Clinical Policy: Brodalumab (Siliq)

Reference Number: ERX.SPA.53
Effective Date: 06.01.17
Last Review Date: 05.21
Line of Business: Commercial, Medicaid

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.

Health plan approved formularies should be reviewed for all coverage determinations. Requirements to use preferred alternative agents apply only when such requirements align with the health plan approved formulary.

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 moderate-to-severe PsO as evidenced by involvement of one of the following (a or b):
   a. ≥ 3% of total body surface area;
   b. Hands, feet, scalp, face, or genital area;
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;
   b. Member has intolerance or contraindication to MTX *(see Appendix D)*, and failure of a ≥ 3 consecutive month trial of cyclosporine or acitretin at up to maximally indicated doses, unless clinically significant adverse effects are experienced or both are contraindicated;
5. Failure of 2 of the following, each used for ≥ 3 consecutive months unless clinically significant adverse effects are experienced or all are contraindicated: adalimumab (*Humira® is preferred*), Cosentyx®, subcutaneous Stelara®, infliximab (*Remicade® is preferred*), Skyrizi®, Tremfya®;
   **Prior authorization may be required for adalimumab, Cosentyx, Stelara, infliximab, Skyrizi, and Tremfya*
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;

C. Combination use of biological disease-modifying antirheumatic drugs (bDMARDs), including any tumor necrosis factor (TNF) antagonists [Cimzia®, Enbrel®, Simponi®, Avsola™, Inflectra™, Remicade®, Renflexis™], interleukin agents [Arcalyst® (IL-1 blocker), Ilaris® (IL-1 blocker), Kineret® (IL-1RA), Actemra® (IL-6RA), Kevzara® (IL-6RA), Stelara® (IL-12/23 inhibitor), Cosentyx® (IL-17A inhibitor), Taltz® (IL-17A inhibitor), Siliq™ (IL-17RA), Ilumya™ (IL-23 inhibitor), Skyrizi™ (IL-23 inhibitor), Tremfya® (IL-23 inhibitor)], janus kinase inhibitors (JAKi) [Xeljanz®/Xeljanz® XR, Rinvoq™], anti-CD20 monoclonal antibodies [Rituxan®, Riabni™, Ruxience™, Truxima®, and Rituxan Hycela®], selective co-stimulation modulators [Orencia®], or integrin receptor antagonists [Entyvio®] because of the possibility of increased immunosuppression, neutropenia and increased risk of infection.

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

Drug Name	Dosing Regimen	Dose Limit/ Maximum Dose
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
Skyrizi® (risankizumab-rzaa)	**PsO** 150 mg (two 75 mg injections) SC at Week 0, Week 4 and every 12 weeks thereafter	150 mg every 12 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
Tremfya® (guselkumab)	**PsO** Initial dose: 100 mg SC at weeks 0 and 4 Maintenance dose: 100 mg SC every 8 weeks	100 mg every 8 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: Contraindications/Boxed Warnings
- Contraindication(s): patients with Crohn's disease
- Boxed warning(s): suicidal ideation and behavior

Appendix D: General Information
- 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; April 2020. Available at: http://www.siliq.com/. Accessed January 6, 2021.
2. Pariser DM, Bagel J, Gelfand JM, et al. National psoriasis foundation clinical consensus on disease severity. *Arch Dermatol*. 2007; 143: 239-242.

3. 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;58(5):826-50.
4. 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;* 2011; 65:137-74.
5. Hsu S, Papp KA, Lebwohl MG, et al. Consensus guidelines for the management of plaque psoriasis. *Arch Dermatol*. 2012; 148(1):95-102
6. Lebwohl M, Strober B, Menter A, et al. Phase 3 Studies Comparing Brodalumab with Ustekinumab in Psoriasis. *N Engl J Med*. 2015;373(14):1318-28. doi: 10.1056/NEJMoa1503824.
7. Farahnik B, Beroukhim K, Abrouk M et al. Brodalumab for the treatment of psoriasis: a review of phase II trials. *Dermatol Ther (Heidelb)*. 2016;6(2):111-24. doi: 10.1007/s13555-016-0121-x.
8. 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;175(2):273-86. doi: 10.1111/bjd.14493.
9. 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. doi:10.1016/j.aad.201811.057.

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
2Q 2018 annual review: no significant changes; modified trial and failure of preferred agents; references reviewed and updated.	02.27.18	05.18
4Q 2018 annual review: no significant changes; references reviewed and updated.	09.04.18	11.18
2Q 2019 annual review: no significant changes; references reviewed and updated.	02.26.19	05.19
2Q 2020 annual review: no significant changes; for PsO, added Tremfya as a preferred option for redirection per formulary status; references reviewed and updated.	02.28.20	05.20
2Q 2021 annual review: added additional criteria related to diagnosis of moderate-to-severe PsO per 2019 AAD/NPF guidelines specifying at least 3% BSA involvement or involvement of areas that severely impact daily function; added Skyrizi as a preferred option for PsO per formulary status; added combination of bDMARDs under Section III; references reviewed and updated.	02.23.21	05.21

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.