

**Complete Patient and Physician information (PLEASE PRINT)**

STEP 1	Member Name:	Physician Name:
	Address:	Address:
	Member ID:	Phone #:
	Member DOB:	Fax #:
		Tax ID or NPI #:

**If Applicable:** Pharmacy Name: \_\_\_\_\_  
Pharmacy Phone: \_\_\_\_\_

**Complete the Clinical Assessment:**

STEP 2	Diagnosis	<input type="checkbox"/> Moderate to severe active Rheumatoid Arthritis	<input type="checkbox"/> Other (please state): _____
	Clinical Consideration	Patients with rheumatoid arthritis must have tried and failed therapy with a Disease Modifying Antirheumatic Drug (DMARD) Patient tried and failed: <input type="checkbox"/> Methotrexate <input type="checkbox"/> sulfasalazine (Azulfidine) <input type="checkbox"/> hydroxychloroquine (Plaquenil) <input type="checkbox"/> azathioprine (Imuran) <input type="checkbox"/> gold salts (Ridaura, Myochrysine, Solganol) <input type="checkbox"/> cyclophosphamide (Cytoxan) <input type="checkbox"/> d-penicillamine (Cuprimine) <input type="checkbox"/> cyclosporine (Sandimmune, Neoral) <input type="checkbox"/> Arava	
	Physician Specialty	<input type="checkbox"/> Rheumatology	<input type="checkbox"/> Physician experienced with Kineret therapy <input type="checkbox"/> Other (please state): _____
	Supporting Documentation	Diagnosis: ICD-9/10 Code #/ Description / J Code (required): Please attach a copy of the prescription or provide ALL of the information below: Kineret® (anakinra) Strength _____ Sig _____ Qty _____ Refills _____  <i>*Please attach all relevant medical records and test results*</i> <b>We will not process incomplete forms.</b> <b>If we do not receive the completed form &amp; all relevant medical records &amp; test results within 10 calendar days of this request, it will be denied.</b>	

STEP 3 I certify that the above is correct and accurate to the best of my knowledge and that the form is complete.  
(please sign and date)

\_\_\_\_\_  
Prescriber Signature Date

STEP 4 Fax completed form to the Rocky Mountain Health Plans Pharmacy Help Desk:  
**970-248-5034**

Name of Person filling out form: \_\_\_\_\_

Pharmacy Technician initials \_\_\_\_\_ Date Initiated \_\_\_\_\_

**Confidentiality Notice:**

This facsimile transmission (and/or documents accompanying it) may contain confidential information. This information is intended only for the use of the individual(s) named above. If you have received this transmission in error, or cannot identify the recipient for distribution purposes, please notify us immediately at 970-244-7760. Plans underwritten by Rocky Mountain HMO or Rocky Mountain HealthCare Options. 04/29/11

## RMHP Formulary Coverage Policy

THIS INFORMATION IS NOT ALL-INCLUSIVE AND IS PROVIDED FOR INFORMATIONAL PURPOSES ONLY

# Kineret (anakinra)

## CLASSIFICATION

- Immune suppressant, Interleukin-1 Inhibitor

## DESCRIPTION

- Anakinra blocks the biologic activity of IL-1 by competitively inhibiting IL-1 binding to the interleukin-1 type I receptor (IL-1RI), which is expressed in a wide variety of tissues and organs.
- IL-1 production is induced in response to inflammatory stimuli and mediates various physiologic responses including inflammatory and immunological responses. IL-1 has a broad range of activities including cartilage degradation by its induction of the rapid loss of proteoglycans, as well as stimulation of bone resorption. The levels of the naturally occurring interleukin-1 receptor antagonist (IL-1Ra) in synovium and synovial fluid from rheumatoid arthritis patients are not sufficient to compete with the elevated amount of locally produced IL-1.
- Anakinra has shown moderate efficacy in severe rheumatoid arthritis when given alone; combined with methotrexate, improved responses were seen compared to previous methotrexate alone. However, the ability of this agent to significantly modify disease progression has not been clearly established based on evaluation of studies; an additional study will be needed to confirm slowing of joint erosions.
- The optimal dose of anakinra is also unclear due to inconsistencies in reported responses, and direct comparisons with leflunomide and other cytokine modulators (eg, etanercept, infliximab) with disease-modifying activity will be essential to establish its role in therapy.
- Both infliximab and etanercept have demonstrated a high degree of efficacy in preventing erosions when combined with methotrexate, and whether there is any advantage of an anakinra-methotrexate combination will also require a direct comparison.
- In general, antagonism of interleukin-1 receptors appears less effective than blockade of tumor necrosis factor-alpha in rheumatoid arthritis
- The requirement of daily subcutaneous doses of anakinra is a disadvantage (inconvenience and side effects). Daily subcutaneous doses may also not provide high enough plasma levels for continuous and full saturation of interleukin-1 receptors
- At present, clinical data for anakinra are insufficient to recommend it over other agents for symptomatic benefit or as disease-modifying therapy in patients with severe disease, or as early therapy to prevent bone erosions. Methotrexate remains the disease-modifying agent of choice.

## FORMULARY COVERAGE

Prior authorization: Required

Good Health Formulary: T5

Commercial Formulary: T4

Medicare Part D coverage: T4

## COVERAGE CRITERIA

Kineret (anakinra) meets the definition of **medical necessity** for the following:

- Rheumatoid arthritis, moderately to severe

Kineret (anakinra) is considered **experimental** for the following:

- Adult onset Still's disease
- Chronic infantile neurological, cutaneous and articular syndrome
- Juvenile rheumatoid arthritis
- Sepsis syndrome

Required Provider Specialty:

- Approval is limited to Rheumatology

## DOSAGE/ADMINISTRATION:

Adult Dosing (safety and efficacy has not been determined for children):

- Rheumatoid arthritis: 100 mg/day SUBQ

Note:

- Severe renal impairment or end stage renal disease: CrCl less than 30 mL/min, 100 mg SUBQ every other day

## PRECAUTIONS:

- Contraindicated in hypersensitivity to anakinra or E-coli derived proteins
- Concomitant use of tumor necrosis factor blocking agents, including etanercept , infliximab , or adalimumab is NOT recommended; increased risk for serious infections
- Live vaccines should NOT be administered concurrently
- Patients with active infection; therapy should NOT be initiated
- Patients with pre-existing neutropenia; potential exacerbation
- Patients who are immunosuppressed or have chronic infections

## Billing/Coding information

### CPT Coding:

96372	Therapeutic, prophylactic, or diagnostic injection (specify substance or drug); subcutaneous or intramuscular
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### HCPCS Coding:

J3590	Unclassified biologics
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### ICD-9 Diagnoses Codes That Support Medical Necessity:

714.0	Rheumatoid arthritis (RA)
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## COST

- AWP (April 2010): Kineret 100mg/0.67ml syringe for subQ injection (30): \$1,751.11

## COMMITTEE APPROVAL:

## GUIDELINE UPDATE INFORMATION:

April 2010	Medical Policy created

## REFERENCES:

- DRUGDEX®, accessed 04/05/2010
- Product Information: KINERET(R) subcutaneous injection, anakinra subcutaneous injection. Amgen, Inc, Thousand Oaks, CA, 2006.