Pharmacy Policy Bulletin: J-1419 Ebglyss (lebrikizumab-lbkz) – Commercial and Healthcare Reform	
Number: J-1419	**Category:** Prior Authorization
Line(s) of Business: ☒ Commercial ☒ Healthcare Reform ☐ Medicare	**Benefit(s):** **Commercial:** **Prior Authorization (1., 2., or 3.):** **1.** Miscellaneous Specialty Drugs Injectable = Yes w/ Prior Authorization **Quantity Limits (1., 2., 3., or 4.):** **1.** Quantity Limits = Safety/Specialty **2.** Quantity Limits = Safety/Specialty + Dose Opt **3.** Quantity Limits = Safety/Specialty + Dose Opt + Watchful **4.** Rx Mgmt Performance = MRXC = Yes **Healthcare Reform:** Not Applicable
Region(s): ☒ All ☐ Delaware ☐ New York ☐ Pennsylvania ☐ West Virginia	**Additional Restriction(s):** None
Version: J-1419-001	**Original Date:** 12/04/2024
Effective Date: 12/20/2024	**Review Date: 12/04/2024**

Drugs Product(s):	• Ebglyss (lebrikizumab-lbkz)
FDA-Approved Indication(s):	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. Ebglyss can be used with or without topical corticosteroids.

Background:	• Ebglyss is a self-administered, subcutaneous (SC), immunoglobulin G4 (IgG4) monoclonal antibody that binds with high affinity and slow off-rate to interleukin (IL)-13 and allows IL-13 to bind to IL-13Rα1 but inhibits human IL-13 signaling through the IL-4Rα/IL-13Rα1 receptor complex. IL-13 is a naturally occurring cytokine of the Type 2 immune response. Inhibiting IL-13-induced responses blocks the release of proinflammatory cytokines, chemokines, and immunoglobulin E (IgE). • Atopic dermatitis (AD) is a chronic, relapsing, pruritic inflammatory skin disease that occurs more commonly in children, but also affects many adults. AD is often associated with elevated serum IgE levels and a personal or family history of type I allergies, allergic rhinitis, and asthma. Clinical features of AD include pruritus, skin dryness, erythema, oozing and crusting, and lichenification. • According to the American Academy of Dermatology (AAD), topical corticosteroids are recommended for initial treatment of AD, followed by non-

steroid therapies. Examples of topical corticosteroids include betamethasone dipropionate, clobetasol propionate, fluocinonide, halobetasol propionate, triamcinolone acetonide, halcinonide, betamethasone valerate, fluocinolone acetonide, fluticasone propionate, hydrocortisone valerate, or mometasone furoate.

- Topical corticosteroids should be avoided if a patient has damaged skin, such as infected skin (unless advised by a doctor), rosacea, acne, and skin ulcers (open sores).
- Protopic (tacrolimus), Elidel (pimecrolimus), Eucrisa (crisaborole), Zoryve (roflumilast) and Opzelura (ruxolitinib) are non-steroid therapies for topical treatment of AD.
    - Elidel (pimecrolimus) cream 1% is indicated as second-line therapy for the short-term and non-continuous chronic treatment of **mild-to-moderate** AD in non-immunocompromised adults and children 2 years of age and older, who have failed to respond adequately to other topical prescription treatments, or when those treatments are not advisable.
    - Protopic (tacrolimus) ointment 0.03% (adults and children 2 years of age and older) and 0.1% (adults and children 16 years of age and older) is indicated as second-line therapy for the short-term and non-continuous chronic treatment of **moderate-to-severe** AD in non-immunocompromised adults and children who have failed to respond adequately to other topical prescription treatments for AD, or when those treatments are not advisable.
    - Eucrisa (crisaborole) 0.15% is a topical phosphodiesterase 4 (PDE-4) inhibitor indicated for topical treatment of **mild-to-moderate** AD in patients 3 months of age and older.
    - Zoryve (roflumilast) is a topical PDE-4 inhibitor indicated for topical treatment of **mild-to-moderate** AD in patients 6 years and older.
    - Opzelura (ruxolitinib) is a topical short-term and non-continuous chronic treatment of **mild-to-moderate** AD in non-immunocompromised patients 12 years of age and older whose disease is not adequately controlled with topical prescription therapies or when those therapies are not advisable.
- Severity of AD is defined by the Validated Investigator's Global Assessment for AD (vIGA-AD)
    - 0 - Clear: No inflammatory signs of atopic dermatitis (no erythema, no induration/papulation, no lichenification, no oozing/crusting). Post-inflammatory hyperpigmentation and/or hypopigmentation may be present.
    - 1 - Almost Clear: Barely perceptible erythema, barely perceptible induration/papulation, and/or minimal lichenification. No oozing or crusting.
    - 2 - Mild: Slight but definite erythema (pink), slight but definite induration/papulation, and/or slight but definite lichenification. No oozing or crusting.
    - 3 - Moderate: Clearly perceptible erythema (dull red), clearly perceptible induration/papulation, and/or clearly perceptible lichenification. Oozing and crusting may be present.
    - 4 - Severe: Marked erythema (deep or bright red), marked induration/papulation, and/or marked lichenification. Disease is widespread in extent. Oozing or crusting may be present.
- For systemic therapies in AD, the AAD makes strong recommendations for the use of dupilumab, tralokinumab, abrocitinib, baricitinib, and upadacitinib. Conditional recommendations are made in favor of using phototherapy,

	azathioprine, cyclosporine, methotrexate, and mycophenolate, and against the use of systemic corticosteroids. • Examples of positive clinical response in AD therapy include 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 AD. • In the clinical trials ADvocate 1 and ADvocate 2, patients that did not achieve Investigator's Global Assessment (IGA) 0 or 1 or Eczema Area and Severity Index (EASI) 75 at week 16 were moved to an open label escape arm to be treated with Ebglyss every 2 weeks. Participation in the study was terminated if EASI 50 response was not achieved after 8 weeks. This study design was used to develop the induction dosing approval duration used in the quantity limits below. • Prescribing Considerations: o Prior to Ebglyss initiation, complete all age-appropriate vaccinations as recommended by current immunization guidelines. Avoid use of live vaccines while on treatment. o Treat patients with pre-existing helminth infections before initiating treatment with Ebglyss. o Patients should report new onset or worsening eye symptoms of conjunctivitis or keratitis to their healthcare provider o An initial dose is recommended of 500 mg (two 250 mg injections) at Week 0 and Week 2, followed by 250 mg every two weeks until Week 16 or later, when adequate clinical response is achieved. The maintenance dosage is 250 mg every four weeks. o For pediatric patients, a caregiver may give the injections after training on SC injection technique.

Approval Criteria

I. Initial Authorization

When a benefit, coverage of Ebglyss may be approved when all of the following criteria are met **(A., through D.)**:

A. The member is 12 years of age or older.

B. For pediatrics, the member weighs greater than or equal to 40 kg.

C. The specialist (dermatologist, allergist or immunologist) submits attestation that the member has a diagnosis of atopic dermatitis (ICD-10: L20), that is moderate-to-severe.

D. The member meets one (1) of the following criteria **(1. or 2.)**:

1. The member has experienced therapeutic failure or intolerance to one (1) of the following **(a. or b.)**:

a. One (1) generic topical corticosteroid

b. One(1) generic topical calcineurin inhibitor (i.e., tacrolimus, pimecrolims)

2. The prescriber attests the member has severe atopic dermatitis and topical therapy would not be advisable for maintenance therapy as evidenced by one (1) of the following **(a. or b.)**:

a. The member is incapable of apply topical therapies due to the extent of body surface are (BSA) involvement.

b. Topical therapies are contraindicated due to severely damaged skin.

II. Reauthorization

When a benefit, reauthorization of Ebglyss may be approved when the following criterion is met **(A.)**:

A. The prescriber attests that the member has experienced positive clinical response to therapy.

III. Quantity Limitations

When prior authorization is approved, Ebglyss may be authorized in quantities as follows.

Diagnosis	Induction Therapy	Maintenance Therapy
Atopic Dermatitis *	Eleven (11) 250 mg syringes/pens within the first sixteen (16) weeks of therapy	One (1) 250 mg syringe/pen every four (4) weeks

*Induction therapy dose of one (1) 250mg syringe/pen every 2 weeks may be approved once for an additional 8 weeks for members who did not achieve clinical response by 16 weeks.

IV. If the patient has already had a trial of at least one biologic agent for the same indication, the patient is not required to "step back" and try a non-biologic agent.

V. An exception to some or all of the criteria above may be granted for select members and/or circumstances based on state and/or federal regulations

Limitations of Coverage

I. Coverage of drug(s) addressed in this policy for disease states outside of the FDA-approved indications should be denied based on the lack of clinical data to support effectiveness and safety in other conditions unless otherwise noted in the approval criteria.

II. For Commercial or HCR members with a closed formulary, a non-formulary product will only be approved if the member meets the criteria for a formulary exception in addition to the criteria outlined within this policy.

Authorization Duration

Initial Authorization

- Commercial and HCR Plans: If approved, up to a 6 month authorization may be granted.
  - Note: For induction therapy authorization duration, refer to the Quantity Limitations tables for the respective drug and diagnosis.

Reauthorization

- Commercial and HCR Plans: If approved, up to a 12 month authorization may be granted.

Automatic Approval Criteria

None.

References:

1. Ebglyss [package insert]. Indianapolis, IN: Eli Lilly and Company; September 2024
2. DRUGDEX System (Micromedex 2.0). Greenwood Village, CO: Truven Health Analytics. 2024.
3. Davis DM, Drucker AM, Alikhan A., et al. Guidelines of care for the management of atopic dermatitis in adults with phototherapy and systemic agents. *J Am Acad Dermatol* 2024; 90: e43-e56.
4. Sidebury R, Alikhan A, Bercovitch L, et al. Guidelines of care for the management of atopic dermatitis with topical therapies management and treatment of atopic dermatitis with topical therapies. *J Am Acad Dermatol*. 2023; 89: e1-e20.
5. Chu DK, Schnieder L, Netahe AR., 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*. Annals of Allergy, Asthma, & Immunology.* 2024;132: 274–312.
6. Boguniewicz M, Fonacier L, Guttman-Yassky E, Ong PY, Silverberg J, Farrar JR. Atopic dermatitis yardstick: Practical recommendations for an evolving Therapeutic Landscape. *Ann. Allergy Asthma Immunol*. 2018;120(1).

7. NHS choices. Available at: https://www.nhs.uk/conditions/topical-steroids/. Accessed October 4, 2024.
8. Validated investigator global assessment scale for atopic dermatitis. Available at: https://www.eczemacouncil.org/assets/docs/Validated-Investigator-Global-Assessment-Scale_vIGA-AD_2017.pdf. Accessed October 4, 2024.