Effective Date **2/1/2024**
Next Review Date… **2/1/2025**
Coverage Policy Number **IP0246**

Brodalumab

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Related Coverage Resources

INSTRUCTIONS FOR USE
The following Coverage Policy applies to health benefit plans administered by Cigna Companies. Certain Cigna Companies and/or lines of business only provide utilization review services to clients and do not make coverage determinations. References to standard benefit plan language and coverage determinations do not apply to those clients. Coverage Policies are intended to provide guidance in interpreting certain standard benefit plans administered by Cigna Companies. Please note, the terms of a customer's particular benefit plan document [Group Service Agreement, Evidence of Coverage, Certificate of Coverage, Summary Plan Description (SPD) or similar plan document] may differ significantly from the standard benefit plans upon which these Coverage Policies are based. For example, a customer's benefit plan document may contain a specific exclusion related to a topic addressed in a Coverage Policy. In the event of a conflict, a customer's benefit plan document always supersedes the information in the Coverage Policies. In the absence of a controlling federal or state coverage mandate, benefits are ultimately determined by the terms of the applicable benefit plan document. Coverage determinations in each specific instance require consideration of 1) the terms of the applicable benefit plan document in effect on the date of service; 2) any applicable laws/regulations; 3) any relevant collateral source materials including Coverage Policies and; 4) the specific facts of the particular situation. Coverage Policies relate exclusively to the administration of health benefit plans. Coverage Policies are not recommendations for treatment and should never be used as treatment guidelines. In certain markets, delegated vendor guidelines may be used to support medical necessity and other coverage determinations.

Overview

This policy supports medical necessity review for brodalumab (Siliq®).

Receipt of sample product does not satisfy any criteria requirements for coverage.

Medical Necessity Criteria

Brodalumab (Siliq) is considered medically necessary when the following are met:

1. **Plaque Psoriasis.** Individual meets **ALL** of the following criteria:
   A. 18 years of age or older
   B. Body Surface Area (BSA) of greater than 5% OR BSA less than 5% and there is involvement of the scalp, face, the palms and soles (i.e., palmoplantar disease), or genitals
   C. Documentation of **ONE** of the following:
      i. Failure to **ONE** of the following, unless contraindicated or intolerant to **ALL** of the following:

a. Topical therapy (for example, topical corticosteroids, topical vitamin D analogs, Tazorac)
b. Systemic therapy (for example, methotrexate, cyclosporine, Soriatane)
c. Phototherapy

ii. Already tried a biologic or targeted synthetic DMARD (tsDMARD) for Plaque Psoriasis

D. Medication is prescribed by, or in consultation with, a dermatologist
E. Non-Preferred Product Criteria is met, refer to the below table(s) [Employer Group Plans, Individual and Family Plans]

Coverage varies across plans and requires the use of preferred products. Refer to the customer's benefit plan document for coverage details.

Employer Group Plans	
Condition	**Non-Preferred Product Criteria**
Plaque Psoriasis - Adult	**Standard/Performance/Legacy Drug List Plans** Documentation of failure, contraindication or intolerance to **TWO** of the following: A. **Adalimumab Product** (**adalimumab-adaz/Hyrimoz** [manufactured by Sandoz/Novartis], **adalimumab – adbm/Cyltezo**, or **Humira**) [requires prior authorization] B. **Cimzia** [requires prior authorization] C. **Enbrel** [requires prior authorization] D. **Otezla** [requires prior authorization] E. **Skyrizi SC** [requires prior authorization] F. **Stelara SC** [requires prior authorization] G. **Taltz** [requires prior authorization] H. **Tremfya** [requires prior authorization] **Value/Advantage/Cigna Total Savings Drug List Plans** Documentation of failure, contraindication or intolerance to **TWO** of the following: A. **Adalimumab Product** (**adalimumab-adaz/Hyrimoz** [manufactured by Sandoz/Novartis], **adalimumab – adbm/ Cyltezo**, **Hadlima,** or **Humira**) [requires prior authorization] B. **Cimzia** [requires prior authorization] C. **Enbrel** [requires prior authorization] D. **Otezla** [requires prior authorization] E. **Skyrizi SC** [requires prior authorization] F. **Stelara SC** [requires prior authorization] G. **Taltz** [requires prior authorization] H. **Tremfya** [requires prior authorization]

Individual and Family Plan	
Condition	**Non-Preferred Product Criteria**
Plaque Psoriasis - Adults	Documentation of failure, contraindication or intolerance to **THREE** of the following: A. **Adalimumab Product** (**adalimumab-adaz/Hyrimoz** [manufactured by Sandoz/Novartis], **adalimumab – adbm/ Cyltezo**, **Hadlima,** or **Humira**) [requires prior authorization] B. **Cimzia** [requires prior authorization] C. **Cosentyx subcutaneous injection** [requires prior authorization]**Enbrel** [requires prior authorization] D. **Otezla** [requires prior authorization] E. **Skyrizi SC** [requires prior authorization]

Individual and Family Plan	
Condition	**Non-Preferred Product Criteria**
	F. **Stelara SC** [requires prior authorization] G. **Tremfya** [requires prior authorization]

When coverage is available and medically necessary, the dosage, frequency, duration of therapy, and site of care should be reasonable, clinically appropriate, and supported by evidence-based literature and adjusted based upon severity, alternative available treatments, and previous response to therapy.

Reauthorization Criteria

Continuation of brodalumab (Siliq) is considered medically necessary for **ALL** covered diagnoses when initial criteria are met AND beneficial response is demonstrated.

Authorization Duration

Initial approval duration: up to 12 months.
Reauthorization approval duration: up to 12 months.

Conditions Not Covered

Any other use is considered experimental, investigational or unproven including the following (this list may not be all inclusive):

1. **Concurrent Use with other Biologics or with Targeted Synthetic Disease-Modifying Antirheumatic Drugs (tsDMARDs).** Siliq should not be administered in combination with a biologic used for an inflammatory condition (see Appendix for examples). Combination therapy with other biologics and/or targeted synthetic DMARDs has a potential for a higher rate of adverse effects and lacks controlled trial data in support of additive efficacy.

   This does NOT exclude the use of conventional synthetic DMARDs (e.g., methotrexate, leflunomide, hydroxychloroquine, and sulfasalazine) in combination with Siliq.

2. **Crohn's Disease.** Siliq is contraindicated in patients with Crohn's disease.[1] There is a published Phase II study evaluating Siliq in Crohn's disease (n = 130) that was terminated early due to a disproportionate number of worsening Crohn's disease and lack of efficacy.[5]

3. **Rheumatoid Arthritis.** Efficacy has not been established. A published Phase II study (n = 252) did not demonstrate improvement in American College of Rheumatology 20/50/70 responses with Siliq vs. placebo for treatment of rheumatoid arthritis in patients who had previously failed methotrexate.[6]

Background

OVERVIEW
Siliq, an interleukin (IL)-17A antagonist, is indicated for treatment of adults with moderate-to-severe **plaque psoriasis** who are candidates for systemic therapy or phototherapy and have failed to respond or have lost response to other systemic therapies.[1] In the pivotal trial, patients were assessed for a response at Week 12.

Guidelines
Joint guidelines from the American Academy of Dermatology (AAD) and National Psoriasis Medical Board (2019) have been published for management of psoriasis with biologics.[2] These guidelines list Siliq as a monotherapy treatment option for patients with moderate to severe plaque psoriasis. Guidelines from the European Dermatology Forum (EDF) [2015] recommend biologics (i.e., etanercept, adalimumab, infliximab, ustekinumab)

as second-line therapy for induction and long-term treatment if phototherapy and conventional systemic agents have failed, are contraindicated, or are not tolerated.[3]

Safety
Siliq has a Boxed Warning, Risk Evaluation and Mitigation Strategy (REMS) program, and limited distribution program due to risks of suicidal ideation and behavior. The REMS program requires prescribers and pharmacies to be certified to prescribe and/or dispense Siliq.[4] Patients must sign a patient-prescriber agreement form and be aware of the need to seek medical attention for any new/worsening suicidal thoughts or behavior, depression, anxiety, or mood changes.

References

1. Siliq® injection [prescribing information]. Bridgewater, NJ: Valeant Pharmaceuticals; February 2017.
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(4):1029-1072.
3. Nast A, Gisondi P, Ormerod AD, et al. European S3-Guidelines on the systemic treatment of psoriasis vulgaris – Update 2015 – Short version – EDF in cooperation with EADV and IPC. *J Eur Acad Dermatol Venereol*. 2015;29(12):2277-2294.
4. US Food and Drug Administration, US Department of Health and Human Services [Web site]. Approved Risk Evaluation and Mitigation Strategies (REMS) (fda.gov). Search term: Siliq. Updated January 22, 2021. Accessed on May 2, 2022.
5. Targan SR, Feagan B, Vermeire S, et al. A randomized, double-blind, placebo-controlled Phase 2 study of brodalumab in patients with moderate-to-severe Crohn's disease. *Am J Gastroenterol*. 2016;111(11):1599-1607.
6. Pavelka K, Chon Y, Newmark R, et al. A study to evaluate the safety, tolerability, and efficacy of brodalumab in subjects with rheumatoid arthritis and an inadequate response to methotrexate. *J Rheumatol*. 2015;42(6):912-919.

APPENDIX

Table 1. Approved TNFis for Targeted Indications.

	Rheumatology					Dermatology	Gastroenterology	
	RA	**JIA**	**AS**	**nr-axSpA**	**PsA**	**PsO**	**CD**	**UC**
Tumor Necrosis Factor Inhibitors								
Cimzia	√	--	√	√	√	√	√	--
Enbrel	√	√	√	--	√	√	--	--
Adalimumab products (Humira, biosimilars)	√	√	√	--	√	√	√	√
Infliximab Products	√	--	√	--	√	√	√	√
Simponi Subcutaneous	√	--	√	--	√	--	--	√
Simponi Aria	√	√	√	--	√	--	--	--

TNFis – Tumor necrosis factor inhibitors; RA – Rheumatoid arthritis; JIA – Juvenile idiopathic arthritis; AS – Ankylosing spondylitis; nr-axSpA – Non-radiographic spondyloarthritis; PsA – Psoriatic arthritis; PsO – Plaque psoriasis; CD – Crohn's disease; UC – Ulcerative colitis.

Table 2. Approved IL-17, IL-23, and IL-12/23 Blockers for Targeted Indications.

	Rheumatology			Dermatology	Gastroenterology	
	Ankylosing Spondylitis	**nr-axSpA**	**Psoriatic Arthritis**	**Plaque Psoriasis**	**Crohn's Disease**	**Ulcerative Colitis**
Interleukin-17 Blockers						
Cosentyx	√	√	√	√	--	--
Siliq	--	--	--	√	--	--
Taltz	√	√	√	√	--	--

Interleukin-23 Blockers						
Ilumya	--	--	--	√	√	--
Skyrizi Intravenous	--	--	--	--	√#	--
Skyrizi Subcutaneous	--	--	√	√	√^	--
Tremfya	--	--	√	√	--	--
Interleukin-12/23 Blockers						
Stelara Subcutaneous	--	--	√	√	√^	√^
Stelara Intravenous	--	--	--	--	√#	√#

IL – Interleukin; nr-axSpA – Non-radiographic spondyloarthritis; ^ Maintenance dosing only; # Induction dosing only

Table 3. Approved Oral tsDMARDs for Targeted Indications.

	Rheumatology					Dermatology	Gastro-enterology
	Rheumatoid Arthritis	**Juvenile Idiopathic Arthritis**	**Ankylosing Spondylitis**	**nr-axSpA**	**Psoriatic Arthritis**	**Plaque Psoriasis**	**Ulcerative Colitis**
Janus Kinases Inhibitors							
Olumiant	√	--	--	--	--	--	--
Rinvoq	√	--	√	√	√	--	√
Xeljanz tablets	√	√#	√	--	√	--	√
Xeljanz oral solution	--	√#	--	--	--	--	--
Xeljanz XR	√	--	√	--	√	--	√
Phosphodiesterase Type 4 Inhibitor							
Otezla	--	--	--	--	√	√	--
Sphingosine 1-Phosphate Receptor Modulator							
Zeposia	--	--	--	--	--	--	√
Tyrosine Kinase 2 Inhibitor							
Sotyktu	--	--	--	--	--	√	--

tsDMARDs – Targeted synthetic disease-modifying antirheumatic drugs; # Indicated in polyarticular JIA.

Table 4. Other Approved Biologics for Targeted Indications.

	Rheumatology		
	Rheumatoid Arthritis	**Juvenile Idiopathic Arthritis**	**Psoriatic Arthritis**
Interleukin-6 Blockers			
Actemra Intravenous	√	√^	--
Actemra Subcutaneous	√	√^	--
Kevzara	√	--	--
Interleukin-1 Blocker			
Kineret	√	--	--
T-Cell Costimulation Modulator			
Orencia Intravenous	√	√#	√
Orencia Subcutaneous	√	√#	√
CD20-Directed Cytolytic Antibody			
Rituximab Intravenous Products	√	--	--

^ Indicated in polyarticular and systemic JIA; # Indicated in polyarticular JIA.

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