VENTURA COUNTY
HEALTH CARE PLAN

FORMULARY EXCEPTION POLICY

POLICY: Inflammatory Conditions – Siliq Formulary Exception Policy
- Siliq™ (brodalumab for subcutaneous injection – Valeant Pharmaceuticals)

REVIEW 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.

CRITERIA

1. **Plaque Psoriasis.** Approve for the duration noted if the patient meets ONE of the following conditions (A or B):Initial Therapy. Approve for 3 months if the patient meets ALL of the following criteria (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 tried at least one traditional systemic agent for psoriasis for at least 3 months, unless intolerant; OR
       Note: Examples of traditional systemic agents for psoriasis include methotrexate, cyclosporine, acitretin, or psoralen plus ultraviolet A light (PUVA). An exception to the requirement for a trial of one traditional systemic agent for psoriasis can be made if the patient has already had a 3-month trial or previous intolerance to at least one biologic for this condition. Refer to **Appendix** for examples of biologics used for psoriasis. 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)** Patient has a contraindication to methotrexate, as determined by the prescriber; AND
   - **iii.** The medication is prescribed by or in consultation with a dermatologist; AND
   - **iv.** Patient has tried TWO of Enbrel, Humira, Otezla, Skyrizi, Stelara subcutaneous, Taltz, 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 (Enbrel, Humira, Otezla, Skyrizi, Stelara subcutaneous, Taltz, or Tremfya) using the appropriate standard *Inflammatory Conditions* criteria.

B) Patient is Currently Receiving Siliq. Approve for 1 year if the patient meets BOTH of the following conditions (i and ii):
- **i.** Patient has responded, as determined by the prescriber. Patient may not have a full response, but there should have been a recent or past response to Siliq; AND
- **ii.** Patient meets ONE of the following conditions (a or b):
  - **a)** Patient has been established on Siliq for at least 90 days and prescription claims history indicates at least a 90-day supply of Siliq was dispensed within the past 130 days **[verification in prescription claims history required]** or, if not available, **[verification by prescriber required]**; AND meets at least ONE of the following [(1), (2), (3), or (4)]:
    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 Siliq for at least 90 days AND the patient has been receiving Siliq via paid claims (e.g., patient has not been receiving samples or coupons or other types of waivers in order to obtain access to Siliq).

(1) According to the prescriber, the patient has previously experienced a sub-therapeutic response or intolerance to Cosentyx or Taltz **[documentation required]**; OR

(2) Patient has previously tried at least one biologic for the current condition, and according to the prescriber, the patient demonstrated inadequate efficacy to that biologic **[documentation required]**; OR

(3) Patient is currently using the requested biologic concomitantly with a traditional systemic agent for the condition being treated **[documentation required]**; OR
Note: Examples of systemic agents taken for psoriasis include methotrexate, acitretin, and cyclosporine.

(4) Patient is taking the requested agent in combination with phototherapy **[documentation required]**.
Note: Examples include narrowband ultraviolet B [NB-UVB] phototherapy. For patients who have not tried the Formulary Products, Taltz is approved for patients who meet criterion iia but do not meet iia (1), (2), (3), or (4); OR

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

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

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., MTX, leflunomide, hydroxychloroquine, and sulfasalazine) in combination with Siliq.

B) Crohn's Disease; OR

C) Rheumatoid arthritis; 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.