Medical Drug Clinical Criteria

Subject:	Ebglyss (lebrikizumab-lbkz)		
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Overview

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

Lebrikizumab was studied in two identically designed, 52-week, randomized, double-blind, placebo-controlled, phase 3 trials. Both trials included a 16-week induction period and a 36-week maintenance period. Eligible patients were diagnosed with moderate to severe atopic dermatitis, were 18 years of age or older, or adolescents defined as 12 to less than 18 years of age and weighed at least 40 kg. Subjects were given lebrikizumab at a loading dose of 500 mg at baseline and week 2 then 250 mg every 2 weeks or placebo. The primary outcome was an Investigator's Global Assessment (IGA) score of 0 or 1 (indicating clear or almost clear skin; range 0 to 4 (severe disease) with a reduction (indicating improvement) of at least 2 points from baseline at week 16. Secondary outcomes included a 75% improvement in the Eczema Area and Severity Index score (EASI-75 response) and assessments of itch and itch interference with sleep (Silverberg 2023).

Other treatments for atopic dermatitis include topical therapies, other monoclonal antibodies such as Dupixent and Adbry, and JAK inhibitors such as Cibinqo and Rinvoq.

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. Phototherapy (UVB or PUVA); **OR**
    F. Non-corticosteroid systemic immunosuppressants (such as cyclosporine, azathioprine, methotrexate, or mycophenolate mofetil); **OR**
    G. Individual has contraindications to topical calcineurin inhibitors AND Eucrisa AND Opzelura 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 Adbry or Dupixent; **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 4 (four) additional 250 mg/2 mL prefilled pen/syringe in the first month of therapy for initiation dose + May approve up to 2 (two)- 250 mg/2 ml pens/syringes per 28 days if clinical response has not been achieved after initiation 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 (Ebglyss)
C9399	Unclassified drugs or biologics (Ebglyss)

ICD-10 Diagnosis

All diagnosis pend

Document History

New: 09/09/2024
Document History:

- 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

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2. DrugPoints® System [electronic version]. Truven Health Analytics, Greenwood Village, CO. Updated periodically.
3. Lexi-Comp ONLINE™ with AHFS™, Hudson, Ohio: Lexi-Comp, Inc. Updated periodically.

4. Sidbury, Robert et al. “Guidelines of care for the management of atopic dermatitis in adults with topical therapies.” Journal of the American Academy of Dermatology vol. 89,1 (2023): e1-e20. doi:10.1016/j.jaad.2022.12.029
5. 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
6. 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