

Clinical Policy: Brodalumab (Siliq)

Reference Number: PA.CHIP.PHAR.375

Effective Date: 01/2026

Last Review Date: 10/2025

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 the member has met all approval criteria.

It is the policy of PA Health & Wellness® that Brodalumab (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. $\geq 3\%$ 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, b, or c):
 - 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 contraindicated or clinically significant adverse effects are experienced;
 - c. Member has intolerance or contraindication to MTX, cyclosporine, and acitretin, and failure of phototherapy, unless contraindicated or clinically significant adverse effects are experienced;
5. Member meets ONE of the following, unless clinically significant adverse effects are experienced or all are contraindicated (a or b, see Appendix D):
 - a. Failure of a ≥ 3 consecutive month trial of one adalimumab* product (e.g., *Hadlima™, Simlandi®, Yusimry™, adalimumab-aaty, adalimumab-adaz, adalimumab-adbm, and adalimumab-fkjp are preferred*);
 - b. History of failure of two TNF blockers;
**Prior authorization may be required for adalimumab products*
6. Failure of a ≥ 3 consecutive month trial of one ustekinumab product (e.g. *Otulsi®, Pyzchiva® (branded), Steqeyma®, Yesintek™ are preferred*), unless clinically significant adverse effects are experienced or all are contraindicated;
**Prior authorization may be required for ustekinumab products*
7. Member does not have combination use with biological disease-modifying antirheumatic

- drugs or Janus kinase inhibitors (*see Section III: Diagnoses/Indications for which coverage is NOT authorized*);
8. 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 (must meet 1 or 2):

1. If this drug has recently (within the last 6 months) undergone a label change (e.g., newly approved indication, age expansion, new dosing regimen) that is not yet reflected in this policy, refer to one of the following policies (a or b):
 - a. For drugs on the (Medicaid), the no coverage criteria policy for the relevant line of business: CP.PMN.255 for Medicaid; or
 - b. For drugs NOT on the PDL (Medicaid), the non-formulary policy for the relevant line of business: CP.PMN.16 for Medicaid; or
2. If the requested use (e.g., diagnosis, age, dosing regimen) is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized) AND criterion 1 above does not apply, refer to the off-label use policy for the relevant line of business: CP.PMN.53 for Medicaid.

II. . Continued Therapy

A. Plaque Psoriasis (must meet all):

1. Member meets one of the following (a or b):
 - a. Currently receiving medication via Fidelis benefit or member has previously met initial approval criteria;
 - b. Member is currently receiving medication and is enrolled in a state and product with continuity of care regulations (*refer to state specific addendums for CC.PHARM.03A and CC.PHARM.03B*);
2. Member is responding positively to therapy;
3. Member does not have combination use with biological disease-modifying antirheumatic drugs or Janus kinase inhibitors (*see Section III: Diagnoses/Indications for which coverage is NOT authorized*);
4. 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. If this drug has recently (within the last 6 months) undergone a label change (e.g., newly approved indication, age expansion, new dosing regimen) that is not yet reflected in this policy, refer to one of the following policies (a or b):
 - a. For drugs on the PDL (Medicaid), the no coverage criteria policy for the relevant line of business: CP.PMN.255 for Medicaid; or
 - b. For drugs NOT on the PDL (Medicaid), the non-formulary policy for the relevant line of business: CP.PMN.16 for Medicaid; or
2. If the requested use (e.g., diagnosis, age, dosing regimen) is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized) AND criterion 1 above does not apply, refer to the off-label use policy for the relevant line of business: CP.PMN.53 for Medicaid.

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 – CP.PMN.53 for Medicaid or evidence of coverage documents;
- B. Combination use with biological disease-modifying antirheumatic drugs (bDMARDs) or potent immunosuppressants, including but not limited to any tumor necrosis factor (TNF) antagonists [e.g., Cimzia®, Enbrel®, Humira® and its biosimilars, Remicade® and its biosimilars, Simponi®], interleukin agents [e.g., Actemra® (IL-6RA) and its biosimilars, Arcalyst® (IL-1 blocker), Bimzelx® (IL-17A and F antagonist), Cosentyx® (IL-17A inhibitor), Ilaris® (IL-1 blocker), Ilumya™ (IL-23 inhibitor), Kevzara® (IL-6RA), Kineret® (IL-1RA), Omvoh™ (IL-23 antagonist), Siliq™ (IL-17RA), Skyrizi™ (IL-23 inhibitor), Spevigo® (IL-36 antagonist), Stelara® (IL-12/23 inhibitor) and its biosimilars, Taltz® (IL-17A inhibitor), Tremfya® (IL-23 inhibitor)], Janus kinase inhibitors (JAKi) [e.g., Cibinquo™, Olumiant™, Rinvoq™, Xeljanz®/Xeljanz® XR,], anti-CD20 monoclonal antibodies [Rituxan® and its biosimilars], selective co-stimulation modulators [Orencia®], integrin receptor antagonists [Entyvio®], tyrosine kinase 2 inhibitors [Sotyktu™], and sphingosine 1-phosphate receptor modulator [Velsipity™] because of the additive immunosuppression, increased risk of neutropenia, as well as increased risk of serious infections;
- C. 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

JAKi: Janus kinase inhibitors

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 and may require prior authorization.

Drug Name	Dosing Regimen	Dose Limit/ Maximum Dose
acitretin (Soriatane®)	25 or 50 mg PO daily	50 mg/day
cyclosporine (Sandimmune®, Neoral®)	2.5 – 4 mg/kg/day PO divided BID	4 mg/kg/day
methotrexate (Trexall®, Otrexup™, Rasuvo®, RediTrex®, Xatmep™, Rheumatrex®)	10 – 25 mg/week PO, IM, or SC or 2.5 mg PO Q12 hr for 3 doses/week	30 mg/week
Hadlima (adalimumab- bwwd), Simlandi (adalimumab- ryvk), Yusimry (adalimumab- aqvh), adalimumab-aaty (Yuflyma®), adalimumab-adaz (Hyrimoz®), adalimumab-fkjp (Hulio®), adalimumab- adbm (Cyltezo®)	PsO <u>Initial dose:</u> 80 mg SC <u>Maintenance dose:</u> 40 mg SC every other week starting one week after initial dose	40 mg every other week
Otulfi® (ustekinumab- aauz), Pyzchiva® (ustekinumab- ttwe), Steqeyma® (ustekinumab- stba), Yesintek™ (ustekinumab- kfce)	PsO Weight based dosing SC at weeks 0 and 4, followed by maintenance dose every 12 weeks <i>Adult:</i> Weight ≤ 100 kg: 45 mg Weight > 100 kg: 90 mg <i>Pediatrics (age 6 years to 17 years):</i> Otulfi, Pyzchiva, Yesintek: Weight < 60 kg: 0.75 mg/kg Otulfi, Pyzchiva, Steqeyma, Yesintek: Weight 60 to 100 kg: 45 mg Weight > 100 kg: 90 mg	90 every 12 weeks

Drug Name	Dosing Regimen	Dose Limit/ Maximum Dose
Taltz® (ixekizumab)	PsO <u>Initial dose:</u> 160 mg (two 80 mg injections) SC at week 0, then 80 mg SC at weeks 2, 4, 6, 8, 10, and 12 <u>Maintenance dose:</u> 80 mg SC every 4 weeks	80 mg every 4 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):
 - Crohn's disease because Siliq may cause worsening of the disease
 - Clinically significant hypersensitivity to brodalumab or to any of the excipients in Siliq or component of the container. Hypersensitivity reactions, including anaphylaxis, have been reported with postmarket use of Siliq
- 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.
- TNF blockers:
 - Etanercept (Enbrel®), adalimumab (Humira®) and its biosimilars, infliximab (Remicade®) and its biosimilars (Avsola™, Renflexis™, Inflectra®), certolizumab pegol (Cimzia®), and golimumab (Simponi®, Simponi Aria®).

V. Dosage and Administration

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

- Siliq Prescribing Information. Bridgewater, NJ: Valeant Pharmaceuticals North

America LLC; August 2024. Available at:
<https://www.bauschhealth.com/Portals/25/Pdf/PI/Siliq- pi.pdf>. Accessed February 28, 2025.

2. 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.
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.

Coding Implications

Codes referenced in this clinical policy are for informational purposes only. Inclusion or exclusion of any codes does not guarantee coverage. Providers should reference the most up-to- date sources of professional coding guidance prior to the submission of claims for reimbursement of covered services.

HCPCS Codes	Description
J3590, C9399	Unclassified drugs or biologicals

Reviews, Revisions, and Approvals	Date
Policy created	10/2025