Clinical Policy: Brodalumab (Siliq)
Reference Number: CP.CPA.305
Effective Date: 03.14.17
Last Review Date: 05.17
Line of Business: Commercial

See Important Reminder at the end of this policy for important regulatory and legal information.

Description
Brodalumab (Siliq™) is a human monoclonal IgG2 antibody, interleukin 17A receptor (IL-17RA) antagonist.

FDA approved indication
Siliq is indicated for the treatment of moderate to severe plaque psoriasis in adult patients who are candidates for systemic therapy or phototherapy and have failed to respond or have lost response to other systemic therapies.

Policy/Criteria
Provider must submit documentation (which may include office chart notes and lab results) supporting that member has met all approval criteria

It is the policy of health plans affiliated with Centene Corporation® that Siliq is medically necessary when the following criteria are met:

I. Initial Approval Criteria
   A. Plaque Psoriasis (must meet all):
      1. Diagnosis of chronic moderate to severe plaque psoriasis;
      2. Prescribed by or in consultation with a Dermatologist or Rheumatologist;
      3. Failure of a trial of one of the following therapies, either alone or in combination, unless contraindicated or clinically significant adverse effects are experienced:
         a. Methotrexate up to a dose of 15-20 mg/week;
         b. If methotrexate is contraindicated, failure of PUVA Therapy or UVB, or cyclosporine or acitretin;
      4. Failure of a trial Humira AND either Stelara or Remicade (at up to maximally indicated doses) unless contraindicated or clinically significant adverse effects are experienced;
      5. Dose does not exceed 210 mg at week 0, 1, and 2 followed by every 2 weeks.

   Approval duration: 6 months or to member’s renewal date, whichever is longer

   B. Other diagnoses/indications
      1. Refer to CP.CPA.09 if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized)

II. Continued Therapy
A. **Plaque Psoriasis** (must meet all):
   1. Currently receiving medication via Centene benefit or member has previously met initial approval criteria;
   2. Member is responding positively to therapy (e.g. labs, sign/symptom reduction, no disease progression, no significant toxicity);
   3. If request is for a dose increase, new dose does not exceed 210 mg every 2 weeks.

   **Approval duration: 6 months or to member’s renewal date, whichever is longer**

B. **Other diagnoses/indications** (must meet 1 or 2):
   1. Currently receiving medication via Centene benefit and documentation supports positive response to therapy.
      
      **Approval duration: Duration of request or 12 months (whichever is less); or**
   2. Refer to CP.CPA.09 if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized).

III. **Diagnoses/Indications for which coverage is NOT authorized:**
   A. Non-FDA approved indications, which are not addressed in this policy, unless there is sufficient documentation of efficacy and safety according to the off-label use policy – CP.CPA.09 or evidence of coverage documents

IV. **Appendices/General Information**
   **Appendix A: Abbreviation/Acronym Key**
   FDA: Food and Drug Administration
   IgG: immunoglobulin G
   IL-17RA: interleukin 17A receptor

   **Appendix B: General Information**
   - Siliq has a black box warning for suicidal ideation and behavior and it is only available through a restricted program called the Siliq REMS program. A causal association between treatment with Siliq and increased risk of suicidal ideation and behavior has not been established. However, because of the observed suicidal ideation and behavior in subjects treated with Siliq, consider discontinuing therapy if an adequate response to Siliq has not been achieved within 12 to 16 weeks.
   - Siliq is contraindicated in patients with Crohn’s disease because Siliq may cause worsening of the disease.

   **Appendix C: Therapeutic Alternatives**

<table>
<thead>
<tr>
<th>Drug</th>
<th>Dosing Regimen</th>
<th>Dose Limit/ Maximum Dose</th>
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</thead>
<tbody>
<tr>
<td>Enbrel® (etanercept)</td>
<td>Subcutaneous injection of 50mg twice weekly for 3 months, followed by 50 mg once weekly</td>
<td>50 mg once weekly</td>
</tr>
<tr>
<td>Remicade® (infliximab)</td>
<td>Intravenous infusion of 5 mg/kg at 0, 2 and 6 weeks, then every 8 weeks</td>
<td>5 mg/kg every 8 weeks</td>
</tr>
<tr>
<td>Humira® (adalimumab)</td>
<td>Subcutaneous injection of 80 mg initial dose, followed by 40 mg every</td>
<td>40 mg every other week</td>
</tr>
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## Therapeutic Alternatives

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<tbody>
<tr>
<td><strong>Stelara® (ustekinumab)</strong></td>
<td>Subcutaneous injection of 45 mg to 90 mg initially and 4 weeks later, then 45 mg to 90 mg every 12 weeks</td>
<td>90 mg every 12 weeks</td>
</tr>
<tr>
<td><strong>Cosentyx® (secukinumab)</strong></td>
<td>Subcutaneous injection of 300 mg at weeks 0, 1, 2, 3, and 4 followed by 300 mg every 4 weeks</td>
<td>300 mg every 4 weeks</td>
</tr>
<tr>
<td><strong>Taltz® (ixekizumab)</strong></td>
<td>Subcutaneous injection of 160 mg (two 80 mg injections) at week 0, followed by 80 mg at weeks 2, 4, 6, 8, 10, and 12, then 80 mg every 4 weeks</td>
<td>80 mg every 4 weeks</td>
</tr>
</tbody>
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*Therapeutic alternatives are listed as Brand name® (generic) when the drug is available by brand name only and generic (Brand name®) when the drug is available by both brand and generic.*

## V. Dosage and Administration

### Indication

| Plaque Psoriasis |

Dosing Regimen: Subcutaneous injection at Weeks 0, 1, and 2 followed by 210 mg every 2 weeks

Maximum Dose: 210 mg

## VI. Product Availability

Injection: 210 mg/1.5 mL solution in a single-dose prefilled syringe.

## VII. References

5. Dermatologic and Ophthalmic Drugs Advisory Committee. Background Package for BLA 761032


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<tr>
<th>Reviews, Revisions, and Approvals</th>
<th>Date</th>
<th>P&amp;T Approval Date</th>
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<tbody>
<tr>
<td>Policy created</td>
<td>03.17</td>
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**Important Reminder**

This clinical policy has been developed by appropriately experienced and licensed health care professionals based on a review and consideration of currently available generally accepted standards of medical practice; peer-reviewed medical literature; government agency/program approval status; evidence-based guidelines and positions of leading national health professional organizations; views of physicians practicing in relevant clinical areas affected by this clinical policy; and other available clinical information. The Health Plan makes no representations and accepts no liability with respect to the content of any external information used or relied upon in developing this clinical policy. This clinical policy is consistent with standards of medical practice current at the time that this clinical policy was approved. “Health Plan” means a health plan that has adopted this clinical policy and that is operated or administered, in whole or in part, by Centene Management Company, LLC, or any of such health plan’s affiliates, as applicable.

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