UnitedHealthcare Pharmacy
Clinical Pharmacy Programs

Program Number	2019 P 3094-3
Program	Step Therapy
Medications	Siliq® (brodalumab)
P&T Approval Date	5/2018, 2/2019
Effective Date	3/15/2018; Oxford only: N/A

1. Background:

Step therapy programs are utilized to encourage use of lower cost alternatives for certain therapeutic classes. This program requires a member to try three preferred self-administered injectable products before providing coverage for Siliq®. Infused medications for any of the conditions referenced in this document are not part of the criteria.

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.[1]

Humira® (adalimumab) is also indicated for the treatment of adult patients with moderate to severe plaque psoriasis who are candidates for systemic therapy or phototherapy, for reducing signs and symptoms, inhibiting the progression of structural damage, and improving physical function in adult patients with active psoriatic arthritis, or for reducing signs and symptoms in adult patients with active ankylosing spondylitis.[2]

Stelara® (ustekinumab) is indicated for the treatment of adult patients with moderate to severe plaque psoriasis who are candidates for systemic therapy or phototherapy or for treatment of adult patients with active psoriatic arthritis.[3]

Cosentyx® (secukinumab) is indicated for the treatment of moderate to severe plaque psoriasis in adult patients who are candidates for systemic therapy or phototherapy. It is also indicated for the treatment of adult patients with active psoriatic arthritis or for treatment of adults with active ankylosing spondylitis.[4]

Tremfya® (guselkumab) is indicated for the treatment of adult patients with moderate-to-severe plaque psoriasis who are candidates for systemic therapy or phototherapy.[5]

Cimzia (certolizumab) is indicated for the treatment of adult patients with moderate to severe plaque psoriasis who are candidates for systemic therapy or phototherapy or for treatment of adult patients with active psoriatic arthritis.[6]

Members currently on Siliq therapy as documented in claims history will be allowed to continue on their current therapy. Members new to therapy will be required to meet the coverage criteria below.

2. Coverage Criteria[a]:

A. Plaque Psoriasis

1. Siliq will be approved based on **one** of the following criteria:

a. **Both** of the following:

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

(a) Humira (adalimumab)
(b) Stelara (ustekinumab)
(c) Tremfya (guselkumab)
(d) Cimzia (certolizumab)

-AND-

(2) History of failure, contraindication, or intolerance to Cosentyx (secukinumab) (document drug, date, and duration of trial).

-OR-

b. **Both** of the following:

(1) Patient is currently on Siliq therapy

-AND-

(2) Patient has **not** received a manufacturer supplied sample at no cost in prescriber office, or any form of assistance from the Valeant Pharmaceuticals sponsored Siliq Solutions™ Instant Savings Program (e.g., sample card which can be redeemed at a pharmacy for a free supply of medication) as a means to establish as a current user of Siliq*

***** Patients requesting initial authorization who were established on therapy via the receipt of a manufacturer supplied sample at no cost in the prescriber's office or any form of assistance from a manufacturer sponsored program **shall be required** to meet initial authorization criteria as if patient were new to therapy.

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.

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.
- Medical Necessity, Supply limits and/or Notification may be in place.

4. References:

1. Siliq [package insert]. Bridgewater, NJ: Valeant Pharmaceuticals North America LLC; February 2017.
2. Humira [package insert]. North Chicago, IL: AbbVie Inc.; December 2017.
3. Stelara [package insert]. Horsham, PA: Janssen Biotech Inc.; February 2018.
4. Cosentyx [package insert]. East Hanover, NJ. Novartis Pharmaceuticals Corp.; January 2018.
5. Tremfya [package insert]. Horsham, PA: Janssen Biotech Inc.; July 2017.
6. Cimzia [package Insert]. Smyrna, GA: UCB, Inc; May 2018.

Program	Step Therapy - Siliq (brodalumab)
Change Control	
5/2017	New program.
2/2019	Annual review. Added manufacturer assistance program information. Updated background. Updated references. Addition of Cimzia as preferred agent.