

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

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.

Documentation

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, medical record documentation, or claims history of prerequisite therapies including response to therapy. If prerequisite therapies are not advisable, documentation of why therapy is 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 Specialties

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

Coverage Criteria

Atopic dermatitis

INITIAL APPROVAL STANDARD REVIEW for up to 6 months:

1. Individual has a confirmed diagnosis of moderate to severe atopic dermatitis supported by the submitted medical records; **AND**
2. Individual is ≥ 12 years old weighing at least 40 kg; **AND**
3. Individual has chronic or relapsing history that has been present for at least 6 months **AND**
4. Individual has a history of pruritus associated with atopic dermatitis (Boguniewicz, 2018); **AND**
5. Individual has at least one of the following (Boguniewicz, 2018):
 - a. Early age of onset (≤ 5 years of age) (Lyons, 2015); **OR**
 - b. Atopy; **OR**
 - c. Family history; **OR**
 - d. Xerosis; **AND**
6. Individual has involvement of $>10\%$ of body surface area **OR** involvement of critical areas (e.g., palms, face, etc) (FDA, 2021) **AND**
7. Individual must have documentation of one of the following (Boguniewicz, 2018):
 - a. For children: facial, neck or extensor involvement; **OR**
 - b. For any age group: current or previous flexural lesions; sparing of groin and axillary regions; **AND**
8. Individual has a skin biopsy consistent with the diagnosis of atopic dermatitis **OR** documentation is provided that other skin conditions have been excluded or adequately treated (such as scabies, seborrheic dermatitis, contact dermatitis (irritant or allergic), ichthyoses, cutaneous T-cell lymphoma, psoriasis, photosensitivity dermatoses, immune deficiency disease, and erythroderma of other causes) (Boguniewicz, 2018) **AND**
9. The drug is authorized and managed by a physician with expertise in the treatment of atopic dermatitis (e.g., allergist/immunologist or dermatologist) **AND**
10. Topical therapy failure (FDA, 2021). The patient has either failed a trial, proved intolerant of a medication, or has contraindications to both below topical treatments in the past year (in accordance with AAD Guidelines (Eichenfield, 2014) (Howe, 2022):
 - a. A topical calcineurin inhibitor with an inadequate response to maintenance therapy that includes intermittent use (at least 2 days per week) for at least 12 weeks; **OR**
 - b. A topical corticosteroid with an inadequate response to maintenance therapy that includes intermittent use (at least 2 days per week) for at least 12 weeks of a moderate-to-high-potency topical corticosteroid, unless involvement is limited to the face and intertriginous areas in which a lower-potency corticosteroid may be used; **AND**
11. The drug will NOT be used in combination with a janus kinase (JAK) inhibitor or another biologic agent for the treatment of atopic dermatitis [e.g., omalizumab (e.g., Xolair), mepolizumab (e.g., Nucala), reslizumab (e.g., Cinqair), tralokinumab (e.g., Adbry), Rinvoq, Dupixent, and rituximab (e.g., Rituxan)] for another atopic condition; **AND**

12. Individual has an Investigator's Global Assessment (IGA) score ≥ 3 (FDA, 2021); **AND**

13. Individual has at least one of the following:

a. Eczema Area and Severity Index (EASI) score ≥ 21 (Simpson, 2016; Simpson 2020);
OR

b. Weekly-average baseline worst itch score (Peak, Pruritus Numerical Rating Scale [NRS]) ≥ 4 (Efficacy, 2022); **AND**

14. Must be dosed in accordance with the FDA label.

Continuation of Therapy

A. Atopic dermatitis

Continued approval for up to 1 year:

Requirement of documentation in the medical records that the member has achieved and maintains a clinically meaningful benefit as defined below:

1. Reduction in disease severity (e.g., erythema, dryness, edema/papulation, excoriations, lichenification, oozing/crusting); **AND**
2. Reduction in the frequency or intensity of pruritus associated with atopic dermatitis; **AND**
3. Reduction in the frequency of disease exacerbations/flairs; **AND**
4. Reduction in the amount of Body Surface Area involvement relative to pretreatment baseline; **AND**
5. Improvement in overall patient quality of life (e.g., improved sleep, less depression or anxiety, etc.); **AND**
6. The drug will NOT be used in combination with a janus kinase (JAK) inhibitor or another biologic agent for the treatment of atopic dermatitis [e.g., omalizumab (e.g., Xolair), mepolizumab (e.g., Nucala), reslizumab (e.g., Cinqair), tralokinumab (e.g., Adbry) and rituximab (e.g., Rituxan)] or another atopic condition **AND**

7. Must be dosed in accordance with the FDA label.

Medication	Standard Limit	Exception Limit
Ebglyss (lebrikizumab-lbkz) 250 mg/ 2 mL single-dose prefilled syringe/pen	2 syringes/pens per 28 days	4 syringes/pens per 14 days

FDA-recommended Dosing

Loading dose:

- 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:

- 250 mg every 4 weeks

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

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	Betamethasone	Ointment	0.05%

Potency	Drug	Dosage form	Strength
(group 2)	dipropionate		
II.High potency (group 2)	Clobetasol propionate	Cream	0.025%
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	Mometasone furoate	Ointment	0.1%

Potency	Drug	Dosage form	Strength
(group 3)			
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%
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	Fluticasone propionate	Cream, Lotion	0.05%

Potency	Drug	Dosage form	Strength
potency (group 5)			
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%
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	Hydrocortisone acetate	Cream	2.5%

Potency	Drug	Dosage form	Strength
(group 7)			
VII. Least potent (group 7)	Hydrocortisone acetate	Lotion	2%
VII. Least potent (group 7)	Hydrocortisone acetate	Cream	1%