

**anakinra (Kineret®)**  
**To Initiate a Coverage Review, call 1 800 753-2851**

<b>Covered Medication</b>
➤ Anakinra injection (Kineret®)

<b>What it does and how it is used</b>
<ul style="list-style-type: none"> <li>➤ Rheumatoid arthritis (RA) is a progressive chronic inflammatory disease that primarily affects large and small joints.</li> <li>➤ The disease is characterized by joint and organ deformities that can lead to neuropathy, cardiac abnormalities, pulmonary fibrosis, and corneal defects. RA is associated with a significant amount of morbidity. These morbidities may increase the risk of mortality in RA patients.</li> <li>➤ The inflammatory manifestations of RA usually present as synovitis (inflammation of the synovial fluid between the joints), swollen or tender joints, and daily severe pain.</li> <li>➤ Inflammatory mediators released during active RA secrete enzymes that are involved in joint and cartilage destruction. Mediators may include prostaglandins and cytokines, such as tumor necrosis factor-alpha (TNF-α) and interleukin-1 (IL-1).</li> <li>➤ Treatment is aggressive soon after diagnosis with the goals of reducing symptoms and future damage caused by RA.</li> <li>➤ Initial treatment is usually with a conventional disease modifying antirheumatic drug, (DMARD) (e.g., methotrexate) and/or a biologic agent (e.g., Enbrel®). DMARDs decrease pain, slow disease progression, and retard development of joint erosions.</li> <li>➤ Kineret®, a biologic agent, is a DMARD that specifically blocks the human interleukin-1 receptor. It exerts its action by decreasing inflammation and disease mediators.</li> <li>➤ Kineret® is used as monotherapy or in combination with methotrexate for the reduction in signs and symptoms of active rheumatoid arthritis.</li> </ul>

<b>Rationale for coverage authorization</b>
To reduce the costs associated with using Kineret® in situations where the use of other DMARDs may be warranted (e.g., in situations where methotrexate has not been tried).

<b>Benefit design</b>
➤ Coverage for Kineret® is determined through prior authorization for every claim.

<b>Coverage authorization criteria</b>
Coverage is determined in accord with the following criteria:
<ul style="list-style-type: none"> <li>➤ For the treatment of moderate to severely active rheumatoid arthritis in patients ≥ 18 years of age.</li> <li>➤ Kineret® is covered when used as first line treatment in combination with methotrexate</li> <li>➤ For situations where Kineret® will be used alone, the prescriber must indicate that the patient has had an inadequate response to treatment with methotrexate unless the patient is unable to receive methotrexate.</li> <li>➤ Benefit coverage is <u>not</u> provided for use of Kineret® in combination with Enbrel®, Humira®, Remicade®, Orencia®, or Rituxan®.</li> </ul>
Coverage is provided for 5 years.

<b>References</b>
<ul style="list-style-type: none"> <li>➤ Bresnihan B, Alvaro-Gracia JM, Cobby M et al. Treatment of rheumatoid arthritis with recombinant human interleukin-1 receptor antagonist. <i>Arthritis &amp; Rheumatism</i>. 1998; 41: 2196-2204.</li> <li>➤ Kineret® (Anakinra) injection. Prescribing information. Thousand Oaks, CA: Amgen, December 2006.</li> </ul>