MEDICAL MUTUAL®

Drug Policy

Policy:	**201713**	**Initial Effective Date: 04/20/2017**
Code(s):	**HCPCS J3590**	**Annual Review Date: 08/15/2024**
SUBJECT:	**Siliq ® (brodalumab)**	**Last Revised Date: 08/15/2024**

Prior approval is required for some or all procedure codes listed in this Corporate Drug Policy.

OVERVIEW

Siliq a human monoclonal immunoglobulin G (IgG)2 antibody which selectively binds to interleukin (IL)-17RA and inhibits its interaction with cytokines IL-17A, IL-17-F, IL-17C, IL-17A/F heterodimer, and IL-25. Blocking IL-17RA inhibits IL-17 cytokine-induced responses, including the release of pro-inflammatory cytokines and chemokines. Siliq 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. In plaque psoriasis, the recommended dose is 210 mg subcutaneously (SC) at Week 0, 1, and 2 followed by 210 mg once every 2 weeks (Q2W). Consider discontinuing if an adequate response has not been achieved after 12 to 16 weeks; continued treatment is unlikely to result in greater success. Siliq is intended for use under the guidance and supervision of a physician. Those trained in SC injection technique may self-inject when deemed appropriate.

Warnings and Precautions

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.[2] 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. Siliq is also contraindicated in Crohn's disease.[1] Other Warnings/Precautions include infections, risk for latent tuberculosis reactivation, and vaccinations.

POLICY STATEMENT

This policy involves the use of Siliq. Prior authorization is recommended for medical benefit coverage of Siliq. Approval is recommended for those who meet the conditions of coverage in the **Criteria, Dosing, Initial/Extended Approval, Duration of Therapy**, and **Labs/Diagnostics** for the diagnosis provided. **Waste Management** applies for all covered conditions that are administered by a healthcare professional. **Conditions Not Recommended for Approval** are listed following the recommended authorization criteria and Waste Management section. Requests for uses not listed in this policy will be reviewed for evidence of efficacy and for medical necessity on a case-by-case basis.

Because of the specialized skills required for evaluation and diagnosis of patients treated with Siliq as well as the monitoring required for AEs and long-term efficacy, initial approval requires Siliq be prescribed by or in consultation with a physician

who specializes in the condition being treated. All approvals for initial therapy are provided for the initial approval duration noted below; if reauthorization is allowed, a response to therapy is required for continuation of therapy unless otherwise noted below. **Siliq is subject to the Inflammatory Conditions Care Value Program under pharmacy benefits.**

RECOMMENDED AUTHORIZATION CRITERIA
Coverage of Siliq is recommended in those who meet the following criteria:

1. **Plaque Psoriasis.** Approve for the duration noted if the patient meets ONE of the following (A or B):
   - **A)** Initial Therapy. Approve if the patient meets ALL the following criteria (i, ii, and iii):
     - **i.** Patient is ≥ 18 years of age; AND
     - **ii.** Patient meets ONE of the following conditions (a or b):
       - **a)** Patient has tried at least at least one traditional systemic agent for psoriasis for at least 3 months, unless intolerant; OR
         Note: Examples include methotrexate, cyclosporine, or acitretin. A 3-month trial of psoralen plus ultraviolet A light (PUVA) also counts. An exception to the requirement for a trial of one traditional systemic agent for psoriasis can be made if the patient has already had a 3-month trial or previous intolerance to at least one biologic other than the requested drug. A biosimilar of the requested biologic does not count. Refer to Appendix for examples of biologics used for plaque psoriasis. A patient who has already tried a biologic for psoriasis is not required to "step back" and try a traditional systemic agent for psoriasis.
       - **b)** Patient has a contraindication to methotrexate, as determined by the prescriber; AND
     - **iii.** The medication is prescribed by or in consultation with a dermatologist.
   - **B)** Patient is Currently Receiving Siliq. Approve for 1 year if the patient meets ALL the following (i, ii, and iii):
     - **i.** Patient has been established on therapy for at least 90 days; AND
       Note: A patient who has received < 90 days of therapy or who is restarting therapy is reviewed under criterion A (Initial Therapy).
     - **ii.** Patient experienced a beneficial clinical response, defined as improvement from baseline (prior to initiating Siliq) in at least one of the following: estimated body surface area, erythema, induration/thickness, and/or scale of areas affected by psoriasis; AND
     - **iii.** Compared with baseline (prior to receiving Siliq), patient experienced an improvement in at least one symptom, such as decreased pain, itching, and/or burning.

Dosing: Administer 210 mg of Siliq by subcutaneous injection at Weeks 0, 1, and 2 followed by 210 mg every 2 weeks.

Duration of Therapy is indefinite or until toxicity occurs.

Labs/Diagnostics. Evaluate patients for TB infection prior to initiating treatment with SILIQ.

Initial Approval/ Extended Approval.
A) *Initial Approval:* 3 months (90 days)
B) *Extended Approval:* 1 year (365 days)

Waste Management for All Indications.

Injection: 210 mg/1.5 mL solution in a single-dose prefilled syringe.

CONDITIONS NOT RECOMMENDED FOR APPROVAL

Siliq has not been shown to be effective, or there are limited or preliminary data or potential safety concerns that are not supportive of general approval for the following conditions. Rationale for non-coverage for these specific conditions is provided below. (Note: This is not an exhaustive list of Conditions Not Recommended for Approval.)

1. **Concurrent Use with other Biologics or with Targeted Synthetic Disease-Modifying Antirheumatic Drugs (DMARDs).** Siliq should not be administered in combination with another biologic or with a targeted synthetic DMARD used for an inflammatory condition (see APPENDIX for examples). Combination therapy is generally not recommended due to a potential for a higher rate of adverse effects with combinations and lack of evidence for additive efficacy.[6-7] Note: This does NOT exclude the use of conventional synthetic DMARDs (e.g., MTX, leflunomide, hydroxychloroquine, and sulfasalazine) in combination with Actemra IV.

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.[8]

3. **Rheumatoid Arthritis.** Efficacy has not been established. A published Phase II study (n = 252) did not demonstrate improvement in American College of Rheumatology (ACR) 20/50/70 responses with Siliq vs. placebo for treatment of rheumatoid arthritis in patients who had previously failed methotrexate.[9]

4. Coverage is not recommended for circumstances not listed in the Recommended Authorization Criteria. Criteria will be updated as new published data are available.

***MMO Site of Care Medical Necessity Criteria:**

- Medications in this policy will be administered in a place of service that identifies the location to be a non-hospital facility based location (i.e., home infusion provider, provider's office, free-standing ambulatory infusion center) unless *at least one* of the following are met[†]:

    1. Age less than 18 years; or
    2. Clinically unstable based upon documented medical history (e.g., patient is hemodynamically unstable); or

3. History of a severe adverse event from previous administration of the prescribed medication; or
4. Requested medication is being administered as follows:
   - part of a chemotherapy regimen (e.g., anti-neoplastic agent, colony stimulating factor, erythropoiesis-stimulating agent, anti-emetic) for treatment of cancer; or
   - administered with dialysis; or
5. Physical or cognitive impairment and caregiver is not available to assist with safe administration of prescribed medication in the home; or
6. Experiencing adverse events that are not managed by premedication or resources available at a non-hospital facility based location.

No initial doses are allowed in a hospital based outpatient facility without other above criteria being met.
* Effective 01/01/2019, age criterion applies to 18 years of older. Age at original effective date (03/01/2016) was 21 years or older.

†This criterion does not apply to Medicare or Medicare Advantage members.

Documentation Requirements:

The Company reserves the right to request additional documentation as part of its coverage determination process. The Company may deny reimbursement when it has determined that the drug provided or services performed were not medically necessary, investigational or experimental, not within the scope of benefits afforded to the member and/or a pattern of billing or other practice has been found to be either inappropriate or excessive. Additional documentation supporting medical necessity for the services provided must be made available upon request to the Company. Documentation requested may include patient records, test results and/or credentials of the provider ordering or performing a service. The Company also reserves the right to modify, revise, change, apply and interpret this policy at its sole discretion, and the exercise of this discretion shall be final and binding.

Prior approval is required for HCPCS Codes J3590

†When *unclassified biologics* (J3590) is determined to be Siliq.

REFERENCES

1. Siliq® injection [prescribing information]. Bridgewater, NJ: Valeant Pharmaceuticals; February 2017.
2. 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):273-286.
3. Lebwohl M, Strober B, Menter A, Gordon K, et al. Phase 3 Studies comparing brodalumab with ustekinumab in psoriasis. *N Engl J Med*. 2015:373(14):1318-1328.
4. Hsu S, Papp KA, Lebwohl MG, et al. Consensus guidelines for the management of plaque psoriasis. *Arch Dermatol*. 2012;148(1):95-102.
5. Furst DE, Keystone EC, So AK, et al. Updated consensus statement on biological agents for the treatment of rheumatic diseases, 2012. *Ann Rheum Dis*. 2013;72 Suppl 2:ii2-34.
6. Xeljanz® tablets [prescribing information]. New York, NY: Pfizer Inc; May 2014.
7. 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.
8. Pavelka K, Chon Y, Newmark R, et al. A study to evaluate the safety, tolerability, and efficacy of brodalumab in subjects

9. Brodalumab. In: DRUGDEX (online database). Truven Health Analytics: Greenwood Village, CO. Last updated 19 Feb. 2018. Accessed on 10 May 2018.

Appendix A

Biologic or Targeted Synthetic DMARD	Mechanism of Action	Indications
Cimzia® (certolizumab pegol for SC injection)	Inhibition of TNF	AS, ASpA ,CD, PPs, PsA, RA
Enbrel® (etanercept for SC injection)	Inhibition of TNF	AS, PPs, PsA, RA
Erelzi™ (etanercept-szzs for SC injection)	Inhibition of TNF	AS, PPs, PsA, RA
Humira® (adalimumab for SC injection)	Inhibition of TNF	AS, CD, HS, PPs, RA, UC, UV
Amjevita™ (adalimumab-atto for SC injection)	Inhibition of TNF	AS, CD, PPs, RA, UC
Cyltezo® (adalimumab-adbm for SC injection)	Inhibition of TNF	AS, CD, PPs, RA, UC
Simponi® (golimumab for SC injection)	Inhibition of TNF	AS, PsA, RA, UC
Simponi® Aria™ (golimumab for IV infusion)	Inhibition of TNF	AS, PsA, RA, UC
Remicade® (infliximab for IV infusion)	Inhibition of TNF	AS, CD, PPs, PsA, RA, UC
Inflectra™ (infliximab-dyyb for IV infusion)	Inhibition of TNF	AS, CD, PPs, PsA, RA, UC
Renflexis® (infliximab-abda for IV infusion)	Inhibition of TNF	AS, CD, PPs, PsA, RA, UC
Actemra® (tocilizumab for IV infusion)	Inhibition of IL-6	CRS, GCA, RA
Actemra® (tocilizumab for SC injection)	Inhibition of IL-6	CRS, GCA, RA
Kevzara® (sarilumab for SC injection)	Inhibition of IL-6	RA
Orencia® (abatacept for IV infusion)	T-cell costimulation modulator	PsA, RA
Orencia® (abatacept for SC injection)	T-cell costimulation modulator	PsA, RA
Rituxan® (rituximab for IV infusion)	CD20-directed cytolytic antibody	Various
Kineret® (anakinra for subcutaneous SC injection)	Inhibition of IL-1	NOMID, RA
Stelara® (ustekinumab for SC injection)	Inhibition of IL-12/23	CD, PPs, PsA, UC
Stelara® (ustekinumab for IV infusion)	Inhibition of IL-12/23	CD, PPs, PsA, UC
Siliq™ (brodalumab SC injection)	Inhibition of IL-17	PPs
Cosentyx™ (secukinumab for SC injection)	Inhibition of IL-17A	AS, PPs, PsA
Taltz® (ixekizumab for SC injection)	Inhibition of IL-17A	AS, PPs, PsA
Ilumya™ (tildrakizumab-asmn for SC injection)	Inhibition of IL-23	PPs
Tremfya® (guselkumab for SC injection)	Inhibition of IL-23	PPs
Otezla® (apremilast tablets)	Inhibition of PDE4	BD, PPs, PsA
Olumiant® (baricitinib tablets)	Inhibition of the JAK pathways	RA
Xeljanz®, Xeljanz XR (tofacitinib tablets, tofacitinib ER tabs)	Inhibition of the JAK pathways	PsA, RA, UC

Agents and associated indications are for reference only.
"The Company also reserves the right to modify, revise, change, apply and interpret this policy at its sole discretion, and the exercise of this discretion shall be final and binding."
AS = Ankylosing Spondylitis, ASpA = Axial Spondyloarthritis, BD = Behcet Disease, CD = Crohn's Disease, CRS = Cytokine Release Syndrome, GCA = Giant Cell Arteritis, GVHD = Graft-Versus-Host Disease, HS = Hidradenitis Suppurativa, NOMID = Neonatal-onset Multisystem Inflammatory Disease, PPs = Plaque Psoriasis, PsA = Psoriatic Arthritis, RA = Rheumatoid Arthritis, SpA = Spondyloarthritis, UC = Ulcerative Colitis, UV = Uveitis
SC – Subcutaneous; TNF – Tumor necrosis factor; IL – Interleukin; IV – Intravenous; PDE4 – Phosphodiesterase 4; JAK – Janus kinase.

Edits and Denials:

Prior approval: Prior approval is required for Siliq **(HCPCS Codes J3590)**. Requests for prior approval will be authorized by a nurse reviewer if submitted documentation meets criteria outlined within the Corporate Medical Policy.

Requests for prior approval will be forwarded to a qualified physician reviewer if submitted documentation does not meet criteria outlined within Corporate Medical Policy.

TOPPS: Claims received with **HCPCS Codes J3590** will pend with **Remark Code M3M or M4M** and will be adjudicated in accordance with the Corporate Medical Policy.

Liability: A participating provider will be required to write off charges denied as not medically necessary.

HCPCS Code(s):	
J3590	Unclassified biologics