Rheumatoid Arthritis (RA) when each of the following criteria are met:
 - A. Individual is 18 years of age or older with moderate to severe RA; **AND**
 - B. Individual has had an inadequate response to, is intolerant of, or has a contraindication to conventional therapy [nonbiologic disease modifying anti-rheumatic agents (DMARDs) (such as methotrexate, sulfasalazine, leflunomide, or hydroxychloroquine)] or a tumor necrosis factor (TNF) antagonist;

AND

 - C. 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, including 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. Pregnant or planning on becoming pregnant; **OR**
 - c. Serious infections or concurrent sepsis;
- OR**
- II. Individual has a diagnosis of treatment-naïve or refractory (DP B IIa) neonatal-onset multisystem inflammatory disease (NOMID), also known as chronic infantile neurological cutaneous and articular (CINCA) syndrome;

OR

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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.

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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 are met (ACR 2013):

- A. Individual is 2 years of age or older with SJIA; **AND**
- B. Individual has had an inadequate response to, is intolerant of, or has a contraindication to corticosteroids or nonsteroidal anti-inflammatory drugs (NSAIDs).

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

- I. All other indications not included above; **OR**
- II. In combination with other IL-1 inhibitors, JAK inhibitors, apremilast, or other biologic drugs (such as IL-6 inhibitors, TNF antagonists, or selective co-stimulation modulators); **OR**
- III. Tuberculosis, or other active serious infections, or a history of recurrent infections; **OR**
- IV. 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 anakinra.

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

Key References:

1. Clinical Pharmacology [database online]. Tampa, FL: Gold Standard, Inc.: 2019. URL: <http://www.clinicalpharmacology.com>. Updated periodically.
2. DailyMed. Package inserts. U.S. National Library of Medicine, National Institutes of Health website. <http://dailymed.nlm.nih.gov/dailymed/about.cfm>. Accessed: September 24, 2019.
3. DrugPoints® System [electronic version]. Truven Health Analytics, Greenwood Village, CO. Updated periodically.
4. Lexi-Comp ONLINE™ with AHFS™, Hudson, Ohio: Lexi-Comp, Inc.; 2019; Updated periodically.
5. NCCN Drugs & Biologics Compendium (NCCN Compendium®) 2019 National Comprehensive Cancer Network, Inc. Available at: NCCN.org. Updated periodically. Accessed on: September 24, 2019.
6. Singh JA, Saag KG, Bridges SL et al. 2015 American College of Rheumatology Guideline for the treatment of rheumatoid arthritis. *Arthritis Rheum.* 2016;68:1-26.
7. 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.

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8. Ringold S, Angeles-Han ST, Beukelman T, et al. 2019 American College of Rheumatology/Arthritis Foundation Guideline for the Treatment of Juvenile Idiopathic Arthritis: Therapeutic Approaches for Non-Systemic Polyarthritis, Sacroiliitis, and Entesitis. *Arthritis Rheum.* 2019; 71(6):846-863.
9. 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 & Research.* 2011; 63(4):465-482.
10. De Benedetti F, Gattorno M, Anton J, et al. Canakinumab for the treatment of autoinflammatory recurrent fever syndromes. *N Engl J Med.* 2018; 378(20):1908-1919.

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