Medical Drug Clinical Criteria

Subject:	Ebglyss (lebrikizumab-lbkz)		
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Overview

This document addresses the use of Ebglyss (lebrikizumab-lbkz). Ebglyss is indicated for 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. Lebrikizumab is a high-affinity IgG4 monoclonal antibody targeting interleukin-13 (IL-13) which prevents interleukin-4 and interlukin-13 signaling.

Atopic dermatitis, the most common form of eczema, is frequently associated with a personal or family history of allergies, allergic rhinitis and asthma. AD typically follows a relapsing/chronic course but often resolves by adulthood. Symptoms can include erythema, edema, xerosis, excoriations, pruritus, oozing and crusting, or lichenification. The 2023 American Academy of Dermatology (AAD) guideline for the treatment of atopic dermatitis with topical therapies indicates that topical therapies are the mainstay of treatment based on their generally favorable safety and efficacy. In 2024, AAD published treatment guidelines for the treatment of AD with systemic therapies. The academy recommends the use of dupilumab, tralokinumab, baricitinib, abrocitinib, and upadacitinib. There are also recommendations for phototherapy, cyclosporine, methotrexate, azathioprine, and mycophenolate. Systemic corticosteroids are not recommended. The 2023 American Academy of Allergy, Asthma and Immunology/American College of Allergy, Asthma and Immunology Joint Task Force (AAAAI/ACAAI JTF) Atopic Dermatitis Guideline, recommend dupilumab and tralokinumab in patients refractory, intolerant, or unable to use topical treatment. In 2025, AAD published a focused update for the AD guidelines, recommending lebrikizumab for moderate to severe AD and nemolizumab with concomitant topical therapy for moderate to severe AD.

Clinical Criteria

Ebglyss (lebrikizumab-lbkz)

Initial requests for Ebglyss (lebrikizumab-lbkz) may be approved if the following criteria are met:

I. Individual has a diagnosis of moderate to severe atopic dermatitis; **AND**
II. Individual is 12 years of age or older and weighs at least 40 kilograms (kg); **AND**
III. Documentation is provided that individual has tried one of the following and treatment failed to achieve and maintain remission of low or mild disease activity:
   - **A.** Topical calcineurin inhibitors; **OR**
   - B. Eucrisa; **OR**
   - C. Opzelura; **OR**
   - D. Zoryve 0.15% Cream; **OR**
   - E. Vtama; **OR**
   - F. Phototherapy (UVB or PUVA); **OR**
   - G. Non-corticosteroid systemic immunosuppressants (such as cyclosporine, azathioprine, methotrexate, or mycophenolate mofetil); **OR**
   - H. Individual has contraindications to topical calcineurin inhibitors AND Eucrisa AND Opzelura AND Vtama AND Zoryve 0.15% Cream AND Non-corticosteroid systemic immunosuppressants (such as cyclosporine, azathioprine, methotrexate, or mycophenolate mofetil) AND unable to use phototherapy.

Continuation requests for Ebglyss (lebrikizumab-lbkz) for atopic dermatitis may be if approved if the following criterion is met:

I. Treatment with Ebglyss has resulted in significant improvement or stabilization in clinical signs and symptoms of disease (including but not limited to decrease in affected body surface area, pruritus, or severity of inflammation, and/or improved quality of life).

Ebglyss (lebrikizumab-lbkz) may not be approved for the following:

I. In combination with oral or topical JAK inhibitors; **OR**
II. In combination with other immunosuppressants (such as cyclosporine, azathioprine, mycophenolate mofetil, or methotrexate) (Silverberg 2023); **OR**
III. In combination with dupilumab, nemolizumab, or tralokinumab; **OR**
IV. Requests for Ebglyss (lebrikizumab-lbkz) may not be approved when the above criteria are not met and for all other indications.

Quantity Limits

Ebglyss (lebrikizumab-lbkz) Quantity Limits

Drug	Quantity Limit
Ebglyss (lebrikizumab-lbkz) 250 mg/2 ml prefilled pen/syringe	1 pen/syringe per 28 days*+
Override Criteria	
*Initiation of therapy: May approve a total of 11 (eleven) 250 mg/2 ml prefilled pens/syringes in the first 16 weeks of therapy to cover 500mg loading doses in weeks 0 and 2, and 250mg doses in weeks 4,6,8,10,12,14 and 16. + May approve up to 2 (two)- 250 mg/2 ml pens/syringes per 28 days if clinical response has not been achieved after initial 16 weeks of therapy or inadequate disease control with standard maintenance dosing (1 pen/syringe per 28 days).	

Coding

The following codes for treatments and procedures applicable to this document are included below for informational purposes. Inclusion or exclusion of a procedure, diagnosis or device code(s) does not constitute or imply member coverage or provider reimbursement policy. Please refer to the member's contract benefits in effect at the time of service to determine coverage or non-coverage of these services as it applies to an individual member.

HCPCS

J3590	Unclassified biologics [when specified as Ebglyss (lebrikizumab-lbkz)]
C9399	Unclassified drugs or biologics [when specified as Ebglyss (lebrikizumab-lbkz)]

ICD-10 Diagnosis

L20.0-L20.9	Atopic dermatitis

Document History

Revised: 08/15/2025
Document History:

- 08/15/2025 – Annual Review: Wording and formatting updates. Coding Reviewed: No changes.
- 02/21/2025 – Annual Review: Add Vtama to criteria, Update quantity limit language and do not approve criteria. Coding Reviewed: Updated descriptions for HCPCS NOC J3590 and C9399. Removed all diagnosis pend. Added ICD-10-CM L20.0-L20.9.
- 09/09/2024 – Select Review: New Clinical criteria and quantity limit for lebrikizumab. Coding Reviewed: Add HCPCS 3590 and C9399 for Ebglyss. All diagnosis pend for NOC codes.

References

1. DailyMed. Package inserts. U.S. National Library of Medicine, National Institutes of Health website. http://dailymed.nlm.nih.gov/dailymed/about.cfm. Updated periodically.
2. Davis DMR, Drucker AM, Alikhan A, et al. Guidelines of care for the management of atopic dermatitis in adults with phototherapy and systemic therapies. J Am Acad Dermatol. 2024;90(2):e43-e56. doi:10.1016/j.jaad.2023.08.102.
3. Davis DMR, Frazer-Green L, Alikhan A, et al. Focused update: Guidelines of care for the management of atopic dermatitis in adults. J Am Acad Dermatol. 2025 Jun 17:S0190-9622(25)02125-5. doi: 10.1016/j.jaad.2025.05.1386.
4. DrugPoints® System [electronic version]. Truven Health Analytics, Greenwood Village, CO. Updated periodically.
5. Lexi-Comp ONLINE™ with AHFS™, Hudson, Ohio: Lexi-Comp, Inc. Updated periodically.
6. Sidbury R, Alikhan A, Bercovitch L, et al. Guidelines of care for the management of atopic dermatitis in adults with topical therapies, Journal of the American Academy of Dermatology (2023), doi: https://doi.org/10.1016/j.jaad.2022.12.029.
7. Silverberg, Jonathan I et al. “Two Phase 3 Trials of Lebrikizumab for Moderate-to-Severe Atopic Dermatitis.” The New England journal of medicine vol. 388,12 (2023): 1080-1091. doi:10.1056/NEJMoa2206714
8. Simpson EL, Gooderham M, Wollenberg A, et al. “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 Dermatol. 2023;159(2):182-191. doi:10.1001/jamadermatol.2022.5534

Federal and state laws or requirements, contract language, and Plan utilization management programs or policies may take precedence over the application of this clinical criteria.