VENTURA COUNTY
HEALTH CARE PLAN

FORMULARY EXCEPTION POLICY

POLICY: Inflammatory Conditions – Orencia® (abatacept for subcutaneous injection – Bristol Myers Squibb)

DATE REVIEWED: 04/19/2019

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

Documentation Required: For rheumatoid arthritis (RA), juvenile idiopathic arthritis (JIA), and psoriatic arthritis (PsA), a trial of two Formulary products is 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 Orencia SC for RA, JIA, and PsA. 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 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 (e.g., Cimzia [certolizumab pegol for SC injection], an etanercept product [e.g., Enbrel], an adalimumab product [e.g., Humira], an infliximab product [e.g., Inflectra, Remicade, Renflexis], Simponi SC or Aria [golimumab SC injection; golimumab IV infusion], Actemra IV or SC [tocilizumab IV infusion; tocilizumab SC injection], Kevzara [sarilumab SC injection], Kineret [anakinra SC injection], and a rituximab 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. Orencia SC 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, or 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), Kevzara, or Simponi (Aria or SC) also counts [documentation required]; OR

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

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 Orencia (IV or SC): 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 Orencia IV or SC; AND

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

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

b) According to the prescribing physician, the patient has been established on Orencia IV for at least 90 days; OR

c) The patient has tried TWO of Actemra SC, Enbrel, Humira, or 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. A trial Actemra IV, Cimzia, an infliximab product (e.g., Inflectra, Remicade, Renflexis), Kevzara, Simponi (Aria or SC) also counts [documentation required]; OR

d) According to the prescribing physician, the patient has heart failure, a previously treated lymphoproliferative disorder, OR a previous serious infection.

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. Juvenile Idiopathic Arthritis (JIA) [or Juvenile Rheumatoid Arthritis {JRA}] (regardless of type of onset):

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

i. The patient meets one of the following conditions (a, b, c, or d):

a) The patient has tried one other agent for this condition (e.g., methotrexate [MTX], sulfasalazine, or leflunomide, a nonsteroidal anti-inflammatory drug [NSAID]).
NOTE: A biologic (e.g., an etanercept product [e.g., Enbrel®], an adalimuamb product [e.g., Humira®], Orencia® [abatacept IV infusion], an infliximab product [Remicade®, Inflectra™, Renflexis®], Kineret® [anakinra SC injection], or Actemra® [tocilizumab IV infusion] also counts as a trial of one agent for JIA); OR

b) The patient will be starting on Orencia SC concurrently with methotrexate (MTX), sulfasalazine, or leflunomide; OR

c) The patient has an absolute contraindication to methotrexate (MTX) [e.g., pregnancy, breast feeding, alcoholic liver disease, immunodeficiency syndrome, blood dyscrasias], sulfasalazine, or leflunomide; OR

d) The patient has aggressive disease, as determined by the prescribing physician; AND

ii. Orencia SC 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 Enbrel, Humira, and Actemra SC. Note: A trial of Actemra IV, Orencia IV, or an infliximab product (e.g., Remicade, Inflectra, Renflexis) also counts [documentation required]; OR

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

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

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

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

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

b) According to the prescribing physician, the patient has been established on Orencia IV for at least 90 days; OR

c) The patient has JIA and has tried TWO of Enbrel, Humira, and Actemra SC. Note: A trial of Actemra IV, Orencia IV, or an infliximab product (e.g., Remicade, Inflectra, Renflexis) also counts[documentation required]; OR

d) According to the prescribing physician, the patient has heart failure, a previously treated lymphoproliferative disorder, OR a previous serious infection.

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

3. Psoriatic Arthritis (PsA):

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

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

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

a) The patient has tried TWO of Cosentyx, Enbrel, Humira, Stelara SC, or Xeljanz/XR [documentation required]. Note: a trial of Cimzia, an infliximab product (e.g., Remicade, Inflectra, Renflexis), or Simponi Aria or SC also counts [documentation required]; OR

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

B) Patient is Currently Receiving Orencia (IV or SC): Approve for 1 year if the patient meets BOTH of the following (i and ii):

i. The patient has responded (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, C-reactive protein]), as determined by the prescriber. The patient may not have a full response, but there should have been a recent or past response to Orencia; AND

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

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

b) According to the prescribing physician, the patient has been established on Orencia IV for at least 90 days; OR

c) The patient has PsA and has tried TWO of Cosentyx, Enbrel, Humira, Stelara SC, or Xeljanz/XR [documentation required]. Note: a trial of Cimzia, an infliximab product (e.g., Remicade, Inflectra, Renflexis), or Simponi Aria or SC also counts [documentation required]; OR

d) According to the prescribing physician, the patient has heart failure, a previously treated lymphoproliferative disorder, OR a previous serious infection.

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.

4. Conditions Not Recommended for Coverage: Patients who meet any of the following criteria (A, B, C, D, or E) do not qualify for treatment with Orencia SC:

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 Orencia SC; OR

C) Inflammatory Bowel Disease (i.e., Crohn's Disease [CD], Ulcerative Colitis [UC]); OR

D) Psoriasis; OR

E) Other circumstances not listed in criterion 1, 2, or 3 (above).