VENTURA COUNTY
HEALTH CARE PLAN

FORMULARY EXCEPTION POLICY

POLICY: Inflammatory Conditions – Kevzara Formulary Exception Policy
- Kevzara™ (sarilumab for subcutaneous injection – Regeneron)

REVEW DATE: 12/11/2020 – Effective 01/01/2021

Documentation Required: The prescriber must provide written documentation supporting the trials of Formulary products, 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.

All reviews for use of Kevzara for COVID-19 and/or cytokine release syndrome associated with COVID-19 will be forwarded to the Medical Director for evaluation.

CRITERIA

1. **Rheumatoid Arthritis**. Approve for the duration noted if the patient meets the ONE of the following (A or B):
   - **A)** Initial Therapy. Approve for 3 months if the patient meets ALL of the following criteria (i, ii and iii):
     - **i.** Patient has tried ONE conventional synthetic disease-modifying antirheumatic drug (DMARD) for at least 3 months; AND
       Note: Examples of conventional synthetic DMARDs include methotrexate (oral or injectable), leflunomide, hydroxychloroquine, and sulfasalazine. 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. Refer to Appendix for examples of biologics used for rheumatoid arthritis. A patient who has already tried a biologic for rheumatoid arthritis is not required to "step back" and try a conventional synthetic DMARD.
     - **ii.** The medication is prescribed by or in consultation with a rheumatologist; AND
     - **iii.** Patient meets ONE of the following conditions (a or b):
       - **a)** The patient has tried TWO of Actemra subcutaneous, Enbrel, Humira, Rinvoq, and Xeljanz/XR **[documentation required]**; OR
         Note: Trial of either or both Xeljanz products (Xeljanz and Xeljanz XR) collectively counts as a trial of **ONE** product. A trial of Actemra intravenous, Cimzia, an infliximab product (e.g., Remicade, biosimilars), Orencia intravenous or subcutaneous, or Simponi Aria or subcutaneous also counts **[documentation required]**.
       - **b)** According to the prescriber, 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 subcutaneous, Enbrel, Humira, Rinvoq, or Xeljanz/XR) using the appropriate standard *Inflammatory Conditions* criteria.
   - **B)** Patient is Currently Receiving Kevzara. Approve for 1 year if the patient meets BOTH of the following (i and ii):
     - **i.** Patient has had a response, as determined by the prescriber; AND

Note: Examples of a response to therapy include 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. The patient may not have a full response, but there should have been a recent or past response to Kevzara.

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

a) 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 prescriber required]**; OR

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).

b) Patient has tried TWO of Actemra subcutaneous, Enbrel, Humira, Rinvoq, and Xeljanz/XR **[documentation required]**; OR

Note: Trial of either or both Xeljanz products (Xeljanz and Xeljanz XR) collectively counts as a trial of **ONE** product. A trial of Actemra intravenous, Cimzia, an infliximab product (e.g., Remicade, biosimilars), Orencia intravenous or subcutaneous, or Simponi Aria or subcutaneous also counts **[documentation required]**.

c) According to the prescriber, 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 subcutaneous, Enbrel, Humira, Rinvoq, or Xeljanz/XR) using the appropriate standard *Inflammatory Conditions* criteria.

2. Conditions Not Recommended for Coverage. A patient who meets any of the following criteria do not qualify for treatment with Kevzara:

A) Ankylosing Spondylitis (AS); OR

B) **COVID-19 (Coronavirus Disease 2019).** Forward all requests to the Medical Director.
Note: This includes requests for patients with cytokine release syndrome associated with COVID-19.

C) 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

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

APPENDIX

	Mechanism of Action	Examples of Inflammatory Indications for Products*
Biologics		
Adalimumab SC Products (Humira®, biosimilars)	Inhibition of TNF	AS, CD, JIA, PsO, PsA, RA, UC
Cimzia® (certolizumab pegol SC injection)	Inhibition of TNF	AS, CD, nr-axSpA, PsO, PsA, RA
Etanercept SC Products (Enbrel®, biosimilars)	Inhibition of TNF	AS, JIA, PsO, PsA
Infliximab IV Products (Remicade®, biosimilars)	Inhibition of TNF	AS, CD, PsO, PsA, RA, UC
Simponi®, Simponi® Aria™ (golimumab SC injection, golimumab IV infusion)	Inhibition of TNF	SC formulation: AS, PsA, RA, UC
		IV formulation: AS, PJIA, PsA, RA
Actemra® (tocilizumab IV infusion, tocilizumab SC injection)	Inhibition of IL-6	SC formulation: PJIA, RA, SJIA
		IV formulation: PJIA, RA, SJIA
Kevzara® (sarilumab SC injection)	Inhibition of IL-6	RA
Orencia® (abatacept IV infusion, abatacept SC injection)	T-cell costimulation modulator	SC formulation: JIA, PSA, RA
		IV formulation: JIA, PsA, RA
Rituximab IV Products (Rituxan®, biosimilars)	CD20-directed cytolytic antibody	RA
Kineret® (anakinra SC injection)	Inhibition of IL-1	JIA^, RA
Stelara® (ustekinumab SC injection, ustekinumab IV infusion)	Inhibition of IL-12/23	SC formulation: CD, PsO, PsA, UC
		IV formulation: CD, UC
Siliq™ (brodalumab SC injection)	Inhibition of IL-17	PsO
Cosentyx™ (secukinumab SC injection)	Inhibition of IL-17A	AS, nr-axSpA, PsO, PsA
Taltz® (ixekizumab SC injection)	Inhibition of IL-17A	AS, nr-axSpA, PsO, PsA
Ilumya™ (tildrakizumab-asmn SC injection)	Inhibition of IL-23	PsO
Skyrizi™ (risankizumab-rzaa SC injection)	Inhibition of IL-23	PsO
Tremfya™ (guselkumab SC injection)	Inhibition of IL-23	PsO
Entyvio™ (vedolizumab IV infusion)	Integrin receptor antagonist	CD, UC
Targeted Synthetic Disease-Modifying Antirheumatic Drugs		
Otezla® (apremilast tablets)	Inhibition of PDE4	PsO, PsA
Olumiant® (baricitinib tablets)	Inhibition of the JAK pathways	RA
Rinvoq® (upadacitinib extended-release tablets)	Inhibition of the JAK pathways	RA
Xeljanz® (tofacitinib tablets)	Inhibition of the JAK pathways	RA, PJIA, PsA, UC
Xeljanz® XR (tofacitinib extended-release tablets)	Inhibition of the JAK pathways	RA, PsA, UC

* Not an all-inclusive list of indication (e.g., oncology indications and rare inflammatory conditions are not listed). Refer to the prescribing information for the respective agent for FDA-approved indications; SC – Subcutaneous; TNF – Tumor necrosis factor; AS – Ankylosing spondylitis; CD – Crohn's disease; JIA – Juvenile idiopathic arthritis; PsO – Plaque psoriasis; PsA – Psoriatic arthritis; RA – Rheumatoid arthritis; UC – Ulcerative colitis; nr-axSpA – Non-radiographic axial spondyloarthritis; IV – Intravenous; PJIA – Polyarticular juvenile idiopathic arthritis; SJIA – Systemic juvenile idiopathic arthritis; ^ Off-label use of Kineret in JIA supported in guidelines; JAK – Janus kinase.