BlueCross BlueShield Arizona

An Independent Licensee of the Blue Cross Blue Shield Association

PHARMACY COVERAGE GUIDELINE

ADBRY™ (tralokinumab) 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/or 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.

Medical Necessity Requirements for ADBRY (tralokinumab)

Criteria for Initial Therapy:

Prescriber Qualifications
- Prescribed by a Dermatologist or is in consultation with a Dermatologist

Indication
- Moderate to severe atopic dermatitis not adequately controlled with topical prescription therapies or when those therapies are not advisable

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Age Requirement
- 12 years of age or older

Baseline Clinical Evaluation
- Lesions involve at least 10 percent of body surface area or sensitive areas (face, head, neck, hands, feet, groin, or intertriginous areas)
- Investigator's Global Assessment score of at least 3
- Eczema Area and Severity Index score greater than 7
- Weekly averaged Worst Daily Peak Pruritus Numeric Rating Scale score of at least 3

Alternative Therapies
- **ONE** of the following:
  - **For sensitive areas** (e.g., eyelids, face, neck intertriginous, and genital areas): Failure, contraindication, intolerance, or is not a candidate for **BOTH** of the following:
    1. A two month trial of **ONE** topical calcineurin inhibitor (pimecrolimus or tacrolimus)
    2. A two month trial of Eucrisa (crisaborole)
  - **For non sensitive areas**: Failure, contraindication, intolerance, or is not a candidate for a trial of **TWO** topical medium to high potency corticosteroids each used for two months (e.g., triamcinolone acetonide 0.1 percent, mometasone furoate 0.1 percent, betamethasone dipropionate 0.05 percent, desoximetasone 0.05 percent)
- Failure, contraindication, intolerance, or is not a candidate for **BOTH** of the following (each used for 3 consecutive months):
  - Dupixent (dupilumab)
  - Rinvoq (upadacitinib)

Brand Specific Criteria
- Have failure, contraindication or intolerance with **THREE** generic equivalents (if available) for at least three months each. **Note**: Any failure, contraindication, or intolerance to the generic drugs should be reported to the FDA (see Definitions section)

Safety
- Will not be used concurrently with live vaccines
- No concomitant use with:
  - Cinqair (reslizumab)
  - Dupixent (dupilumab)
  - Fasenra (benralizumab)
  - Nucala (mepolizumab)
  - Xolair (omalizumab)
  - Any other biologic therapy (e.g., rituximab, infliximab, etanercept)

Additional Requirements
- All age appropriate vaccinations have been completed per current immunization guidelines

Documentation Requirements
- A completed request form must be submitted including:
  - Chart notes

ORIGINAL EFFECTIVE DATE: 02/17/2022 | ARCHIVE DATE: | LAST REVIEW DATE: 02/19/2026 | LAST CRITERIA REVISION DATE: 02/19/2026

- Lab results (IGA score, EASI score, Pruritus NRS score)
- Supporting clinical documentation

Initial Therapy Criteria Approval Duration

- 6 months OR end of plan year

Criteria for Continuation of Therapy (renewal therapy):

Note: Manufacturer assistance (e.g., coupons, samples, etc.) are not considered for continuation of therapy.

Prescriber Qualification

- Continues to be seen by a Dermatologist or is in consultation with a Dermatologist

Clinical Response

- No evidence of disease progression
- Documented evidence of efficacy, disease stability and/or improvement
- Achieved and maintains an Investigator's Global Assessment score of 0 or 1 (clear or almost clear) or EASI 75 (at least 75 percent improvement from baseline)

Adherence

- Adherence to the prescribed therapy regimen has been documented

Brand Specific Criteria

- Have failure, contraindication or intolerance with **THREE** generic equivalents (if available) for at least three months each. **Note**: Any failure, contraindication, or intolerance to the generic drugs should be reported to the FDA (see Definitions section)

Safety

- Will not be used concurrently with live vaccines
- No concomitant use with:
  - Cinqair (reslizumab)
  - Dupixent (dupilumab)
  - Fasenra (benralizumab)
  - Nucala (mepolizumab)
  - Xolair (omalizumab)
  - Any other biologic therapy for atopic dermatitis (e.g., rituximab, infliximab, etanercept)

Documentation Requirements

- Chart notes
- Supporting clinical documentation with evidence of improvement in atopic dermatitis
- Lab values confirming safe use

Continuation Therapy Criteria Approval Duration

- 12 months OR end of plan year

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Criteria for Off-Label Use Requests:

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:

Adbry (tralokinumab) is an interleukin-13 antagonist indicated for the treatment of moderate-to-severe atopic dermatitis in adult patients whose disease is not adequately controlled with topical prescription therapies or when those therapies are not advisable.

Tralokinumab-ldrm is a human IgG4 monoclonal antibody that specifically binds to human interleukin-13 (IL-13) and inhibits its interaction with the IL-13 receptor α1 and α2 subunits (IL-13Rα1 and IL-13Rα2). IL-13 is a naturally occurring cytokine of the Type 2 immune response. Tralokinumab-ldrm inhibits the bioactivity of IL-13 by blocking IL-13 interaction with IL-13Rα1/IL-4Rα receptor complex. Tralokinumab-ldrm 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 with choice of strength and formulation of the preparation 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, such as the face, neck, intertriginous and genital areas.

Definitions:

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

Atopic Dermatitis 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

Mild atopic dermatitis – Areas of dry skin, infrequent itching (with or without small areas of redness); little impact on everyday activities, sleep, and psychosocial wellbeing

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, incessant 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

Diagnostic criteria for atopic dermatitis: (*Diagnosis requires the presence of at least **3** major & **3** minor criteria)*

Major criteria
Pruritus
Dermatitis affecting flexural surfaces in adults and the face and extensors in infants
Chronic or relapsing dermatitis
Personal or family history of cutaneous or respiratory atopy
Minor criteria
Features of the so-called "atopic facies"
Facial pallor or erythema

Hypopigmented patches
Infraorbital darkening
Infraorbital folds or wrinkles
Cheilitis
Recurrent conjunctivitis
Anterior neck folds
Triggers of atopic dermatitis
Foods
Emotional factors
Environmental factors
Skin irritants such as wool, solvents and sweat
Complications of atopic dermatitis
Susceptibility to cutaneous viral and bacterial infections
Impaired cell-mediated immunity
Immediate skin-test reactivity
Raised serum IgE
Keratoconus
Anterior subcapsular cataracts
Others
Early age of onset
Dry skin
Ichthyosis
Hyperlinear palms
Keratosis pilaris (plugged hair follicles of proximal extremities)
Hand and foot dermatitis
Nipple eczema
White dermatographism
Perifollicular accentuation

Adapted from: Hanifin JM, Rajka G, Acta Dermatol Venereol 1980; 92(Suppl):44.

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 limbs 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

Resources:

Adbry (tralokinumab) product information, revised by Leo Pharma 06-2024. Available at DailyMed http://dailymed.nlm.nih.gov. Accessed October 28, 2025.

Paller AS, Butala S, Howe W. Treatment of atopic dermatitis (eczema). In: UpToDate, Dellavalle RP, Levy ML, Fowler J, Hussain Z, Corona R (Eds), UpToDate, Waltham MA.: UpToDate Inc. Available at http://uptodate.com. Literature current through November 2025. Topic last updated October 17, 2025. Accessed December 29, 2025.

Gonzalez ME. Management of severe refractory atopic dermatitis (eczema) in children. In: UpToDate, Dellavalle RP, Levy ML, Fowler J, Corona R (Eds), UpToDate, Waltham MA.: UpToDate Inc. Available at http://uptodate.com. Literature current through November 2025. Topic last updated June 02, 2025. Accessed December 29, 2025.

Berger TG. Evaluation and management of severe refractory atopic dermatitis (eczema) in adults. In: UpToDate, Fowler J, Levy ML, Dellavalle RP, Corona R (Eds), UpToDate, Waltham MA.: UpToDate Inc. Available at http://uptodate.com. Literature current through November 2025. Topic last updated June 09, 2025. Accessed December 29, 2025.

Silverberg JI, Howe W. Atopic dermatitis (eczema): Pathogenesis, clinical manifestations, and diagnosis. In: UpToDate, Dellavalle RP, Levy ML, Fowler J, Hussain Z, Corona R (Eds), UpToDate, Waltham MA.: UpToDate Inc. Available at http://uptodate.com. Literature current through November 2025. Topic last updated December 08, 2025. Accessed December 29, 2025.