CareSource

PHARMACY POLICY STATEMENT **Indiana Medicaid**	
DRUG NAME	Siliq (brodalumab)
BILLING CODE	Must use valid NDC code
BENEFIT TYPE	Pharmacy
SITE OF SERVICE ALLOWED	Home
COVERAGE REQUIREMENTS	Prior Authorization Required (Preferred Product) QUANTITY LIMIT— 420 mg or 3 mL per 28 days (after loading dose)
LIST OF DIAGNOSES CONSIDERED **NOT** MEDICALLY NECESSARY	Click Here

Siliq (brodalumab) is a **preferred** product and will only be considered for coverage under the **pharmacy** benefit when the following criteria are met:

Members must be clinically diagnosed with one of the following disease states and meet their individual criteria as stated.

PLAQUE PSORIASIS (PsO)

For **initial** authorization:

1. Member must be 18 years of age or older; AND
2. Member must have a documented negative TB test (i.e., tuberculosis skin test (PPD), an interferon-release assay (IGRA)) within 12 months prior to starting therapy; AND
3. Medication must be prescribed by a dermatologist or rheumatologist; AND
4. Member has PsO for 6 months or longer; AND
5. Member is not going to receive systemic therapy or phototherapy while on Siliq; AND
6. Member's PsO involving 10% or more of the body surface area (BSA) or 5% or more of BSA if psoriasis involves sensitive areas (hands, feet, face, or genitals); AND
7. Member's Psoriasis Area and Severity Index (PASI) score ≥ 12; AND
8. Member must **not** have a diagnosis of Crohn's Disease (Siliq is contraindicated in patients with Crohn's disease); AND
9. Documented consultation on risks of suicidal ideation or behavior while on Siliq is submitted with member's chart notes; AND
10. Member has tried and failed to respond to treatment with at least **one** of the following:
    a) At least 12 weeks of photochemotherapy (i.e., psoralen plus ultraviolet A therapy);
    b) At least 12 weeks of phototherapy (i.e., UVB light therapy, Excimer laser treatments (tanning beds emit mostly UVA light and therefore would not meet this criteria));
    c) At least a 4 week trial with topical antipsoriatic agents (i.e., anthralin, calcipotriene, coal tar, corticosteroids, tazarotene); AND
11. Member has tried and failed to respond to treatment with traditional first-line oral/systemic therapies (i.e., cyclosporine, methotrexate, acitretin) for at least 12 weeks.
12. **Dosage allowed:** 210 mg subcutaneously once weekly at weeks 0, 1, and 2 followed by 210 mg every 2 weeks.

If member meets all the requirements listed above, the medication will be approved for 12 months.

For **reauthorization**:

1. Member must have been retested for TB with a negative result within the past 12 months; AND
2. Member must be in compliance with all other initial criteria; AND
3. Chart notes have been provided that show the member has shown improvement of signs and symptoms of disease (e.g., documented member's PASI score improvement, etc.).

If member meets all the reauthorization requirements above, the medication will be approved for an additional 12 months.

CareSource considers Siliq (brodalumab) not medically necessary for the treatment of the following disease states based on a lack of robust clinical controlled trials showing superior efficacy compared to currently available treatments:

- Active infections
- Ankylosing spondylitis
- Asthma
- Cellulitis
- Crohn's Disease
- Dissecting scalp cellulitis
- For use in combination with other TNF-inhibitors (i.e., Humira, Kineret, Enbrel, Remicade)
- Giant-cell arteritis
- Infectious uveitis
- Juvenile idiopathic arthritis
- Lupus perino
- Osteoarthritis
- Psoriatic Arthritis
- Recurrent pregnancy loss
- Relapsing polychondritis
- Rheumatoid arthritis
- Sarcoidosis
- Sciatica
- Spondyloarthritis (other than ankylosing spondylitis)
- Takayasu's arteritis
- Ulcerative Colitis
- Vogt-Koyanagi

DATE	ACTION/DESCRIPTION
05/09/2017	New policy for Siliq created.
02/26/2019	Humira and Enbrel trials removed from criteria. Reauthorization criteria on documented member's PASI score improvement incorporated into general chart noted documentation requirements. Static Physician's Global Assessment (sPGA) score removed. Ulcerative Colitis added to not covered diagnosis. "Immunosuppressant therapies" changed to "treatment of traditional first-line oral/systemic" therapies. TB test allowed to be done within 12 months prior to initiation of therapy; chest x-ray option removed. References added.

References:

1. Siliq [prescribing information]. Bridgewater, NJ; Valeant Pharmaceuticals North America LLC. Revised February 2017.
2. Hsu S, Papp KA, Lebwohl MG, et al. Consensus guidelines for the management of plaque psoriasis. Arch Dermatol. 2012 Jan;148(1):95-102.
3. Sbidian E, et al. Systemic pharmacological treatments for chronic plaque psoriasis: a network metaanalysis. Cochrane Database Syst Rev. 2017;12:CD011535. Epub 2017 Dec 22.
4. Nast A, et al. European S3-Guideline on the systemic treatment of psoriasis vulgaris - Update Apremilast and Secukinumab - EDF in cooperation with EADV and IPC. J Eur Acad Dermatol Venereol. 2017;31(12):1951.
5. Smith CH, et al. British Association of Dermatologists guidelines for biologic therapy for psoriasis 2017. Br J Dermatol. 2017 Sep;177(3):628-636.

Effective date: 04/01/2019
Revised date: 02/26/2019