GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have a diagnosis of moderate to severe rheumatoid arthritis (RA) and meet ALL of the following criteria?
   - Therapy is prescribed by or given in consultation with a rheumatologist
   - Previous trial of at least one of the following DMARDs (disease-modifying antirheumatic drugs) such as methotrexate, leflunomide, hydroxychloroquine, or sulfasalazine
   - The patient is 18 years of age or older
   - Previous trial of the preferred TNF (tumor necrosis factor) inhibitors: Enbrel and Humira

   If yes, **approve for 6 months by HICL with a quantity limit of #28 syringes per 28 days.**
   **APPROVAL TEXT:** Renewal requires that the patient has experienced or maintained a 20% or greater improvement in tender joint count or swollen joint count while on therapy. If no, continue to #2.

2. Does the patient have a diagnosis of Neonatal-Onset Multisystem Inflammatory Disease (NOMID) Cryopyrin-Associated Periodic Syndromes (CAPS)?

   If yes, **approve for 12 months by HICL with a quantity limit of #56 syringes per 28 days.**
   If no, do not approve.
   **DENIAL TEXT:** The guideline named **ANAKINRA (Kineret)** requires a diagnosis of moderate to severe rheumatoid arthritis or a diagnosis of Neonatal-Onset Multisystem Inflammatory Disease (NOMID) Cryopyrin-Associated Periodic Syndromes (CAPS). In addition, the following criteria must be met.
   **For patients with moderate to severe rheumatoid arthritis, approval requires all of the following:**
   - Therapy is prescribed by or given in consultation with a rheumatologist
   - Previous trial of at least one of the following DMARDs (disease-modifying antirheumatic drugs) such as methotrexate, leflunomide, hydroxychloroquine, or sulfasalazine
   - The patient is 18 years of age or older
   - Previous trial of the preferred TNF (tumor necrosis factor) inhibitors: Enbrel and Humira

   **CONTINUED ON NEXT PAGE**
ANAKINRA

GUIDELINES FOR USE (CONTINUED)

RENEWAL CRITERIA

1. Does the patient have a diagnosis of moderate to severe rheumatoid arthritis (RA) with documentation that the patient has experienced or maintained a 20% or greater improvement in tender joint count or swollen joint count while on therapy?

   If yes, **approve for 12 months by HICL with a quantity limit of #28 syringes per 28 days.**
   If no, continue to #2.

2. Does the patient have a diagnosis of Neonatal-Onset Multisystem Inflammatory Disease (NOMID) Cryopyrin-Associated Periodic Syndromes (CAPS)?

   If yes, **approve for 12 months by HICL with a quantity limit of #56 syringes per 28 days.**
   If no, do not approve.

**DENIAL TEXT:** The guideline named **ANAKINRA (Kineret)** renewal requires a diagnosis of moderate to severe rheumatoid arthritis or a diagnosis of Neonatal-Onset Multisystem Inflammatory Disease (NOMID) Cryopyrin-Associated Periodic Syndromes (CAPS). In addition, renewal for the diagnosis of moderate to severe rheumatoid arthritis requires documentation that the patient has experienced or maintained a 20% or greater improvement in tender joint count or swollen joint count while on therapy.

RATIONALE
Ensure appropriate diagnostic, utilization, and safety criteria are used for the management of requests for anakinra.

FDA APPROVED INDICATIONS
ANAKINRA (Kineret) is an interleukin-1 receptor antagonist indicated for:

Rheumatoid Arthritis (RA)
- Reduction in signs and symptoms and slowing the progression of structural damage in moderately to severely active rheumatoid arthritis, in patients 18 years of age or older who have failed 1 or more disease modifying antirheumatic drugs (DMARDs).

Cryopyrin-Associated Periodic Syndromes (CAPS)
- Treatment of Neonatal-Onset Multisystem Inflammatory Disease (NOMID).

CONTINUED ON NEXT PAGE
ANAKINRA

REFERENCES


Created: 01/11/18
Effective: 03/01/18