

Title: anakinra (Kineret)

Origination: 08/23/10	Revised: 05/25/11	Annual Review: 12/15/11
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Purpose:

To provide guidelines and criteria for the review and decision determination of requests for medications that requires prior authorization.

Background Information:

Medication Summary

- Kineret blocks the activity of interleukin-1 (IL-1), a protein involved in the inflammatory process and is FDA-approved only in the treatment of moderate to severe rheumatoid arthritis (RA).
- Kineret is indicated for the reduction of signs and symptoms and slowing the progression of structural damage in Members 18 years of age and older with moderately to severely active rheumatoid arthritis (RA) who have failed one (1) or more disease-modifying antirheumatic drug (DMARD).
- It may be used alone or in combination with DMARDs other than tumor necrosis factor (TNF) blocking agents.
- The recommended dose for Kineret[®] in adult Members with RA is 100mg daily. Higher doses did not result in an increased response.

Reference Statement

- Guidelines are compiled from available US Food and Drug Administration (FDA) approved indications, general practice guidelines, and/or evidence-based uses established through phase III clinical studies without published conflicting data. Only clinical studies published in their entirety in reputable peer-reviewed journals will be evaluated.

Eligibility Criteria

- Member must be eligible and have applicable benefit coverage (i.e., self-injectable rider) within the specified date(s) of service.
- Prior authorization requests that do not meet clinical criteria in this Procedure will be forwarded to a Clinical Pharmacist for review.

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Procedure:

- 1.0 Request for *initial therapy* with Kineret for **rheumatoid arthritis (RA)** requires documentation from the Member's medical records maintained by the requesting independent practitioner verifying **ALL** of the following:
 - 1.1 Prescriber must be a rheumatologist;
 - 1.2 Diagnosis of moderate to severe rheumatoid arthritis (RA);
 - 1.3 Member is **not** currently on any of the following medications:
 - 1.3.1 Enbrel;
 - 1.3.2 Humira;
 - 1.3.3 Raptiva;
 - 1.3.4 Remicade;
 - 1.4 Member shows inadequate response to a three (3) to six (6) month minimum trial of an adequate dose of methotrexate; **OR**
 - 1.4 Member has contraindication to methotrexate as evidenced by **at least one (1)** of the following:
 - 1.4.1 Chronic liver disease;
 - 1.4.2 Leukopenia;
 - 1.4.3 Thrombocytopenia;
 - 1.4.4 Creatinine clearance less than 40mL/minute;
 - 1.4.5 Immunodeficiency; **AND**
 - 1.5 Member shows inadequate response to a three (3) to six (6) month minimum trial of an adequate dose of **OR** is not a candidate for at least (1) of the following DMARDs:
 - 1.5.1 Oral or Injectable Gold;
 - 1.5.2 Leflunomide (Arava);
 - 1.5.3 Hydroxychloroquine (Plaquenil);
 - 1.5.4 Sulfasalazine;
 - 1.5.5 Azathioprine (Imuran);
 - 1.5.6 D-Penicillamine;
 - 1.5.7 Cyclosporine; **AND**

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Procedure, continued:

- 1.0 Request for *initial therapy* with Kineret for **rheumatoid arthritis (RA)** requires documentation from the Member's medical records maintained by the requesting independent practitioner verifying **ALL** of the following, continued:
 - 1.6 **For Commercial Members only-** Member shows inadequate response to a three (3) to six (6) month minimum trial of an adequate dose of **both** Humira (adalimumab) and Enbrel (etanercept);
 - 1.7 **For Medicare and Miami Dade County Members only-** Member shows inadequate response to a three (3) to six (6) month minimum trial of an adequate dose of one (1) of the following medications:
 - 1.7.1 Cimzia;
 - 1.7.2 Enbrel;
 - 1.7.3 Humira;
 - 1.7.4 Remicade;
 - 1.7.5 Raptiva;
 - 1.7.6 Simponi;
 - 1.8 If all criteria are met, therapy may be approved for three (3) months at a dose of 100mg SQ once daily.
- 2.0 Request for *continuation of therapy* beyond initial authorization period for **RA** requires documentation from the Member's medical records maintained by the requesting independent practitioner verifying a reduction in Member's signs and symptoms of RA (i.e., 20% improvement in painful joint count, ESR, CRP, or morning stiffness) and/or an improvement in Member's physical functioning:
 - 2.1 If criteria are met, may approve for one (1) year at a dose of 100mg SQ once daily.

References:

1. Harris: Kelley's Textbook of Rheumatology, 7th ed. Saunders, 2005.
2. Cohen SB. "The use of anakinra, an interleukin-1 receptor antagonist, in the treatment of rheumatoid arthritis." *Rheum Dis Clin of N.A.* 2004 May;30(2):365-80.
3. American College of rheumatology (ACR) Subcommittee on Rheumatoid Arthritis Guidelines. "Guidelines for the management of rheumatoid arthritis. 2002 update." *Arthritis Rheum.* 2002;46:328-46.
4. Amgen, Kineret[®] Package Insert. Thousand Oaks, CA. 2005.



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Disclaimer Information:

Prior Authorization criteria are developed to determine coverage for AvMed Health Plans' benefits, and are published to provide a better understanding of the basis upon which coverage decisions are made. AvMed Health Plans makes coverage decisions based on the Member's benefit plan contract and these criteria. This guideline sets forth concise clinical coverage criteria which have been developed from a review of current literature, policies of the FDA and other government agencies, and other appropriate references, in consultation and with approval from practicing physicians who are members of AvMed's Pharmacy and Therapeutic committee. Treating providers are solely responsible for the medical advice and treatment of Members. This guideline may be updated and therefore is subject to change. The use of these criteria is neither a guarantee of payment nor a final prediction of how specific claim(s) will be adjudicated.