MEDICAL POLICY STATEMENT

Original Effective Date	Next Annual Review Date	Last Review / Revision Date
06/15/2011	02/15/2016	02/15/2015

Policy Name	Policy Number
Anakinra (Kineret) Injection	SRx-0010

Medical Policy Statements prepared by CSMG Co. and its affiliates (including CareSource) are derived from literature based on and supported by clinical guidelines, nationally recognized utilization and technology assessment guidelines, other medical management industry standards, and published MCO clinical policy guidelines. Medically necessary services include, but are not limited to, those health care services or supplies that are proper and necessary for the diagnosis or treatment of disease, illness, or injury and without which the patient can be expected to suffer prolonged, increased or new morbidity, impairment of function, dysfunction of a body organ or part, or significant pain and discomfort. These services meet the standards of good medical practice in the local area, are the lowest cost alternative, and are not provided mainly for the convenience of the member or provider. Medically necessary services also include those services defined in any Evidence of Coverage documents, Medical Policy Statements, Provider Manuals, Member Handbooks, and/or other policies and procedures.

Medical Policy Statements prepared by CSMG Co. and its affiliates (including CareSource) do not ensure an authorization or payment of services. Please refer to the plan contract (often referred to as the Evidence of Coverage) for the service(s) referenced in the Medical Policy Statement. If there is a conflict between the Medical Policy Statement and the plan contract (i.e., Evidence of Coverage), then the plan contract (i.e., Evidence of Coverage) will be the controlling document used to make the determination.

For Medicare plans please reference the below link to search for Applicable National Coverage Descriptions (NCD) and Local Coverage Descriptions (LCD):

A. SUBJECT

Anakinra (Kineret) Injection

B. BACKGROUND

The CareSource Medication Policies are therapy class policies that are used as a guide when determining health care coverage for our members with benefit plans covering prescription drugs. Medication Policies are written on selected prescription drugs requiring prior authorization or Step-Therapy. The Medication Policy is used as a tool to be interpreted in conjunction with the member's specific benefit plan.

The intent of the **anakinra (Kineret)** PA program is to encourage appropriate selection of therapy for patients according to product labeling and/or clinical guidelines and/or clinical studies, and also to encourage use of preferred agents.

C. DEFINITIONS

N/A

D. POLICY

Kineret is a recombinant IL-1 receptor antagonist (IL-1Ra), blocks the biologic activity of both IL-1α and IL-1β by competitively inhibiting IL-1 binding to the IL-1 type 1 receptor (IL-1R1), which is expressed in a wide variety of tissues and organs. Secretion of IL-1β has an important role in the systemic inflammation of RA.

CareSource will approved the use of anakinra (Kineret) and consider its use as medically necessary when the following criteria have been met for:

Prior Authorization Criteria:
Rheumatoid arthritis, as indicated by the following:

- Age 18 years or older
- Documented diagnosis of moderate to severe active rheumatoid arthritis (at least 6 swollen and 9 tender joints)
- Prescribed by a rheumatologist or under recommendation of a rheumatologist
- Failure of a 3 month trail of one or more DMARD, e.g., Hydroxycholroquine, Leflunomide, Methotretxate or Sulfasalizine **AND failure of a 3 month trial with Tumor Necrosis Factor (TNF) inhibitors**
  OR
- Unable to tolerate, or has a medical contraindication, of conventional therapies
- No concurrent treatment with anti-tumor necrosis factor drug

Juvenile idiopathic arthritis (systemic), as indicated by the following:

- Systemic juvenile idiopathic arthritis, as indicated by arthritis involving **1 or more** joints ***AND*** **1 or more** of the following:
  - Evanescent erythematous rash
  - Fever for at least 2 weeks
  - Generalized lymphadenopathy
  - Hepatomegaly or splenomegaly
  - Pericarditis, pleuritis, or peritonitis
- Inadequate response to **ALL** of the following:
  - Glucocorticosteroids
  - Methotrexate
  - NSAIDs
  - Tumor necrosis factor-alpha inhibitor (eg, adalimumab)

Cryopyrin-associated periodic syndrome (CAPS) which includes severe familial cold autoinflammatory syndrome, Muckle-Wells syndrome, and neonatal-onset multisystem inflammatory disease and are associated with a mutation in the NALP3 gene.

- Diagnosis of Neonatal-Onset Multisystem Inflammatory Disease (NOMID)

Note: Documented diagnosis must be confirmed by contemporaneous portions of the individual's medical record which will confirm the presence of disease and will need to be supplied with prior authorization request. These medical records may include, but not limited to test reports, chart notes from provider's office or hospital admission notes. All other uses of Kineret are considered experimental/investigational and therefore, will follow CareSource's off-label policy. Refer to the product package insert for dosing, administration and safety guidelines.

For Medicare Plan members, refer to the CareSource Policy and Applicable National Coverage Descriptions (NCD) and Local Coverage Descriptions (LCD):

If there is no NCD or LCD present, reference the CareSource Policy for coverage.

CONDITIONS OF COVERAGE

HCPCS J3490
CPT

PLACE OF SERVICE
Office, Outpatient, Home
*****Preferred place of service is in the home*.**
Note: CareSource supports administering injectable medications in various settings, as long as those services are furnished in the most appropriate and cost effective setting that are supportive of the patient's medical condition and unique needs and condition. The decision on the most appropriate setting for administration is based on the member's current medical condition and any required monitoring or additional services that may coincide with the delivery of the specific medication.

AUTHORIZATION PERIOD
Approved authorizations are good for 1 year. Continued treatment may be considered when the member has shown biological response to treatment. **ALL** authorizations are subject to continued eligibility.

E. REVIEW/REVISION HISTORY

Date Issued:	06/15/2011
Date Reviewed:	06/15/2011, 01/18/2013, 02/15/2014, 02/15/2015
Date Revised:	01/18/2013 Removed indications for JRA, safety and pregnancy sections. 02/15/2014 – added • No concurrent treatment with anti-tumor necrosis factor drug, authorization period 1 yr 02/15/2015 – revised trials for RA, added diagnosis CAPS and JIA

F. REFERENCES

1. Kineret [package insert]. Thousand Oaks, CA: Amgen Inc.; December 2012.
2. Winifred S. Hayes, Inc. *Infliximab for Rheumatoid Arthritis*. www.hayesinc.com Published: April 29, 2004 (February 8, 2011)
3. FDA Approves New Drug for Rheumatoid Arthritis; Pharmacist's Letter; March 2010; Vol: 26 Rheumatoid arthritis: the role of DMARDs. Pharmacist's Letter/Prescriber's Letter 2009;25(2):250210.
4. American College of Rheumatology 2008 *Recommendations for the use of non-biologic and biologic disease modifying antirheumatic drugs in rheumatoid arthritis. Arthritis & Rheumatism (Arthritis Care & Research)* Vol. 59. No. 6. June 15. 2008: 762-784, DOI 10. 1002/art.23721
5. U.S. Food and Drug Administration Drugs @ FDA. http://www.accessdata.fda.gov/scripts/cder/drugsatfda/index.cfm?fuseaction=Search.DrugDetails, (February 25, 2011)
6. Beukelman T, Patkar NM, Saag KG, et al. 2011 American College of Rheumatology recommendations for the treatment of juvenile idiopathic arthritis: initiation and safety monitoring of therapeutic agents for the treatment of arthritis and systemic features. *Arthritis Care Res*. (Hoboken). 2011 Apr;63(4):465-82.
7. Milliman Clincal Guidelines 19th edition, 2015.

The medical Policy Statement detailed above has received due consideration as defined in the Medical Policy Statement Policy and is approved.

Independent medical review – 5/2011