

## Pharmacy Policy Bulletin

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**Title:** Anakinra (Kineret®)

**Policy #:** FS.CLIN.71

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***Application of pharmacy policy is determined by benefits and contracts. Benefits may vary based on product line, group, or contract. Some medications may be subject to precertification, age, gender or quantity restrictions. Individual member benefits must be verified.***

***This pharmacy policy document describes the status of pharmaceutical information and/or technology at the time the document was developed. Since that time, new information relating to drug efficacy, interactions, contraindications, dosage, administration routes, safety, or FDA approval may have changed. This pharmacy policy will be reviewed regularly and updated as scientific and medical literature becomes available. This information may include new FDA-approved indications, withdrawals, or other FDA alerts. This type of information is relevant not only when considering whether this policy should be updated, but also when applying it to current requests for coverage.***

***Members are advised to use participating pharmacies in order to receive the highest level of benefits.***

### Intent

**Anakinra (Kineret®)** is indicated for the treatment of moderate to severe rheumatoid arthritis.

The use of anakinra (Kineret®) requires prior authorization (i.e. clinical pharmacy and/or Medical Director review).

### Description:

**Anakinra (Kineret®)** is a synthetic, injectable interleukin-1 (IL-1) receptor antagonist that blocks the effects of human IL-1. IL-1 is a protein produced by many cells in the body, but it is found in increased amounts within joints that are inflamed from rheumatoid arthritis (RA). IL-1 attaches to receptors on the tissues within and surrounding the joints, as well as to the cells that are responsible for inflammation (e.g. white blood cells). The attachment of IL-1 to its receptors activates inflammation and the release of enzymes that destroy cartilage and bone, which contributes to joint pain and swelling. By binding to these receptors, anakinra (Kineret®) prevents the inflammatory and enzyme-releasing effects of IL-1, thereby reducing joint pain and swelling.

### Policy

**Anakinra (Kineret®)** is approved when the following inclusion criterion is met:

- Documentation of a diagnosis of moderate to severe rheumatoid arthritis and **all** of the following:
  - Patient is an adult (≥ 18 years)
  - Medication is being recommended and prescribed by a rheumatologist
  - Patient had at least a 30 day trial and failure with **one** of the following disease-modifying anti-rheumatic drugs (DMARDs) OR contraindication to **all** of the following DMARDs:
    - Methotrexate
    - Hydroxychloroquine
    - Leflunomide
    - Azathioprine
    - Sulfasalazine
    - Adalimumab (Humira®)
    - Etanercept (Enbrel®)

- Patient is not on concurrent therapy with tumor necrosis factor antagonists
- Patient does not have active infections or sepsis
- Patient has been evaluated (i.e. tuberculin skin test) and does not have active or latent tuberculosis
- Patient does not have active malignancy

## Guidelines

Refer to the specific manufacturer's prescribing information for administration and dosage details and any applicable Black Box warnings.

### BENEFIT APPLICATION

Subject to the terms and conditions of the applicable benefit contract, the applicable drug(s) identified in this policy is (are) covered under the pharmacy benefits of the Company's products when the medical necessity criteria listed in this pharmacy policy are met. Any products that are experimental/investigational or cosmetic are benefit contract exclusions for all products of the Company.

## References

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## Applicable Drugs

**i** Inclusion of a drug in this table does not imply coverage. Eligibility, benefits, limitations, exclusions, precertification/referral requirements, provider contracts, and Company policies apply.

Drug Name	Strength and/or formulation
Anakinra (Kineret)	All

## Cross References

**Policy version number:** 4.0  
**P&T approval date:** 9/8/2011  
**Policy effective date:** 12/1/2011  
**Next required review date:** 9/8/2012

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