

Clinical Pharmacy Program Guidelines for Siliq

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| Program | Prior Authorization |
| Medication | Siliq (brodalumab) |
| Markets in Scope | California, Florida-CHIP, Hawaii, Maryland, Nevada, New Mexico, New York, Ohio, Rhode Island |
| Issue Date | 5/2017 |
| Pharmacy and Therapeutics Approval Date | 2/2018 |
| Effective Date | 4/2018 |

1. Background:

Siliq (brodalumab) is a human interleukin-17A receptor 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:

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| <p>A. <u>Plaque Psoriasis</u></p> <p>1. <u>Initial Authorization</u></p> <p>a. Siliq will be approved based on one of the following criteria:</p> <p>(1) Submission of medical records (e.g., chart notes, laboratory values, prescription claims history) documenting all of the following:</p> <p style="padding-left: 40px;">(a) Diagnosis of chronic moderate to severe plaque psoriasis</p> <p style="text-align: center;">-AND-</p> <p style="padding-left: 40px;">(b) Greater than or equal to 5% body surface area involvement, palmoplantar, facial, or genital involvement, or severe scalp psoriasis</p> <p style="text-align: center;">-AND-</p> <p style="padding-left: 40px;">(c) History of failure, contraindication, or intolerance to both of the following conventional therapies:</p> |
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i. Topical therapy with **one** of the following:

- Corticosteroids (e.g., betamethasone, clobetasol, desonide)
- Vitamin D analogs (e.g., calcitriol, calcipotriene)
- Tazarotene
- Calcineurin inhibitors (e.g., tacrolimus, pimecrolimus)
- Anthralin
- Coal tar

-AND-

ii. Systemic therapy of at least 3 months duration with methotrexate

-AND-

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

- i. Humira (adalimumab)
- ii. Enbrel (etanercept)

-AND-

(e) **One** of the following (document drug, date, and duration of trial):

- i. History of 6 month trial of Cosentyx (secukinumab) with moderate clinical response yet residual disease activity

-OR-

ii. **Both** of the following:

- History of intolerance or adverse event to Cosentyx
- Physician attests that in their clinical opinion the same intolerance or adverse event would not be expected to occur with Siliq

-AND-

(f) Patient is not receiving Siliq in combination with any of the following:

- i. Biologic DMARD [e.g., Humira (adalimumab), Cimzia (certolizumab), Simponi (golimumab), Cosentyx (secukinumab), Orencia (abatacept)]
- ii. Janus kinase inhibitor [e.g., Xeljanz (tofacitinib)]
- iii. Phosphodiesterase 4 (PDE4) inhibitor [e.g. Otezla (apremilast)]

-OR-

(2) **Both** of the following:

- (a) Patient is currently on Siliq therapy

-AND-

(b) Patient is not receiving Siliq in combination with any of the following:

- i. Biologic DMARD [e.g., Humira (adalimumab), Cimzia (certolizumab), Simponi (golimumab), Cosentyx (secukinumab), Orencia (abatacept)]
- ii. Janus kinase inhibitor [e.g., Xeljanz (tofacitinib)]
- iii. Phosphodiesterase 4 (PDE4) inhibitor [e.g. Otezla (apremilast)]

Authorization will be issued for 12 months.

2. **Reauthorization**

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

(1) Documentation of positive clinical response to Siliq therapy

-AND-

(2) Patient is not receiving Siliq in combination with **any** of the following:

- i. Biologic DMARD [e.g., Humira (adalimumab), Cimzia (certolizumab), Simponi (golimumab), Cosentyx (secukinumab), Orencia (abatacept)]
- ii. Janus kinase inhibitor [e.g., Xeljanz (tofacitinib)]
- iii. Phosphodiesterase 4 (PDE4) inhibitor [e.g. Otezla (apremilast)]

Authorization will be issued for 12 months.

3. References:

1. Siliq Prescribing Information. Bridgewater, NJ: Valeant Pharmaceuticals North America LLC; February 2017.
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.
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4. Menter A, Korman NJ, Elmetts 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, Elmetts 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, Elmetts 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, Elmetts 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.

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| Program | Prior Authorization –Siliq (brodalumab) |
| Change Control | |
| Date | Change |
| 5/2017 | New program |
| 9/2017 | Updated preferred biologic products to include Otezla |
| 2/2018 | Removed Otezla as a step therapy medication |