

PHARMACY POLICY STATEMENT Indiana Medicaid	
DRUG NAME	Siliq (brodalumab)
BILLING CODE	Must use valid NDC code
BENEFIT TYPE	Pharmacy
SITE OF SERVICE ALLOWED	Home
COVERAGE REQUIREMENTS	Prior Authorization Required (Preferred Product) QUANTITY LIMIT— 420 mg or 3 mL (2 syringes) per 28 days (after loading dose)
LIST OF DIAGNOSES CONSIDERED NOT MEDICALLY NECESSARY	<u>Click Here</u>

Siliq (brodalumab) is a **preferred** product and will only be considered for coverage under the **pharmacy** benefit when the following criteria are met:

Members must be clinically diagnosed with one of the following disease states and meet their individual criteria as stated.

PLAQUE PSORIASIS (PsO)

For **initial** authorization:

- 1. Member must be 18 years of age or older; AND
- 2. Medication must be prescribed by a dermatologist certified with a Siliq REMS program; AND
- 3. Member has clinical documentation of moderate to severe plaque psoriasis characterized by 3% or more of body surface area (BSA) or disease affecting sensitive areas (e.g., hands, feet, face, genitals, etc.); AND
- 4. Member must have a documented negative TB test (i.e., tuberculosis skin test (PPD), interferongamma release assay (IGRA)) within 12 months prior to starting therapy; AND
- 5. Member has tried and failed to respond to treatment with at least **one** of the following:
 - a) At least 12 weeks of photochemotherapy (i.e., psoralen plus ultraviolet A therapy);
 - b) At least 12 weeks of phototherapy (i.e., UVB light therapy, Excimer laser treatments);
 - c) At least a 4 week trial with topical antipsoriatic agents (i.e., anthralin, calcipotriene, coal tar, corticosteroids, tazarotene, tacrolimus, pimecrolimus); AND
- 6. Member has tried and failed, or unable to tolerate a systemic non-biologic DMARD (i.e., cyclosporine, methotrexate, acitretin) for at least 12 weeks; AND
- 7. Member does not have Crohn's Disease; AND
- 8. Documented consultation on risks of suicidal ideation or behavior while on Siliq is submitted with member's chart notes.
- 9. **Dosage allowed:** 210 mg subcutaneously once weekly at weeks 0, 1, and 2 followed by 210 mg every 2 weeks.

If member meets all the requirements listed above, the medication will be approved for 4 months. For reauthorization:

- 1. Member must be in compliance with all other initial criteria; AND
- 2. Chart notes have been provided that show the member has shown improvement of signs and symptoms of disease (e.g., documented member's BSA improvement, etc.).



If member meets all the reauthorization requirements above, the medication will be approved for an additional 12 months.

CareSource considers Siliq (brodalumab) not medically necessary for the treatment of the diseases that are not listed in this document.

DATE	ACTION/DESCRIPTION
05/09/2017	New policy for Siliq created.
02/26/2019	Humira and Enbrel trials removed from criteria. Reauthorization criteria on documented member's PASI score improvement incorporated into general chart noted documentation requirements. Static Physician's Global Assessment (sPGA) score removed. Ulcerative Colitis added to not covered diagnosis. "Immunosuppressant therapies" changed to "treatment of traditional first-line oral/systemic" therapies. TB test allowed to be done within 12 months prior to initiation of therapy; chest x-ray option removed. References added.
11/18/2020	Removed rheumatologist from prescriber but specified that prescriber is certified by Siliq REMS program. Removed PsO 6 months or longer. Removed not going to receive systemic/phototherapy while on Siliq. Changed BSA to 3% or sensitive areas. Removed PASI score. Changed initial auth to 4 months because per package insert, must discontinue if no benefit observed after 4 months. Removed repeat TB for reauth. Replaced the list of excluded diagnoses with the generic statement. Updated references.

References:

- 1. Siliq [prescribing information]. Bridgewater, NJ; Valeant Pharmaceuticals North America LLC. Revised April 2020.
- 2. Elmets CA, Korman NJ, Prater EF, et al. Joint AAD-NPF Guidelines of care for the management and treatment of psoriasis with topical therapy and alternative medicine modalities for psoriasis severity measures [published online ahead of print, 2020 Jul 30]. *J Am Acad Dermatol*. 2020;S0190-9622(20)32288-X.
- 3. Menter A, Gelfand JM, Connor C, et al. Joint American Academy of Dermatology-National Psoriasis Foundation guidelines of care for the management of psoriasis with systemic nonbiologic therapies. *J Am Acad Dermatol*. 2020;82(6):1445-1486.
- 4. Menter A, Strober BE, Kaplan DH, et al. Joint AAD-NPF guidelines of care for the management and treatment of psoriasis with biologics. *J Am Acad Dermatol*. 2019;80(4):1029-1072.
- 5. Elmets CA, Lim HW, Stoff B, et al. Joint American Academy of Dermatology-National Psoriasis Foundation guidelines of care for the management and treatment of psoriasis with phototherapy [published correction appears in J Am Acad Dermatol. 2020 Mar;82(3):780]. *J Am Acad Dermatol*. 2019;81(3):775-804.
- 6. Menter A, Cordoro KM, Davis DM, et al. Joint AAD-NPF Guidelines of care for the management and treatment of psoriasis in pediatric patients. *J Am Acad Dermatol* 2020;82:161-201.

Effective date: 04/01/2021 Revised date: 11/18/2020