BlueCross BlueShield Arizona

An Independent Licensee of the Blue Cross Blue Shield Association

PHARMACY COVERAGE GUIDELINE

EBGLYSS™ (lebrikizumab-lbkz) subcutaneous injection Generic Equivalent (if available)

This Pharmacy Coverage Guideline (PCG):
- Provides information about the reasons, basis, and information sources we use for coverage decisions
- Is not an opinion that a drug (collectively "Service") is clinically appropriate or inappropriate for a patient
- Is not a substitute for a provider's judgment (Provider and patient are responsible for all decisions about appropriateness of care)
- Is subject to all provisions e.g. (benefit coverage, limits, and exclusions) in the member's benefit plan; and
- Is subject to change as new information becomes available.

Scope
- This PCG applies to Commercial and Marketplace plans
- This PCG does not apply to the Federal Employee Program, Medicare Advantage, Medicaid or members of out-of-state Blue Cross and/or Blue Shield Plans

Instructions & Guidance
- To determine whether a member is eligible for the Service, read the entire PCG.
- This PCG is used for FDA approved indications including, but not limited to, a diagnosis and/or treatment with dosing, frequency, and duration.
- Use of a drug outside the FDA approved guidelines, refer to the appropriate Off-Label Use policy.
- The "Criteria" section outlines the factors and information we use to decide if the Service is medically necessary as defined in the Member's benefit plan.
- The "Description" section describes the Service.
- The "Definition" section defines certain words, terms or items within the policy and may include tables and charts.
- The "Resources" section lists the information and materials we considered in developing this PCG
- **We do not accept patient use of samples as evidence of an initial course of treatment, justification for continuation of therapy, or evidence of adequate trial and failure.**
- Information about medications that require prior authorization is available at www.azblue.com/pharmacy. You must fully complete the request form and provide chart notes, lab workup and any other supporting documentation. The prescribing provider must sign the form. Fax the form to BCBSAZ Pharmacy Management at (602) 864-3126 or email it to Pharmacyprecert@azblue.com.

Criteria:

➢ **Criteria for initial therapy:** Ebglyss (lebrikizumab-lbkz) and/or generic equivalent (if available) is considered ***medically necessary*** and will be approved when **ALL** the following criteria are met:

1. Prescriber is a physician specializing in the patient's diagnosis or is in consultation with a Dermatologist
2. Individual is 12 years of age or older who weigh at least 40 kilograms
3. Individual has a confirmed diagnosis of **moderate-to-severe atopic dermatitis** whose disease is not adequately controlled with topical prescription therapies or when those therapies are not advisable
4. Individual with moderate to severe atopic dermatitis with **ALL** of the following:

a. Lesions involve at least 10% of body surface area or involve sensitive areas of the face, head, neck, hands, feet, groin, or intertriginous areas
b. Current weekly averaged worst daily peak pruritus Numeric Rating Scale (NRS) of at least 3
c. **ONE** of the following disease intensity measures:
    i. Disease severity defined by an Investigator's Global Assessment (IGA) score of at least 3 in the overall assessment of lesions
    ii. Eczema Area and Severity Index (EASI) score of at least 7

5. Individual has documented failure, contraindication per FDA label, intolerance, or is not a candidate for at least a 2 consecutive month trial of **ONE** of the following topical treatments:
    a. Medium to high potency corticosteroid
    b. Calcineurin inhibitor (Protopic (tacrolimus) or Elidel (pimecrolimus))
    c. Phosphodiesterase 4 inhibitor (Eucrisa (crisaborole))

6. Individual has documented failure, contraindication per FDA label, intolerance, or is not a candidate for **BOTH** of the following:
    a. Dupixent (dupilumab)
    b. Rinvoq (upadacitinib)

7. **If available:** Individual has failure after adequate trial, contraindication per FDA label, intolerance, or is not a candidate for a **generic equivalent** [Note: Failure, contraindication or intolerance to the generic should be reported to the FDA] (see Definitions section)

8. Age-appropriate vaccinations according to current immunization guidelines have been completed before initiation of treatment

9. Individual is not currently taking any other drugs that may cause a severe adverse reaction or a significant drug interaction requiring discontinuation

10. Individual does not have a parasitic (helminth) Infection, any pre-existing infection should be treated before initiation of Ebglyss (lebrikizumab-ibkz)

11. There is no concurrent use with Cinqair (reslizumab), Fasenra (benralizumab), Nucala (mepolizumab), Tezspire (tezepelumab), Xolair (omalizumab), Adbry (tralokinumab), Rinvoq (upadacitinib), Cibinqo (abrocitinib), or any other biologic therapy [e.g., rituximab (Rituxan and rituximab biosimilars), infliximab (Remicade and infliximab biosimilars), Enbrel (etanercept)], others

12. Requested agent will not be used with live vaccines

Initial approval duration: 6 months

- **Criteria for continuation of coverage (renewal request):** Ebglyss (lebrikizumab-lbkz) and/or generic equivalent (if available) is considered ***medically necessary*** and will be approved when **ALL** the following criteria are met **(samples are not considered for continuation of therapy)**:

1. Individual continues to be seen by a physician specializing in the patient's diagnosis or is in consultation with a Dermatologist

2. Individual has documentation of positive clinical response to therapy defined as the following:
    a. No evidence of disease progression
    b. Documented evidence of efficacy, disease stability and/or improvement
    c. Achieved and maintains an IGA of 0 or 1 (clear or almost clear) **or** EASI-75 (improvement of at least 75%) in score from baseline

3. Individual has been adherent with the medication

4. **If available:** Individual has failure after adequate trial, contraindication per FDA label, intolerance, or is not a candidate for a **generic equivalent** [Note: Failure, contraindication or intolerance to the generic should be reported to the FDA] (see Definitions section)

5. Individual has not developed any contraindications or other significant adverse drug effects that may exclude continued use

6. Individual is not currently taking any other drugs that may cause a severe adverse reaction or a significant drug interaction requiring discontinuation

7. Individual does not have a parasitic (helminth) Infection

8. There is no concurrent use with Cinqair (reslizumab), Fasenra (benralizumab), Nucala (mepolizumab), Tezspire (tezepelumab), Xolair (omalizumab), Adbry (tralokinumab), Rinvoq (upadacitinib), Cibinqo (abrocitinib), or any other biologic therapy [e.g., rituximab (Rituxan and rituximab biosimilars), infliximab (Remicade and infliximab biosimilars), Enbrel (etanercept)], others

9. Requested agent will not be used with live vaccines

Renewal duration: 12 months

- Criteria for a request for non-FDA use or indication, treatment with dosing, frequency, or duration outside the FDA-approved dosing, frequency, and duration, refer to one of the following Pharmacy Coverage Guideline:

    1. **Off-Label Use of Non-Cancer Medications**

    2. **Off-Label Use of Cancer Medications**

Description:

Ebglyss (lebrikizumab-lbkz) is an interleukin-13 antagonist indicated for the treatment of adults and pediatric individuals 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. Lebrikizumab-lbkz is an immunoglobulin G4 (IgG4) monoclonal antibody that binds to interleukin (IL)-13 and inhibits IL-13 signaling through the IL-4Rα/IL-13Rα1 receptor complex. IL-13 is a naturally occurring cytokine that is involved in Type 2 inflammation, which is an important component in the pathogenesis of atopic dermatitis.

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Lebrikizumab-lbkz inhibits IL-13-induced responses including the release of proinflammatory cytokines, chemokines and IgE.

Treatment of atopic dermatitis initially involves use of topical prescription therapies such as corticosteroids, calcineurin inhibitors (tacrolimus ointment, pimecrolimus cream) and topical phosphodiesterase 4 (PDE-4) inhibitors (crisaborole ointment). Topical corticosteroids are considered the standard of care; strength and formulation of the preparation is selected based on severity, duration of treatment, location of exacerbation, and age of individual. Topical calcineurin and topical PDE-4 inhibitors should be reserved for problem areas only, such as the face, neck, intertriginous and genital areas. Ebglyss (lebrikizumab-lbkz) can be used with or without topical corticosteroids.

Dupixent (dupilumab) is a monoclonal antibody used for the treatment of adults and pediatric patients aged 6-months and older with moderate-to-severe atopic dermatitis not adequately controlled with topical prescription therapies or when those therapies are not advisable. It can be used with or without topical corticosteroids.

Definitions:

U.S. Food and Drug Administration (FDA) MedWatch Forms for FDA Safety Reporting
MedWatch Forms for FDA Safety Reporting | FDA

Atopic Dermatitis:
Moderate atopic dermatitis – Areas of dry skin, frequent itching, redness (with or without excoriation and localized skin thickening); moderate impact on everyday activities and psychosocial wellbeing, frequently disturbed sleep.

Severe atopic dermatitis – Widespread areas of dry skin, continuous itching, redness (with or without excoriation, extensive skin thickening, bleeding, oozing, cracking, and alteration of pigmentation); severe limitation of everyday activities and psychosocial functioning, nightly loss of sleep.

Atopic Dermatitis Topical Therapies:

Topical corticosteroids (TCS):
- Low-potency corticosteroids are recommended for maintenance therapy
- Intermediate and high-potency corticosteroids should be used for the treatment of clinical exacerbation over short periods of time
- Ultra-high-potency corticosteroids should be used only for very short periods (1-2 weeks) and in non-facial non-skinfold areas.
- Do not use potent fluorinated corticosteroids on the face, eyelids, genitalia, and intertriginous areas or in young infants.

Topical calcineurin inhibitors (TCI):
- Tacrolimus ointment (Protopic and generics) is indicated as second-line therapy for moderate to severe atopic dermatitis
- Pimecrolimus cream (Elidel and generics) is indicated as second line therapy for mild to moderate atopic dermatitis

Topical phosphodiesterase 4 (PDE-4) inhibitor:
- Eucrisa (crisaborole) ointment is indicated for treatment of mild to moderate atopic dermatitis

Relative Potency of Selected Topical Corticosteroid Products:

Product	Dosage form	Strength
Category I – Very high potency		
Augmented betamethasone dipropionate	Gel, ointment	0.05
Clobetasol propionate	Ointment, gel, cream	0.05
Fluocinonide	Cream	0.1
Diflorasone diacetate	Ointment	0.05
Halobetasol propionate	Ointment, cream	0.05
Category II – High potency		
Amcinonide	Ointment, cream, lotion	0.1
Augmented betamethasone dipropionate	Cream, lotion	0.05
Betamethasone dipropionate	Ointment, cream	0.05
Betamethasone valerate	Ointment	0.1
Desoximetasone	Ointment, cream	0.25
Desoximetasone	Gel	0.05
Diflorasone diacetate	Ointment (emollient base), cream	0.05
Fluocinonide	Ointment, gel, cream	0.05
Halcinonide	Ointment, cream	0.1

Investigator Global Assessment Scale (IGA):
Validated-Investigator-Global-Assessment-Scale_vIGA-AD_2017.pdf (eczemacouncil.org) [Accessed October 09, 2021]

The IGA score is selected using the morphologic descriptors that best describe the overall appearance of the lesions at a given time point. It is not necessary that all characteristics under Morphological Description be present.

Score	Morphological Description
0 – Clear	No inflammatory signs of atopic dermatitis (no erythema, no induration/papulation, no lichenification, no oozing/crusting). Post-inflammatory hyperpigmentation and/or hypopigmentation may be present.
1 – Almost clear	Barely perceptible erythema, barely perceptible induration/papulation, and/or minimal lichenification. No oozing or crusting.
2 – Mild	Slight but definite erythema (pink), slight but definite induration/papulation, and/or slight but definite lichenification. No oozing or crusting.
3 – Moderate	Clearly perceptible erythema (dull red), clearly perceptible induration/papulation, and/or clearly perceptible lichenification. Oozing and crusting may be present.
4 – Severe	Marked erythema (deep or bright red), marked induration/papulation, and/or marked lichenification. Disease is widespread in extent. Oozing or crusting may be present.

Notes:
1. In indeterminate cases, use extent to differentiate between scores.
For example: • Patient with marked erythema (deep or bright red), marked papulation and/or marked lichenification that is limited in extent (instead of widespread), would be considered "3 – Moderate".

2. Excoriations should not be considered when assessing disease severity

Eczema Area and Severity Index (EASI) score (A-E):
An EASI score is a tool used to measure the extent (area) and severity of atopic eczema. EASI score does not include a grade for dryness or scaling. Include only inflamed areas.

A. Body regions:
There are four body regions:

- Head and neck
  - Face occupies 33% (17% each side), neck 33% (17% front and back) and scalp 33% of the head and neck region
- Trunk (including genital area)
  - Front occupies 55% and back 45% of the trunk
- Upper limbs
  - Each arm occupies 50% of the upper limb region (front or back of one arm is 25%)
- Lower limbs (including buttocks)
  - Each leg occupies 45% (front or back of one leg is 22.5%) and buttocks 10% of the lower limbs region

B. Area score:
Area score is recorded for each of the four regions of the body. The area score is the percentage of skin affected by eczema for each body region.

Area score	Percentage of skin affected by eczema in each region
0	No active eczema in this region
1	1-9
2	10-29
3	30-49
4	50-69
5	70-89
6	90-100: the entire region is affected by eczema

C. Severity score:
Severity score is recorded for each of the four regions of the body. The severity score is the sum of the intensity scores for four signs. The four signs are:

1. Redness (erythema, inflammation)
2. Thickness (induration, papulation, swelling—acute eczema)
3. Scratching (excoriation)
4. Lichenification (lined skin, furrowing, prurigo nodules—chronic eczema).

The *average* intensity of each sign in each body region is assessed as: none (0), mild (1), moderate (2) and severe (3). Half scores are allowed. It may be difficult to assess redness in dark skin. If in doubt, increase the average redness score by one level.

Score	Intensity of redness, thickness/swelling, scratching. lichenification
0	None, absent
1	Mild (just perceptible)
2	Moderate (obvious)

3	Severe

D. Calculations:
For each region, record the intensity for each of four signs and calculate the severity score.

- Severity score = redness intensity + thickness intensity + scratching intensity + lichenification intensity

For each region, multiple the severity score by the area score and by a multiplier. The multiplier is different for each body site.

- Head and neck: severity score x area score x 0.1 (in children 0–7 years, x 0.2)
- Trunk: severity score x area score x 0.3
- Upper limbs: severity score x area score x 0.2
- Lower limbs: severity score x area score x 0.4 (in children 0–7 years, x 0.3)

Add up the total scores for each region to determine the final EASI score. The minimum EASI score is 0 and the maximum EASI score is 72.

E. Interpretation:
The suggested severity levels for the EASI are as follows:

0	Clear
0.1-1.0	Almost clear
1.1-7.0	Mild
7.1-21.0	Moderate
21.1-50.0	Severe
50.1-72.0	Very severe

Pruritus Numerical Rating Scale (NRS):
Numerical Rating Scale - Pruritus Resources (pruritussymposium.de) [Accessed October 09, 2021]

The NRS is comprised of one item and is represented by numbers 0 (“no itch”) to 10 (“worst imaginable itch”). Patients are asked to rate the intensity of their itch using this scale. It features high reliability and concurrent validity and is a popular choice for all patients due to its simple format. Time needed for completion: 1 minute. It has been validated in several languages.

- It can be interpreted as follows:
  - NRS 0 - no pruritus
  - NRS < 3 - mild pruritus
  - NRS ≥ 3 < 7 - moderate pruritus
  - NRS ≥ 7 < 9 - severe pruritus
  - NRS ≥ 9 - very severe pruritus

On a scale from 0 (no itch) to 10 (worst imaginable itch), how would you rate your itch overall (on average) during the past 24-hour? (Select number)										
0	1	2	3	4	5	6	7	8	9	10

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Resources:

Ebglyss (lebrikizumab-lbkz) product information, revised by Eli Lilly and Company 05-2025. Available at DailyMed http://dailymed.nlm.nih.gov. Accessed June 27, 2025.

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