

## SPECIALTY GUIDELINE MANAGEMENT

### SILIQ (brodalumab)

#### POLICY

##### I. INDICATIONS

The indications below including FDA-approved indications and compendial uses are considered a covered benefit provided that all the approval criteria are met and the member has no exclusions to the prescribed therapy.

##### FDA-Approved Indication

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

All other indications are considered experimental/investigational and are not a covered benefit.

##### II. CRITERIA FOR INITIAL APPROVAL

##### **Moderate to severe plaque psoriasis**

- A. Authorization of 24 months may be granted for members who are 18 years of age or older and who have received Siliq, Otezla, or any other biologic DMARD indicated for the treatment of moderate to severe plaque psoriasis in a paid claim through a pharmacy or medical benefit in the previous 120 days of the initial request for Siliq.
- B. Authorization of 24 months may be granted for treatment of moderate to severe plaque psoriasis for members who are 18 years of age or older when all of the following criteria are met:
  - 1. At least 5% of body surface area (BSA) is affected OR crucial body areas (e.g., hands, feet, face, neck, scalp, genitals/groin, intertriginous areas) are affected.
  - 2. Member meets any of the following criteria:
    - a. Member has had an inadequate response or intolerance to pharmacologic treatment with methotrexate, cyclosporine or acitretin.
    - b. Member has a clinical reason to avoid pharmacologic treatment with methotrexate, cyclosporine or acitretin (see Appendix).

##### III. CONTINUATION OF THERAPY

Authorization of 24 months may be granted for all members (including new members) who meet all initial authorization criteria and achieve or maintain positive clinical response after at least 3 months of therapy with Siliq as evidenced by low disease activity or improvement in signs and symptoms of the condition.

##### IV. APPENDIX

##### **Examples of Clinical Reasons to Avoid Pharmacologic Treatment with Methotrexate, Cyclosporine or Acitretin**

- 1. Alcoholism, alcoholic liver disease or other chronic liver disease

Siliq SGM P2017

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2. Breastfeeding
3. Cannot be used due to risk of treatment-related toxicity
4. Drug interaction
5. Pregnancy or planning pregnancy (male or female)
6. Significant comorbidity prohibits use of systemic agents (examples include liver or kidney disease, blood dyscrasias, uncontrolled hypertension)

## V. REFERENCES

1. Siliq [package insert]. Bridgewater, NJ: Valeant Pharmaceuticals North America LLC; February 2017.
2. Lebwohl M, Strober B, Menter A, et al. Phase 3 studies comparing brodalumab with ustekinumab in psoriasis. *N Engl J Med*. 2015;373(14):1318-1328.
3. Menter A, Korman NJ, Elmets CA, et al. Guidelines of care for the management of psoriasis and psoriatic arthritis. Section 6: Guidelines of care for the treatment of psoriasis and psoriatic arthritis: case-based presentations and evidence-based conclusions. *J Am Acad Dermatol*. 2011;65(1):137-174.