AETNA BETTER HEALTH®
Coverage Policy/Guideline

Name:	Ebglyss (lebrikizumab-lbkz)	Page:	1 of 8
Effective Date:	12/26/2024	Last Review Date:	12/2024

Applies to:	☐ Illinois	☐ Florida	☒ New Jersey
	☒ Maryland	☒ Florida Kids	☒ Pennsylvania Kids
	☐ Michigan	☐ Virginia	☒ KY PRMD

Intent:

The intent of this policy/guideline is to provide information to the prescribing practitioner outlining the coverage criteria for Ebglyss under the patient's prescription drug benefit.

Description:

FDA-Approved Indication

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.

Applicable Drug List:

Ebglyss

Policy/Guideline:

Documentation

Note: Requests require that the patient is unable to take Dupixent and Rinvoq for the given diagnosis due to a trial and inadequate treatment response or intolerance, or a contraindication. Documentation is required for approval.

Submission of the following information is necessary to initiate the prior authorization review:

Initial requests:

- Chart notes or medical records showing affected area(s) and body surface area (where applicable).
- Chart notes or medical record documentation and claims history of prerequisite therapies (including topical calcineurin inhibitors, topical corticosteroids, or biologics/targeted synthetic drugs) including dosage, duration, and response to therapy. If prerequisite therapy is not advisable, documentation of why topical corticosteroid and/or topical calcineurin inhibitor is/are not advisable for the member.

Continuation requests:

- Documentation (e.g., chart notes) that the member has experienced a positive clinical response to therapy as evidenced by low disease activity or improvement in signs or symptoms of atopic dermatitis.

Prescriber Specialty

This medication must be prescribed by or in consultation with a dermatologist or allergist/immunologist.

Criteria for Initial Approval

Atopic dermatitis

Authorization of 4 months may be granted for members 12 years of age or older weighing at least 40 kg who have previously received a biologic (e.g., Dupixent) or targeted synthetic drug (e.g., Cibinqo, Rinvoq) indicated for moderate-to-severe atopic dermatitis in the past 180 days.

Authorization of 4 months may be granted for members 12 years of age or older weighing at least 40 kg for treatment of moderate-to-severe atopic dermatitis when both of the following criteria are met:

- 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.
- Member meets either of the following:
    - Member has had an inadequate treatment response with either of the following in the past 180 days:
        - A high potency or super-high potency topical corticosteroid (see Appendix)
        - A topical calcineurin inhibitor
    - The use of high potency or super-high potency topical corticosteroid and topical calcineurin inhibitor are not advisable for the member (e.g., due to contraindications, prior intolerances, potency not appropriate for member's age).

Continuation of Therapy

Authorization of 12 months may be granted for members 12 years of age or older (including new members) weighing at least 40 kg who are using the requested medication for moderate-to-severe atopic dermatitis when the member has achieved or maintained a

positive clinical response as 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).

Other
Member cannot use the requested medication concomitantly with any other biologic drug or targeted synthetic drug for the same indication.

Dosage and Administration
Approvals may be subject to dosing limits in accordance with FDA-approved labeling, accepted compendia, and/or evidence-based practice guidelines.

Appendix
Table. Relative potency of select topical corticosteroid products

Potency	Drug	Dosage form	Strength
I.Super-high potency (group 1)	Augmented betamethasone dipropionate	Ointment, Lotion, Gel	0.05%
I.Super-high potency (group 1)	Clobetasol propionate	Cream, Gel, Ointment, Solution, Cream (emollient), Lotion, Shampoo, Foam, Spray	0.05%
I.Super-high potency (group 1)	Fluocinonide	Cream	0.1%
I.Super-high potency (group 1)	Flurandrenolide	Tape	4 mcg/cm^2
I.Super-high potency (group 1)	Halobetasol propionate	Cream, Lotion, Ointment, Foam	0.05%
II.High potency (group 2)	Amcinonide	Ointment	0.1%
II.High potency (group 2)	Augmented betamethasone dipropionate	Cream	0.05%
II.High potency (group 2)	Betamethasone dipropionate	Ointment	0.05%
II.High potency (group 2)	Clobetasol propionate	Cream	0.025%

Potency	Drug	Dosage form	Strength
II.High potency (group 2)	Desoximetasone	Cream, Ointment, Spray	0.25%
II.High potency (group 2)	Desoximetasone	Gel	0.05%
II.High potency (group 2)	Diflorasone diacetate	Ointment, Cream (emollient)	0.05%
II.High potency (group 2)	Fluocinonide	Cream, Ointment, Gel, Solution	0.05%
II.High potency (group 2)	Halcinonide	Cream, Ointment	0.1%
II.High potency (group 2)	Halobetasol propionate	Lotion	0.01%
III.High potency (group 3)	Amcinonide	Cream, Lotion	0.1%
III.High potency (group 3)	Betamethasone dipropionate	Cream, hydrophilic emollient	0.05%
III.High potency (group 3)	Betamethasone valerate	Ointment	0.1%
III.High potency (group 3)	Betamethasone valerate	Foam	0.12%
III.High potency (group 3)	Desoximetasone	Cream, Ointment	0.05%
III.High potency (group 3)	Diflorasone diacetate	Cream	0.05%
III.High potency (group 3)	Fluocinonide	Cream, aqueous emollient	0.05%
III.High potency (group 3)	Fluticasone propionate	Ointment	0.005%
III.High potency (group 3)	Mometasone furoate	Ointment	0.1%
III.High potency (group 3)	Triamcinolone acetonide	Cream, Ointment	0.5%
IV.Medium potency (group 4)	Betamethasone dipropionate	Spray	0.05%
IV.Medium potency (group 4)	Clocortolone pivalate	Cream	0.1%

Potency	Drug	Dosage form	Strength
IV.Medium potency (group 4)	Fluocinolone acetonide	Ointment	0.025%
IV.Medium potency (group 4)	Flurandrenolide	Ointment	0.05%
IV.Medium potency (group 4)	Hydrocortisone valerate	Ointment	0.2%
IV.Medium potency (group 4)	Mometasone furoate	Cream, Lotion, Solution	0.1%
IV.Medium potency (group 4)	Triamcinolone acetonide	Cream	0.1%
IV.Medium potency (group 4)	Triamcinolone acetonide	Ointment	0.05% and 0.1%
IV.Medium potency (group 4)	Triamcinolone acetonide	Aerosol Spray	0.2 mg per 2-second spray
V.Lower-mid potency (group 5)	Betamethasone dipropionate	Lotion	0.05%
V.Lower-mid potency (group 5)	Betamethasone valerate	Cream	0.1%
V.Lower-mid potency (group 5)	Desonide	Ointment, Gel	0.05%
V.Lower-mid potency (group 5)	Fluocinolone acetonide	Cream	0.025%
V.Lower-mid potency (group 5)	Flurandrenolide	Cream, Lotion	0.05%

Potency	Drug	Dosage form	Strength
V.Lower-mid potency (group 5)	Fluticasone propionate	Cream, Lotion	0.05%
V.Lower-mid potency (group 5)	Hydrocortisone butyrate	Cream, Lotion, Ointment, Solution	0.1%
V.Lower-mid potency (group 5)	Hydrocortisone probutate	Cream	0.1%
V.Lower-mid potency (group 5)	Hydrocortisone valerate	Cream	0.2%
V.Lower-mid potency (group 5)	Prednicarbate	Cream (emollient), Ointment	0.1%
V.Lower-mid potency (group 5)	Triamcinolone acetonide	Lotion	0.1%
V.Lower-mid potency (group 5)	Triamcinolone acetonide	Ointment	0.025%
VI.Low potency (group 6)	Alclometasone dipropionate	Cream, Ointment	0.05%
VI.Low potency (group 6)	Betamethasone valerate	Lotion	0.1%
VI.Low potency (group 6)	Desonide	Cream, Lotion, Foam	0.05%
VI.Low potency (group 6)	Fluocinolone acetonide	Cream, Solution, Shampoo, Oil	0.01%
VI.Low potency (group 6)	Triamcinolone acetonide	Cream, lotion	0.025%
VII. Least potent (group 7)	Hydrocortisone (base, greater than or equal to 2%)	Cream, Ointment, Solution	2.5%
VII. Least potent (group 7)	Hydrocortisone (base, greater than or equal to 2%)	Lotion	2%

Potency	Drug	Dosage form	Strength
VII. Least potent (group 7)	Hydrocortisone (base, less than 2%)	Cream, Ointment, Gel, Lotion, Spray, Solution	1%
VII. Least potent (group 7)	Hydrocortisone (base, less than 2%)	Cream, Ointment	0.5%
VII. Least potent (group 7)	Hydrocortisone acetate	Cream	2.5%
VII. Least potent (group 7)	Hydrocortisone acetate	Lotion	2%
VII. Least potent (group 7)	Hydrocortisone acetate	Cream	1%

Approval Duration and Quantity Restrictions:

Initial Approval: 4 months
Renewal Approval: 12 months

Quantity Level Limits:

- Loading dose: 4 syringes/pens per 14 days (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)
- Maintenance dose: 2 syringes/pens per 28 days (250mg every 4 weeks)

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. Topical Corticosteroids. Drug Facts and Comparisons. Facts & Comparisons [database online]. St. Louis, MO: Wolters Kluwer Health Inc; July 18, 2024. Accessed October 2, 2024.