EXPRESS SCRIPTS®

FORMULARY EXCEPTION POLICY

POLICY: Inflammatory Conditions – Siliq™ (brodalumab for subcutaneous injection – Valeant Pharmaceuticals)

DATE REVIEWED: 10/14/2019

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.** Initial Therapy. Approve for 3 months if the patient meets ALL of the following criteria (i, ii, iii, and iv):
   - **i.** The patient is ≥ 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 for at least 3 months, unless intolerant.
       Note: Examples of traditional systemic agents for psoriasis include methotrexate (MTX), cyclosporine, acitretin tablets, 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 (e.g., an etanercept product, a certolizumab pegol product [Cimzia], Cosentyx [secukinumab for SC injection], an adalimumab product, Ilumya (tildrakizumab-asmn SC injection), an infliximab product, Skyrizi (risankizumab SC injection), 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 prescriber; AND
   - **iii.** Siliq 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) Patient is Currently Receiving Siliq. Approve for 1 year if the patient meets BOTH of the following conditions (i and ii):
   - **i.** The patient has responded, as determined by the prescriber. The patient may not have a full response, but there should have been a recent or past response to Siliq; AND
   - **ii.** The patient meets ONE of the following conditions (a or b):
     - **a)** The 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 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 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); AND meets at least ONE of the following [(1), (2), (3), or (4)]:

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

(2) The 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; OR

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

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

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). Note: This does NOT exclude the use of conventional synthetic DMARDs (e.g., MTX, leflunomide, hydroxychloroquine, and sulfasalazine) in combination with Siliq; OR

B) Crohn's Disease (CD); OR

C) Rheumatoid arthritis (RA); OR

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