

Siliq (brodalumab)
Effective January 1, 2020

Plan	<input type="checkbox"/> MassHealth <input checked="" type="checkbox"/> Commercial/Exchange	Program Type	<input checked="" type="checkbox"/> Prior Authorization <input type="checkbox"/> Quantity Limit <input type="checkbox"/> Step Therapy
Benefit	<input checked="" type="checkbox"/> Pharmacy Benefit <input checked="" type="checkbox"/> Medical Benefit (NLX)		
Specialty Limitations	This medication has been designated specialty and must be filled at a contracted specialty pharmacy.		
Contact Information	Specialty Medications		
	All Plans	Phone: 866-814-5506	Fax: 866-249-6155
	Non-Specialty Medications		
	MassHealth	Phone: 877-433-7643	Fax: 866-255-7569
	Commercial	Phone: 800-294-5979	Fax: 888-836-0730
	Exchange	Phone: 855-582-2022	Fax: 855-245-2134
	Medical Specialty Medications (NLX)		
	All Plans	Phone: 844-345-2803	Fax: 844-851-0882
Exceptions	N/A		

Overview

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.

Coverage Guidelines

Moderate to severe plaque psoriasis

1. Authorization may be granted for members who are currently receiving treatment with Siliq, excluding when the product is obtained as samples or via manufacturer’s patient assistance programs.
OR
2. Authorization may be granted for treatment of moderate to severe plaque psoriasis when all the following criteria are met:
 - a. Member has had a documented inadequate response or intolerable adverse event with ALL the preferred products (Cosentyx, Enbrel, Humira, Otezla, Skyrizi and Stelara) unless there is a documented clinical reason to avoid the products.
 - b. 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.

- c. Member meets any of the following criteria:
- Member has experienced an inadequate response or adverse reaction to TWO conventional therapies in any one of the following combinations:
 - 1 topical agent + 1 systemic agent (methotrexate, acitretin, or cyclosporine)
 - 1 topical agent + 1 phototherapy (e.g., UVB, PUVA)
 - 1 systemic agent + 1 phototherapy (e.g., UVB, PUVA)
 - 2 systemic agents
 - Member has a clinical reason to avoid ALL conventional therapies (topical agents, phototherapy and systemic agents). See Appendix.
 - Member has severe psoriasis that warrants a biologic DMARD as first-line therapy.

Continuation of Therapy

Reauthorization 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.

Limitations

1. Approvals will be granted for 24 months
2. For all indications: Member has a pretreatment tuberculosis (TB) screening with a TB skin test or an interferon gamma release assay (e.g., QFT-GIT, T-SPOT.TB).
 - a. Note: Members who have received Siliq or any other biologic DMARD or targeted synthetic DMARD (e.g., Xeljanz) are exempt from requirements related to TB screening in this Policy.

Appendix

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

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

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.

Review History

02/26/18 – Reviewed

06/01/18 - Implemented

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02/20/19 – Updated

11/20/19 – Added Skyrizi as a preferred trial for PS

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