MEDICAL MUTUAL®

Drug Policy

Policy:	Ebglyss (lebrikizumab-lbkz)	Annual Review Date: New policy Last Revised Date: 12/19/2024

OVERVIEW

Ebglyss, an interleukin (IL)-13 antagonist, is indicated for the treatment of moderate to severe atopic dermatitis in adults and pediatric patients ≥ 12 years of age who weigh ≥ 40 kg whose disease is not adequately controlled with topical prescription therapies or when those therapies are not advisable.[1] Ebglyss may be used with or without topical corticosteroids (TCSs).

POLICY STATEMENT

This policy involves the use of Ebglyss. Prior authorization is recommended for pharmacy benefit coverage of Ebglyss. Approval is recommended for those who meet the conditions of coverage in the **Criteria and Initial/Extended Approval** for the diagnosis provided. **Conditions Not Recommended for Approval** are listed following the recommended authorization criteria. Requests for uses not listed in this policy will be reviewed for evidence of efficacy and for medical necessity on a case-by-case basis.

Because of the specialized skills required for evaluation and diagnosis of patients treated with Ebglyss as well as the monitoring required for adverse events and long-term efficacy, initial approval requires Ebglyss be prescribed by or in consultation with a physician who specializes in the condition being treated. All approvals for initial therapy are provided for the initial approval duration noted below; if reauthorization is allowed, a response to therapy is required for continuation of therapy unless otherwise noted below.

RECOMMENDED AUTHORIZATION CRITERIA

Coverage of Ebglyss is recommended in those who meet the following criteria:

1. **Atopic Dermatitis.** Approve for the duration noted if the patient meets ONE of the following conditions (A or B):
   - **A)** Initial Therapy. Approve for 4 months if the patient meets ALL of the following criteria (i, ii, iii, and iv):
     - **i.** Patient meets ONE of the following criteria (a or b):
       - **a)** Patient is ≥ 18 years of age; OR
       - **b)** Patient meets BOTH of the following criteria (1 and 2):
         - **1)** Patient is 12 to 17 years of age; AND
         - **2)** Patient weighs ≥ 40 kg; AND
     - **ii.** Patient has atopic dermatitis involvement estimated to be ≥ 10% of the body surface area according to the prescriber; AND
     - **iii.** Patient meets **two of the following three** conditions (a, b, and c):

a) Patient did not respond adequately to (or is not a candidate for) a 3-month minimum trial of topical agents [e.g., corticosteroids, calcineurin inhibitors (e.g., tacrolimus or pimecrolimus), crisaborole, etc.]; OR

b) Patient did not respond adequately to (or is not a candidate for) a 3-month minimum trial of at least one (1) systemic agent (e.g., cyclosporine, azathioprine, methotrexate, mycophenolate mofetil, oral corticosteriods etc.); OR

c) Patient did not respond adequately to (or is not a candidate for) a 3-month minimum trial of phototherapy (e.g., Psoralens with UVA light (PUVA), UVB, etc.); AND
Note: Examples of contraindications to phototherapy (PUVA or UVB) include the following: Xeroderma pigmentosa; pregnancy or lactation (PUVA only); lupus erythematosus; immunosuppression in an organ transplant patient (UVB only); photosensitizing medications (PUVA only); severe liver, renal, or cardiac disease; age less than 12 years old (PUVA only); and history of photosensitivity diseases (e.g., chronic actinic dermatitis, solar urticaria), melanoma, non-melanoma skin cancer, extensive solar damage (PUVA only), or treatment with arsenic or ionizing radiation.

iv. The medication is prescribed by or in consultation with an allergist, immunologist, or dermatologist.

B) Patient is Currently Receiving Ebglyss. Approve for 1 year if the patient meets BOTH of the following criteria (i and ii):

i. Patient has already received at least 4 months of therapy with Ebglyss; AND
Note: A patient who has received < 4 months of therapy or who is restarting therapy with Ebglyss should be considered under criterion 1A (Atopic Dermatitis, Initial Therapy).

ii. Patient has responded to therapy as determined by the prescriber.
Note: Examples of a response to Ebglyss therapy are marked improvements in erythema, induration/papulation/edema, excoriations, and lichenification; reduced pruritus; decreased requirement for other topical or systemic therapies; reduced body surface area affected with atopic dermatitis; or other responses observed.

Initial Approval/ Extended Approval.
A) *Initial Approval:* **4 months**
B) *Extended Approval:* **12 months**

CONDITIONS NOT RECOMMENDED FOR APPROVAL

Ebglyss has not been shown to be effective, or there are limited or preliminary data or potential safety concerns that are not supportive of general approval for the following conditions. (Note: This is not an exhaustive list of Conditions Not Recommended for Approval).

1. **Asthma.** Ebglyss is not indicated for the treatment of asthma.[1] Several studies, including one Phase III study, evaluated Ebglyss for the treatment of adults with asthma with mixed results.[8-11] Two replicate Phase IIb studies (designed as Phase III, but host-cell impurity in the study drug material was discovered), LUTE and VERSE (published) [n = 463] evaluated Ebglyss in patients with uncontrolled asthma despite treatment with medium- to high-dose inhaled corticosteroids and a second asthma controller.[10] Following a mean 24 weeks of treatment, Ebglyss significantly reduced asthma exacerbations vs. placebo in patients with in patients who had baseline periostin levels > 50 ng/mL.

However, in the Phase III study, STRETTO (published) [n = 310], Ebglyss did not significantly improve forced expiratory volume in 1 second compared with placebo in patients with mild to moderate asthma.[11]

2. **Concurrent use of Ebglyss with another Monoclonal Antibody Therapy (i.e., Adbry, Dupixent, Cinqair, Fasenra, Nemluvio, Nucala, Tezspire, or Xolair).** The efficacy and safety of Ebglyss in combination with other monoclonal antibodies have not been established.

3. **Concurrent Use of Ebglyss with Janus Kinase Inhibitors (JAKis) [oral or topical].** Use of JAK inhibitors is not recommended for use in combination with other JAK inhibitors, biologic immunomodulators (e.g., Ebglyss), or with other immunosuppressants.[12-15]
   Note: Examples of JAK inhibitors are Cibinqo® (abrocitinib tablets), Leqselvi™ (deuruxolitinib tablets), Rinvoq®/Rinvoq® LQ (upadacitinib tablets and oral solution), and Opzelura® (ruxolitinib cream).

4. **Idiopathic Pulmonary Fibrosis.** Ebglyss is not indicated for the treatment of idiopathic pulmonary fibrosis.[1] In one Phase II, randomized, placebo-controlled study (published) [n = 505], Ebglyss was not found to provide a benefit in forced vital capacity decline vs. placebo when either administered as monotherapy or in combination with pirfenidone.[16]

5. Coverage is not recommended for circumstances not listed in the Recommended Authorization Criteria. Criteria will be updated as new published data are available.

Documentation Requirements:

The Company reserves the right to request additional documentation as part of its coverage determination process. The Company may deny reimbursement when it has determined that the drug provided or services performed were not medically necessary, investigational, or experimental, not within the scope of benefits afforded to the member and/or a pattern of billing or other practice has been found to be either inappropriate or excessive. Additional documentation supporting medical necessity for the services provided must be made available upon request to the Company. Documentation requested may include patient records, test results and/or credentials of the provider ordering or performing a service. The Company also reserves the right to modify, revise, change, apply and interpret this policy at its sole discretion, and the exercise of this discretion shall be final and binding.

REFERENCES

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13. Rinvoq® tablets [prescribing information]. North Chicago, IL: AbbVie; April 2024.
14. Opzelura® cream [prescribing information]. Wilmington, DE: Incyte; March 2023.
15. Leqselvi™ tablets [prescribing information]. Whippany, NJ: Sun/Halo; July 2024.
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