COMMON GROUND
HEALTHCARE COOPERATIVE

PHARMACY POLICY STATEMENT
Common Ground Healthcare Cooperative (CGHC)

DRUG NAME	Siliq (brodalumab)
BILLING CODE	Must use valid NDC code
BENEFIT TYPE	Pharmacy
SITE OF SERVICE ALLOWED	Home
STATUS	Prior Authorization Required

Siliq (brodalumab) is an anti-interleukin 17-receptor antibody, anti-psoriatic agent; and monoclonal antibody initially approved by the FDA in 2017. It is FDA approved for the treatment of moderate to severe plaque psoriasis, a common autoimmune disease, in adult patients who are candidates for systemic therapy or phototherapy and have failed to respond or have lost response to other systemic therapies.[7] Plaque psoriasis is a skin disease that causes dry, raised, red patches covered with silvery scales on the skin.[8]

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 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 had a negative TB test within the last 12 months; 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 been unable to tolerate a systemic non-biologic DMARD (i.e., cyclosporine, methotrexate, acitretin) for at least 12 weeks; AND
7. Member has tried and failed, or been unable to tolerate, at least two preferred biologic DMARD therapies (see Appendix); AND
8. Member does not have Crohn's Disease; AND
9. Documented consultation on risks of suicidal ideation or behavior while on Siliq is submitted with member's chart notes.
10. **Dosage allowed/Quantity limit:** 210 mg subcutaneously once weekly at weeks 0, 1, and 2 followed by 210 mg every 2 weeks (Quantity Limit 420mg or 3mL (2 syringes) per 28 days, after loading dose).

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

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For **reauthorization**:
1. 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 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.
04/01/2022	Added requirement to trial two preferred biologic DMARD therapies; added appendix
02/10/2023	Added Amjevita to the Appendix as a preferred alternative

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.
7. Brodalumab: Drug information. In: Post TW, ed. *UpToDate.* UpToDate; 2022. Accessed February 22, 2022. https://www.uptodate.com/contents/brodalumab-drug-

information?search=Siliq&source=panel_search_result&selectedTitle=1~18&usage_type=panel&kp_tab=drug_general&display_rank=1#F49629469
8. Psoriatic arthritis. https://www.mayoclinic.org/diseases-conditions/psoriatic-arthritis/symptoms-causes/syc-20354076. Accessed February 22, 2022.

Effective date: 01/01/2025
Revised date: 02/10/2023

Appendix: Preferred Biologic Products	
Approved for Rheumatoid Arthritis	• Actemra *(requires step through Humira or Amjevita)* • Amjevita • Enbrel • Humira
Approved for Juvenile Idiopathic Arthritis	• Actemra *(requires step through Humira or Amjevita)* • Amjevita • Enbrel • Humira
Approved for Ankylosing Spondylitis	• Amjevita • Cosentyx • Enbrel • Humira • Rinvoq
Approved for Non-radiographic Axial	• Cimzia • Cosentyx
Approved for Atopic Dermatitis	• Rinvoq
Approved for Psoriatic Arthritis	• Amjevita • Cosentyx • Enbrel • Humira • Otezla • Skyrizi • Stelara • Tremfya
Approved for Psoriasis	• Amjevita • Cosentyx • Enbrel • Humira • Otezla • Skyrizi • Stelara • Tremfya
Approved for Crohn's Disease	• Amjevita • Humira • Stelara

Approved for Ulcerative Colitis	• Amjevita • Humira • Stelara • Rinvoq