Drug Therapy Guidelines

Siliq™ (brodalumab)

<table>
<thead>
<tr>
<th>Pharmacy Formulary 1</th>
<th>x</th>
<th>Date of Origin: 4/17</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pharmacy Formulary 2</td>
<td>x</td>
<td>Next Review: 9/19</td>
</tr>
<tr>
<td>Pharmacy Formulary 3/Exclusive</td>
<td>x</td>
<td>Review Dates: 3/17, 9/17, 9/18, 6/19</td>
</tr>
<tr>
<td>Pharmacy Formulary 4/AON</td>
<td>x</td>
<td></td>
</tr>
</tbody>
</table>

I. Medication Description

Brodalumab is a human monoclonal IgG2 antibody that selectively binds to human IL-17RA and inhibits its interactions with cytokines IL-17A, IL-17F, IL-17C, IL-17A/F heterodimer and IL-25. IL-17RA is a protein expressed on the cell surface and is a required component of receptor complexes utilized by multiple IL-17 family cytokines. Blocking IL17RA inhibits IL-17 cytokine-induced responses including the release of pro-inflammatory cytokines and chemokines. Elevated levels of IL-17A, IL-17C and IL-17F are found in psoriatic plaques. Serum IL-17A levels, measured at Weeks 12, 24, and 48 of Siliq 210 mg every 2 weeks of treatment, were higher than the baseline levels in subjects with moderate to severe plaque psoriasis. The relationship between the pharmacodynamic activity and the mechanism(s) by which brodalumab exerts its clinical effects is unknown.

Siliq is available only through a restricted program called the Siliq REMS Program.

II. Position Statement

Coverage is determined through a prior authorization process with supporting clinical documentation for all requests.

III. Policy

Coverage of Siliq is provided when the following criteria are met:

- Patient has been diagnosed with moderate to severe plaque psoriasis AND
- Medication is prescribed by a dermatologist or a rheumatologist AND
- At least 10% of BSA affected or less than 10% BSA affected but with palmar, plantar, head/neck, or genitalia involvement AND
- Patient has had an inadequate response to PUVA or UVB therapy unless contraindicated AND
- Patient has had an inadequate response to non-biologic systemic therapy (i.e. methotrexate, cyclosporine, acitretin) unless contraindicated AND
- When requesting coverage of a brand medication for which an A/B rated generic is available, coverage will be provided when there is sufficient evidence that the use of the A/B rated generic equivalent has resulted in inadequate results AND
- Coverage will be provided when the member has experienced intolerance or therapeutic failure with at least TWO plan-preferred medications (Cosentyx, Humira, Otezla, Skyrizi, Stelara SC or Tremfya) first OR when at least ONE of the following criteria have been met:
The plan-preferred medications are contraindicated or will likely cause an adverse reaction by or physical or mental harm to the member.

- The plan-preferred medications are expected to be ineffective based on the known clinical history and conditions of the member and the member’s prescription drug regimen.

- The member has tried the plan-preferred medications or another prescription drug in the same pharmacologic class or with the same mechanism of action and such prescription drug was discontinued due to lack of efficacy or effectiveness, diminished effect, or an adverse event.

- The member is stable on the medication selected by their healthcare professional for the medical condition under consideration (where “stable” is defined as receiving the medication for an adequate period of time, have achieved optimal response, and continued favorable outcomes are expected UNLESS the medication was initially selected solely due to the availability of a drug sample or a coupon card and the member does not otherwise meet the definition of “stable”).

- The plan-preferred medication is not in the best interest of the member because it will likely cause a significant barrier to the member’s adherence or to compliance with the member’s plan of care, will likely worsen a comorbid condition of the member, or will likely decrease the member’s ability to achieve or maintain reasonable functional ability in performing daily activities.

IV. **Quantity Limitations**

Coverage is available as follows:

- Up to 3 syringes (630 mg) covered in the first 28 days to accommodate induction dosing
- Up to 2 syringes (420 mg) are covered every 4 weeks in subsequent months to accommodate maintenance dosing

V. **Coverage Duration**

Coverage may be provided for up to 12 months and may be renewed.

VI. **Coverage Renewal Criteria**

Coverage can be renewed based upon the following:
- Stabilization of disease or in absence of disease progression AND
- Absence of unacceptable toxicity from the drug

VII. **Billing/Coding Information**

Siliq is available as a carton of two 210mg/1.5ml single-dose prefilled syringes.

VIII. **Summary of Policy Changes**

- 4/10/17: new policy
IX. References


- 5/1/17: step therapy criteria added
- 10/16/17: no policy changes
- 11/1/18: REMS program stated in description
- 7/23/19: added Skyrizi and Tremfya to plan-preferred list

*The Plan fully expects that only appropriate and medically necessary services will be rendered. The Plan reserves the right to conduct pre-payment and post-payment reviews to assess the medical appropriateness of the above-referenced therapies. The preceding policy is a guideline to allow for coverage of the pertinent medication/product, and is not meant to serve as a clinical practice guideline.*