

PHARMACY POLICY STATEMENT

Marketplace

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

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Revised date: 10/01/2024