



AETNA BETTER HEALTH®
Coverage Policy/Guideline

Name: Siliq

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Effective Date: 9/28/2023

Last Review Date: 7/19/2023

Applies to:	<input type="checkbox"/> Illinois	<input type="checkbox"/> Florida	<input checked="" type="checkbox"/> Florida Kids
	<input type="checkbox"/> New Jersey	<input checked="" type="checkbox"/> Maryland	<input type="checkbox"/> Michigan
	<input checked="" type="checkbox"/> Pennsylvania Kids	<input type="checkbox"/> Virginia	<input checked="" type="checkbox"/> Kentucky PRMD

Intent:

The intent of this policy/guideline is to provide information to the prescribing practitioner outlining the coverage criteria for Siliq under the patient's prescription drug benefit.

Description:

FDA-Approved Indication

Treatment of moderate to severe plaque psoriasis (PsO) 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 not medically necessary.

Applicable Drug List:

Non-Preferred: Siliq

Policy/Guideline:

Documentation for all indications:

The patient is unable to take ONE preferred anti-TNF (Enbrel or preferred adalimumab product) AND Kevzara, where indicated, for the given diagnosis due to a trial and inadequate treatment response or intolerance, or a contraindication. Documentation is required for approval.

Documentation:

A. Initial requests:

1. Chart notes or medical record documentation of affected area(s) and body surface area (BSA) affected (if applicable).
2. Chart notes, medical record documentation, or claims history supporting previous medications tried (if applicable), including response to therapy. If therapy is not advisable, documentation of clinical reason to avoid therapy.

B. Continuation requests: Chart notes or medical record documentation of decreased body surface area (BSA) affected and/or improvement in signs and symptoms.

Prescriber Specialty:

This medication must be prescribed by or in consultation with a dermatologist.

Criteria for Initial Approval:



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- A. Authorization of 12 months may be granted for adult members who have previously received a biologic or targeted synthetic drug (e.g., Sotyktu, Otezla) indicated for treatment of moderate to severe plaque psoriasis.
- B. Authorization of 12 months may be granted for adult members for treatment of moderate to severe plaque psoriasis when any of the following criteria is met:
1. Crucial body areas (e.g., hands, feet, face, neck, scalp, genitals/groin, intertriginous areas) are affected.
 2. At least 10% of body surface area (BSA) is affected.
 3. At least 3% of body surface area (BSA) is affected and the member meets any of the following criteria:
 - i. Member has had an inadequate response or intolerance to either phototherapy (e.g., UVB, PUVA) or pharmacologic treatment with methotrexate, cyclosporine, or acitretin.
 - ii. Member has a clinical reason to avoid pharmacologic treatment with methotrexate, cyclosporine, and acitretin (see Appendix).

Continuation of Therapy:

Authorization of 12 months may be granted for all adult members (including new members) who are using the requested medication for moderate to severe plaque psoriasis and who achieve or maintain a positive clinical response as evidenced by low disease activity or improvement in signs and symptoms of the condition when either of the following is met:

- A. Reduction in body surface area (BSA) affected from baseline
- B. Improvement in signs and symptoms from baseline (e.g., itching, redness, flaking, scaling, burning, cracking, pain)

Other Criteria:

Member has had a documented negative tuberculosis (TB) test (which can include a tuberculosis skin test [PPD], an interferon-release assay [IGRA], or a chest x-ray)* within 6 months of initiating therapy for persons who are naïve to biologic drugs or targeted synthetic drugs associated with an increased risk of TB.

* If the screening testing for TB is positive, there must be further testing to confirm there is no active disease. Do not administer the requested medication to members with active TB infection. If there is latent disease, TB treatment must be started before initiation of the requested medication.

Member cannot use the requested medication concomitantly with any other biologic drug or targeted synthetic drug.



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APPENDIX

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

1. Clinical diagnosis of alcohol use disorder, alcoholic liver disease or other chronic liver disease
2. Drug interaction
3. Risk of treatment-related toxicity
4. Pregnancy or currently planning pregnancy
5. Breastfeeding
6. Significant comorbidity prohibits use of systemic agents (e.g., liver or kidney disease, blood dyscrasias, uncontrolled hypertension)
7. Hypersensitivity
8. History of intolerance or adverse event

Approval Duration and Quantity Restrictions:

Approval:

Initial and Renewal Approval: 12 months

Quantity Level Limit:

Medication	Standard Limit	Exception Limit*	FDA-recommended dosing
Siliq 210 mg/ 1.5 mL prefilled syringe	2 syringes per 28 days	4 syringes per 28 days	<ul style="list-style-type: none">• Loading doses: 210 mg at week 0, 1, and 2• Maintenance dose: 210 mg every 2 weeks

*Coverage up to the exception limits may be provided with prior authorization

References:

1. Siliq [package insert]. Bridgewater, NJ: Bausch Health US, LLC; April 2020.
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.
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. Testing for TB Infection. Centers for Disease Control and Prevention. Retrieved on January 4, 2023 from: <https://www.cdc.gov/tb/topic/basics/risk.htm>.
6. Coates LC, Soriano ER, Corp N, et al. Group for Research and Assessment of Psoriasis and Psoriatic Arthritis (GRAPPA): updated treatment recommendations for psoriatic arthritis 2021. *Nat Rev Rheumatol*. 2022;18(8):465-479.



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7. 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. doi:10.1016/j.jaad.2020.02.044.