



PRIOR AUTHORIZATION POLICY

POLICY: Inflammatory Conditions – Siliq Prior Authorization Policy

- Siliq® (brodalumab subcutaneous injection – Valeant)

REVIEW DATE: 06/12/2024; selected revision 09/11/2024, 10/02/2024

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CIGNA NATIONAL FORMULARY COVERAGE:

OVERVIEW

Siliq, an interleukin (IL)-17A antagonist, is indicated for treatment of adults with moderate to severe **plaque psoriasis** who are candidates for systemic therapy or phototherapy and who have failed to respond or have lost response to other systemic therapies.¹ In the pivotal trial, patients were assessed for a response at Week 12.

Guidelines

Joint guidelines from the American Academy of Dermatology and National Psoriasis Medical Board (2019) have been published for management of psoriasis with biologics.² These guidelines list Siliq as a monotherapy treatment option for patients with moderate to severe plaque psoriasis. Guidelines from the European Dermatology Forum (2015) recommend biologics (i.e., etanercept, adalimumab, infliximab, Stelara® [ustekinumab subcutaneous injection]) as second-line therapy for induction and long-term treatment if phototherapy and conventional systemic agents have failed, are contraindicated, or are not tolerated.³

Safety

Siliq has a Boxed Warning, Risk Evaluation and Mitigation Strategy (REMS) program, and limited distribution program due to risks of suicidal ideation and behavior. The REMS program requires prescribers and pharmacies to be certified to prescribe and/or

dispense Siliq.⁴ Patients must sign a patient-prescriber agreement form and be aware of the need to seek medical attention for any new/worsening suicidal thoughts or behavior, depression, anxiety, or mood changes.

POLICY STATEMENT

Prior Authorization is recommended for prescription benefit coverage of Siliq. All approvals are provided for the duration noted below. In cases where the approval is authorized in months, 1 month is equal to 30 days. Because of the specialized skills required for evaluation and diagnosis of patients treated with Siliq as well as the monitoring required for adverse events and long-term efficacy, initial approval requires Siliq to be prescribed by or in consultation with a physician who specializes in the condition being treated.

• **Siliq® (brodalumab subcutaneous injection – Valeant)**
is(are) covered as medically necessary when the following criteria is(are) met for FDA-approved indication(s) or other uses with supportive evidence (if applicable):

FDA-Approved Indication

1. Plaque Psoriasis. Approve for the duration noted if the patient meets ONE of the following (A or B):

A) Initial Therapy. Approve for 3 months if the patient meets ALL of the following (i, ii, iii, iv, v, and vi):

i. Patient is \geq 18 years of age; AND

ii. Patient meets ONE of the following (a or b):

a) Patient has tried at least one traditional systemic agent for psoriasis for at least 3 months, unless intolerant; OR

Note: Examples include methotrexate, cyclosporine, or acitretin. A 3-month trial of psoralen plus ultraviolet A light (PUVA) also counts. An exception to the requirement for a trial of one traditional systemic agent for psoriasis can be made if the patient has already had a 3-month trial or previous intolerance to at least one biologic other than the requested drug. A biosimilar of the requested biologic does not count. Refer to [Appendix](#) for examples of biologics used for plaque psoriasis. A patient who has already tried a biologic for psoriasis is not required to “step back” and try a traditional systemic agent for psoriasis.

b) Patient has a contraindication to methotrexate, as determined by the prescriber; AND

iii. The prescriber attests that the patient has been assessed and evaluated for risks of suicidal ideation or behavior versus benefits of therapy; AND

iv. The patient does **not** have moderately severe to severe depression; AND

v. Within the past 5 years, the patient does **not** have a history of suicidal ideation or suicidal behavior; AND

vi. The medication is prescribed by or in consultation with a dermatologist.

- B) Patient is Currently Receiving Siliq.** Approve for 1 year if the patient meets ALL of the following (i, ii, iii, iv, v, and vi):
- i.** Patient has been established on therapy for at least 3 months; AND
Note: A patient who has received < 3 months of therapy or who is restarting therapy is reviewed under criterion A (Initial Therapy).
 - ii.** The prescriber attests that the patient has been assessed and evaluated for risks of suicidal ideation or behavior versus benefits of therapy; AND
 - iii.** The patient does **not** have moderately severe to severe depression; AND
 - iv.** According to the prescriber, the patient does **not** have suicidal ideation or suicidal behavior; AND
 - v.** Patient experienced a beneficial clinical response, defined as improvement from baseline (prior to initiating Siliq) in at least one of the following: estimated body surface area, erythema, induration/thickness, and/or scale of areas affected by psoriasis; AND
 - vi.** Compared with baseline (prior to receiving Siliq), patient experienced an improvement in at least one symptom, such as decreased pain, itching, and/or burning.

CONDITIONS NOT COVERED

• **Siliq® (brodalumab subcutaneous injection – Valeant)** is(are) considered experimental, investigational or unproven for ANY other use(s) including the following (this list may not be all inclusive; criteria will be updated as new published data are available):

- 1. Concurrent Use with a Biologic or with a Targeted Synthetic Oral Small Molecule Drug.** This medication should not be administered in combination with another biologic or with a targeted synthetic oral small molecule drug used for an inflammatory condition (see [Appendix](#) for examples). Combination therapy is generally not recommended due to a potentially higher rate of adverse events and lack of controlled clinical data supporting additive efficacy.
Note: This does NOT exclude the use of conventional synthetic disease-modifying antirheumatic drug(s) [DMARDs] (e.g., methotrexate, leflunomide, hydroxychloroquine, or sulfasalazine) in combination with this medication.
- 2. Crohn’s Disease.** Siliq is contraindicated in patients with Crohn’s disease.¹ There is a published Phase II study evaluating Siliq in Crohn’s disease (n = 130) that was terminated early due to a disproportionate number of worsening Crohn’s disease and lack of efficacy.⁵
- 3. Rheumatoid Arthritis.** Efficacy has not been established. A published Phase II study (n = 252) did not demonstrate improvement in American College of Rheumatology 20/50/70 responses with Siliq vs. placebo for treatment of rheumatoid arthritis in patients who had previously failed methotrexate.⁶

REFERENCES

1. Siliq® subcutaneous injection [prescribing information]. Bridgewater, NJ: Valeant; February 2017.
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3. Nast A, Gisondi P, Ormerod AD, et al. European S3-Guidelines on the systemic treatment of psoriasis vulgaris – Update 2015 – Short version – EDF in cooperation with EADV and IPC. *J Eur Acad Dermatol Venereol*. 2015;29(12):2277-2294.
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5. Targan SR, Feagan B, Vermeire S, et al. A randomized, double-blind, placebo-controlled Phase 2 study of brodalumab in patients with moderate-to-severe Crohn's disease. *Am J Gastroenterol*. 2016;111(11):1599-1607.
6. Pavelka K, Chon Y, Newmark R, et al. A study to evaluate the safety, tolerability, and efficacy of brodalumab in subjects with rheumatoid arthritis and an inadequate response to methotrexate. *J Rheumatol*. 2015;42(6):912-919.

HISTORY

Type of Revision	Summary of Changes	Review Date
Annual Revision	No criteria changes.	05/10/2023
Selected Revision	Plaque Psoriasis: For a patient currently taking Siliq, the timeframe for established on therapy was changed from 90 days to 3 months.	03/27/2024
Annual Revision	Plaque Psoriasis: In the Note, psoralen plus ultraviolet A light (PUVA) was removed from the examples of traditional systemic therapies. An additional Note was added that a 3-month trial of PUVA counts as a traditional systemic therapy.	06/12/2024
Selected Revision	Conditions Not Covered : Concurrent use with a Biologic or with a Targeted Synthetic Oral Small Molecule Drug was changed to as listed (previously oral small molecule drug was listed as Disease-Modifying Antirheumatic Drug).	09/11/2024
Selected Revision	Plaque Psoriasis: For initial approval and for a patient currently receiving Siliq, requirements were added that the prescriber attests the patient has been evaluated for the risks of suicidal ideation and behavior versus the benefits of therapy and that the patient does not have moderately severe to severe depression. For initial approval, a requirement was added that within the past 5 years, the patient does not have a history of suicidal ideation or suicidal behavior; for a patient currently receiving Siliq, a requirement was added that, according to the prescriber the patient does <u>not</u> have suicidal ideation or suicidal behavior.	10/02/2024

APPENDIX

	Mechanism of Action	Examples of Indications*
Biologics		
Adalimumab SC Products (Humira®, biosimilars)	Inhibition of TNF	AS, CD, JIA, PsO, PsA, RA, UC
Cimzia® (certolizumab pegol SC injection)	Inhibition of TNF	AS, CD, JIA, nr-axSpA, PsO, PsA, RA
Etanercept SC Products (Enbrel®, biosimilars)	Inhibition of TNF	AS, JIA, PsO, PsA, RA
Infliximab IV Products (Remicade®, biosimilars)	Inhibition of TNF	AS, CD, PsO, PsA, RA, UC
Zymfentra® (infliximab-dyyb SC injection)	Inhibition of TNF	CD, UC
Simponi®, Simponi Aria® (golimumab SC injection, golimumab IV infusion)	Inhibition of TNF	SC formulation: AS, PsA, RA, UC
		IV formulation: AS, PJIA, PsA, RA
Tocilizumab Products (Actemra® IV, biosimilar; Actemra SC, biosimilar)	Inhibition of IL-6	SC formulation: PJIA, RA, SJIA
		IV formulation: PJIA, RA, SJIA
Kevzara® (sarilumab SC injection)	Inhibition of IL-6	RA
Orencia® (abatacept IV infusion, abatacept SC injection)	T-cell costimulation modulator	SC formulation: JIA, PSA, RA
		IV formulation: JIA, PsA, RA
Rituximab IV Products (Rituxan®, biosimilars)	CD20-directed cytolytic antibody	RA
Kineret® (anakinra SC injection)	Inhibition of IL-1	JIA [^] , RA
Omvoh® (mirikizumab IV infusion, SC injection)	Inhibition of IL-23	UC
Stelara® (ustekinumab SC injection, ustekinumab IV infusion)	Inhibition of IL-12/23	SC formulation: CD, PsO, PsA, UC
		IV formulation: CD, UC
Siliq® (brodalumab SC injection)	Inhibition of IL-17	PsO
Cosentyx® (secukinumab SC injection; secukinumab IV infusion)	Inhibition of IL-17A	SC formulation: AS, ERA, nr-axSpA, PsO, PsA
		IV formulation: AS, nr-axSpA, PsA
Taltz® (ixekizumab SC injection)	Inhibition of IL-17A	AS, nr-axSpA, PsA, PsO
Bimzelx® (bimekizumab-bkzx SC injection)	Inhibition of IL-17A/17F	AS, nr-axSpA, PsA, PsO
Ilumya® (tildrakizumab-asmn SC injection)	Inhibition of IL-23	PsO
Skyrizi® (risankizumab-rzaa SC injection, risankizumab-rzaa IV infusion)	Inhibition of IL-23	SC formulation: CD, PSA, PsO, UC
		IV formulation: CD, UC
Tremfya® (guselkumab SC injection, guselkumab IV infusion)	Inhibition of IL-23	SC formulation: PsA, PsO, UC IV formulation: UC
Entyvio® (vedolizumab IV infusion, vedolizumab SC injection)	Integrin receptor antagonist	CD, UC
Oral Therapies/Targeted Synthetic Oral Small Molecule Drugs		
Otezla® (apremilast tablets)	Inhibition of PDE4	PsO, PsA
Cibinqo™ (abrocitinib tablets)	Inhibition of JAK pathways	AD
Olumiant® (baricitinib tablets)	Inhibition of JAK pathways	RA, AA
Litfulo® (ritlecitinib capsules)	Inhibition of JAK pathways	AA

Leqselvi [®] (deuruxolitinib tablets)	Inhibition of JAK pathways	AA
Rinvoq [®] (upadacitinib extended-release tablets)	Inhibition of JAK pathways	AD, AS, nr-axSpA, RA, PsA, UC
Rinvoq [®] LQ (upadacitinib oral solution)	Inhibition of JAK pathways	PsA, PJIA
Sotyktu [®] (deucravacitinib tablets)	Inhibition of TYK2	PsO
Xeljanz [®] (tofacitinib tablets/oral solution)	Inhibition of JAK pathways	RA, PJIA, PsA, UC
Xeljanz [®] XR (tofacitinib extended-release tablets)	Inhibition of JAK pathways	RA, PsA, UC
Zeposia [®] (ozanimod tablets)	Sphingosine 1 phosphate receptor modulator	UC
Velsipity [®] (etrasimod tablets)	Sphingosine 1 phosphate receptor modulator	UC

* Not an all-inclusive list of indications. Refer to the prescribing information for the respective agent for FDA-approved indications; SC – Subcutaneous; TNF – Tumor necrosis factor; AS – Ankylosing spondylitis; CD – Crohn’s disease; JIA – Juvenile idiopathic arthritis; PsO – Plaque psoriasis; PsA – Psoriatic arthritis; RA – Rheumatoid arthritis; UC – Ulcerative colitis; nr-axSpA – Non-radiographic axial spondyloarthritis; IV – Intravenous, PJIA – Polyarticular juvenile idiopathic arthritis; IL – Interleukin; SJIA – Systemic juvenile idiopathic arthritis; ^ Off-label use of Kineret in JIA supported in guidelines; ERA – Enthesitis-related arthritis; DMARD – Disease-modifying antirheumatic drug; PDE4 – Phosphodiesterase 4; JAK – Janus kinase; AD – Atopic dermatitis; AA – Alopecia areata; TYK2 – Tyrosine kinase 2.

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