UnitedHealthcare Pharmacy
Clinical Pharmacy Programs

Program Number	2024 P 2126-14
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, 5/2022, 11/2022, 1/2023, 4/2023, 7/2023, 10/2024
Effective Date	1/1/2025

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]:

A. Plaque Psoriasis

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

(1) Submission of medical records (e.g., chart notes, laboratory values, prescription claims history) documenting **all** of the following:

(a) Diagnosis of chronic moderate to severe plaque psoriasis

-AND-

(b) **One** of the following:

i. **All** of the following:

1. Greater than or equal to 3% body surface area involvement, palmoplantar, facial, genital involvement, or severe scalp psoriasis

-AND-

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):

- 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 targeted immunomodulator 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), adalimumab, Otezla (apremilast), Skyrizi (risankizumab), Stelara (ustekinumab), Tremfya (guselkumab), Enbrel (etanercept)].

-AND-

(c) History of failure, contraindication, or intolerance to **three** of the following preferred products (document drug, date, and duration of trial):^

i. One of the preferred adalimumab products (i.e. Adalimumab-adaz (unbranded Hyrimoz), Amjevita for Nuvaila, Humira)
ii. Cimzia (certolizumab)
iii. Cosentyx (secukinumab)
iv. Enbrel (etanercept)
v. Skyrizi (risankizumab)
vi. Sotyktu (deucravacitinib)
vii. Stelara (ustekinumab)
viii. Tremfya (guselkumab)

-AND-

(d) Patient is not receiving Siliq in combination with another targeted immunomodulator [e.g., Enbrel (etanercept), Cimzia (certolizumab), Simponi (golimumab), Orencia (abatacept), adalimumab, Stelara (ustekinumab), Skyrizi (risankizumab), Tremfya (guselkumab), Cosentyx (secukinumab), Taltz (ixekizumab), Ilumya (tildrakizumab), Xeljanz (tofacitinib), Olumiant (baricitinib), Rinvoq (upadacitinib), Otezla (apremilast)]

-AND-

(e) 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, Kentucky and Mississippi business only a 30-day trial will be required.
^Tried/failed alternative(s) are supported by FDA labeling.

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.
5/2022	Updated with Tried/failed alternative(s) are supported by FDA labeling footnote. Added Mississippi to state mandate.
11/2022	Added Enbrel as a preferred product step option. Added Enbrel as an example where appropriate.
1/2023	Updated step therapy requirements to Humira or Amjevita. Updated listed examples from Humira to adalimumab.
4/2023	Updated step therapy requirement from Humira or Amjevita to one of the preferred adalimumab products and added the footnote "For a list of preferred adalimumab products please reference drug coverage tools."
7/2023	Updated not receiving in combination language to targeted immunomodulator and updated examples.
10/2024	Updated step requirement noting Adalimumab-adaz (unbranded Hyrimoz), Amjevita for Nuvaila, and Humira as preferred adalimumab products with no change to clinical intent. Removed preferred adalimumab footnote. Added Sotyktu as step therapy agent. Moved Cosentyx to preferred step agent and changed step to three agents. Updated state mandate footnote.