

Policies Repository



Policy Title Anakinra (Kineret®)

Policy Number FS.CLIN.71

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 edits. 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. If the Medical/Pharmacy Reviewer is aware of any new information on the subject of this document, please provide it promptly to the Medical/Pharmacy Policy Department. 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.

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

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

Policy 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 (eg, 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 Guideline Inclusion

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

Policy Guideline Exclusion

Anakinra (Kineret®) is denied when **any** of the following exclusion criteria are present:

- No documentation of a diagnosis of moderate to severe rheumatoid arthritis
- Patient is less than 18 years old
- Medication is not being prescribed by a

rheumatologist

- Patient does not have 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 on concurrent therapy with other tumor necrosis factor antagonists
- Patient has active infections or sepsis
- Patient has not been evaluated using tuberculin skin test
- Patient has active or latent tuberculosis
- Patient has active malignancy

Policy List of Applicable Drugs

Brand Name	Generic Name
Kineret	anakinra

Dosing and Administration

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

Policy References

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Policy Link to Related Policies

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01/04/2011 10:06:37

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