VENTURA COUNTY
HEALTH CARE PLAN

Kineret® (anakinra injection-Biovitrim)

Effective Date: 10/22/13
Date Developed: 9/3/13 by Albert Reeves MD
Last Approval Date: 1/26/16, 1/24/17, 1/23/18, 1/22/19
(Archived 1/22/19)

OVERVIEW

Kineret is an interleukin-1 (IL-1) receptor antagonist.[1] IL-1 production is induced in response to inflammation and mediates various physiologic responses including inflammatory and immunological responses.

Kineret is indicated to reduce the signs and symptoms and slow the progression of structural damage in adult patients with moderately to severely active rheumatoid arthritis (RA) who have failed one or more disease-modifying anti-rheumatic drugs (DMARDs).[1-5] Kineret is also indicated in Cryopyrin-Associated Periodic Syndromes (CAPS) for treatment of Neonatal-Onset Multisystem Inflammatory Disease (NOMID).[1,6] In RA, Kineret can be used alone or in combination with DMARDs other than tumor necrosis factor (TNF) blocking agents (e.g., Cimzia® [certolizumab pegol], Enbrel® [etanercept], Humira® [adalimumab], Remicade® [infliximab], Simponi™ [golimumab]).[1]

CAPS

CAPS is a rare inherited inflammatory disease associated with overproduction of IL-1. CAPS encompasses three rare genetic syndromes. Familial Cold Autoinflammatory Syndrome (FCAS), Muckle-Wells Syndrome (MWS), and NOMID or chronic infantile neurological cutaneous and articular syndrome (CINCA) are thought to be one condition along a spectrum of disease severity.[7-8] FCAS is the mildest phenotype and NOMID is the most severe. There are no reliable prevalence statistics for CAPS, but the estimated number of persons with CAPS in the U.S. is 200 to 500. These autoinflammatory syndromes are caused by episodes of inflammation and are distinct from autoimmune disorders. The inflammatory symptoms in these patients include atypical urticaria, rash that is worse in the evening, fever, chills, fatigue, arthralgia, and conjunctival erythema. Exacerbations or flares can be triggered by exposure to cold, stress, exercise, or other stimuli. Patients with NOMID may have sensorineural hearing impairment, increased intracranial pressure, and joint abnormalities. One fourth of patients with MWS may develop systemic AA amyloidosis which usually presents with renal impairment and nephrotic syndrome; amyloidosis is less common in the other forms of CAPS. Ilaris® (canakinumab for injection) and Arcalyst® (rilonacept for injection) are IL-1 blockers indicated for the treatment of CAPS, including FCAS and MWS, in adults and children aged 4 years and older and 12 years and older, respectively.[9-10]

POLICY STATEMENT

Prior authorization is recommended for prescription benefit coverage of Kineret. Because of the specialized skills required for evaluation and diagnosis of patients treated with Kineret as well as the monitoring required for adverse events and long-term efficacy, initial approval requires Kineret to be prescribed by or in consultation with a physician who specializes in the condition being treated. All approvals are provided for 12 months in duration unless otherwise noted below.

PRIOR-AUTHORIZATION CRITERIA
Coverage of Kineret is recommended in those who meet one of the following criteria:

Food and Drug Administration (FDA)-Approved Indications

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1. **Rheumatoid arthritis in an adult**. Approve if the patient meets the following criteria (a and b):
   a) The patient has had a 3 month trial of Xeljanz or one of the following biologic DMARDs, unless intolerant: Orencia® (abatacept), Rituxan® (rituximab), or a TNF antagonist (e.g., Humira, Cimzia, Enbrel, Remicade, or Simponi); AND
   b) Kineret is prescribed by or in consultation with a rheumatologist.

   Kineret is indicated for moderate or severe active RA in adults and can be used alone or in combination with DMARDs other than TNF antagonists.[1] Injections are administered subcutaneously every day. Most patients will have received initial therapy with an oral DMARD(s) (e.g., hydroxychloroquine, leflunomide, sulfasalazine, methotrexate [MTX]) and with a TNF antagonist.[6] Current recommendations for the treatment of RA from the American College of Rheumatology (ACR) [2012] do not make a recommendation for the use of Kineret.[11] The recommendations also note that Kineret is used infrequently for RA and that TNF antagonists are appropriate initial biologic therapy for most patients with RA. In the professional opinion of specialist physicians reviewing the data, we have adopted the criteria requirements for previous therapy.

2. **Cryopyrin-Associated Periodic Syndromes (CAPS).** Approve if the patient meets the following criteria (a and b):
   a) Kineret is being used for treatment of Neonatal Onset Multisystem Inflammatory Disease (NOMID), Familial Cold Autoinflammatory Syndrome (FCAS), Muckle-Wells Syndrome (MWS), and/or chronic infantile neurological cutaneous and articular (CINCA) syndrome; AND
   b) Kineret is prescribed by or in consultation with a rheumatologist, geneticist, or a dermatologist.

   Kineret is indicated for treatment of the NOMID variant of CAPS.[1] However, MWS and CINCA are also variants of CAPS, and all are uncommon conditions with limited therapeutic options. In case reports, Kineret has been effective in treating the dermatologic and rheumatic manifestations in patients with NALP3-associated periodic fever syndromes and also in resolution of AA amyloidosis-associated nephrotic syndrome.[12-16] Patients have maintained control of the inflammatory manifestations of MWS while on Kineret for up to almost 5 years without disease progression.[12] In eight family members with FCAS, Kineret 100 mg daily for 4 weeks was effective in resolving the signs and symptoms of FCAS and in decreasing C-reactive protein (CRP) and serum amyloid A protein.[13] The effect was sustained at 4 and 16 months follow-up in the five patients who continued with Kineret. Patients have maintained control of the inflammatory manifestations of MWS while on Kineret for up to almost 5 years without disease progression.[12]

Other Uses with Supportive Evidence

3. **Active systemic juvenile idiopathic arthritis (SJIA).**[17-21] Approve if the patient meets the following criteria (a and b):
   a) Patient meets one of the following conditions:
      i. The patient has tried one systemic corticosteroid (e.g., prednisone, methylprednisolone) or

MTX, leflunomide, or sulfasalazine, or one biologic agent such as Actemra, Enbrel, Humira, or Remicade; OR

ii. The patient has systemic arthritis with active systemic features and features of poor prognosis, as determined by the prescribing physician (e.g., arthritis of the hip, radiographic damage); AND

b) Kineret is prescribed by or in consultation with a rheumatologist.

The 2011 ACR recommendations for the treatment of JIA do recommend Kineret as initial DMARD therapy in certain patients with systemic arthritis; however, initiating therapy with a biologic agent such as Kineret alone should be rare.[19] Most patients will have received initial therapy with another agent (e.g., nonsteroidal anti-inflammatory drugs [NSAIDs], systemic glucocorticoids, Actemra® [tocilizumab infusion], TNF inhibitor, or MTX).

In the professional opinion of specialist physicians reviewing the data, we have adopted the criteria requirements for previous therapy.

4. **Still's Disease.** Approve if the patient meets the following criteria (a, b, and c):
   a) The patient has tried one corticosteroid; AND
   b) The patient has had an inadequate response to one non-biologic DMARD such as MTX given for at least 2 months or was intolerant to a non-biologic DMARD; AND
   c) Kineret is prescribed by or in consultation with a rheumatologist.

   Still's disease presents in adults with features similar to those of SJIA.[24] As in SJIA, Kineret has been effective in reducing fever, symptoms, and markers of inflammation in patients with adult-onset Still's disease who were refractory to treatment with prednisone and MTX.[17,25-28] In the professional opinion of specialist physicians reviewing the data, we have adopted the criteria requirements for previous therapy.

5. **Patient has been started on Kineret.** Approve for an indication or condition addressed as an approval in the Recommended Authorization Criteria section (FDA-Approved Indications and Other Uses with Supportive Evidence). (In the professional opinion of specialist physicians reviewing the data, we have adopted this criterion.)

EXCLUSIONS

Coverage of Kineret is not recommended in the following circumstances:

1. **Acute gout.** More data are needed. Current data are limited. A randomized controlled trial is needed to determine if Kineret is effective in acute gout.

2. **Ankylosing spondylitis.** Kineret has been beneficial in a few patients with ankylosing spondylitis, but results are not consistent.[30-31]

3. **Concurrent use with another biologic therapy or with Xeljanz.** Kineret should not be administered in combination with another biologic agent for an inflammatory condition (e.g., Actemra, Orencia, Rituxan, or TNF antagonists [Cimzia, Enbrel, Humira, Remicade, or Simponi]). Combination therapy with two biologic agents is not recommended due to a higher rate of adverse effects with combinations and lack of additive efficacy.[33] Xeljanz should not be used in combination with biologic DMARDs such as Actemra.[34]

4. **Diabetes mellitus, type 2.** Further studies are needed to evaluate long-term use and higher doses.

5. **Familial Mediterranean Fever (FMF).** More data are needed. Current data are limited.

6. **JIA or Juvenile rheumatoid arthritis (JRA),** (NOTE: for active systemic JIA, use criterion 2 above in other uses with supportive evidence). The guidelines do not mention the use of Kineret in patients with arthritis of four or fewer joints and note that use of Kineret is uncertain in arthritis in patients with a history of arthritis of five or more joints.

7. **Lupus arthritis.** The effectiveness and safety of Kineret were evaluated in an open 3-month pilot trial. The results from this study are preliminary and a larger controlled study is needed.
8. **Osteoarthritis (OA), symptomatic.** In a Phase II study in patients with painful OA of the knee, Kineret 150 mg administered by intraarticular injection was well tolerated.[46] There were no significant differences in improvement in knee pain, stiffness, function or cartilage turnover between Kineret doses and placebo. Similar to other studies in this population, there was a significant placebo effect noted.

9. **Schnitzler's syndrome.** More data are needed. Current data are limited.

10. **Tumor necrosis factor receptor-associated periodic syndrome (TRAPS).** More data are needed. Limited information is available on the use of Kineret for TRAPS.

11. Coverage is not recommended for circumstances not listed in the Recommended Authorization Criteria. Criteria will be updated as new published data are available.

DOSING:

Dosing: Adult

Neonatal-onset multisystem inflammatory disease (NOMID): SubQ: Initial: 1-2 mg/kg daily in 1-2 divided doses; adjust dose in 0.5-1 mg/kg increments as needed; usual maintenance dose: 3-4 mg/kg daily (maximum: 8 mg/kg daily). **Note:** The prefilled syringe does not allow doses lower than 20 mg to be administered.

Rheumatoid arthritis (RA): SubQ: 100 mg once daily (administer at approximately the same time each day)

Dosage adjustment in renal impairment: Adults: Cl_{cr} <30 mL/minute and/or end-stage renal disease: 100 mg every other day

Dosage adjustment in hepatic impairment: There are no dosage adjustments recommended in manufacturer's labeling.

Dosing: Pediatric

Systemic onset JIA (data based on clinical trials): SubQ: Initial dose: 1 mg/kg once daily; if no response, may increase to 2 mg/kg (maximum dose: 100 mg). Not studied in children <1 year.

Polyarticular course JIA (data based on clinical trials): SubQ: 1 mg/kg once daily (maximum dose: 100 mg). Not studied in children <2 years.

CINCA (and similar congenital autoinflammatory diseases): SubQ: ≥4 years: Initial dose: 1 mg/kg once daily; if no response, may increase up to 2 mg/kg.

Neonatal-onset multisystem inflammatory disease (NOMID): Infants, Children, and Adolescents: SubQ: Refer to adult dosing.

DOSAGE FORMS:

Solution, Subcutaneous [preservative free]:

Kineret: 100 mg/0.67 mL (0.67 mL) [contains disodium edta, polysorbate 80]

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HISTORY

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