

Siliq (brodalumab)

Override(s)	Approval Duration
Prior Authorization Quantity Limit	1 year

Medications	Quantity Limit
Siliq (brodalumab) 210 mg/1.5 mL*	2 prefilled syringes per 28 days

*Initiation of therapy for Plaque Psoriasis (Psoriasis Vulgaris): May approve up to 2 (two) additional syringes (210 mg) in the first 28 days (4 weeks) of treatment.

APPROVAL CRITERIA

Initial requests for Siliq (brodalumab) may be approved for the following:

- I. Plaque psoriasis (Ps) (psoriasis vulgaris) when each of the following criteria are met:
 - A. Individual is 18 years of age or older with chronic moderate to severe (that is, extensive or disabling) plaque Ps (psoriasis vulgaris) with either of the following (AAD 2019):
 1. Plaque Ps (psoriasis vulgaris) involving greater than three percent (3%) body surface area (BSA); **OR**
 2. Plaque Ps (psoriasis vulgaris) involving less than or equal to three percent (3%) BSA involving sensitive areas or areas that significantly impact daily function (such as, palms, soles of feet, head, neck, or genitalia); **AND**
 - B. Individual has had an inadequate response to or is intolerant of phototherapy or other systemic therapy (such as acitretin, cyclosporine, or methotrexate); **OR**
 - C. Individual has a contraindication to phototherapy, acitretin, cyclosporine, and methotrexate;

AND

- D. Documentation is provided that individual has had a trial and inadequate response or intolerance of TWO (2) preferred biologic agents [Current preferred biologics include - adalimumab-adbm, Cosentyx (secukinumab)*, Enbrel (etanercept), Humira (adalimumab), Otezla (apremilast), Simponi (golimumab), Stelara (ustekinumab), Tremfya (guselkumab)*]. Medication samples/coupons/discount cards are excluded from consideration as a trial.;

AND

1. Documentation is provided describing the nature of the inadequate response or intolerance for each product tried;
- OR**
2. Documentation is provided that a completed FDA MedWatch Adverse Event Reporting Form has been submitted to the FDA for each product tried;

OR

- E. Documentation is provided that individual has been receiving and is maintained on a stable dose of Siliq (brodalumab). Medication samples/coupons/discount cards are excluded from consideration as a trial.

*Note – Trial of Cosentyx (secukinumab) not required in states where not covered (CA, CO). Prior trial of Tremfya (guselkumab) not required in states where not covered (CA, CO, GA, IN, KY, ME, MO, NH, NY, OH, VA, WI].

Continuation requests for Siliq (brodalumab) may be approved if the following criterion is met:

- I. Documentation is provided that individual has been receiving and is maintained on a stable dose of Siliq. Medication samples/coupons/discount cards are excluded from consideration as a trial.; **AND**
- II. There is clinically significant improvement or stabilization in clinical signs and symptoms of disease.

Requests for Siliq (brodalumab) may not be approved for the following:

- I. In combination with phototherapy; **OR**
- II. In combination with JAK inhibitors, ozanimod, etrasimod, apremilast, deucravacitinib, or any of the following biologic immunomodulators: TNF antagonists, IL-23 inhibitors, other IL-17 inhibitors, vedolizumab, ustekinumab, abatacept, IL-1 inhibitors, IL-6 inhibitors, rituximab or natalizumab); **OR**
- III. Tuberculosis, invasive fungal infection, other active serious infections, or a history of recurrent infections [repeat TB testing not required for ongoing therapy]; **OR**
- IV. If initiating therapy, individual has not had a tuberculin skin test (TST) or a Centers for Disease Control and Prevention (CDC) and Prevention-recommended equivalent test to evaluate for latent tuberculosis (unless switching therapy from another targeted immune modulator and no new risk factors); **OR**
- V. Individual has Crohn's disease; **OR**
- VI. When the above criteria are not met and for all other indications.

Key References:

1. Centers for Disease Control and Prevention (CDC). Tuberculosis (TB). Available at: <https://www.cdc.gov/tb/topic/basics/risk.htm>. Last updated: March 18, 2016. Accessed October 12, 2023.
2. DailyMed. Package inserts. U.S. National Library of Medicine, National Institutes of Health website. <http://dailymed.nlm.nih.gov/dailymed/about.cfm>. Accessed: October 12, 2023.
3. DrugPoints® System [electronic version]. Truven Health Analytics, Greenwood Village, CO. Updated periodically.
4. Lexi-Comp ONLINE™ with AHFS™, Hudson, Ohio: Lexi-Comp, Inc.; 2023; Updated periodically.
5. 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.

Federal and state laws or requirements, contract language, and Plan utilization management programs or policies may take precedence over the application of this clinical criteria.

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