Clinical Policy: Brodalumab (Siliq)

Reference Number: ERX.SPA.53
Effective Date: 06.01.17
Last Review Date: 05.18 Revision Log

See Important Reminder at the end of this policy for important regulatory and legal information.

Description
Brodalumab (Siliq™) is an interleukin 17A (IL-17A) receptor antagonist.

FDA Approved Indication(s)
Siliq is indicated for the treatment of moderate-to-severe plaque psoriasis (PsO) in adult patients who are candidates for systemic therapy or phototherapy and have failed to respond or have lost response to other systemic therapies.

Policy/Criteria
Provider must submit documentation (such as office chart notes, lab results or other clinical information) supporting that member has met all approval criteria.

It is the policy of health plans affiliated with Envolve Pharmacy Solutions™ that Siliq is **medically necessary** when the following criteria are met:

I. Initial Approval Criteria

A. Plaque Psoriasis (must meet all)**:**

1. Diagnosis of PsO;
2. Prescribed by or in consultation with a dermatologist or rheumatologist;
3. Age ≥ 18 years;
4. Member meets one of the following (a or b):
   a. Failure of a ≥ 3 consecutive month trial of methotrexate (MTX) at up to maximally indicated doses, unless contraindicated or clinically significant adverse effects are experienced;
   b. If intolerance or contraindication to MTX *(see Appendix C)*, failure of a ≥ 3 consecutive month trial of cyclosporine or acitretin at up to maximally indicated doses, unless contraindicated or clinically significant adverse effects are experienced;
5. Failure of 2 of the following, each used for ≥ 3 consecutive months unless contraindicated or clinically significant adverse effects are experienced: adalimumab (*Humira® is preferred*), Cosentyx®, subcutaneous Stelara®, or infliximab (*Remicade® is preferred*);
   **Prior authorization is required for adalimumab, Cosentyx, Stelara, and infliximab*
6. Dose does not exceed 210 mg at weeks 0, 1, and 2, followed by maintenance dose of 210 mg every 2 weeks.

Approval duration: 6 months

B. Other diagnoses/indications

1. Refer to ERX.PA.01 if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized).

II. Continued Therapy

A. Plaque Psoriasis (must meet all)**:**

1. Currently receiving medication via a health plan affiliated with Envolve Pharmacy Solutions or member has previously met initial approval criteria;
2. Member is responding positively to therapy;
3. If request is for a dose increase, new dose does not exceed 210 mg every 2 weeks.

Approval duration: 12 months

B. Other diagnoses/indications (must meet 1 or 2)**:**

1. Currently receiving medication via a health plan affiliated with Envolve Pharmacy Solutions and documentation supports positive response to therapy.
   Approval duration: Duration of request or 6 months (whichever is less); or
2. Refer to ERX.PA.01 if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized).

III. Diagnoses/Indications for which coverage is NOT authorized:

A. Non-FDA approved indications, which are not addressed in this policy, unless there is sufficient documentation of efficacy and safety according to the off-label use policy – ERX.PA.01 or evidence of coverage documents;

B. Treatment of patients with Crohn's disease.

IV. Appendices/General Information

Appendix A: Abbreviation/Acronym Key

FDA: Food and Drug Administration
IL-17A: interleukin 17A
MTX: methotrexate
PsO: plaque psoriasis

Appendix B: Therapeutic Alternatives

This table provides a listing of preferred alternative therapy recommended in the approval criteria. The drugs listed here may not be a formulary agent for all relevant lines of business and may require prior authorization.

Drug Name	Dosing Regimen	Dose Limit/ Maximum Dose
acitretin (Soriatane®)	**PsO** 25 or 50 mg PO daily	50 mg/day
cyclosporine (Sandimmune®, Neoral®)	**PsO** 2.5 – 4 mg/kg/day PO divided BID	4 mg/kg/day
methotrexate (Rheumatrex®)	**PsO** 10 – 25 mg/week PO or 2.5 mg PO Q12 hr for 3 doses/week	30 mg/week
Humira® (adalimumab)	**PsO** Initial dose: 80 mg SC Maintenance dose: 40 mg SC every other week starting one week after initial dose	40 mg every other week
Cosentyx® (secukinumab)	**PsO (with or without PsA)** 300 mg SC at week 0, 1, 2, 3, and 4, followed by 300 mg every 4 weeks	300 mg every 4 weeks
Remicade® (infliximab)	**PsO** Initial dose: 5 mg/kg IV at weeks 0, 2 and 6 Maintenance dose: 5 mg/kg IV every 8 weeks	5 mg/kg every 8 weeks
Stelara® (ustekinumab)	**PsO** Weight based dosing SC at weeks 0 and 4, followed by maintenance dose every 12 weeks Weight ≤ 100 kg: 45 mg Weight > 100 kg: 90 mg	90 mg every 12 weeks

Therapeutic alternatives are listed as Brand name® (generic) when the drug is available by brand name only and generic (Brand name®) when the drug is available by both brand and generic.

Appendix C: General Information

- Contraindications:
  - Siliq is contraindicated in patients with Crohn's disease because Siliq may cause worsening of the disease.
- Definition of failure of MTX or DMARDs:
  - Child-bearing age is not considered a contraindication for use of MTX. Each drug has risks in pregnancy. An educated patient and family planning would allow use of MTX in patients who have no intention of immediate pregnancy.
  - Social use of alcohol is not considered a contraindication for use of MTX. MTX may only be contraindicated if patients choose to drink over 14 units of alcohol per week. However, excessive alcohol drinking can lead to worsening of the condition, so patients who are serious about clinical response to therapy should refrain from excessive alcohol consumption.

V. Dosage and Administration

Indication	Dosing Regimen	Maximum Dose
PsO	Initial dose: 210 mg SC at weeks 0, 1, and 2 Maintenance dose: 210 mg SC every 2 weeks	210 mg every 2 weeks

VI. Product Availability

Single-dose prefilled syringe: 210 mg/1.5 mL

VII. References

1. Siliq Prescribing Information. Bridgewater, NJ: Valeant Pharmaceuticals North America LLC; February 2017. Available at http://www.valeant.com/Portals/25/Pdf/PI/Siliq-pi.pdf. Accessed February 27, 2018.
2. Papp KA, Reich K, Paul C et al. A prospective phase III, randomized, double-blind, placebo-controlled study of brodalumab in patients with moderate-to-severe plaque psoriasis. Br J Dermatol. 2016 Aug;175(2):273-86. doi: 10.1111/bjd.14493.
3. Lebwohl M, Strober B, Menter A et al. Phase 3 Studies Comparing Brodalumab with Ustekinumab in Psoriasis. N Engl J Med. 2015 Oct;373(14):1318-28. doi: 10.1056/NEJMoa1503824.
4. Farahnik B, Beroukhim K, Abrouk M et al. Brodalumab for the treatment of psoriasis: a review of phase II trials. Dermatol Ther (Heidelb). 2016 Jun;6(2):111-24. doi: 10.1007/s13555-016-0121-x.
5. Menter A, Gottlieb A, Feldman SR, Van Voorhees AS, Leonardi CL, Gordon KB,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 May;58(5):826-50.
6. Menter A, Korman NJ, Elmets CA et al. 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 2011July; 65:137-74.
7. Hsu S, Papp KA, Lebwohl MG et al. Consensus guidelines for the management of plaque psoriasis. Arch Dermatol. 2012 Jan; 148(1):95-102
8. Pariser DM, Bagel J, Gelfand JM et al. National psoriasis foundation clinical consensus on disease severity. Arch Dermatol. 2007 Feb; 143: 239-242.

Reviews, Revisions, and Approvals	Date	P&T Approval Date
Policy created	03.17	05.17
4Q17 Annual Review Added age requirement per PI and safety guidance. Removed option for trial of PUVA or UVB therapy if contraindicated to MTX to ensure a systemic therapy is used prior to receiving biologic therapy.	09.29.17	11.17

Reviews, Revisions, and Approvals	Date	P&T Approval Date
2Q 2018 annual review: no significant changes; modified trial and failure of preferred agents; references reviewed and updated.	02.27.18	05.18

Important Reminder
This clinical policy has been developed by appropriately experienced and licensed health care professionals based on a review and consideration of currently available generally accepted standards of medical practice; peer-reviewed medical literature; government agency/program approval status; evidence-based guidelines and positions of leading national health professional organizations; views of physicians practicing in relevant clinical areas affected by this clinical policy; and other available clinical information.

This Clinical Policy is not intended to dictate to providers how to practice medicine, nor does it constitute a contract or guarantee regarding payment or results. Providers are expected to exercise professional medical judgment in providing the most appropriate care, and are solely responsible for the medical advice and treatment of members.