Ebglyss® (lebrikizumab-lbkz)

BENEFIT APPLICATION

Benefit determinations are based on the applicable contract language in effect at the time the services were rendered. Exclusions, limitations or exceptions may apply. Benefits may vary based on contract, and individual member benefits must be verified. Wellmark determines medical necessity only if the benefit exists and no contract exclusions are applicable. This medical policy may not apply to FEP. Benefits are determined by the Federal Employee Program.

DESCRIPTION

The intent of the policy is to provide coverage consistent with product labeling, FDA guidance, standards of medical practice, evidence-based drug information, and/or published guidelines. The indications below including FDA-approved indications and compendial uses are considered covered benefits 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 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

POLICY

Required Documentation

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

A. Atopic dermatitis

1. Initial requests:
    i. Member's chart notes or medical records showing affected area(s) and body surface area (where applicable).
    ii. Member's chart notes or medical record documentation and claims history of prerequisite therapies (see Criteria for Initial Approval A.2) including dosage, duration, and response to therapy. If prerequisite therapies are not advisable, documentation of why therapies are not advisable for the member.
2. 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

The requested medication must be prescribed by or in consultation with a dermatologist or allergist/immunologist

Criteria for Initial Approval

A. Moderate-to-severe atopic dermatitis

1) Authorization of **4 months** may be granted for members 12 years of age or older 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 year

2) Authorization of **4 months** may be granted for treatment of moderate-to-severe atopic dermatitis in members 12 years of age or older when all of the following criteria are met:
   A. Affected body surface area is greater than or equal to 10% OR crucial body areas (e.g., hands, feet, face, neck, scalp, genitals/groin, intertriginous areas) are affected.
   B. Member meets one of the following:
      i. Member has had an inadequate treatment response to one of the following in the past 180 days:
         a. A medium potency to super-high potency topical corticosteroid (see Appendix A)
         b. A topical calcineurin inhibitor
      ii. The use of medium potency to super-high potency topical corticosteroids and topical calcineurin inhibitors are not advisable for the member (e.g., due to contraindications, prior intolerances, potency not appropriate for member's age)
   C. Member will not exceed the maximum FDA-approved dose for this indication.
   D. Member will not use Ebglyss concomitantly with other biologics or JAK inhibitors indicated for atopic dermatitis.

Continuation of Therapy

A. Moderate-to-severe atopic dermatitis

Authorization of **12 months** may be granted for members 12 years of age or older when all of the following criteria is met:

1. Member has achieved or maintained a positive clinical response with Ebglyss therapy for moderate-to-severe atopic dermatitis 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).
2. Member will not exceed the maximum FDA-approved dose for this indication
3. Member will not use Ebglyss concomitantly with other biologics or JAK inhibitors indicated for atopic dermatitis.

Other

Ebglyss is considered **not medically necessary** for members who do not meet the criteria set forth above.

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

Members currently receiving the requested medication as samples or via the manufacturer's patient assistance program will be required to meet the criteria for initial approval. This ensures that members are treated equally regardless of their provider's ability to access medication samples.

Dosing and Administration

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

Quantity Limits

Medication	Standard Limit	FDA Recommended Dosing
Ebglyss (lebrikizumab-lbkz) 250 mg/2 mL pre-filled syringe or pen-injector	Initiation of therapy: 4 syringes/pens per first 28 days 2 syringes/pens until week 16 Maintenance: 1 syringe/pen per 28 days	**Atopic dermatitis** • Initial dose of 500 mg (two 250 mg injections) at Week 0 and Week 2, followed by 250 mg every other week until Week 16 • Maintenance dose of 250 mg every 4 weeks

Appendices

Appendix A: Relative potency of select topical corticosteroid products

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%
	Clobetasol propionate	Cream, Gel, Ointment, Solution, Cream (emollient), Lotion, Shampoo, Foam, Spray	0.05%
	Fluocinonide	Cream	0.1%
	Flurandrenolide	Tape	4 mcg/cm^2
	Halobetasol propionate	Cream, Lotion, Ointment, Foam	0.05%
II. High potency (group 2)	Amcinonide	Ointment	0.1%
	Augmented betamethasone dipropionate	Cream	0.05%
	Betamethasone dipropionate	Ointment	0.05%
	Clobetasol propionate	Cream	0.025%
	Desoximetasone	Cream, Ointment, Spray	0.25%
		Gel	0.05%
	Diflorasone diacetate	Ointment, Cream (emollient)	0.05%
	Fluocinonide	Cream, Ointment, Gel, Solution	0.05%
	Halcinonide	Cream, Ointment	0.1%
	Halobetasol propionate	Lotion	0.01%
III. High potency (group 3)	Amcinonide	Cream, Lotion	0.1%
	Betamethasone dipropionate	Cream, hydrophilic emollient	0.05%
	Betamethasone valerate	Ointment	0.1%
		Foam	0.12%
	Desoximetasone	Cream, Ointment	0.05%
	Diflorasone diacetate	Cream	0.05%
	Fluocinonide	Cream, aqueous emollient	0.05%
	Fluticasone propionate	Ointment	0.005%
	Mometasone furoate	Ointment	0.1%

Relative potency of select topical corticosteroid products			
Potency	**Drug**	**Dosage form**	**Strength**
	Triamcinolone acetonide	Cream, Ointment	0.5%
IV. Medium potency (group 4)	Betamethasone dipropionate	Spray	0.05%
	Clocortolone pivalate	Cream	0.1%
	Fluocinolone acetonide	Ointment	0.025%
	Flurandrenolide	Ointment	0.05%
	Hydrocortisone valerate	Ointment	0.2%
	Mometasone furoate	Cream, Lotion, Solution	0.1%
	Triamcinolone acetonide	Cream	0.1%
		Ointment	0.05% and 0.1%
		Aerosol Spray	0.2 mg per 2-second spray
V. Lower-mid potency (group 5)	Betamethasone dipropionate	Lotion	0.05%
	Betamethasone valerate	Cream	0.1%
	Desonide	Ointment, Gel	0.05%
	Fluocinolone acetonide	Cream	0.025%
	Flurandrenolide	Cream, Lotion	0.05%
	Fluticasone propionate	Cream, Lotion	0.05%
	Hydrocortisone butyrate	Cream, Lotion, Ointment, Solution	0.1%
	Hydrocortisone probutate	Cream	0.1%
	Hydrocortisone valerate	Cream	0.2%
	Prednicarbate	Cream (emollient), Ointment	0.1%
	Triamcinolone acetonide	Lotion	0.1%
		Ointment	0.025%
VI. Low potency (group 6)	Alclometasone dipropionate	Cream, Ointment	0.05%
	Betamethasone valerate	Lotion	0.1%
	Desonide	Cream, Lotion, Foam	0.05%
	Fluocinolone acetonide	Cream, Solution, Shampoo, Oil	0.01%
	Triamcinolone acetonide	Cream, Lotion	0.025%
VII. Least potent (group 7)	Hydrocortisone (base, greater than or equal to 2%)	Cream, Ointment, Solution	2.5%
		Lotion	2%
	Hydrocortisone (base, less than 2%)	Cream, Ointment, Gel, Lotion, Spray, Solution	1%
		Cream, Ointment	0.5%
	Hydrocortisone acetate	Cream	2.5%
		Lotion	2%
		Cream	1%

PROCEDURES AND BILLING CODES

To report provider services, use appropriate CPT* codes, Alpha Numeric (HCPCS level 2) codes, Revenue codes, and/or ICD diagnostic codes.

REFERENCES

Ebglyss. Prescribing information. Eli Lilly and Company; September 2024. Accessed September 20, 2024.

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National Institute of Health and Care Excellence (NICE). Abrocitinib, tralokinumab or upadacitinib for treating moderate to severe atopic dermatitis. August 3, 2022. Accessed September 20, 2024. https://www.nice.org.uk/guidance/ta814

National Institute for Health and Care Excellence (NICE). Lebrikizumab for treating moderate to severe atopic dermatitis in people 12 years and over. July 10, 2024. Accessed September 24, 2024. https://www.nice.org.uk/guidance/ta986

POLICY HISTORY

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