

PHARMACY POLICY STATEMENT

Georgia Medicaid

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| DRUG NAME | Ebglyss (lebrikizumab-lbkz) |
| BENEFIT TYPE | Pharmacy or medical |
| STATUS | Prior Authorization Required |

Ebglyss, approved by the FDA in 2024, 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 can be used with or without topical corticosteroids.

Ebglyss (lebrikizumab-lbkz) will be considered for coverage when the following criteria are met:

Atopic Dermatitis (AD)

For **initial** authorization:

1. Member is at least 12 years of age and at least 40 kg; AND
2. Medication must be prescribed by or in consultation with a dermatologist, allergist, or immunologist; AND
3. Member has a diagnosis of moderate to severe AD; AND
4. Member's atopic dermatitis involves 10% or more of the body surface area (BSA) OR involves highly visible or functional areas (e.g., neck, face, genitals, palms) and is significantly impairing quality of life; AND
5. Member has a documented trial and failure to **ONE** of the following:
 - a) **TWO** trials of medium to very high potency topical corticosteroids for 2 weeks;

Note: a topical calcineurin inhibitor (e.g., tacrolimus, pimecrolimus) for 6 weeks, Eucrisa for 4 weeks or Opzelura for 8 weeks may also be acceptable.
 - b) At least 8 weeks of phototherapy treatment (i.e., UV-A, UV-B, a combination of both or UV-B1 (narrow-band UV-B)) AND **ONE** trial of medium to very high potency topical corticosteroids for 2 weeks;

Note: a topical calcineurin inhibitor (e.g., tacrolimus, pimecrolimus) for 6 weeks, Eucrisa for 4 weeks or Opzelura for 8 weeks may also be acceptable.
 - c) **ONE** 12-week trial of an oral immunomodulatory agent (e.g., cyclosporine, methotrexate, azathioprine) AND **ONE** trial of medium to very high potency topical corticosteroids for 2 weeks.

Note: a topical calcineurin inhibitor (e.g., tacrolimus, pimecrolimus) for 6 weeks, Eucrisa for 4 weeks or Opzelura for 8 weeks may also be acceptable.
6. **Dosage allowed/Quantity limit:** administer 500 mg subcutaneously at Week 0 and Week 2, followed by 250 mg subcutaneously every 2 weeks until Week 16 or later, when adequate clinical response is achieved. The maintenance dose is 250 mg subcutaneously every 4 weeks. Quantity limit: 1 pen/syringe per 28 days after loading doses.

If all the above requirements are met, the medication will be approved for 4 months.

For reauthorization:

1. Chart notes demonstrate improvement of signs and symptoms such as fewer flares, less itching/erythema, improved quality of life, etc.

If all the above requirements are met, the medication will be approved for an additional 12 months.

CareSource considers Ebglyss (lebrikizumab-lbkz) not medically necessary for the treatment of conditions that are not listed in this document. For any other indication, please refer to the Off-Label policy.

| DATE | ACTION/DESCRIPTION |
|------------|---------------------------------|
| 10/01/2024 | New policy for Ebglyss created. |

References:

1. Ebglyss [prescribing information]. Eli Lilly and Company; 2024.
2. Wollenberg A, Kinberger M, Arents B, et al. European guideline (EuroGuiDerm) on atopic eczema: part I - systemic therapy. *J Eur Acad Dermatol Venereol.* 2022;36(9):1409-1431. doi:10.1111/jdv.18345
3. Eichenfield LF, Tom WL, Chamlin SL et al. Guidelines of care for the management of atopic dermatitis: section 1. Diagnosis and assessment of atopic dermatitis. *J Am Acad Dermatol.* 2014; 70(1):338-51.
4. Eichenfield LF, Tom WL, Berger TG, et al. Guidelines of care for the management of atopic dermatitis: section 2. Management and treatment of atopic dermatitis with topical therapies. *J Am Acad Dermatol.* 2014;71(1):116-132.
5. Sidbury R, Davis DM, Cohen DE, et al. Guidelines of care for the management of atopic dermatitis: Section 3. Management and treatment with phototherapy and systemic agents. *J Am Acad Dermatol.* 2014 Aug;71(2):327-49.
6. Davis DMR, Drucker AM, Alikhan A, et al. Guidelines of care for the management of atopic dermatitis in adults with phototherapy and systemic therapies [published online ahead of print, 2023 Nov 3]. *J Am Acad Dermatol.* 2023;S0190-9622(23)02878-5. doi:10.1016/j.jaad.2023.08.102
7. AAAAI/ACAAI JTF Atopic Dermatitis Guideline Panel, Chu DK, Schneider L, et al. Atopic dermatitis (eczema) guidelines: 2023 American Academy of Allergy, Asthma and Immunology/American College of Allergy, Asthma and Immunology Joint Task Force on Practice Parameters GRADE- and Institute of Medicine-based recommendations. *Ann Allergy Asthma Immunol.* 2024;132(3):274-312. doi:10.1016/j.anai.2023.11.009

Effective date: 02/01/2026

Revised date: 10/01/2024