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6634-A

# Specialty Guideline Management

## Ebglyss

### Products Referenced by this Document

Drugs that are listed in the following table include both brand and generic and all dosage forms and strengths unless otherwise stated. Over-the-counter (OTC) products are not included unless otherwise stated.

Brand Name	Generic Name
Ebglyss	lebrikizumab-lbkz

### Indications

The indications below including FDA-approved indications and compendial 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 Indication<sup>1</sup>

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.

### Documentation

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

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## Initial requests

- Chart notes or medical record documentation showing affected area(s) and body surface area (where applicable).
- Chart notes, medical record documentation, or claims history supporting previous medications tried, including response to therapy. If therapy is not advisable, documentation of clinical reason to avoid therapy.

## Continuation requests

Chart notes or medical record documentation supporting positive clinical response.

## Prescriber Specialties

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

## Coverage Criteria

### Atopic dermatitis<sup>1-6,8</sup>

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., Adbry, Dupixent, Nemluvio) or systemic targeted synthetic drug (e.g., Cibinqo, Rinvoq) indicated for moderate-to-severe atopic dermatitis in the past year.

Authorization of 4 months may be granted for treatment of moderate-to-severe atopic dermatitis in members 12 years of age or older weighing at least 40 kg 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 one of the following in the past year:
    - A medium potency to super-high potency topical corticosteroid (see Appendix)
    - A topical calcineurin inhibitor
    - A topical Janus kinase (JAK) inhibitor
    - A topical phosphodiesterase-4 (PDE-4) inhibitor
  - The use of medium potency to super-high potency topical corticosteroid, topical calcineurin inhibitor, topical JAK inhibitor, and topical PDE-4 inhibitor are not advisable for the member (e.g., due to contraindications, prior intolerances).

# 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.

# Appendix

Table. Relative Potency of Select Topical Corticosteroid Products<sup>7</sup>

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 <sup>2</sup>
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%

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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%
IV.Medium potency (group 4)	Fluocinolone acetonide	Ointment	0.025%
IV.Medium potency (group 4)	Flurandrenolide	Ointment	0.05%

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Potency	Drug	Dosage form	Strength
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%
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%

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Potency	Drug	Dosage form	Strength
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%
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%

## References

1. Ebglyss [package insert]. Indianapolis, IN: Eli Lilly and Company; September 2024.
2. Silverberg JI, Guttman-Yassky E, Taçi 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. Sidbury R, Alikhan A, Bercovitch L, et. al. Guidelines of care for the management of atopic dermatitis in adults with topical therapies. *J Am Acad Dermatol.* 2023;89(1):e1-e20.
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 November 9, 2024.
8. 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 Feb;90(2):e43-e56.