VENTURA COUNTY
HEALTH CARE PLAN

FORMULARY EXCEPTION POLICY

POLICY: Inflammatory Conditions – Cimzia® (certolizumab pegol for subcutaneous injection [lyophilized] and SC injection [solution] – UCB)

DATE REVISED: 06/14/2019

Documentation 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.

CRITERIA

1. **Ankylosing Spondylitis (AS).**
   - **A)** Initial Therapy. Approve for 3 months if the patient meets BOTH of the following conditions (i and ii):
     - **i.** Cimzia is prescribed by or in consultation with a rheumatologist; AND
     - **ii.** The patient has tried TWO of Cosentyx, Enbrel, and Humira [documentation required].

     NOTE: If the patient has met criterion i but criterion ii is not met, offer to review for a Formulary product (Cosentyx, Enbrel, or Humira) using the appropriate *ESI Inflammatory Conditions* criteria
   - **B)** Patients Currently Receiving Cimzia. Approve for 1 year if the patient meets BOTH of the following conditions (i and ii):
     - **i.** The patient has had a response (e.g., decreased pain or stiffness, improved function or activities of daily living), as determined by the prescriber. The patient may not have a full response, but there should have been a recent or past response to Cimzia; AND
     - **ii.** The patient meets ONE of the following conditions (a or b):
       - **a)** The patient has been established on Cimzia for at least 90 days and prescription claims history indicates at least a 90-day supply of Cimzia 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 Cimzia for at least 90 days AND the patient has been receiving Cimzia via paid claims (e.g., patient has not been receiving samples or coupons or other types of waivers in order to obtain access to Cimzia); OR
       - **b)** The patient has tried TWO of Cosentyx, Enbrel, and Humira [documentation required].

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

2. **Crohn's Disease in an Adult.** (Note: Patients with fistulizing Crohn's disease or Crohn's disease of the ileal pouch must meet these criteria for Crohn's disease in adults.)
   - **A)** Initial Therapy. Approve for 3 months if the patient meets the following criteria (i, ii, and iii):
     - **i.** The patient meets ONE of the following conditions (a or b):
       - **a)** The patient has tried or is currently taking corticosteroids, or corticosteroids are contraindicated in this patient; OR

b) The patient has tried one other agent for Crohn's disease (e.g., azathioprine, 6-mercaptopurine, methotrexate [MTX].
NOTE: A previous trial of a biologic (e.g., an infliximab product [e.g., Inflectra, Remicade, Renflexis], an adalimumab product [e.g., Humira], Entyvio® [vedolizumab for IV infusion]), or Stelara [ustekinumab IV infusion, ustekinumab SC injection] also counts as a trial of one other agent for Crohn's disease; AND

ii. Cimzia is prescribed by or in consultation with a gastroenterologist; AND

iii. The patient has tried Humira.

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

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

i. The patient has had a response (e.g., decrease in symptoms such as diarrhea, pain, bleeding; improvement in erythrocyte sedimentation rate [ESR], C-reactive protein [CRP], complete blood count [CBC], and/or fecal calprotectin [fCal]), as determined by the prescriber. The patient may not have a full response, but there should have been a recent or past response to Cimzia; AND

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

a) The patient has been established on Cimzia for at least 90 days and prescription claims history indicates at least a 90-day supply of Cimzia 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 Cimzia for at least 90 days AND the patient has been receiving Cimzia via paid claims (e.g., patient has not been receiving samples or coupons or other types of waivers in order to obtain access to Cimzia); OR

b) The patient has tried Humira.

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

3. Plaque Psoriasis.

A) Initial Therapy. Approve for 3 months if the patient meets the following criteria (i, ii, iii, and iv):

i. The patient is an adult greater than or equal to 18 years of age; AND

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

a) The patient has tried at least one traditional systemic agent for psoriasis (e.g., methotrexate [MTX], cyclosporine, acitretin tablets, or psoralen plus ultraviolet A light [PUVA]) for at least 3 months, unless intolerant.
NOTE: An exception to the requirement for a trial of one traditional systemic agent for psoriasis can be made if the patient has already has a 3-month trial or previous intolerance to at least one biologic (e.g., an adalimumab product [e.g., Humira], an etanercept product [e.g., Enbrel], an infliximab product [e.g., Remicade, Renflexis, Inflectra], Cosentyx [secukinumab SC injection], Ilumya [tildrakizumab SC injection], Siliq [brodalumab SC injection], Skyrizi (risankizumab), Stelara [ustekinumab SC injection], Taltz [ixekizumab SC injection], or Tremfya [guselkumab SC injection]). These patients who have already tried a biologic for psoriasis are not required to "step back" and try a traditional systemic agent for psoriasis); OR

b) The patient has a contraindication to methotrexate (MTX), as determined by the prescribing physician; AND

iii. Cimzia is prescribed by or in consultation with a dermatologist; AND

iv. The patient has tried TWO of Cosentyx, Humira, Otezla, Skyrizi, Stelara SC, or Tremfya [documentation required].

NOTE: If the patient has met criterion i, ii, and iii but criterion iv is not met, offer to review for a Formulary product (Cosentyx, Humira, Otezla, Skyrizi, Stelara SC, or Tremfya) using the appropriate *ESI Inflammatory Conditions* criteria

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

i. 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 Cimzia; AND

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

a) The patient has been established on Cimzia for at least 90 days and prescription claims history indicates at least a 90-day supply of Cimzia 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 Cimzia for at least 90 days AND the patient has been receiving Cimzia via paid claims (e.g., patient has not been receiving samples or coupons or other types of waivers in order to obtain access to Cimzia); OR

b) The patient has tried TWO of Cosentyx, Humira, Otezla, Skyrizi, Stelara SC, or Tremfya [documentation required].

NOTE: If the patient has met criterion i but criterion ii is not met, offer to review for a Formulary product (Cosentyx, Humira, Otezla, Skyrizi, Stelara SC, or Tremfya) using the appropriate *ESI Inflammatory Conditions* criteria.

4. Psoriatic Arthritis (PsA).

A) Initial Therapy. Approve for 3 months if BOTH of the following conditions (i and ii):

i. Cimzia is prescribed by or in consultation with a rheumatologist or a dermatologist; AND

ii. The patient has tried TWO of Cosentyx, Enbrel, Humira, Stelara SC, and Xeljanz/XR [documentation required].

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

B) Patients Currently Receiving Cimzia. Approve for 1 year if the patient meets BOTH of the following conditions (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; improvements in acute phase reactants [for example, CRP]), as determined by the prescriber. The patient may not have a full response, but there should have been a recent or past response to Cimzia; AND

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

a) The patient has been established on Cimzia for at least 90 days and prescription claims history indicates at least a 90-day supply of Cimzia 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 Cimzia for at least 90 days AND the patient has been receiving Cimzia via paid claims

(e.g., patient has not been receiving samples or coupons or other types of waivers in order to obtain access to Cimzia); OR

b) The patient has tried TWO of Cosentyx, Enbrel, Humira, Stelara SC, or Xeljanz/XR [documentation required].

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

5. Rheumatoid Arthritis (RA).

A) Initial Therapy. Approve for 3 months if the patient meets 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 has a 3-month trial at least one biologic disease-modifying antirheumatic drug (DMARD) [e.g., an etanercept product {e.g., Enbrel}, an adalimumab product {e.g., Humira}, an infliximab product {e.g., Inflectra, Remicade, Renflexis}, Simponi {golimumab SC injection}, Simponi Aria {golimumab SC injection}, Actemra {tocilizumab IV infusion, tocilizumab SC injeciton}, Kevzara (sarilumab SC injection), Kineret {anakinra SC injection}, Orencia {abatacept IV infusion, abatacept SC injection}, and a rituximab product {e.g., Rituxan IV}]. These patients who have already tried a biologic for RA are not required to "step back" and try a conventional synthetic DMARD; AND

ii. Cimzia 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: A trial of either or both Xeljanz products (Xeljanz and Xeljanz XR) collectively counts as a trial of **ONE** product.

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 Cimzia. Approve for 1 year if the patient meets BOTH of the following conditions (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 Cimzia; AND

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

a) The patient has been established on Cimzia for at least 90 days and prescription claims history indicates at least a 90-day supply of Cimzia 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 Cimzia for at least 90 days AND the patient has been receiving Cimzia via paid claims (e.g., patient has not been receiving samples or coupons or other types of waivers in order to obtain access to Cimzia); 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.

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.

6. **Non-Radiographic Axial Spondyloarthritis (nr-axSpA).** Approve for the duration noted if the patient meets ONE of the following (A or B):
   - **A)** Initial Therapy. Approve for 3 months if the patient meets BOTH of the following (i and ii):
     - **i.** The patient has objective signs of inflammation, defined as at least one of the following (a or b):
       - **a)** C-reactive protein (CRP) elevated beyond the upper limit of normal for the reporting laboratory; OR
       - **b)** Sacroiliitis reported on magnetic resonance imaging (MRI); AND
     - **ii.** Cimzia is prescribed by or in consultation with a rheumatologist.
   - **B)** Patients Currently Receiving Cimzia. Approve for 3 years if the patient has had a response (e.g., decreased pain or stiffness, improved function or activities of daily living), as determined by the prescriber. The patient may not have a full response, but there should have been a recent or past response to Cimzia.

7. **Spondyloarthritis (SpA), Other Subtypes** (e.g., undifferentiated arthritis, reactive arthritis [Reiter's disease]) [NOTE: For ankylosing spondylitis, psoriatic arthritis, or non-radiographic axial spondyloarthrits, refer to the respective criteria under FDA-approved indications]. Approve for the duration noted if the patient meets ONE of the following conditions (A or B):
   - **A)** Initial Therapy. Approve for 3 months if the patient meets ALL of the following conditions (i, ii, and iii):
     - **i.** The patient has arthritis primarily in the knees, ankles, elbows, wrists, hands, and/or feet; AND
     - **ii.** The patient has tried at least ONE conventional synthetic disease-modifying antirheumatic drug (DMARD) [e.g., methotrexate [MTX], leflunomide, sulfasalazine]; AND
     - **iii.** Cimzia is prescribed by or in consultation with a rheumatologist.
   - **B)** Patients Currently Receiving Cimzia. Approve for 1 year if the patient has had a response (e.g., decreased pain or stiffness, improved function or activities of daily living), as determined by the prescriber. The patient may not have a full response, but there should have been a recent or past response to Cimzia.

8. **Conditions Not Recommended for Coverage.** Patients who meet any of the following criteria do not qualify for treatment with Cimzia:
   - **A)** 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 Cimzia; OR
   - **B)** Other circumstances not listed in criterion 1 through 6 (above).