UnitedHealthcare Pharmacy
Clinical Pharmacy Programs

Program Number	2022 P 3094-7
Program	Step Therapy
Medications	Siliq® (brodalumab)* *Siliq is excluded from coverage for the majority of our benefits
P&T Approval Date	5/2018, 2/2019, 9/2019, 12/2020, 2/2022
Effective Date	5/1/2022; 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®(brodalumab). 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.

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, and when other systemic therapies are medically less appropriate.

Stelara® (ustekinumab) and Cosentyx® (secukinumab) are indicated for the treatment of patients 6 years or older with moderate to severe plaque psoriasis who are candidates for systemic therapy or phototherapy.

Tremfya® (guselkumab), Cimzia® (certolizumab), and Skyrizi™ (risankizumab) is indicated for the treatment of adult patients with moderate to severe plaque psoriasis who are candidates for systemic therapy or phototherapy.

Members will be required to meet the coverage criteria below.

2. Coverage Criteria[a]:

A. <u>Plaque Psoriasis</u>

1. **Siliq** will be approved based on **<u>both</u>** of the following criteria^:

   a. History of failure, contraindication, or intolerance to **<u>two</u>** of the following preferred products (document drug, date, and duration of trial):

      (1) Humira (adalimumab)
      (2) Stelara (ustekinumab)
      (3) Tremfya (guselkumab)
      (4) Cimzia (certolizumab)
      (5) Skyrizi (risankizumab)

-AND-

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

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

4. References:

1. Siliq [package insert]. Bridgewater, NJ: Bausch Health US, LLC; April 2020.
2. Humira [package insert]. North Chicago, IL: AbbVie Inc.; February 2021.
3. Stelara [package insert]. Horsham, PA: Janssen Biotech Inc.; December 2020.
4. Cosentyx [package insert]. East Hanover, NJ. Novartis Pharmaceuticals Corp.; May 2021.
5. Tremfya [package insert]. Horsham, PA: Janssen Biotech Inc.; July 2020.
6. Cimzia [package Insert]. Smyrna, GA: UCB, Inc; September 2019.
7. Skyrizi [package Insert]. North Chicago, IL: AbbVie Inc.; April 2021.

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.
9/2019	Updated background and criteria adding Skyrizi as preferred medication. Added coverage exclusion statement. Updated references.
12/2020	Annual review. Consolidated background to include only information on plaque psoriasis. Clarified documentation requirement for Cosentyx. Updated references.
2/2022	Annual review. Removed biologic language with no changes to step criteria. Updated background and references. Added footnote to support FDA labeled first line requirements.
3/2022	Administrative change to adjust footnote location.