lebrikizumab-lbkz (Ebglyss™)

Policy # 00922
Original Effective Date: 04/01/2025
Current Effective Date: 04/01/2025

Applies to all products administered or underwritten by Blue Cross and Blue Shield of Louisiana and its subsidiary, HMO Louisiana, Inc. (collectively referred to as the "Company"), unless otherwise provided in the applicable contract. Medical technology is constantly evolving, and we reserve the right to review and update Medical Policy periodically.

When Services May Be Eligible for Coverage

Coverage for eligible medical treatments or procedures, drugs, devices or biological products may be provided only if:

- *Benefits are available in the member's contract/certificate, and*
- *Medical necessity criteria and guidelines are met.*

Based on review of available data, the Company may consider lebrikizumab-lbkz (Ebglyss™)‡ for the treatment of atopic dermatitis to be **eligible for coverage.****

Patient Selection Criteria
Coverage eligibility for lebrikizumab-lbkz (Ebglyss) for the treatment of atopic dermatitis will be considered when the patient selection criteria are met:

Initial:

- Patient has a diagnosis of moderate to severe atopic dermatitis; AND
- Patient is 12 years of age or older; AND
- Patient weighs 40 kg or more; AND
- Patient has had chronic atopic dermatitis for at least 6 months; AND
  *(Note: This specific patient selection criterion is an additional Company requirement for coverage eligibility and will be denied as not medically necessary** if not met).*
- Patient has atopic dermatitis involvement estimated to be ≥ 10% of the body surface area (BSA) according to the prescribing physician; AND
  *(Note: This specific patient selection criterion is an additional Company requirement for coverage eligibility and will be denied as not medically necessary** if not met).*
- Patient has tried and failed (e.g., intolerance or inadequate response) at least ONE prescription GENERIC topical corticosteroid, unless there is clinical evidence or patient history that suggests the use of ONE prescription GENERIC topical corticosteroid will be ineffective or cause an adverse reaction to the patient; AND
- Patient has tried and failed (e.g., intolerance or inadequate response) GENERIC tacrolimus ointment OR GENERIC pimecrolimus cream, unless there is clinical evidence or patient history that suggests the use of these products will be ineffective or cause an adverse reaction to the patient; AND

- Patient has tried and failed TWO of the following after at least 3 months of therapy with each product: dupilumab (Dupixent®)‡, tralokinumab (Adbry™)‡, or upadacitinib (Rinvoq®)‡ unless there is clinical evidence or patient history that suggest the use of these therapies will be ineffective or cause an adverse reaction to the patient; AND
  *(Note: This specific patient selection criterion is an additional Company requirement for coverage eligibility and will be denied as not medically necessary** if not met).*
- Requested drug is NOT being used in combination with JAK (janus kinase) inhibitors (e.g., upadacitinib [Rinvoq], ruxolitinib [Opzelura™]‡, abrocitinib [Cibinqo®]‡) or monoclonal antibodies (e.g., dupilumab [Dupixent]) typically used to treat atopic dermatitis; AND
- If a patient has achieved an adequate clinical response by week 16 or later with a 250 mg every 2 weeks dosage, a maintenance dose of 250 mg every 4 weeks will be used.

Continuation:

- Patient has received an initial authorization; AND
- Patient has received at least 6 months of therapy with the requested drug; AND
  *(Note: This specific patient selection criterion is an additional Company requirement for coverage eligibility and will be denied as not medically necessary** if not met).*
- Patient has been adherent to the requested drug and other medications for the condition being treated; AND
  *(Note: This specific patient selection criterion is an additional Company requirement for coverage eligibility and will be denied as not medically necessary** if not met).*
- Patient has had a clinically meaningful beneficial response to Ebglyss therapy as compared to their baseline status (before Ebglyss therapy) as evidenced by TWO or more of the following:
  - Reduction in disease severity (e.g., erythema, dryness, edema/papulation, excoriations, lichenification, oozing/crusting)
  - Reduction in the frequency or intensity of pruritus
  - Reduction in the frequency of disease exacerbations/flares
  - Reduction in the BSA with atopic dermatitis involvement (a 20% reduction in percent BSA involved over baseline)
  - Improvement in overall patient quality of life (e.g., improved sleep, less depression or anxiety, etc.); AND

  *(Note: This specific patient selection criterion is an additional Company requirement for coverage eligibility and will be denied as not medically necessary** if not met).*
- Requested drug is NOT being used in combination with JAK (janus kinase) inhibitors (e.g., upadicitinib [Rinvoq], ruxolitinib [Opzelura], abrocitinib [Cibinqo]) or monoclonal antibodies (e.g., dupilumab [Dupixent]) typically used to treat atopic dermatitis; AND
- If a patient has achieved an adequate clinical response with a 250 mg every 2 weeks dosage, a maintenance dose of 250 mg every 4 weeks will be used.

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When Services Are Considered Not Medically Necessary

Based on review of available data, the Company considers the use of lebrikizumab-lbkz (Ebglyss) when ANY of the following criteria are NOT met to be **not medically necessary**:**

- Patient has had chronic atopic dermatitis for at least 6 months
- Patient has atopic dermatitis involvement estimated to be ≥ 10% of the BSA according to the prescribing physician
- Patient has tried and failed (e.g., intolerance or inadequate response) TWO of the following after at least 3 months of therapy with EACH product: dupilumab (Dupixent), tralokinumab-ldrm (Adbry), or upadacitinib (Rinvoq)
- For continuation requests: Patient has received at least 6 months of therapy with the requested drug
- For continuation requests: Patient has been adherent to the requested drug and other medications for the condition being treated
- For continuation requests: Patient has had a clinically meaningful beneficial response to Ebglyss therapy as compared to their baseline status (before Ebglyss therapy) as evidenced by TWO or more of the following:
    - Reduction in disease severity (e.g., erythema, dryness, edema/papulation, excoriations, lichenification, oozing/crusting)
    - Reduction in the frequency or intensity of pruritus
    - Reduction in the frequency of disease exacerbations/flares
    - Reduction in the BSA with AD involvement (a 20% reduction in percent BSA involved over baseline)
    - Improvement in overall patient quality of life (e.g., improved sleep, less depression or anxiety, etc.)

When Services Are Considered Investigational

Coverage is not available for investigational medical treatments or procedures, drugs, devices or biological products.

Based on review of available data, the Company considers the use of lebrikizumab-lbkz (Ebglyss) when the patient selection criteria are not met (EXCEPT those denoted as **not medically necessary****) to be **investigational.***

Based on review of available data, the Company considers the use of lebrikizumab-lbkz (Ebglyss) for any non-FDA approved indication to be **investigational.***

Based on review of available data, the Company considers the use of lebrikizumab-lbkz (Ebglyss) dosed at 250 mg every 2 weeks (rather than a maintenance dose of 250 mg every 4 weeks) when the patient has achieved an adequate clinical response at week 16 or later to be **investigational.***

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Background/Overview

Ebglyss is an interleukin-13 antagonist indicated for the treatment of adults 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. It is available as a prefilled syringe and a prefilled pen, both at a concentration of 250 mg/ml, that can be self-administered after proper training by a healthcare professional. The recommended dose of Ebglyss is 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 an adequate clinical response is achieved. The maintenance dose of Ebglyss is 250 mg every 4 weeks.

Atopic Dermatitis

Atopic dermatitis, the most common type of a group of conditions known as eczema, is a chronic skin condition that causes dry, inflamed, and itchy skin. It commonly affects both children and adults. There are various treatment options for atopic dermatitis, including first line agents such as topical corticosteroids (many of which are in generic form) and topical immunomodulatory agents such as generic tacrolimus and generic pimecrolimus. For those that are refractory to topical therapies, systemic immunomodulatory agents are an option for therapy.

FDA or Other Governmental Regulatory Approval

U.S. Food and Drug Administration (FDA)

Ebglyss is indicated for the treatment of adults 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.

Rationale/Source

This medical policy was developed through consideration of peer-reviewed medical literature generally recognized by the relevant medical community, U.S. Food and Drug Administration approval status, nationally accepted standards of medical practice and accepted standards of medical practice in this community, technology evaluation centers, reference to regulations, other plan medical policies, and accredited national guidelines.

Three multicenter, randomized, double-blind, placebo-controlled trials, ADvocate 1, ADvocate 2 and ADhere enrolled a total of 1062 subjects 12 years of age and older with moderate-to-severe atopic dermatitis not adequately controlled by topical medication(s) and who were candidates for systemic therapy. Disease severity was defined by an Investigator's Global Assessment (IGA) score ≥ 3 in the overall assessment of atopic dermatitis (AD) lesions on a severity scale of 0 to 4, an Eczema Area and Severity Index (EASI) score ≥ 16 on a scale of 0 to 72, and a minimum body surface area involvement of ≥ 10%.

In all three trials, subjects in the Ebglyss group received subcutaneous injections of Ebglyss 500 mg at Week 0 and at Week 2, followed by 250 mg every other week (Q2W) through Week 16.

To evaluate the maintenance and durability of response in the monotherapy trials (ADvocate 1 and ADvocate 2), subjects originally randomized to Ebglyss who achieved an IGA score of 0 or 1, or at least a 75% reduction in EASI from baseline [EASI-75] at Week 16 and did not require rescue therapy were re-randomized to an additional 36 weeks of either a maintenance dose of Ebglyss 250 mg Q2W (every 2 weeks), Ebglyss 250 mg Q4W (every 4 weeks), or placebo.

Subjects who did not achieve IGA 0 or 1 or EASI-75 at Week 16 or subjects who required rescue therapy during the first 16 weeks were treated with open-label Ebglyss 250 mg Q2W.

In the concomitant therapy trial (ADhere), subjects received Ebglyss + topical corticosteroid (TCS) or placebo + TCS. Topical calcineurin inhibitors (TCI) were permitted for sensitive areas only, such as the face, neck, intertriginous and genital areas.

All three trials assessed the primary endpoint, the proportion of subjects who achieved an IGA score of 0 (clear) or 1 (almost clear) and at least a 2-point improvement from baseline at Week 16. Other evaluated outcomes at Week 16 included the proportion of subjects with EASI-75 and EASI-90, and improvement in itch severity as defined by a reduction of at least 4 points on an 11-point Pruritus NRS. ADvocate 1 and ADvocate 2 also evaluated the maintenance and durability of response through Week 52.

In ADvocate 1, at Week 16, 43.1% of patients treated with Ebglyss 250 mg Q2W achieved an IGA response compared with 12.7% of patients treated with placebo. Similarly, 58.8% and 16.2% of patients, respectively, achieved EASI-75 at Week 16. In ADvocate 2, at Week 16, 33.2% of patients treated with Ebglyss 250 mg Q2W achieved an IGA response compared with 10.8% of patients treated with placebo. Additionally, 52.1% and 18.1% of patients, respectively, achieved EASI-75 at Week 16. Among patients who had an IGA response or an EASI-75 response at Week 16 and were re-randomized to receive Ebglyss 250 mg Q4W, 76.9% of patients achieved an IGA response and 81.7% of patients had an EASI-75 response at Week 52. Similar results were observed in patients who continued with Ebglyss Q2W dosing. In ADhere, at Week 16, 41.2% of patients treated with Ebglyss 250 mg Q2W + TCS achieved an IGA response compared with 22.1% of patients treated with placebo + TCS. Additionally, 69.5% of patients treated with Ebglyss + TCS achieved EASI-75 compared with 42.2% of patients treated with placebo + TCS.

References

1. Ebglyss [package insert]. Eli Lilly and Company. Indianapolis, Indiana. Updated November 2024.
2. Ebglyss Drug Evaluation. Express Scripts. Updated September 2024.

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Policy History

Original Effective Date: 04/01/2025
Current Effective Date: 04/01/2025
03/06/2025 Medical Policy Committee review
03/12/2025 Medical Policy Implementation Committee approval. New policy.
Next Scheduled Review Date: 03/2026

*Investigational – A medical treatment, procedure, drug, device, or biological product is Investigational if the effectiveness has not been clearly tested and it has not been incorporated into standard medical practice. Any determination we make that a medical treatment, procedure, drug, device, or biological product is Investigational will be based on a consideration of the following:

A. Whether the medical treatment, procedure, drug, device, or biological product can be lawfully marketed without approval of the U.S. Food and Drug Administration (FDA) and whether such approval has been granted at the time the medical treatment, procedure, drug, device, or biological product is sought to be furnished; or
B. Whether the medical treatment, procedure, drug, device, or biological product requires further studies or clinical trials to determine its maximum tolerated dose, toxicity, safety, effectiveness, or effectiveness as compared with the standard means of treatment or diagnosis, must improve health outcomes, according to the consensus of opinion among experts as shown by reliable evidence, including:
    1. Consultation with technology evaluation center(s);
    2. Credible scientific evidence published in peer-reviewed medical literature generally recognized by the relevant medical community; or
    3. Reference to federal regulations.

**Medically Necessary (or "Medical Necessity") - Health care services, treatment, procedures, equipment, drugs, devices, items or supplies that a Provider, exercising prudent clinical judgment, would provide to a patient for the purpose of preventing, evaluating, diagnosing or treating an illness, injury, disease or its symptoms, and that are:

A. In accordance with nationally accepted standards of medical practice;
B. Clinically appropriate, in terms of type, frequency, extent, level of care, site and duration, and considered effective for the patient's illness, injury or disease; and
C. Not primarily for the personal comfort or convenience of the patient, physician or other health care provider, and not more costly than an alternative service or sequence of services at least as likely to produce equivalent therapeutic or diagnostic results as to the diagnosis or treatment of that patient's illness, injury or disease.

For these purposes, "nationally accepted standards of medical practice" means standards that are based on credible scientific evidence published in peer-reviewed medical literature generally recognized by the relevant medical community, Physician Specialty Society recommendations and the views of Physicians practicing in relevant clinical areas and any other relevant factors.

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‡ Indicated trademarks are the registered trademarks of their respective owners.

NOTICE: If the Patient's health insurance contract contains language that differs from the BCBSLA Medical Policy definition noted above, the definition in the health insurance contract will be relied upon for specific coverage determinations.

NOTICE: Medical Policies are scientific based opinions, provided solely for coverage and informational purposes. Medical Policies should not be construed to suggest that the Company recommends, advocates, requires, encourages, or discourages any particular treatment, procedure, or service, or any particular course of treatment, procedure, or service.

NOTICE: Federal and State law, as well as contract language, including definitions and specific contract provisions/exclusions, take precedence over Medical Policy and must be considered first in determining eligibility for coverage.