Effective Date: 5/1/2025
Reviewed: 2/25 Scope: Medicaid

Ebglyss (lebrikizumab-lbkz)

POLICY

I. INDICATIONS

The indications below including FDA-approved indications and compendia uses are considered a covered benefit provided that all the approval criteria are met, and the member has no exclusions to the prescribed therapy.

FDA-Approved Indications

Ebglyss is indicated for the treatment of adults and pediatric patients aged 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.

All other indications are considered experimental/investigational and not medically necessary.

II. CRITERIA FOR INITIAL APPROVAL

Moderate-to-severe atopic dermatitis

Authorization of 4 months may be granted for treatment of moderate-to-severe atopic dermatitis when all of the following criteria are met:

1. Member is 12 years of age or older
2. Documentation that the member weighs at least 40 kg
3. The medication must be prescribed by or in consultation with a dermatologist or allergist/immunologist
4. Documentation that the affected body surface is greater than or equal to 10% body surface area OR crucial body areas (e.g., hands, feet, face, neck, scalp, genitals/groin, intertriginous areas) are affected
5. Documentation that the member has had an inadequate treatment response to at least one medium to super-high potency topical corticosteroid for ≥ 2 consecutive weeks (see Appendix) or use of a topical corticosteroid is not advisable for the member (e.g., due to contraindications, prior intolerances)
6. Documentation that the member has had an inadequate treatment response to pimecrolimus cream or tacrolimus ointment for ≥ 6 consecutive weeks, experienced an intolerance or is contraindicated to topical calcineurin inhibitors
7. Documentation that the member has had an inadequate treatment response with a 4-month trial, intolerance or contraindication to Dupixent
8. Documentation that the member has had an inadequate treatment response with a 4-month trial, intolerance or contraindication to Adbry or Nemluvio
9. Member will not use Ebglyss concomitantly with any other biologic drug or targeted synthetic drug, including JAK inhibitors, indicated for atopic dermatitis.

III. CONTINUATION OF THERAPY

Moderate-to-severe atopic dermatitis

Requests for 250mg every 4 weeks:

Authorization of 12 months may be granted for members 12 years of age or older who are using the requested medication for moderate-to-severe atopic dermatitis when both of the following are met:

A. Documentation that member has achieved or maintained a positive clinical response with Ebglyss therapy evidenced by low disease activity (i.e., clear or almost clear skin), or improvement in signs and symptoms of atopic dermatitis (e.g., redness, itching, oozing/crusting).
B. Member will not use Ebglyss concomitantly with other biologics or JAK inhibitors indicated for atopic dermatitis.

Requests for 250mg every 2 weeks:
Authorization of 6 months may be granted on a case-by-case basis for members 12 years of age or older who are using the requested medication for moderate-to-severe atopic dermatitis when both of the following are met:
A. Documentation that member has achieved a positive clinical response with Ebglyss therapy after at least 16 weeks of starting therapy evidenced by lower disease activity or improvement in signs and symptoms of atopic dermatitis (e.g., redness, itching, oozing/crusting), and medical rationale provided for continuing every 2-week dosing frequency.
B. Member will not use Ebglyss concomitantly with other biologics or JAK inhibitors indicated for atopic dermatitis.

IV. QUANTITY LIMIT

Ebglyss 250mg/2ml pen and prefilled syringe have a quantity limit of 1 pen/prefilled syringe (2ml) per 28 days (daily dose of 0.072), with an exception provided for the induction regimen of two initial loading doses of 4 pens/prefilled syringes per 28 days (daily dose of 0.29) and 2 pens/prefilled syringes per 28 days (daily dose of 0.143) for 12 weeks (3 fills). An exception may also be provided to continue a dose of 250mg every 2 weeks (2 pens/prefilled syringes per 28 days, daily dose of 0.143) with documentation provided of inadequate clinical response.

V. DOSAGE AND ADMINISTRATION

Indication	Recommended Dosage
Atopic Dermatitis	*Adults and pediatric patients 12 years of age and older:* 500mg (two 250mg injections) SC initially at Week 0 and Week 2, followed by 250mg SC every 2 weeks until Week 16 or later, when adequate clinical response is achieved Maintenance dose: 250mg every 4 weeks

VI. APPENDIX

Relative potency of select topical corticosteroid products

Potency	Drug	Dosage form	Strength
I. Super-high potency (group 1)	Augmented betamethasone dipropionate	Ointment, Gel	0.05%
	Clobetasol propionate	Cream, Ointment, Solution, Cream (emollient)	0.05%

Potency	Drug	Dosage form	Strength
	Fluocinonide	Cream	0.1%
II. High potency (group 2)	Augmented betamethasone dipropionate	Cream	0.05%
	Betamethasone dipropionate	Ointment	0.05%
	Fluocinonide	Cream, Ointment, Gel, Solution	0.05%
III. High potency (group 3)	Betamethasone dipropionate	Cream	0.05%
	Betamethasone valerate	Ointment	0.1%
	Fluocinonide	Cream, aqueous emollient	0.05%
	Fluticasone propionate	Ointment	0.005%
	Mometasone furoate	Ointment	0.1%
	Triamcinolone acetonide	Cream, Ointment	0.5%
IV. Medium potency (group 4)	Fluocinolone acetonide	Ointment	0.025%
	Mometasone furoate	Cream	0.1%
	Triamcinolone acetonide	Cream	0.1%
		Ointment	0.05% and 0.1%

VII. REFERENCES

1. Ebglyss [package insert]. Indianapolis, IN: Eli Lilly and Company; September 2024.
2. Silverberg JI, Guttman-Yassky E, Thaçi D, et al. Two Phase 3 Trials of Lebrikizumab for Moderate-to-Severe Atopic Dermatitis. *N Engl J Med.* 2023;388(12):1080-1091.
3. 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.
4. Eichenfield LF, Tom WL, Chamlin SL, et. al. Guidelines of care for the management of atopic dermatitis: Section 1. Diagnosis and Assessment of Atopic Dermatitis. *J Am Acad Dermatol.* 2014;70:338-351.
5. Eichenfield LF, Tom WL, Berger TG, et. al. Guidelines of care for the management of atopic dermatitis: Section 2. Management and treatment of atopic dermatitis with topical therapies. *J Am Acad Dermatol.* 2014;71:116-132.
6. 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.
7. Chu DK, Schneider L, 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. Ann Allergy Asthma Immunol 132(2024) 274−312.
8. Topical Corticosteroids. Drug Facts and Comparisons. Facts & Comparisons [database online]. St. Louis, MO: Wolters Kluwer Health Inc; July 18, 2024. Accessed October 2, 2024.