

## Clinical Policy: Brodalumab (Siliq)

Reference Number: IL.PHAR.375

Effective Date: 1.1.20

Last Review Date: 5.31.24

Line of Business: 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.*

It is the policy of health plans affiliated with Centene Corporation® 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.  $\geq 3\%$  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  $\geq 18$  years;
4. Member meets one of the following (a,b or c):
  - a. Failure of a  $\geq 3$  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 D*), failure of a  $\geq 3$  consecutive month trial of cyclosporine 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 failure of phototherapy, unless contraindicated or clinically significant adverse effects are experienced;
5. Failure of at least TWO of the following, each used for  $\geq 3$  consecutive months, unless contraindicated or clinically significant adverse effects are experienced: Enbrel®, Humira®, Cimzia®;

*\*Prior authorization is required for Enbrel, Humira, and Cimzia*

6. 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);
7. 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 formulary (commercial, health insurance marketplace) or 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 formulary (commercial, health insurance marketplace) or 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 Centene 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 formulary (commercial, health insurance marketplace) or 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 formulary (commercial, health insurance marketplace) or 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 and HIM-Medical Benefit 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<sup>®</sup>, Enbrel<sup>®</sup>, Humira<sup>®</sup> and its biosimilars, Remicade<sup>®</sup> and its biosimilars (Avsola<sup>™</sup>, Inflectra<sup>™</sup>, Renflexis<sup>™</sup>, Zymfentra<sup>®</sup>), Simponi<sup>®</sup>], interleukin agents [e.g., Actemra<sup>®</sup> (IL-6RA), Arcalyst<sup>®</sup> (IL-1 blocker), Bimzelx<sup>®</sup> (IL-17A and F antagonist), Cosentyx<sup>®</sup> (IL-17A inhibitor), Ilaris<sup>®</sup> (IL-1 blocker), Ilumya<sup>™</sup> (IL-23 inhibitor), Kevzara<sup>®</sup> (IL-6RA), Kineret<sup>®</sup> (IL-1RA), Omvoh<sup>™</sup> (IL-23 antagonist), Siliq<sup>™</sup> (IL-17RA), Skyrizi<sup>™</sup> (IL-23 inhibitor), Stelara<sup>®</sup> (IL-12/23 inhibitor), Taltz<sup>®</sup> (IL-17A inhibitor), Tofidence<sup>™</sup> (IL-6), Tremfya<sup>®</sup> (IL-23 inhibitor), Wezlana<sup>™</sup> (IL-12/23 inhibitor)], Janus kinase inhibitors (JAKi) [e.g., Cibinco<sup>™</sup>, Olumiant<sup>™</sup>, Rinvoq<sup>™</sup>, Xeljanz<sup>®</sup>/Xeljanz<sup>®</sup> XR,], anti-CD20 monoclonal antibodies [Rituxan<sup>®</sup> and its biosimilars (Riabni<sup>™</sup>, Ruxience<sup>™</sup>, Truxima<sup>®</sup>), Rituxan Hycela<sup>®</sup>], selective co-stimulation modulators [Orencia<sup>®</sup>], integrin receptor antagonists [Entyvio<sup>®</sup>], tyrosine kinase 2 inhibitors [Sotyktu<sup>™</sup>], and sphingosine 1-phosphate receptor modulator [Velsipity<sup>™</sup>] 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

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
cyclosporine (Sandimmune <sup>®</sup> , Neoral <sup>®</sup> )	2.5 – 4 mg/kg/day PO divided BID	4 mg/kg/day

Drug Name	Dosing Regimen	Dose Limit/ Maximum Dose
methotrexate (Trexall <sup>®</sup> , Otrexup <sup>™</sup> , Rasuvo <sup>®</sup> , RediTrex <sup>®</sup> , Xatmep <sup>™</sup> , Rheumatrex <sup>®</sup> )	10 – 25 mg/week PO, IM, or SC or 2.5 mg PO Q12 hr for 3 doses/week	30 mg/week
Humira <sup>®</sup> (adalimumab) Hadlima (adalimumab- bwwd), Yusimry (adalimumab- aqvh), adalimumab-adaz (Hyrimoz <sup>®</sup> ), adalimumab-fkjp (Hulio <sup>®</sup> ), adalimumab- adbm (Cyltezo <sup>®</sup> )	<b>PsO</b> <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
Enbrel <sup>®</sup> (etanercept)	<b>PsO</b> <u>Initial dose:</u> 50 mg SC twice weekly for 3 months  <u>Maintenance dose:</u> 50mg SC weekly	50 mg/week
Cimzia <sup>®</sup> (certolizumab)	<b>PsO</b> 400 mg SC every other week. For some patients (with body weight ≤ 90 kg), a dose of 400 mg SC at 0, 2 and 4 weeks, followed by 200 mg SC every other week may be considered.	400 mg every other week

*Therapeutic alternatives are listed as Brand name<sup>®</sup> (generic) when the drug is available by brand name only and generic (Brand name<sup>®</sup>) 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*

- 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.
- 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**

1. Siliq Prescribing Information. Bridgewater, NJ: Valeant Pharmaceuticals North America LLC; April 2020. Available at: <http://www.siliq.com/>. Accessed February 7, 2024 .
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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.
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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.
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Reviews, Revisions, and Approvals	Date	P&T Approval Date
New policy created, adapted CP.PHAR.375 Brodalumab (Siliq) policy.	12.11.19	1.7.20
2Q2021 annual review: added 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; Reviewed and updated references	6.18.21	
2Q 2022 annual review: for PsO, allowed phototherapy as alternative to systemic conventional DMARD if contraindicated or clinically 02.21.22 11.21 05.22 significant adverse effects are experienced; reiterated requirement against combination use with a bDMARD or JAKi from Section III to Sections I and II; references reviewed	7.25.22	
2Q 2023 annual review: no significant changes; updated Appendix B to include all relevant formulations of MTX; template changes applied to other diagnoses/indications and continued therapy section; references reviewed and updated.	4.15.23	
2Q 2024 annual review: added Bimzelx, Zymfentra, Omvoh, Wezlana, Sotyktu, Tofidence, and Velsipity to section III.B; Appendix B and D updated; references reviewed and updated.	5.31.24	

**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. The Health Plan makes no representations and accepts no liability with respect to the content of any external information used or relied upon in developing this clinical policy. This clinical policy is consistent with standards of medical practice current at the time that this clinical policy was approved. “Health Plan” means a health plan that has adopted this clinical policy and that is operated or administered, in whole or in part, by Centene Management Company, LLC, or any of such health plan’s affiliates, as applicable.

The purpose of this clinical policy is to provide a guide to medical necessity, which is a component of the guidelines used to assist in making coverage decisions and administering benefits. It does not constitute a contract or guarantee regarding payment or results. Coverage decisions and the administration of benefits are subject to all terms, conditions, exclusions and limitations of the coverage documents (e.g., evidence of coverage, certificate of coverage, policy, contract of insurance, etc.), as well as to state and federal requirements and applicable Health Plan-level administrative policies and procedures.

This clinical policy is effective as of the date determined by the Health Plan. The date of posting may not be the effective date of this clinical policy. This clinical policy may be subject to applicable legal and regulatory requirements relating to provider notification. If there is a discrepancy between the effective date of this clinical policy and any applicable legal or regulatory requirement, the requirements of law and regulation shall govern. The Health Plan retains the right to change, amend or withdraw this clinical policy, and additional clinical policies may be developed and adopted as needed, at any time.

This clinical policy does not constitute medical advice, medical treatment or medical care. It is not intended to dictate to providers how to practice medicine. 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. This clinical policy is not intended to recommend treatment for members. Members should consult with their treating physician in connection with diagnosis and treatment decisions.

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**Note: For Medicaid members**, when state Medicaid coverage provisions conflict with the coverage provisions in this clinical policy, state Medicaid coverage provisions take precedence. Please refer to the state Medicaid manual for any coverage provisions pertaining to this clinical policy.

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