

UnitedHealthcare Pharmacy
Clinical Pharmacy Programs

Program Number	2021 P 2126-8
Program	Prior Authorization/Medical Necessity
Medication	Siliq (brodalumab)* *Siliq is excluded from coverage for the majority of our benefits
P&T Approval Date	5/2017, 2/2018, 2/2019, 9/2019, 5/2020, 5/2021, 6/2021, 12/2021
Effective Date	3/1/2022; Oxford only: 3/1/2022

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^a:

<p>A. <u>Plaque Psoriasis</u></p> <p>a. Siliq will be approved based on 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) One of the following:</p> <p>i. All of the following:</p> <p>1. Greater than or equal to 3 % body surface area involvement, palmoplantar, facial, genital involvement, or severe scalp psoriasis</p> <p style="text-align: center;">-AND-</p> <p>2. 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):</p> <ul style="list-style-type: none"> ▪ Corticosteroids (e.g., betamethasone, clobetasol, desonide) ▪ Vitamin D analogs (e.g., calcitriol, calcipotriene) ▪ Tazarotene ▪ Calcineurin inhibitors (e.g., tacrolimus, pimecrolimus)

- Anthralin
- Coal tar

-AND-

3. History of failure to a 3 month trial of methotrexate at maximally indicated dose, unless contraindicated or clinically significant adverse effects are experienced (document drug, date, and duration of trial)^b

-OR-

- ii. Patient has been previously treated with a biologic or targeted synthetic DMARD FDA-approved for the treatment of plaque psoriasis as documented by claims history or submission of medical records (Document drug, date, and duration of therapy) [e.g., Cimzia (certolizumab), Humira (adalimumab), Otezla (apremilast), Skyrizi (risankizumab-rzaa), Stelara (ustekinumab), Tremfya (guselkumab)].

-AND-

- (c) History of failure, contraindication, or intolerance to **two** of the following preferred products (document drug, date, and duration of trial):
 - i. Humira (adalimumab)
 - ii. Stelara (ustekinumab)
 - iii. Tremfya (guselkumab)
 - iv. Cimzia (certolizumab)
 - v. Skyrizi (risankizumab)

-AND-

- (d) **One** of the following (document date and duration of trial):
 - i. History of 6 month trial of Cosentyx (secukinumab) with moderate clinical response yet residual disease activity.^b

-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-

- (e) 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-

(f) Prescribed by or in consultation with a dermatologist

Authorization will be issued for 12 months.

^a State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

^b For Connecticut business, only a 60-day trial will be required. For Kentucky business only a 30-day trial will be required.

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.
- *Siliq is excluded from coverage for the majority of our benefits
- Supply limits may be in place.

4. **References:**

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

9. 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;80:1029-72.

Program	Prior Authorization/Medical Necessity-Siliq (brodalumab)
Change Control	
Date	Change
5/2017	New Program.
2/2018	Updated criteria, adding Tremfya as an additional preferred agent for plaque psoriasis.
2/2019	Annual review. Added manufacturer assistance program information. Updated background. Addition of Cimzia as preferred agent.
9/2019	Updated criteria adding Skyrizi as preferred medication. Added coverage exclusion statement. Updated references.
5/2020	Updated formatting without change to clinical intent.
5/2021	Annual review. Removed drug documentation where only one drug is required. Updated references.
6/2021	Added coverage criteria for patients previously treated with a biologic DMARD.
12/2021	Updated the following with no change to clinical intent: updated conventional DMARD bypass language for psoriasis, removed “biologic” from required preferred product criteria language and updated CT/KY footnote.