VENTURA COUNTY
HEALTH CARE PLAN

# FORMULARY EXCEPTION POLICY

**POLICY:** Inflammatory Conditions – Simponi Subcutaneous Formulary Exception Policy
- Simponi® (golimumab for subcutaneous injection – Janssen Biotech, Inc.)

**REVIEW DATE:** 12/04/2020 – Effective 01/01/2021

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**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.** 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 BOTH of the following conditions (i and ii):
     - **i.** The medication is prescribed by or in consultation with a rheumatologist; AND
     - **ii.** Patient has tried TWO of Enbrel, Humira, and Taltz **[documentation required]**.

     Note: If the patient has met criterion i but criterion ii is not met, offer to review for a Formulary product (Enbrel, Humira, or Taltz) using the appropriate standard *Inflammatory Conditions* criteria
   - **B)** Patient is Currently Receiving Simponi Subcutaneous or Simponi Aria. Approve for 1 year if the patient meets BOTH of the following conditions (i and ii):
     - **i.** Patient has had a response, as determined by the prescriber; AND

       Note: Examples of a response include decreased pain or stiffness and improved function or activities of daily living. Patient may not have a full response, but there should have been a recent or past response to Simponi subcutaneous or Simponi Aria.
     - **ii.** Patient meets ONE of the following conditions (a, b, or c):
       - **a)** Patient has been established on Simponi subcutaneous for at least 90 days and prescription claims history indicates at least a 90-day supply of Simponi subcutaneous 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 Simponi subcutaneous for at least 90 days AND the patient has been receiving Simponi subcutaneous via paid claims (e.g., patient has not been receiving samples or coupons or other types of waivers in order to obtain access to Simponi subcutaneous).
       - **b)** According to the prescriber, the patient has been established on Simponi Aria for at least 90 days; OR
       - **c)** Patient has tried TWO of Enbrel, Humira, and Taltz **[documentation required]**.

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

**2. Psoriatic Arthritis.** 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 BOTH of the following conditions (i and ii):

**i.** The medication is prescribed by or in consultation with a rheumatologist or a dermatologist; AND

**ii.** Patient has tried TWO of Enbrel, Humira, Otezla, Stelara subcutaneous, Taltz, Tremfya, 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 (Enbrel, Humira, Otezla, Stelara subcutaneous, Taltz, Tremfya, or Xeljanz/XR) using the appropriate standard *Inflammatory Conditions* criteria.

**B)** Patient is Currently Receiving Simponi Subcutaneous or Simponi Aria. Approve for 1 year if the patient meets BOTH of the following conditions (i and ii):

**i.** Patient has had a response, as determined by the prescriber; AND

Note: Examples of a response include less joint pain, morning stiffness, or fatigue; improved function or activities of daily living; decreased soft tissue swelling in joints or tendon sheaths; and improvements in acute phase reactants such as C-reactive protein (CRP). The patient may not have a full response, but there should have been a recent or past response to Simponi subcutaneous or Simponi Aria.

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

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

**b)** According to the prescriber, the patient has been established on Simponi Aria for at least 90 days; OR

**c)** Patient has tried TWO of Enbrel, Humira, Otezla, Stelara subcutaneous, Taltz, Tremfya, 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 (Enbrel, Humira, Otezla, Stelara subcutaneous, Taltz, Tremfya, or Xeljanz/XR) using the appropriate standard *Inflammatory Conditions* criteria.

**4. Rheumatoid Arthritis.** 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 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 has a 3-month trial at least one biologic DMARD. Refer to Appendix for examples of biologics used for RA. A patient who has already tried a biologic for RA 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 has tried TWO of Actemra subcutaneous, Enbrel, Humira, Rinvoq, 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 subcutaneous, Enbrel, Humira, Rinvoq, or Xeljanz/XR) using the appropriate standard *Inflammatory Conditions* criteria.

**B)** Patient is Currently Receiving Simponi Subcutaneous or Aria. Approve for 1 year if the patient meets BOTH of the following conditions (i and ii):

**i.** Patient has had a response, as determined by the prescriber; AND
Note: Examples of a response 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 Simponi subcutaneous or Simponi Aria.

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

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

**b)** According to the prescriber, the patient has been established on Simponi Aria for at least 90 days; OR

**c)** Patient has tried TWO of Actemra subcutaneous, Enbrel, Humira, Rinvoq, 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 subcutaneous, Enbrel, Humira, Rinvoq, or Xeljanz/XR) using the appropriate standard *Inflammatory Conditions* criteria.

**5. Ulcerative Colitis.** 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, iii, and iv):

**i.** Patient is ≥ 18 years of age; AND

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

**a)** Patient has had a 2-month trial of one conventional systemic agent or was intolerant to one of these agents for ulcerative colitis; OR
Note: Examples of systemic therapies for ulcerative colitis include 6-mercaptopurine, azathioprine, cyclosporine, and tacrolimus. An exception to this criterion can be made if the patient has already tried a biologic. Refer to Appendix for examples of biologics used for ulcerative colitis. A patient who has already received a biologic is not required to "step back" and try another agent]).

**b)** Patient meets BOTH of the following [(1) and (2)]:

**(1)** Patient has pouchitis; AND

**(2)** Patient has tried therapy with an antibiotic, probiotic, corticosteroid enema, or Rowasa® (mesalamine) enema; AND
Note: Examples of antibiotics include metronidazole and ciprofloxacin. Hydrocortisone enemas is an examples of a corticosteroid enemas.

**iii.** The medication is prescribed by or in consultation with a gastroenterologist; AND

**iv.** Patient has tried Humira.

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

**B)** Patient is Currently Receiving Simponi Subcutaneous or Simponi Aria. Approve for 1 year if the patient meets BOTH of the following conditions (i and ii):

**i.** Patient has had a response, as determined by the prescriber; AND
Note: Examples of a response include decreased stool frequency or rectal bleeding. The patient may not have a full response, but there should have been a recent or past response to Simponi subcutaneous or Simponi Aria.

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

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

**b)** According to the prescriber, the patient has been established on Simponi Aria for at least 90 days; OR

**c)** 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 subcutaneous) using the appropriate standard *Inflammatory Conditions* criteria.

**6. Spondyloarthritis, Other Subtypes** . Approve for the duration noted if the patient meets one of the following (A or B):
Note: Other subtypes include undifferentiated arthritis, reactive arthritis (Reiter's disease). For ankylosing spondylitis, psoriatic arthritis, or non-radiographic axial spondyloarthritis, refer to the respective criteria under FDA-approved indications.

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

**i.** Patient meets one of the following conditions (i or ii):

**a)** Patient has arthritis primarily in the knees, ankles, elbows, wrists, hands, and/or feet AND has tried at least ONE conventional synthetic DMARD has been tried.
Note: Examples of conventional synthetic DMARDs include methotrexate (MTX), leflunomide, and sulfasalazine; OR

**b)** Patient has axial spondyloarthritis AND has objective signs of inflammation, defined as at least one of the following [(1) or (2)]:

**(1)** C-reactive protein (CRP) elevated beyond the upper limit of normal for the reporting laboratory; OR

**(2)** Sacroiliitis reported on magnetic resonance imaging; AND

**ii.** The medication is prescribed by or in consultation with a rheumatologist.

**B)** Patient is Currently Receiving Simponi Subcutaneous or Simponi Aria. Approve for 1 year if the patient has had a response, as determined by the prescriber.
Note: Examples of a response include decreased pain or stiffness and improved function or activities of daily living. The patient may not have a full response, but there should have been a recent or past response to Simponi subcutaneous or Simponi Aria.

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

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

**B)** Plaque Psoriasis without Psoriatic Arthritis; OR

**C)** Other circumstances not listed in criterion 1 through 6 (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-rzza 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 DMARDs** | | |
| **Otezla®** (apremilast tablets) | Inhibition of PDE4 | PsO, PsA |
| **Olumiant®** (baricitinib tablets) | Inhibition of JAK pathways | RA |
| **Rinvoq®** (upadacitinib extended-release tablets) | Inhibition of JAK pathways | RA |
| **Xeljanz®** (tofacitinib tablets) | Inhibition of JAK pathways | RA, PJIA, PsA, UC |
| **Xeljanz® XR** (tofacitinib extended-release tablets) | Inhibition of 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; IV – Intravenous, IL – Interleukin; PDE4 – Phosphodiesterase 4; JAK – Janus kinase; 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; ^ Off-label use of Kineret in JIA supported in guidelines; DMARDs – Disease-modifying antirheumatic drug.