

Clinical Pharmacy Program Guidelines for Siliq

Program	Prior Authorization
Medication	Siliq (brodalumab)
Markets in Scope	California, Hawaii, Maryland, Nevada, New Jersey, New York, Pennsylvania- CHIP, Rhode Island, South Carolina
Issue Date	5/2017
Pharmacy and Therapeutics Approval Date	5/2020
Effective Date	7/2020

1. Background:

Siliq (brodalumab) 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.

2. Coverage Criteria:

<p>A. <u>Plaque Psoriasis</u></p> <p>1. <u>Initial Authorization</u></p> <p>a. Siliq will be approved based on one of the following criteria:</p> <p>(1) Submission of medical records (e.g., chart notes, laboratory values, prescription claims history) documenting all of the following:</p> <p>(a) Diagnosis of chronic moderate to severe plaque psoriasis</p> <p style="text-align: center;">-AND-</p> <p>(b) Greater than or equal to 3% body surface area involvement, palmoplantar, facial, or genital involvement, or severe scalp psoriasis</p> <p style="text-align: center;">-AND-</p> <p>(c) Both of the following:</p>

- i. History of failure to one of the following topical therapies, unless contraindicated or clinically significant adverse effects are experienced (document drug, date, and duration of trial):
 - Corticosteroids (e.g., betamethasone, clobetasol, desonide)
 - Vitamin D analogs (e.g., calcitriol, calcipotriene)
 - Tazarotene
 - Calcineurin inhibitors (e.g., tacrolimus, pimecrolimus)
 - Anthralin
 - Coal tar

-AND-

- ii. History of failure to a 3 month trial of methotrexate at maximally indicated dose within the last 6 months, unless contraindicated or clinically significant adverse effects are experienced (document drug, date, and duration of trial)

-AND-

- (d) History of failure, contraindication, or intolerance to **two** of the following preferred biologic products (document drug, date, and duration of trial):

- i. Humira (adalimumab)
- ii. Enbrel (etanercept)
- iii. Cimzia (certolizumab)
- iv. Ilumya (tildrakizumab)

-AND-

- (e) **One** of the following (document drug, date, and duration of trial):

- i. History of 6 month trial of Cosentyx (secukinumab) with moderate clinical response yet residual disease activity

-OR-

- ii. **Both** of the following:
 - History of intolerance or adverse event to Cosentyx
 - Physician attests that in their clinical opinion the same intolerance or adverse event would not be expected to occur with Siliq

-AND-

- (f) Patient is not receiving Siliq in combination with **any** of the following:
- i. Biologic DMARD [e.g., Humira (adalimumab), Cimzia (certolizumab), Simponi (golimumab), Cosentyx (secukinumab), Orencia (abatacept)]
 - ii. Janus kinase inhibitor [e.g., Xeljanz (tofacitinib)]
 - iii. Phosphodiesterase 4 (PDE4) inhibitor [e.g. Otezla (apremilast)]

-AND-

- (g) Prescribed by or in consultation with a dermatologist

-OR-

- (2) **All** of the following:

- (a) Patient is currently on Siliq therapy as documented by claims history or medical records (document drug, date, and duration of therapy)

-AND-

- (b) Diagnosis of chronic moderate to severe plaque psoriasis

-AND-

- (c) Patient is not receiving Siliq in combination with **any** of the following:

- i. Biologic DMARD [e.g., Humira (adalimumab), Cimzia (certolizumab), Simponi (golimumab), Cosentyx (secukinumab), Orencia (abatacept)]
- ii. Janus kinase inhibitor [e.g., Xeljanz (tofacitinib)]
- iii. Phosphodiesterase 4 (PDE4) inhibitor [e.g. Otezla (apremilast)]

-AND-

- (d) Prescribed by or in consultation with a dermatologist

Authorization will be issued for 12 months.

2. Reauthorization

a. **Siliq** will be approved based on **all** of the following criteria:

(1) Documentation of positive clinical response to Siliq therapy

-AND-

(2) Patient is not receiving Siliq in combination with **any** of the following:

- i. Biologic DMARD [e.g., Humira (adalimumab), Cimzia (certolizumab), Simponi (golimumab), Cosentyx (secukinumab), Orencia (abatacept)]
- ii. Janus kinase inhibitor [e.g., Xeljanz (tofacitinib)]
- iii. Phosphodiesterase 4 (PDE4) inhibitor [e.g. Otezla (apremilast)]

-AND-

(3) Prescribed by or in consultation with a dermatologist

Authorization will be issued for 12 months.

3. Additional Clinical Rules:

- Notwithstanding Coverage Criteria, UnitedHealthcare may approve initial and re-authorization based solely on previous claim/medication history, diagnosis codes (ICD-10) and/or claim logic. Use of automated approval and re-approval processes varies by program and/or therapeutic class.
- Supply limits may be in place.

4. References:

1. Siliq [package insert]. Bridgewater, NJ: Valeant Pharmaceuticals North America LLC; February 2017.
2. Menter A, Gottlieb A, Feldman SR, et al. Guidelines of care for the management of psoriasis and psoriatic arthritis: Section 1. Overview of psoriasis and guidelines of care for the treatment of psoriasis with biologics. *J Am Acad Dermatol* 2008; 58(5):826-50.
3. Gottlieb A, Korman NJ, Gordon KB, et al. Guidelines of care for the management of psoriasis and psoriatic arthritis. *Psoriatic arthritis: Overview and guidelines of care*

- for treatment with an emphasis on the biologics. J Am Acad Dermatol 2008;58(5):851-64.
4. Menter A, Korman NJ, Elmets CA, et al. Guidelines of care for the management of psoriasis and psoriatic arthritis. Section 3. Guidelines of care for the management and treatment of psoriasis with topical therapies. J Am Acad Dermatol 2009;60(4):643-59.
 5. Menter A, Korman NJ, Elmets CA, et al. Guidelines of care for the management of psoriasis and psoriatic arthritis. Guidelines of care for the treatment of psoriasis with phototherapy and photochemotherapy. J Am Acad Dermatol 2010;62(1):114-35.
 6. Menter A, Korman NJ, Elmets CA, et al. Guidelines of care for the management of psoriasis and psoriatic arthritis. Guidelines of care for the management and treatment of psoriasis with traditional systemic agents. J Am Acad Dermatol 2009;61(3):451-85.
 7. Menter A, Korman NJ, Elmets CA, Feldman SR, Gelfand JM, Gordon KB, 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 Jul;65(1):137-74.
 8. Nast A, et al; European S3-Guidelines on the systemic treatment of psoriasis vulgaris – update 2015 – short version – EFF in cooperation with EADV and IPC, J Eur Acad Derm Venereol 2015;29:2277-94.

Program	Prior Authorization –Siliq (brodalumab)
Change Control	
Date	Change
5/2017	New program
9/2017	Updated preferred biologic products to include Otezla
2/2018	Removed Otezla as a step therapy medication
2/2019	Minor revisions to language/formatting to align with other psoriasis programs. Added Cimzia as a step therapy medication for psoriasis.
11/2019	Annual review. No changes to criteria.
12/2019	Revised prerequisite therapies and added documentation of drug, date, and duration of trials.
1/2020	Revised step therapy medications due to PDL changes.
5/2020	Added prescriber requirement. Minor updates to prerequisite therapy requirements. Changed BSA requirement to 3% to align with current psoriasis guidelines.