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 Policy Number: C17334-A

Siliq (brodalumab)

PRODUCTS AFFECTED

Siliq (brodalumab)

COVERAGE POLICY

Coverage for services, procedures, medical devices and drugs are dependent upon benefit eligibility as outlined in the member's specific benefit plan. This Coverage Guideline must be read in its entirety to determine coverage eligibility, if any. This Coverage Guideline provides information related to coverage determinations only and does not imply that a service or treatment is clinically appropriate or inappropriate. The provider and the member are responsible for all decisions regarding the appropriateness of care. Providers should provide Molina Healthcare complete medical rationale when requesting any exceptions to these guidelines.

Documentation Requirements:

Molina Healthcare reserves the right to require that additional documentation be made available as part of its coverage determination; quality improvement; and fraud; waste and abuse prevention processes. Documentation required may include, but is not limited to, patient records, test results and credentials of the provider ordering or performing a drug or service. Molina Healthcare may deny reimbursement or take additional appropriate action if the documentation provided does not support the initial determination that the drugs or services were medically necessary, not investigational or experimental, and otherwise within the scope of benefits afforded to the member, and/or the documentation demonstrates a pattern of billing or other practice that is inappropriate or excessive.

DIAGNOSIS:

Moderate to severe plaque psoriasis.

REQUIRED MEDICAL INFORMATION:

This clinical policy is consistent with standards of medical practice current at the time that this clinical policy was approved. If a drug within this policy receives an updated FDA label within the last 180 days, medical necessity for the member will be reviewed using the updated FDA label information along with state and federal requirements, benefit being administered and formulary preferencing. Coverage will be determined on a case-by-case basis until the criteria can be updated through Molina Healthcare, Inc. clinical governance. Additional information may be required on a case-by-case basis to allow for adequate review. When the requested drug product for coverage is dosed by weight, body surface area or other member specific measurement, this data element is required as part of the medical necessity review. The Pharmacy and Therapeutics Committee has determined that the drug benefit shall be a mandatory generic and that generic drugs will be dispensed whenever available.

FOR ALL INDICATIONS:

1. (a) Prescriber attests, or clinical reviewer has found, member has had a negative TB screening* or TB test (if indicated)** result within the last 12 months for initial and continuation of therapy requests
 *MOLINA REVIEWER NOTE: TB SCREENING assesses patient for future or ongoing TB exposure or

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risk and includes reviewing if they have been exposed to tuberculosis, if they have resided or traveled to areas of endemic tuberculosis, if patient resides or works in a congregate setting (e.g., correctional facilities, long-term care facilities, homeless shelters), etc.

****MOLINA REVIEWER NOTE: TB SKIN TEST (TST, PPD) AND TB BLOOD TEST (QuantiFERON TB Gold, T-Spot) are not required or recommended in those without risk factors for tuberculosis**

OR

(b) For members who have a positive test for latent TB, provider documents member has completed a treatment course (a negative chest x-ray is also required every 12 months) OR that member has been cleared by an infectious disease specialist to begin treatment

AND

2. Member is not on concurrent treatment or will not be used in combination with TNF- inhibitor, biologic response modifier or other biologic DMARDs, Janus kinase Inhibitors, or Phosphodiesterase 4 inhibitor (i.e., apremilast, tofacitinib, baricitinib) as verified by prescriber attestation, member medication fill history, or submitted documentation
AND
3. Prescriber attests member does not have an active infection, including clinically important localized infections
AND
4. Prescriber attests to (or the clinical reviewer has found that) the member not having any FDA labeled contraindications that haven't been addressed by the prescriber within the documentation submitted for review [Contraindications to SILIQ (brodalumab) include: Crohn's disease, concurrent use of live vaccines]
AND
5. IF THIS IS A NON-FORMULARY/NON-PREFERRED PRODUCT: Documentation of trial/failure of or serious side effects to a majority (not more than 3) of the preferred formulary/PDL alternatives for the given diagnosis. Submit documentation including medication(s) tried, dates of trial(s) and reason for treatment failure(s).

A. CHRONIC PLAQUE PSORIASIS:

1. Documented diagnosis of moderate to severe psoriasis (BSA \geq 3%) OR $<$ 3% body surface area with plaque psoriasis that involves sensitive areas of the body or areas that would significantly impact daily function (e.g., face, neck, hands, feet, genitals)
AND
2. (a) Documentation of treatment failure, serious side effects, or a clinical contraindication to TWO of the following systemic therapies for \geq 3 months: Methotrexate (oral or IM at a minimum dose of 15 mg/week), cyclosporine, acitretin, azathioprine, hydroxyurea, leflunomide, mycophenolate mofetil, or tacrolimus
OR
(b) Documentation of treatment failure to Phototherapy for \geq 3 months with either psoralens with ultraviolet A (PUVA) or ultraviolet B (UVB) radiation (provider to submit documentation of duration of treatment, dates of treatment, and number of sessions; contraindications include type 1 or type 2 skin, history of photosensitivity, treatment of facial lesions, presence of premalignant lesions, history of melanoma or squamous cell carcinoma, or physical inability to stand for the required exposure time)
AND
3. Documentation of prescriber baseline disease activity evaluation and goals for treatment to be used to evaluate efficacy of therapy at renewal [DOCUMENTATION REQUIRED]
AND
4. Prescriber attests the member will be evaluated for adequate treatment response after 12-16 weeks per the FDA label for potential treatment discontinuation
NOTE: Continued treatment beyond 16 weeks in patients who have not achieved an adequate response is not likely to result in greater success.

CONTINUATION OF THERAPY:

A. CHRONIC PLAQUE PSORIASIS:

1. Adherence to therapy at least 85% of the time as verified by the prescriber or member's medication fill history OR adherence less than 85% of the time due to the need for surgery or treatment of an

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infection, causing temporary discontinuation

AND

2. Prescriber attests to or clinical reviewer has found no evidence of intolerable adverse effects or drug toxicity, including new or worsening psychiatric symptoms
AND
3. Documentation of positive clinical response as demonstrated by low disease activity and/or improvements in the condition's signs and symptoms. [DOCUMENTATION REQUIRED]
AND
4. (a) Prescriber attests, or clinical reviewer has found, member has had a negative TB screening* or TB test (if indicated)** result within the last 12 months for initial and continuation of therapy requests
*MOLINA REVIEWER NOTE: TB SCREENING assesses patient for future or ongoing TB exposure or risk and includes reviewing if they have been exposed to tuberculosis, if they have resided or traveled to areas of endemic tuberculosis, if patient resides or works in a congregate setting (e.g., correctional facilities, long-term care facilities, homeless shelters), etc.
**MOLINA REVIEWER NOTE: TB SKIN TEST (TST, PPD) AND TB BLOOD TEST (Quantiferon TB Gold, T-Spot) are not required or recommended in those without risk factors for tuberculosis
OR
(b) For members who have a positive test for latent TB, provider documents member has completed a treatment course (a negative chest x-ray is also required every 12 months) OR that member has been cleared by an infectious disease specialist to begin treatment

DURATION OF APPROVAL:

Initial authorization: 6 months, Continuation of therapy: 12 months

PRESCRIBER REQUIREMENTS:

Prescribed by or in consultation with a board-certified dermatologist [If prescribed in consultation, consultation notes must be submitted with initial request and reauthorization requests]

AGE RESTRICTIONS:

18 years of age and older

QUANTITY:

210 mg by subcutaneous injection at Weeks 0,1, and 2 followed by 210mg every 2 weeks

PLACE OF ADMINISTRATION:

The recommendation is that injectable medications in this policy will be for pharmacy benefit coverage and patient self-administered.

DRUG INFORMATION

ROUTE OF ADMINISTRATION:

Subcutaneous injection

DRUG CLASS:

Antipsoriatics - Systemic

FDA-APPROVED USES:

Indicated for the treatment of moderate to severe plaque psoriasis in adult patients who are candidates for systemic therapy or phototherapy and have failed to respond or have lost response to other systemic therapies.

COMPENDIAL APPROVED OFF-LABELED USES:

None

APPENDIX

APPENDIX:

None

BACKGROUND AND OTHER CONSIDERATIONS

BACKGROUND:

Siliq is 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 proinflammatory 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.

REMS Program

SILIQ is available only through a restricted program under a REMS called the SILIQ REMS Program because of the observed suicidal ideation and behavior in subjects treated with SILIQ.

Notable requirements of the SILIQ REMS Program include the following:

- Prescribers must be certified with the program.
- Patients must sign a Patient-Prescriber Agreement Form.
- Pharmacies must be certified with the program and must only dispense to patients who are authorized to receive SILIQ.

Further information, including a list of qualified pharmacies, is available at www.SILIQREMS.com or by calling the SILIQ REMS Program Call Center at 855-511-6135.

Continuation of REMS

“The Hospital Anxiety and Depression Scale (HADS) is a 14-item questionnaire to assess patients on seven items reflecting anxiety and seven reflecting depression. A scaled score is given and HADS severity groups are categorized as normal, mild, moderate, and severe.”² Clinical assessment of these scores, as well as other relevant information deemed appropriate by REMS certified physician or psychiatrist, should be interpreted to determine if Member is eligible to continue with treatment.

CONTRAINDICATIONS/EXCLUSIONS/DISCONTINUATION:

All other uses of Siliq (brodalumab) are considered experimental/investigational and therefore, will follow Molina’s Off- Label policy. Contraindications to Siliq (brodalumab) include: Crohn’s disease, concurrent use of live vaccines.

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.

- (a) *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. 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.

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- (b) *Crohn's Disease*. Siliq is contraindicated in patients with Crohn's disease. 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.
- (c) *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

OTHER SPECIAL CONSIDERATIONS:

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. 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.

CODING/BILLING INFORMATION

Note: 1) This list of codes may not be all-inclusive. 2) Deleted codes and codes which are not effective at the time the service is rendered may not be eligible for reimbursement

HCPCS CODE	DESCRIPTION
N/A	

AVAILABLE DOSAGE FORMS:

Siliq SOSY 210MG/1.5ML

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SUMMARY OF REVIEW/REVISIONS	DATE
REVISION- Notable revisions: Required Medical Information Continuation of Therapy Prescriber Requirements Drug Class Appendix Background Available Dosage Forms	Q4 2023
REVISION- Notable revisions: Required Medical Information Continuation of Therapy Prescriber Requirements Age Restrictions Appendix Contraindications/Exclusions/Discontinuation Other Special Considerations References	Q4 2022
Q2 2022 Established tracking in new format	Historical changes on file