VENTURA COUNTY
HEALTH CARE PLAN

FORMULARY EXCEPTION POLICY

POLICY: Inflammatory Conditions – Kevzara™ (sarilumab for subcutaneous injection – Regeneron)

DATE REVEWED: 04/19/2019

Continuation of Therapy: Approval for a patient continuing therapy with Kevzara 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 Kevzara 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 Kevzara for at least 90 days, AND that the patient has been receiving Kevzara via paid claims (e.g., patient has not been receiving samples or coupons or other types of waivers in order to obtain access to Kevzara).

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 Kevzara 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 tried ONE conventional synthetic disease-modifying antirheumatic drug (DMARD) for at least 3 months (e.g., methotrexate [oral or injectable], leflunomide, hydroxychloroquine, and sulfasalazine).
       NOTE: An exception to the requirement for a trial of one conventional synthetic DMARD can be made if the patient has already had a 3-month trial of at least one biologic DMARD (e.g., Actemra [tocilizumab IV infusion, tocilizumab SC injection], Cimzia [certolizumab pegol SC injection], an etanercept product [e.g, Enbrel], an adalimumab product [e.g., Humira], an infliximab product [e.g., Remicade, Inflectra, Renflexis], Simponi [golimumab SC injection], Simponi Aria [golimumab IV infusion], Kineret [anakinra SC injection], Orencia [abatacept IV infusion; abatacept SC injection], and a rituximab IV product [e.g., Rituxan, Truxima]). These patients who have already tried a biologic for RA are not required to "step back" and try a conventional synthetic DMARD); AND
     - **ii.** Kevzara is prescribed by or in consultation with a rheumatologist; AND
     - **iii.** The patient meets ONE of the following conditions (a or b):

a) 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, an infliximab product (e.g., Inflectra, Remicade, Renflexis), Orencia IV or SC, or Simponi (Aria or SC) also counts [documentation required]; OR

b) According to the prescribing physician, the patient has heart failure OR a previously treated lymphoproliferative disorder.

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 Kevzara. 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 Kevzara; AND

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

a) The patient has been established on Kevzara for at least 90 days and prescription claims history indicates at least a 90-day supply of Kevzara 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 Kevzara for at least 90 days AND the patient has been receiving Kevzara via paid claims (e.g., patient has not been receiving samples or coupons or other types of waivers in order to obtain access to Kevzara); 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, an infliximab product (e.g., Inflectra, Remicade, Renflexis), Orencia IV or SC, or Simponi (Aria or SC) also counts [documentation required]; OR

c) According to the prescribing physician, the patient has heart failure OR a previously treated lymphoproliferative disorder.

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

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 Kevzara.; OR

C) Other circumstances not listed in criterion 1 (above).