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Section:	Prescription Drugs	**Effective Date:**	October 1, 2024
Subsection:	Topical Products	**Original Policy Date:**	March 31, 2017
Subject:	Siliq	**Page:**	1 of 8

Last Review Date: September 6, 2024

Siliq

Description

Siliq (brodalumab)

Background
Siliq (brodalumab) is subcutaneous injectable treatment that helps regulate inflammation in people with moderate to severe plaque psoriasis (PsO). Siliq is an antibody that binds to interleukin 17A (IL-17A) a protein involved in inflammation. Brodalumab binds to IL-17A and prevents it from binding to its receptor, and it inhibits its ability to trigger the inflammatory response that plays a role in the development of plaque psoriasis (1).

Regulatory Status
FDA-approved indication: Siliq 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 (1).

Siliq has a boxed warning for suicidal ideation and behavior which occurred in patients treated with Siliq. A causal association between treatment with Siliq and increased risk of suicidal ideation and behavior has not been established. Prescribers should weigh the potential risks and benefits before using Siliq in patients with a history of depression or suicidality. Patients with new or worsening symptoms of depression or suicidality should be referred to a mental health professional, as appropriate. Prescribers should also reevaluate the risks and benefits of continuing treatment with Siliq if such events occur. Siliq is available only through a restricted program under the SILIQ REMS Program because of the observed suicidal ideation and behavior in subjects treated with Siliq (1).

Siliq is contraindicated in patients with Crohn's disease because it may cause worsening of the disease (1).

Evaluate patients for tuberculosis (TB) infection prior to initiating treatment with Siliq. Do not administer to patients with active TB infection. Initiate treatment for latent TB prior to administering Siliq. Consider anti-TB therapy prior to initiation of Siliq in patients with a past history of latent or active TB in whom an adequate course of treatment cannot be confirmed. Closely monitor patients receiving Siliq for signs and symptoms of active TB during and after treatment (1).

Siliq affects the immune system, thus patients may be at greater risk for infection. If a patient develops a serious infection or is not responding to standard therapy for the infection, monitor the patient closely and discontinue Siliq therapy until the infection resolves (1).

Avoid use of live vaccines in patients treated with Siliq. There is no data available on the ability of live or inactive vaccines to elicit an immune response in patients being treated with Siliq (1).

The safety and effectiveness of Siliq have not been evaluated in pediatric patients (1).

Related policies
Cosentyx, Taltz

Policy

This policy statement applies to clinical review performed for pre-service (Prior Approval, Precertification, Advanced Benefit Determination, etc.) and/or post-service claims.

Siliq may be considered **medically necessary** if the conditions indicated below are met.

Siliq may be considered **investigational** for all other indications.

Prior-Approval Requirements

Age 18 years of age or older

Diagnosis

Patient must have the following:

1. Moderate to severe Plaque Psoriasis (PsO)

AND ALL of the following:

a. Inadequate treatment response, intolerance, or contraindication to either conventional systemic therapy (see Appendix 1) or phototherapy
   i. If the patient is intolerant or contraindicated to one therapy then the patient must have an inadequate treatment response, intolerance, or contraindication to the other treatment option
b. Prescriber agrees to monitor for onset or exacerbations of Crohn's disease and discontinue if necessary
c. Prescriber agrees to participate in Siliq REMS Program and to monitor for onset of suicidal ideation and behavior and discontinue if necessary
d. Patient's condition will be re-evaluated at week 12 - 16 to confirm if therapy with Siliq may continue
e. Prescriber will not exceed the FDA labeled maintenance dose of 210 mg every 2 weeks
f. **NOT** to be used in combination with any other biologic DMARD or targeted synthetic DMARD (see Appendix 1)
g. Result for latent TB infection is negative **OR** result was positive for latent TB and patient completed treatment (or is receiving treatment) for latent TB
h. Absence of active infection [including tuberculosis and hepatitis B virus (HBV)]
i. **NOT** given concurrently with live vaccines
j. Patient **MUST** have tried the preferred product(s) (see Appendix 2) if adjudicated through the pharmacy benefit unless the patient has a valid medical exception (e.g., inadequate treatment response, intolerance, contraindication)

Prior – Approval *Renewal* Requirements

Age 18 years of age or older

Diagnosis

Patient must have the following:

1. Plaque Psoriasis (PsO)

AND ALL of the following:

a. Condition has shown improvement or stabilization

b. Prescriber agrees to monitor for onset or exacerbations of Crohn's disease and discontinue if necessary
c. Prescriber agrees to participate in Siliq REMS Program and to monitor for onset of suicidal ideation and behavior and discontinue if necessary
d. Prescriber will not exceed the FDA labeled maintenance dose of 210 mg every 2 weeks
e. **NOT** to be used in combination with any other biologic DMARD or targeted synthetic DMARD (see Appendix 1)
f. Absence of active infection [including tuberculosis and hepatitis B virus (HBV)]
g. **NOT** given concurrently with live vaccines
h. Patient **MUST** have tried the preferred product(s) (see Appendix 2) if adjudicated through the pharmacy benefit unless the patient has a valid medical exception (e.g., inadequate treatment response, intolerance, contraindication)

Policy Guidelines

Pre - PA Allowance

None

Prior - Approval Limits

Quantity 28 (210mg) syringes
(injection at Weeks 0, 1, 2 then every 2 weeks)

Duration 12 months

Prior – Approval *Renewal* Limits

Quantity 6 (210mg) syringes per 84 days

Duration 18 months

Rationale

Summary

Siliq is 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. It is administered as an injection under the skin. Because

of the observed suicidal behavior in subjects treated with Siliq, Siliq is available only through a restricted Risk Evaluation and Mitigation Strategy (REMS) program called the SILIQ REMS Program (1).

Prior approval is required to ensure the safe, clinically appropriate, and cost-effective use of Siliq while maintaining optimal therapeutic outcomes.

References

1. Siliq [package insert]. Bridgewater, NJ: Bausch Health US, LLC; April 2020.

Policy History

Date	Action
March 2017	Addition to PA
June 2017	Annual review
December 2017	Annual review
June 2018	Addition of additional requirements to initiation criteria For diagnosis of PsO: if the patient is intolerant or contraindicated to either therapy then the other treatment option needs to be tried Addition of List of DMARDs Appendix Removal of requirements: documented baseline evaluation of the condition using one of the scoring tools and scoring tools in renewal
September 2018	Annual editorial review
September 2019	Annual review
December 2019	Annual review. Addition of requirement to trial preferred product
September 2020	Annual review and reference update
December 2020	Annual editorial review. Added Appendix 2 with a list of preferred medications based on diagnosis and plan. Changed initial approval duration to 12 months. Added initiation requirement “Patient’s condition will be re-evaluated at week 12 - 16 to confirm if therapy with Siliq may continue”. Added requirements to dose within the FDA labeled maintenance dosing
March 2021	Annual editorial review. Clarification added to the t/f, intolerance, C/I to preferred products requirement indicating that it only applies to claims adjudicated through the pharmacy benefit. Appendix 1 updated.
September 2022	Annual review
December 2022	Annual review
September 2023	Annual review
March 2024	Annual editorial review. Revised FDA dosing language

September 2024 Annual review

Keywords

This policy was approved by the FEP® Pharmacy and Medical Policy Committee on September 6, 2024 and is effective on October 1, 2024.

Appendix 1 - List of DMARDs

Conventional disease-modifying antirheumatic drugs (DMARDs)

Generic Name	Brand Name
azathioprine	Azasan, Imuran
cyclophosphamide	Cytoxan
cyclosporine	Neoral, Gengraf, Sandimmune
hydroxychloroquine	Plaquenil
leflunomide	Arava
methotrexate	Rheumatrex, Trexall
mycophenolate	Cellcept
sulfasalazine	Azulfidine, Sulfazine

Biological disease-modifying antirheumatic drugs (DMARDs)

Generic Name	Brand Name
abatacept	Orencia
adalimumab	Humira
anakinra	Kineret
brodalumab	Siliq
certolizumab	Cimzia
etanercept	Enbrel
golimumab	Simponi/Simponi Aria
guselkumab	Tremfya
infliximab	Remicade/Avsola/Inflectra/Renflexis
ixekizumab	Taltz
risankizumab-rzaa	Skyrizi
rituximab	Rituxan/Riabni/Ruxience/Truxima
sarilumab	Kevzara
secukinumab	Cosentyx
spesolimab-sbzo	Spevigo
tildrakizumab-asmn	Ilumya
tocilizumab	Actemra
ustekinumab	Stelara
vedolizumab	Entyvio

Targeted synthetic disease-modifying antirheumatic drugs (DMARDs)

Generic Name	Brand Name
apremilast	Otezla
baricitinib	Olumiant
deucravacitinib	Sotyktu

tofacitinib	Xeljanz/XR
upadactinib	Rinvoq

Appendix 2 - List of Preferred Products

Diagnosis	Standard Option/Basic Option Preferred Products	Blue Focus Preferred Products
Plaque Psoriasis (PsO)	*must try **TWO** preferred products: Enbrel Humira** Otezla Skyrizi Stelara (SC) Taltz Tremfya	*must try ONE preferred product: Enbrel Humira**

**Including all preferred biosimilars (see reference product criteria)