VENTURA COUNTY
HEALTH CARE PLAN

FORMULARY EXCEPTION POLICY

POLICY: Inflammatory Conditions – Kineret® (anakinra for subcutaneous injection – Biovitrim)

DATE REVIEWED: 04/19/2019

Continuation of Therapy: Approval for a patient continuing therapy with Kineret must be supported with verification, noted in the criteria as either [verification in prescription claims history required] or, if not available, [verification by prescribing physician required].

- If the patient has at least 130 days of prescription claims history on file, claims history must support that the patient has received Kineret for 90 days within a 130-day look-back period; OR
- When 130 days of the patient's prescription claim history file is unavailable for verification, the prescriber must verify that the patient has been receiving Kineret for at least 90 days, AND that the patient has been receiving Kineret via paid claims (e.g., patient has not been receiving samples or coupons or other types of waivers in order to obtain access to Kineret).

Documentation Required: For rheumatoid arthritis (RA), a trial of two Formulary products are required. The prescriber must provide written documentation supporting the trials of these other agents, noted in the criteria as [documentation required]. Documentation may include, but is not limited to, chart notes, prescription claims records, and/or prescription receipts.

Approval Duration: All approvals are provided for the duration noted below. In cases where the initial approval is authorized in months, 1 month is equal to 30 days.

Formulary Products: Unless exception criteria are met, a trial of two Formulary products is required prior to approval of Kineret for RA. When this requirement is not met, the Formulary products will be offered for review.

CRITERIA

1. **Rheumatoid Arthritis (RA):**
   - **A)** Initial Therapy: Approve for 3 months if the patient meets ALL of the following criteria (i, ii and iii):
     - **i.** The patient has had a 3-month trial of a biologic OR targeted synthetic DMARD for this condition, unless intolerant.
       NOTE: examples of biologics include: Actemra® [tocilizumab for IV infusion, tocilizumab for SC injection], Kevzara [sarilumab SC injection], Orencia® [abatacept for IV infusion, abatacept for SC injection], a rituximab product [Rituxan, Truxima], tumor necrosis factor [TNF] antagonists [e.g., an adalimumab product [Humira], Cimzia, an etanercept product [Enbrel, Erelzi], an infliximab product [e.g., Inflectra, Remicade, Renflexis], Simponi SC, or Simponi Aria]. Example of targeted synthetic DMARD: Xeljanz®/XR [tofacitinib tablets, tofacitinib extended-release tablets], Olumiant [baricitinib tablets]). [NOTE: Conventional synthetic DMARDs such as methotrexate {MTX}, leflunomide, hydroxychloroquine, and sulfasalazine do not count.]; AND
     - **ii.** Kineret is prescribed by or in consultation with a rheumatologist; AND
     - **iii.** The patient has tried TWO of Actemra SC, Enbrel, Humira, and Xeljanz/XR [documentation required]. Note: Trial of either or both Xeljanz products (Xeljanz and Xeljanz XR) collectively counts as a trial of **ONE** product. A trial of Actemra IV, Cimzia, Orencia (IV or

SC), an infliximab product (e.g., Inflectra, Remicade, Renflexis), Kevzara, and Simponi (Aria or SC) also counts [documentation required].

NOTE: If the patient has met criterion i and ii but criterion iii is not met, offer to review for a Formulary product (Actemra SC, Enbrel, Humira, or Xeljanz/XR) using the appropriate *ESI Inflammatory Conditions* criteria.

B) Patients Currently Receiving Kineret: Approve for 1 year if the patient meets BOTH of the following (i and ii):

i. The patient has had a response (e.g., less joint pain, morning stiffness, or fatigue; improved function or activities of daily living; decreased soft tissue swelling in joints or tendon sheaths; improved laboratory values; reduced dosage of corticosteroids), as determined by the prescriber. The patient may not have a full response, but there should have been a recent or past response to Kineret; AND

ii. The patient meets ONE of the following conditions (a or b):

a) The patient has been established on Kineret at least 90 days and prescription claims history indicates at least a 90-day supply of Kineret was dispensed within the past 130 days [verification in prescription claims history required] or, if not available, [verification by prescribing physician required]. Note: In cases when 130 days of the patient's prescription claim history file is unavailable to be verified, an exception to this requirement is allowed if the prescriber has verified that the patient has been receiving Kineret for at least 90 days AND the patient has been receiving Kineret via paid claims (e.g., patient has not been receiving samples or coupons or other types of waivers in order to obtain access to Kineret); OR

b) The patient has tried TWO of Actemra SC, Enbrel, Humira, and Xeljanz/XR [documentation required]. Note: Trial of either or both Xeljanz products (Xeljanz and Xeljanz XR) collectively counts as a trial of **ONE** product. A trial of Actemra IV, Cimzia, Orencia (IV or SC), an infliximab product (e.g., Inflectra, Remicade, Renflexis), Kevzara, or Simponi (Aria or SC) also counts [documentation required].

NOTE: If the patient has met criterion i but criterion ii is not met, offer to review for a Formulary product (Actemra SC, Enbrel, Humira, or Xeljanz/XR) using the appropriate *ESI Inflammatory Conditions* criteria.

2. Cryopyrin-Associated Periodic Syndromes (CAPS):

A) Initial Therapy: Approve for 3 months if the patient meets BOTH of the following criteria (i and ii):

i. 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

ii. Kineret is prescribed by or in consultation with a rheumatologist, geneticist, or a dermatologist.

B) Patients Currently Receiving Kineret: Approve for 1 year if the patient has had a response, as determined by the prescriber. The patient may not have a full response, but there should have been a recent or past response to Kineret.

3. Systemic Juvenile Idiopathic Arthritis (SJIA):

A) Initial Therapy: Approve for 3 months if the patient meets BOTH of the following criteria (i and ii):

i. Patient meets ONE of the following conditions (a, b, or c):

a) The patient has tried one other systemic agent for this condition (e.g., a corticosteroid [oral, IV]; a conventional synthetic disease-modifying antirheumatic drug [DMARD;

e.g., methotrexate {MTX}, leflunomide, sulfasalazine]; or a 1-month trial of a nonsteroidal anti-inflammatory drug [NSAID]).
NOTE: A previous trial of a biologic DMARD such as Actemra IV, a tumor necrosis factor [TNF] inhibitor [e.g., an etanercept product [Enbrel, Erelzi], an adalimumab product [Humira], or an infliximab product [e.g., Inflectra, Remicade, Renflexis], or Ilaris [canakinumab for SC injection] also counts towards a trial of one other systemic agent for SJIA; OR

b) The patient has at least moderate to severe active systemic features of this condition (e.g., fever, rash, lymphadenopathy, hepatomegaly, splenomegaly, serositis) OR the patient has active systemic features with an active joint count of one joint or greater, according to the prescribing physician; OR

c) The patient has active systemic features with concerns of progression to macrophage activation syndrome (MAS), as determined by the prescribing physician; AND

ii. Kineret is prescribed by or in consultation with a rheumatologist.

B) Patients Currently Receiving Kineret: Approve for 1 year if the patient has responded (e.g., has improvement in limitation of motion; less joint pain or tenderness; decreased duration of morning stiffness or fatigue; improved function or activities of daily living; reduced dosage of corticosteroids), as determined by the prescriber. The patient may not have a full response, but there should have been a recent or past response to Kineret.

4. Still's Disease: Approve for 1 year if the patient meets the following criteria (A or B):

A) The patient meets ALL of the following criteria (i, ii, and iii):

i. The patient has tried one corticosteroid; AND

ii. The patient has had an inadequate response to one conventional synthetic disease-modifying antirheumatic drug (DMARD) such as methotrexate (MTX) given for at least 2 months or was intolerant to a conventional synthetic DMARD; AND

iii. Kineret is prescribed by or in consultation with a rheumatologist.

B) The patient is currently established on Kineret for ≥ 90 days.

5. Conditions Not Recommended for Coverage: Patients who meet any of the following criteria do not qualify for treatment with Kineret:

A) Ankylosing Spondylitis (AS); OR

B) Concurrent Use with a Biologic or with a Targeted Synthetic Disease-Modifying Antirheumatic Drug (DMARD).
Note: This does NOT exclude the use of conventional synthetic DMARDs (e.g., MTX, leflunomide, hydroxychloroquine, and sulfasalazine) in combination with Kineret; OR

C) Lupus Arthritis; OR

D) Osteoarthritis (OA), Symptomatic; OR

E) Other circumstances not listed in criterion 1 through 4 (above).