

PHARMACY POLICY STATEMENT

North Carolina Marketplace

DRUG NAME	Siliq (brodalumab)
BENEFIT TYPE	Pharmacy
STATUS	Prior Authorization Required

Siliq, initially approved by the FDA in 2017, is a human interleukin-17 receptor A (IL-17RA) antagonist 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.

Psoriasis is recognized as the most prevalent immune-mediated inflammatory disease with plaque psoriasis being the most common. Plaque psoriasis presents with large oval-circular plaques over the scalp, trunk, legs and arms. It is marked by periods of acute flares and relapses.

Siliq (brodalumab) will be considered for coverage when the following criteria are met:

Plaque Psoriasis (PsO)

For **initial** authorization:

1. Member must be 18 years of age or older; AND
2. Medication must be prescribed by or in consultation with a dermatologist; 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 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
5. 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
6. Provider attests that member does not have Crohn's disease; AND
7. Documented consultation on risks of suicidal ideation or behavior while on Siliq is submitted with member's chart notes; AND
8. Member has had a negative tuberculosis test within the last 12 months.
9. **Dosage allowed/Quantity limit:** 210 mg subcutaneously once weekly at weeks 0, 1, and 2 followed by 210 mg every 2 weeks. Quantity limit: 2 syringes per 28 days after loading dose.

If all the above requirements are met, the medication will be approved for 4 months.

For **reauthorization**:

1. Chart notes have been provided that show the member has shown improvement of signs and symptoms of disease such as documented member's BSA improvement, etc.

If all the above requirements are met, the medication will be approved for an additional 12 months.

CareSource considers Siliq (brodalumab) not medically necessary for the treatment of conditions that are not listed in this document. For any other indication, please refer to the Off-Label policy.

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 added 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.
02/22/2022	Transferred policy to new format; removed initial criteria from reauthorization; Simplified TB wording.
10/17/2024	Added in consultation with for prescriber specialty and removed REMS requirement; added provider attestation for the existing criteria that member does not have Crohn's disease

References:

1. Siliq [prescribing information]. Valeant Pharmaceuticals North America LLC; 2024.
2. Elmetts 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. Elmetts 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: 04/01/2025

Revised date: 10/17/2024