Original Effective Date: 04/04/2025
Current Effective Date: 09/10/2025
Last P&T Approval/Version: 07/30/2025
Next Review Due By: 04/2026
Policy Number: C29044-A

Ebglyss (lebrikizumab)

PRODUCTS AFFECTED

Ebglyss (lebrikizumab-lbkz)

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 Atopic Dermatitis

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.

A. MODERATE-TO-SEVERE ATOPIC DERMATITIS:
   1. Documented diagnosis of moderate to severe chronic atopic dermatitis (eczema)
      AND
   2. Member is not on concurrent treatment with, or Ebglyss 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. Documentation of ONE of the following:
   i. Member has atopic dermatitis involvement estimated to be ≥10% of the body surface area (BSA) according to the prescribing physician
   ii. Member has atopic dermatitis involvement estimated to be < 10% of the BSA affecting face, eyes/eyelids, skin folds, and/or genitalia according to the prescribing physician

   AND
4. Documentation of inadequate response, serious side effects, or contraindication to TWO of the following: topical corticosteroids or preferred/formulary topical calcineurin inhibitor (tacrolimus, pimecrolimus)
   AND
5. Documentation of inadequate response, serious side effects, or contraindication to ONE of the following: Eucrisa (crisaborole), Opzelura (ruxolitinib), Vtama (tapinarof), or Zoryve (roflumilast)
   AND
6. Documentation of prescriber baseline assessment of disease activity (e.g., erythema, induration/papulation/edema, excoriations, lichenification, pruritus, BSA affected, topical requirement, etc.)
   AND
7. 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).

CONTINUATION OF THERAPY:

A. MODERATE-TO-SEVERE ATOPIC DERMATITIS:

1. Adherence to therapy at least 85% of the time as verified by the prescriber or member medication fill history OR adherence less than 85% of the time due to the need for surgery or treatment of an infection, causing temporary discontinuation
   AND
2. Prescriber attests to or clinical reviewer has found no evidence of intolerable adverse effects or drug toxicity
   AND
3. Documentation of positive clinical response as demonstrated by low disease activity and/or improvements in the condition's signs and symptoms (e.g., marked improvements in erythema, induration/papulation/edema, excoriations, and lichenification; reduced pruritus; decreased requirement for other topical or systemic therapies; reduced body surface area (BSA) affected with atopic dermatitis; or other responses observed)

DURATION OF APPROVAL:

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

PRESCRIBER REQUIREMENTS:

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

AGE RESTRICTIONS:

12 years of age and older

QUANTITY:

Initial Loading Dose: 500 mg (two 250 mg injections) at Week 0 and Week 2, followed by 250 mg every two weeks until Week 16 or later, when adequate clinical response is achieved

Maintenance Dose: 250 mg every four 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

DRUG CLASS:
Atopic Dermatitis – Monoclonal Antibodies

FDA-APPROVED USES:
Indicated for the treatment of adult and pediatric patients 12 years of age and older who weigh at least 40 kg with moderate-to-severe atopic dermatitis whose disease is not adequately controlled with topical prescription therapies or when those therapies are not advisable. Ebglyss can be used with or without topical corticosteroids.

COMPENDIAL APPROVED OFF-LABELED USES:
None

APPENDIX

APPENDIX:
None

BACKGROUND AND OTHER CONSIDERATIONS

BACKGROUND:
Atopic dermatitis (AD) is a chronic inflammatory skin condition characterized by itching and recurring eczematous lesions. Ebglyss (lebrikizumab-lbkz) is an interleukin-13 (IL-13) antagonist, developed for treating moderate-to-severe atopic dermatitis in adults and children aged 12 years and older who weigh at least 40 kg. IL-13 plays a significant role in the inflammation and skin barrier dysfunction associated with AD. This cytokine contributes to skin inflammation, increased epidermal thickness, itching, and elevated infection risk, all of which are commonly observed in AD.

The safety and efficacy of Ebglyss were evaluated in multiple clinical trials, including randomized, placebo-controlled studies such as ADvocate 1, ADvocate 2, and ADhere. In these trials, patients were either given Ebglyss or placebo, with efficacy primarily measured using the Investigator's Global Assessment (IGA) score and the Eczema Area and Severity Index (EASI). Successful treatment was defined by achieving an IGA score of 0 or 1 or a 75% improvement in the EASI score (EASI-75). In these studies, Ebglyss successfully met its primary endpoints, demonstrating clinically meaningful improvements.

CONTRAINDICATIONS/EXCLUSIONS/DISCONTINUATION:
All other uses of Ebglyss (lebrikizumab-lbkz) are considered experimental/investigational and therefore, will follow Molina's Off- Label policy. Contraindications to Ebglyss (lebrikizumab-lbkz) include: prior serious hypersensitivity to lebrikizumab-lbkz or any excipients in Ebglyss, avoid use of live vaccines during treatment with Ebglyss.

Exclusions/Discontinuation:

Hypersensitivity reactions including angioedema and urticaria, have occurred after administration of Ebglyss. Discontinue Ebglyss in the event of a serious hypersensitivity reaction.

Patients with pre-existing helminth infections should receive treatment prior to initiating Ebglyss therapy. If a helminth infection develops during Ebglyss treatment and does not respond to standard anti-helminth therapy, Ebglyss should be discontinued until the infection resolves.

OTHER SPECIAL CONSIDERATIONS:

Prior to Ebglyss treatment, complete all age-appropriate vaccinations according to current immunization guidelines.

CODING/BILLING INFORMATION

CODING DISCLAIMER. *Codes listed in this policy are for reference purposes only and may not be all-inclusive or applicable for every state or line of business. Deleted codes and codes which are not effective at the time the service is rendered may not be eligible for reimbursement. Listing of a service or device code in this policy does not guarantee coverage. Coverage is determined by the benefit document. Molina adheres to Current Procedural Terminology (CPT®), a registered trademark of the American Medical Association (AMA). All CPT codes and descriptions are copyrighted by the AMA; this information is included for informational purposes only. Providers and facilities are expected to utilize industry-standard coding practices for all submissions. Molina has the right to reject/deny the claim and recover claim payment(s) if it is determined it is not billed appropriately or not a covered benefit. Molina reserves the right to revise this policy as needed.*

HCPCS CODE	DESCRIPTION
NA	

AVAILABLE DOSAGE FORMS:

Ebglyss SOAJ 250MG/2ML single-dose prefilled pen
Ebglyss SOSY 250MG/2ML single-dose prefilled syringe

REFERENCES

1. Ebglyss (lebrikizumab-lbkz) injection, for subcutaneous use [prescribing information]. Indianapolis, IN: Eli Lilly and Company, May 2025.
2. Silverberg, J. I., Guttman-Yassky, E., Thaçi, D., Irvine, A. D., Stein Gold, L., Blauvelt, A., Simpson, E. L., Chu, C. Y., Liu, Z., Gontijo Lima, R., Pillai, S. G., Seneschal, J., & ADvocate1 and ADvocate2 Investigators (2023). Two Phase 3 Trials of Lebrikizumab for Moderate-to-Severe Atopic Dermatitis. The New England journal of medicine, 388(12), 1080–1091. https://doi.org/10.1056/NEJMoa2206714
3. Simpson, E. L., Gooderham, M., Wollenberg, A., Weidinger, S., Armstrong, A., Soung, J., Ferrucci, S., Lima, R. G., Witte, M. M., Xu, W., ElMaraghy, H., Natalie, C. R., Pierce, E., Blauvelt, A., & Adhere Investigators (2023). Efficacy and Safety of Lebrikizumab in Combination With Topical Corticosteroids in Adolescents and Adults With Moderate-to-Severe Atopic Dermatitis: A Randomized Clinical Trial (ADhere). *JAMA dermatology*, *159*(2), 182–191. https://doi.org/10.1001/jamadermatol.2022.5534
4. Davis, D. M., Drucker, A. M., Alikhan, A., Bercovitch, L., Cohen, D., Darr, J. M., … Sidbury, R. (2023). Guidelines of care for the management of atopic dermatitis in adults with phototherapy and systemic therapies. Journal of the American Academy of Dermatology, 90(2). https://doi.org/10.1016/j.jaad.2023.08.102

SUMMARY OF REVIEW/REVISIONS	DATE
REVISION- Notable revisions: Required Medical Information Exclusions/Discontinuation Other Special Considerations Available Dosage Forms References	Q3 2025
NEW CRITERIA CREATION	Q1 2025