PRIOR AUTHORIZATION POLICY

POLICY: Immunologicals – Ebglyss Prior Authorization Policy
- Ebglyss® (lebrikizumab-lbkz subcutaneous injection – Eli Lilly)

REVIEW DATE: 09/03/2025

INSTRUCTIONS FOR USE

THE FOLLOWING COVERAGE POLICY APPLIES TO HEALTH BENEFIT PLANS ADMINISTERED BY CIGNA COMPANIES. CERTAIN CIGNA COMPANIES AND/OR LINES OF BUSINESS ONLY PROVIDE UTILIZATION REVIEW SERVICES TO CLIENTS AND DO NOT MAKE COVERAGE DETERMINATIONS. REFERENCES TO STANDARD BENEFIT PLAN LANGUAGE AND COVERAGE DETERMINATIONS DO NOT APPLY TO THOSE CLIENTS. COVERAGE POLICIES ARE INTENDED TO PROVIDE GUIDANCE IN INTERPRETING CERTAIN STANDARD BENEFIT PLANS ADMINISTERED BY CIGNA COMPANIES. PLEASE NOTE, THE TERMS OF A CUSTOMER'S PARTICULAR BENEFIT PLAN DOCUMENT [GROUP SERVICE AGREEMENT, EVIDENCE OF COVERAGE, CERTIFICATE OF COVERAGE, SUMMARY PLAN DESCRIPTION (SPD) OR SIMILAR PLAN DOCUMENT] MAY DIFFER SIGNIFICANTLY FROM THE STANDARD BENEFIT PLANS UPON WHICH THESE COVERAGE POLICIES ARE BASED. FOR EXAMPLE, A CUSTOMER'S BENEFIT PLAN DOCUMENT MAY CONTAIN A SPECIFIC EXCLUSION RELATED TO A TOPIC ADDRESSED IN A COVERAGE POLICY. IN THE EVENT OF A CONFLICT, A CUSTOMER'S BENEFIT PLAN DOCUMENT ALWAYS SUPERSEDES THE INFORMATION IN THE COVERAGE POLICIES. IN THE ABSENCE OF A CONTROLLING FEDERAL OR STATE COVERAGE MANDATE, BENEFITS ARE ULTIMATELY DETERMINED BY THE TERMS OF THE APPLICABLE BENEFIT PLAN DOCUMENT. COVERAGE DETERMINATIONS IN EACH SPECIFIC INSTANCE REQUIRE CONSIDERATION OF 1) THE TERMS OF THE APPLICABLE BENEFIT PLAN DOCUMENT IN EFFECT ON THE DATE OF SERVICE; 2) ANY APPLICABLE LAWS/REGULATIONS; 3) ANY RELEVANT COLLATERAL SOURCE MATERIALS INCLUDING COVERAGE POLICIES AND; 4) THE SPECIFIC FACTS OF THE PARTICULAR SITUATION. EACH COVERAGE REQUEST SHOULD BE REVIEWED ON ITS OWN MERITS. MEDICAL DIRECTORS ARE EXPECTED TO EXERCISE CLINICAL JUDGMENT WHERE APPROPRIATE AND HAVE DISCRETION IN MAKING INDIVIDUAL COVERAGE DETERMINATIONS. WHERE COVERAGE FOR CARE OR SERVICES DOES NOT DEPEND ON SPECIFIC CIRCUMSTANCES, REIMBURSEMENT WILL ONLY BE PROVIDED IF A REQUESTED SERVICE(S) IS SUBMITTED IN ACCORDANCE WITH THE RELEVANT CRITERIA OUTLINED IN THE APPLICABLE COVERAGE POLICY, INCLUDING COVERED DIAGNOSIS AND/OR PROCEDURE CODE(S). REIMBURSEMENT IS NOT ALLOWED FOR SERVICES WHEN BILLED FOR CONDITIONS OR DIAGNOSES THAT ARE NOT COVERED UNDER THIS COVERAGE POLICY (SEE "CODING INFORMATION" BELOW). WHEN BILLING, PROVIDERS MUST USE THE MOST APPROPRIATE CODES AS OF THE EFFECTIVE DATE OF THE SUBMISSION. CLAIMS SUBMITTED FOR SERVICES THAT ARE NOT ACCOMPANIED BY COVERED CODE(S) UNDER THE APPLICABLE COVERAGE POLICY WILL BE DENIED AS NOT COVERED. COVERAGE POLICIES RELATE EXCLUSIVELY TO THE ADMINISTRATION OF HEALTH BENEFIT PLANS. COVERAGE POLICIES ARE NOT RECOMMENDATIONS FOR TREATMENT AND SHOULD NEVER BE USED AS TREATMENT GUIDELINES. IN CERTAIN MARKETS, DELEGATED VENDOR GUIDELINES MAY BE USED TO SUPPORT MEDICAL NECESSITY AND OTHER COVERAGE DETERMINATIONS.

CIGNA NATIONAL FORMULARY COVERAGE:

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).

Clinical Efficacy

Three pivotal studies of Ebglyss enrolled patients ≥ 12 years of age with moderate to severe chronic atopic dermatitis affecting ≥ 10% of their body surface area.[1-4] Patients also had a history of an inadequate response to a sufficient course of topical therapy (e.g., topical corticosteroids). At Week 16, Ebglyss was found to be more effective in achieving a clinical response compared with placebo. In the monotherapy trials, the majority of patients who achieved a clinical response to Ebglyss at Week 16 experienced sustained efficacy at Week 52.

Guidelines

Current atopic dermatitis guidelines do not make recommendations regarding Ebglyss. The **American Academy of Dermatology** (AAD) Guidelines for the Care and Management of Atopic Dermatitis in Adults (topical therapies update in 2022 and systemic agents update in 2023) and the **American Academy of Allergy, Asthma and Immunology (AAAAI)/American College of Allergy, Asthma and Immunology (ACAAI) Joint Task Force on Practice Parameters** Atopic Dermatitis Guidelines (2023) continue to affirm that despite the availability of newer, systemic therapies, topical agents remain the mainstay of treatment due to their proven track record and favorable safety profiles.[5-7] Several topical agents are recommended, with topical corticosteroids commonly used first-line for mild to severe atopic dermatitis in all skin regions. If topical therapy and basic management (e.g., moisturizers, bathing modifications) have been optimized and the patient has not achieved adequate control, systemic therapy may be considered.

POLICY STATEMENT

Prior Authorization is recommended for prescription benefit coverage of Ebglyss. All approvals are provided for the duration noted below. In cases where the approval is authorized in months, 1 month is equal to 30 days. 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 to be prescribed by or in consultation with a physician who specializes in the condition being treated.

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is(are) covered as medically necessary when the following criteria is(are) met for FDA-approved indication(s) or other uses with supportive evidence (if applicable):

FDA-Approved Indication

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 ALL of the following criteria (a, b, and c):

a) Patient has tried at least one medium-, medium-high, high-, and/or super-high-potency prescription topical corticosteroid; AND
b) This topical corticosteroid was applied daily for at least 28 consecutive days; AND
c) Inadequate efficacy was demonstrated with this topical corticosteroid therapy, according to the prescriber; AND

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

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.

CONDITIONS NOT COVERED

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is(are) considered not medically necessary for ANY other use(s) including the following (this list may not be all inclusive; criteria will be updated as new published data are available):

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] In the Phase III LAVOLTA I and II trials, Ebglyss was evaluated in adults with uncontrolled asthma despite standard therapy.[17] Ebglyss significantly reduced exacerbation rates in biomarker-high patients (elevated periostin or eosinophils) in LAVOLTA I, but the results were not consistently replicated in LAVOLTA II.

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]

REFERENCES

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13. Rinvoq® tablets [prescribing information]. North Chicago, IL: AbbVie; April 2025.
14. Opzelura® cream [prescribing information]. Wilmington, DE: Incyte; August 2024.
15. Leqselvi™ tablets [prescribing information]. Whippany, NJ: Sun/Halo; July 2025.
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HISTORY

Type of Revision	Summary of Changes	Review Date
New Policy	--	09/18/2024
Annual Revision	No criteria changes.	09/03/2025