

## Clinical Policy: Brodalumab (Siliq)

Reference Number: CP.PHAR.375

Effective Date: 06.01.18

Last Review Date: 05.24

Line of Business: Medicaid

[Coding Implications](#)

[Revision Log](#)

See [Important Reminder](#) at the end of this policy for important regulatory and legal information.

### Description

Brodalumab (Siliq<sup>™</sup>) 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<sup>®</sup> 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;
  - b. Member has intolerance or contraindication to MTX (*see Appendix D*), and failure of a  $\geq 3$  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 contraindicated or clinically significant adverse effects are experienced (a or b, *see Appendix D*):

- a. Failure of a  $\geq 3$  consecutive month trial of one adalimumab\* product (e.g. *Hadlima, Yusimry, 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  $\geq 3$  consecutive month trial of Taltz\*, unless contraindicated or clinically significant adverse effects are experienced;  
*\*Prior authorization may be required for Taltz*
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 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 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., Cibinqo<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

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.*

<b>Drug Name</b>	<b>Dosing Regimen</b>	<b>Dose Limit/ Maximum Dose</b>
acitretin (Soriatane <sup>®</sup> )	25 or 50 mg PO daily	50 mg/day
cyclosporine (Sandimmune <sup>®</sup> , Neoral <sup>®</sup> )	2.5 – 4 mg/kg/day PO divided BID	4 mg/kg/day
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
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
Taltz <sup>®</sup> (ixekizumab)	<b>PsO</b> <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<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<sup>®</sup>), adalimumab (Humira<sup>®</sup>) and its biosimilars, infliximab (Remicade<sup>®</sup>) and its biosimilars (Avsola<sup>™</sup>, Renflexis<sup>™</sup>, Inflectra<sup>®</sup>), certolizumab pegol (Cimzia<sup>®</sup>), and golimumab (Simponi<sup>®</sup>, Simponi Aria<sup>®</sup>).

**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: <https://www.bauschhealth.com/Portals/25/Pdf/PI/Siliq-pi.pdf>. Accessed February 7, 2024.
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

<b>Reviews, Revisions, and Approvals</b>	<b>Date</b>	<b>P&amp;T Approval Date</b>
2Q 2020 annual review: no significant changes; 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 combination of bDMARDs under Section III; references reviewed and updated.	02.23.21	05.21
Per August SDC and prior clinical guidance, removed redirection to Taltz ; added Legacy WellCare line of business to policy (WCG.CP.PHAR.375 to be retired); added coding implications section.	08.25.21	11.21
2Q 2022 annual review: for PsO, allowed phototherapy as alternative to systemic conventional DMARD if contraindicated or clinically significant adverse effects are experienced; removed legacy Wellcare approval durations; reiterated requirement against combination use with a bDMARD or JAKi from Section III to Sections I and II; references reviewed and updated.	02.21.22	05.22
Template changes applied to other diagnoses/indications and continued therapy section.	09.22.22	
2Q 2023 annual review: no significant changes; updated Appendix B to include all relevant formulations of MTX; references reviewed and updated.	02.10.23	05.23
2Q 2024 annual review: added Bimzelx, Zymfentra, Omvoh, Wezlana, Sotyktu, Tofidence, and Velsipity to section III.B; references reviewed and updated. Per March SDC, added criteria requiring use of Taltz and preferred adalimumab products (Hadlima, Yusimry, adalimumab-adaz, adalimumab-adbm, and adalimumab-fkjp); added therapeutic alternatives Taltz and adalimumab products to Appendix B; updated Appendix D with examples of TNF blockers.	03.12.24	05.24

**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.

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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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