

**tralokinumab-ldrm (Adbry™)****Policy # 00796**

Original Effective Date: 07/11/2022

Current Effective Date: 07/01/2026

*Applies to all products administered or underwritten by Blue Cross and Blue Shield of Louisiana and its subsidiary, HMO Louisiana, Inc. (collectively referred to as the "Company"), unless otherwise provided in the applicable contract. Medical technology is constantly evolving, and we reserve the right to review and update Medical Policy periodically.*

*Investigational or experimental services are not covered. This includes any drug, device, procedure, or service provided under the investigational arm of a clinical trial or clinical study. These services are excluded from coverage under benefits.*

**When Services May Be Eligible for Coverage**

*Coverage for eligible medical treatments or procedures, drugs, devices or biological products may be provided only if:*

- *Benefits are available in the member's contract/certificate, and*
- *Medical necessity criteria and guidelines are met.*

Based on review of available data, the Company may consider the use of tralokinumab-ldrm (Adbry™)† for the treatment of atopic dermatitis to be **eligible for coverage.\*\***

**Patient Selection Criteria**

Coverage eligibility for tralokinumab-ldrm (Adbry) will be considered when the following criteria are met:

**Initial:**

- Patient has a diagnosis of moderate to severe atopic dermatitis; AND
- Patient is 12 years of age or older; AND
- Patient has had chronic atopic dermatitis for at least 6 months; AND  
*(Note: This specific patient selection criterion is an additional Company requirement for coverage eligibility and will be denied as not medically necessary\*\* if not met.)*
- Patient has atopic dermatitis involvement estimated to be greater than 10% of the body surface area (BSA) according to the prescribing physician; AND  
*(Note: This specific patient selection criterion is an additional Company requirement, based on clinical trials, for coverage eligibility and will be denied as not medically necessary\*\* if not met.)*
- Patient has tried and failed (e.g., intolerance or inadequate response) at least ONE prescription GENERIC topical corticosteroid, unless there is clinical evidence or patient history that suggests the use of ONE prescription GENERIC topical corticosteroid will be ineffective or cause an adverse reaction to the patient; AND
- Patient has tried and failed (e.g., intolerance or inadequate response) GENERIC tacrolimus ointment OR GENERIC pimecrolimus cream, unless there is clinical evidence or patient history that suggests the use of these products will be ineffective or cause an adverse reaction to the patient; AND
- Requested drug is NOT being used in combination with JAK (janus kinase) inhibitors (e.g., upadacitinib [Rinvoq®]‡, ruxolitinib [Opzelura™]‡, abrocitinib [Cibinqo®]‡) or monoclonal antibodies (e.g., dupilumab [Dupixent®]‡) typically used to treat atopic dermatitis.

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**Continuation:**

- Patient has received an initial authorization; AND
- Patient has received at least 6 months of therapy with the requested drug; AND  
*(Note: This specific patient selection criterion is an additional Company requirement for coverage eligibility and will be denied as not medically necessary\*\* if not met.)*
- Patient has been adherent to the requested drug and other medications for the condition being treated; AND  
*(Note: This specific patient selection criterion is an additional Company requirement for coverage eligibility and will be denied as not medically necessary\*\* if not met.)*
- Patient has had a clinically meaningful beneficial response to Adbry therapy as compared to their baseline status (before Adbry therapy) as evidenced by TWO or more of the following:
  - Reduction in disease severity (e.g., erythema, dryness, edema/papulation, excoriations, lichenification, oozing/crusting)
  - Reduction in the frequency or intensity of pruritus
  - Reduction in the frequency of disease exacerbations/flare
  - Reduction in the BSA with atopic dermatitis involvement (a 20% reduction in percent BSA involved over baseline)
  - Improvement in overall patient quality of life (e.g., improved sleep, less depression or anxiety, etc.); AND  
*(Note: This specific patient selection criterion is an additional Company requirement for coverage eligibility and will be denied as not medically necessary\*\* if not met.)*
- Requested drug is NOT being used in combination with JAK (janus kinase) inhibitors (e.g., upadacitinib [Rinvoq], ruxolitinib [Opzelura], abrocitinib [Cibinqo]) or monoclonal antibodies (e.g., dupilumab [Dupixent]) typically used to treat atopic dermatitis; AND
- If the patient is below 100 kg and has achieved clear or almost clear skin after 24 weeks of treatment with a 300 mg every 2 weeks dosage, a dosage of 300 mg every 4 weeks must be attempted. If the patient has tried and failed the 300 mg every 4 weeks dosage, the 300 mg every 2 weeks dosage will be approved.  
*(Note: This specific patient selection criterion is an additional Company requirement for coverage eligibility and will be denied as not medically necessary\*\* if not met.)*

## **When Services Are Considered Not Medically Necessary**

Based on review of available data, the Company considers the use of tralokinumab-ldrm (Adbry) when any of the following criteria are NOT met to be **not medically necessary\*\***:

- Patient has had chronic atopic dermatitis for at least 6 months
- Patient has atopic dermatitis involvement estimated to be greater than or equal to 10% of the body surface area (BSA) according to the prescribing physician
- For continuation requests: Patient has received at least 6 months of therapy with the requested drug
- For continuation requests: Patient has been adherent to the requested drug and other medications for the condition being treated

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- For continuation requests: Patient has had a clinically meaningful beneficial response to Adbry therapy as compared to their baseline status (before Adbry therapy) as evidenced by TWO or more of the following:
  - Reduction in disease severity (e.g., erythema, dryness, edema/papulation, excoriations, lichenification, oozing/crusting)
  - Reduction in the frequency or intensity of pruritus
  - Reduction in the frequency of disease exacerbations/flare
  - Reduction in the BSA with atopic dermatitis involvement (a 20% reduction in percent BSA involved over baseline)
  - Improvement in overall patient quality of life (e.g., improved sleep, less depression or anxiety, etc.)
- For continuation requests: If the patient is below 100 kg and has achieved clear or almost clear skin after 24 weeks of treatment with a 300 mg every 2 weeks dosage, a dosage of 300 mg every 4 weeks must be attempted.

## When Services Are Considered Investigational

*Coverage is not available for investigational medical treatments or procedures, drugs, devices or biological products.*

Based on review of available data, the Company considers the use of tralokinumab-ldrm (Adbry) when the patient selection criteria are not met to be **investigational\*** (with the exception of those denoted above as **not medically necessary\*\***).

## Background/Overview

Adbry is an interleukin-13 antagonist indicated for the treatment of moderate-to-severe atopic dermatitis in patients aged 12 years and older whose disease is not adequately controlled with topical prescription therapies or when those therapies are not advisable. Adbry is supplied as a 150 mg/mL solution in a single-dose prefilled syringe. The recommended dosage of Adbry for adults 18 years and older is 600 mg given subcutaneously, followed by 300 mg given subcutaneously every other week. A dosage of 300 mg given subcutaneously every 4 weeks may be considered for patients below 100 kg who achieve clear or almost clear skin after 16 weeks of treatment. For pediatric patients 12 to 17 years of age, the initial loading dose of Adbry is 300 mg, followed by 150 mg every other week.

### **Atopic Dermatitis**

There are various treatment options for atopic dermatitis, including first line agents such as topical corticosteroids (many of which are in generic form) and topical immunomodulatory agents such as generic tacrolimus and generic pimecrolimus. For those that are refractory to topical therapies, systemic immunomodulatory agents are an option for therapy. Adbry has not yet been integrated into the American Academy of Dermatology guidelines at the time of this publication.

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## **FDA or Other Governmental Regulatory Approval**

### **U.S. Food and Drug Administration (FDA)**

Adbry is indicated for the treatment of moderate-to-severe atopic dermatitis in patients aged 12 years and older whose disease is not adequately controlled with topical prescription therapies or when those therapies are not advisable.

## **Rationale/Source**

This medical policy was developed through consideration of peer-reviewed medical literature generally recognized by the relevant medical community, U.S. Food and Drug Administration approval status, nationally accepted standards of medical practice and accepted standards of medical practice in this community, technology evaluation centers, reference to federal regulations, other plan medical policies, and accredited national guidelines.

### **Adult Trial Background**

The efficacy of Adbry was assessed in three randomized, double-blind, placebo-controlled trials (ECZTRA 1, ECZTRA 2, and ECZTRA 3). Efficacy was assessed in a total of 1,934 subjects 18 years of age and older with moderate-to-severe atopic dermatitis (AD) not adequately controlled by topical medication(s). Disease severity was defined by an Investigator's Global Assessment (IGA) score  $\geq 3$  in the overall assessment of AD lesions on a severity scale of 0 to 4, an Eczema Area and Severity Index (EASI) score  $\geq 16$  on a scale of 0 to 72, and a minimum body surface area (BSA) involvement of  $\geq 10\%$ .

In all three trials, subjects received subcutaneous injections of Adbry 600 mg or placebo on Day 0, followed by 300 mg every other week or placebo for 16 weeks. Responders were defined as achieving an IGA 0 or 1 ("clear" or "almost clear") or EASI-75 (improvement of at least 75% in EASI score from baseline) at Week 16.

To evaluate maintenance of response in the monotherapy trials (ECZTRA 1 and ECZTRA 2), subjects responding to initial treatment with Adbry 300 mg every other week were re-randomized to Adbry 300 mg every other week, Adbry 300 mg every 4 weeks or placebo every other week for another 36 weeks following first dose administration. Subjects randomized to placebo in the initial treatment period who achieved a clinical response at Week 16 continued to receive placebo every other week for another 36 weeks. Non-responders at Week 16, and subjects who lost clinical response during the maintenance period were placed on open-label treatment with Adbry 300 mg every other week and optional use of topical corticosteroids.

In the combination therapy trial (ECZTRA 3), subjects received either Adbry 300 mg every other week with topical corticosteroids or placebo with topical corticosteroids and as needed topical calcineurin inhibitors (TCI) until Week 16. Subjects in the Adbry 300 mg with topical corticosteroids group who achieved clinical response at Week 16 were re-randomized to Adbry 300 mg every other week with topical corticosteroids or Adbry every 4 weeks with topical corticosteroids for another 16 weeks following first dose administration. Subjects in the placebo with topical corticosteroids group who achieved clinical response at Week 16 continued on placebo with topical corticosteroids for another 16 weeks. Subjects who did not achieve clinical response at Week 16 received Adbry 300 mg every other week for another 16 weeks. A mid-potency topical corticosteroid (i.e., mometasone

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furoate 0.1% cream) was dispensed at each dosing visit. Subjects were instructed to apply a thin film of the dispensed topical corticosteroid as needed once daily to active lesions from Week 0 to Week 32 and were to discontinue treatment with topical corticosteroids when control was achieved. An additional, lower potency topical corticosteroid or TCI could be used at the investigator's discretion on areas of the body where use of the supplied topical corticosteroid was not advisable, such as areas of thin skin.

### **Adult Response at Week 16**

All three trials assessed the primary endpoints of the proportion of subjects with an IGA 0 or 1 at Week 16 and the proportion of subjects with EASI-75 at Week 16. In ECZTRA 1, 16% of the Adbry subjects achieved an IGA of 0 or 1 vs. 7% in the placebo group. In ECZTRA 2, 21% of the Adbry subjects achieved an IGA of 0 or 1 vs. 9% in the placebo group. In ECZTRA 3, 38% of the Adbry + topical corticosteroids subjects achieved an IGA of 0 or 1 vs. 27% in the placebo + topical corticosteroids group. In ECZTRA 1, 25% of the Adbry subjects achieved EASI-75 vs. 13% in the placebo group. In ECZTRA 2, 33% of the Adbry subjects achieved an EASI-75 vs. 10% in the placebo group. In ECZTRA 3, 56% of the Adbry + topical corticosteroids subjects achieved an EASI-75 vs. 37% in the placebo + topical corticosteroids group.

### **Adult Maintenance Period**

In ECZTRA 1, 179 Adbry 300 mg every other week responders (IGA 0/1 or EASI-75) were re-randomized (and dosed) at Week 16 to Adbry 300 mg every other week (68 subjects), Adbry 300 mg every 4 weeks (76 subjects) or placebo (35 subjects). Among these subjects, 39 subjects in Adbry 300 mg every other week arm, 36 subjects in Adbry 300 mg every 4 weeks arm and 19 subjects in placebo arm were IGA 0/1 responders at Week 16. Maintenance of IGA 0/1 response at Week 52 was as follows: 20 subjects (51%) in the every other week arm, 14 subjects (39%) in the every 4 weeks arm and 9 subjects (47%) in the placebo arm. Among the re-randomized subjects, 47 subjects in Adbry 300 mg every other week arm, 57 subjects in Adbry 300 mg every 4 weeks arm and 30 subjects in placebo arm were EASI-75 responders at Week 16. Maintenance of EASI-75 response at Week 52 was as follows: 28 subjects (60%) in the every other week arm, 28 subjects (49%) in the every 4 weeks arm and 10 subjects (33%) in the placebo arm.

In ECZTRA 2, 218 Adbry 300 mg every other week responders (IGA 0/1 or EASI-75) were re-randomized (and dosed) at Week 16 to Adbry 300 mg every other week (90 subjects), Adbry 300 mg every 4 weeks (84 subjects) or placebo (44 subjects). Among these subjects, 53 subjects in the Adbry 300 mg every other week arm, 44 subjects in the Adbry 300 mg every 4 weeks arm and 26 subjects in the placebo arm were IGA 0/1 responders at Week 16. Maintenance of IGA 0/1 response at Week 52 was as follows: 32 subjects (60%) in the every other week arm, 22 subjects (50%) in the every 4 weeks arm and 6 subjects (23%) in the placebo arm. Among the re-randomized subjects, 76 subjects in the Adbry 300 mg every other week arm, 69 subjects in the Adbry 300 mg every 4 weeks arm and 40 subjects in the placebo arm were EASI-75 responders at Week 16. Maintenance of EASI-75 response at Week 52 was as follows: 43 subjects (57%) in the every other week arm, 38 subjects (55%) in the every 4 weeks arm and 8 subjects (20%) in the placebo arm.

In ECZTRA 3, 131 Adbry 300 mg every other week + topical corticosteroids responders (IGA 0/1 or EASI-75) were re-randomized (and dosed) at Week 16 to Adbry 300 mg every other week + topical corticosteroids (65 subjects) or Adbry 300 mg every 4 weeks + topical corticosteroids (66

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subjects). Among these subjects, 45 subjects in Adbry 300 mg every other week + topical corticosteroids arm and 46 subjects in Adbry 300 mg every 4 weeks + topical corticosteroids arm were IGA 0/1 responders at Week 16. Maintenance of IGA 0/1 response at Week 32 was as follows: 40 subjects (89%) in the every other week arm and 35 subjects (76%) every 4 weeks arm. Among the re-randomized subjects, 65 subjects in Adbry 300 mg every other week arm and 62 subjects in Adbry 300 mg every 4 weeks arm were EASI-75 responders at Week 16. Maintenance of EASI-75 response at Week 32 was as follows: 60 subjects (92%) in the every other week arm and 56 subjects (90%) in the every 4 weeks arm.

### **Pediatric Trial Background**

The efficacy and safety of Adbry monotherapy in pediatric subjects 12 to 17 years of age was evaluated in a multicenter, randomized, double-blind, placebo-controlled trial (ECZTRA 6) in 289 pediatric subjects 12 to 17 years of age with moderate-to-severe AD defined by IGA score  $\geq 3$  in the overall assessment of AD lesions on a severity scale of 0 to 4, an EASI score  $\geq 16$  at baseline, and a minimum BSA involvement of  $\geq 10\%$ . Eligible subjects enrolled into this trial had previous inadequate response to topical medication.

A total of 98 subjects received an initial dose of Adbry 300 mg followed by 150 mg every other week up to Week 16. Subjects who met the clinical response criteria (IGA of 0 or 1 or EASI-75) at Week 16 without the use of rescue medication were re-randomized in a 1:1 ratio to either Adbry every other week or every 4 weeks up to Week 52, receiving the same dose as during the initial 16-week treatment period. Subjects who did not meet the clinical response criteria at Week 16 or did not maintain the response during the maintenance treatment period, or used rescue medication during the initial treatment period were transferred to open-label treatment with Adbry 300 mg every other week with optional use of topical corticosteroids. Subjects randomized to placebo in the initial treatment period who achieved a clinical response at Week 16 continued to receive placebo every other week in the maintenance treatment period.

### **Pediatric Response at Week 16**

The primary endpoints were the proportion of subjects with IGA 0 or 1 at Week 16 (“clear” or “almost clear”) and the proportion of patients with EASI-75 (improvement of at least 75% in EASI from baseline) at Week 16. In ECZTRA 6, 21% of the Adbry subjects achieved an IGA of 0 or 1 vs. 4% in the placebo group and 29% of the Adbry subjects achieved EASI-75 vs. 6% in the placebo group.

## **References**

1. Adbry [package insert]. Leo Pharma. Madison, New Jersey. Updated December 2023.

## **Policy History**

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06/02/2022 Medical Policy Committee review

06/08/2022 Medical Policy Implementation Committee approval. New policy.

06/01/2023 Medical Policy Committee review

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06/14/2023 Medical Policy Implementation Committee approval. Coverage eligibility unchanged.

06/06/2024 Medical Policy Committee review

06/12/2024 Medical Policy Implementation Committee approval. Changed age from 18 years to 12 years per the FDA package insert indication change.

06/05/2025 Medical Policy Committee review

06/11/2025 Medical Policy Implementation Committee approval. Coverage eligibility unchanged.

06/04/2026 Medical Policy Committee review.

06/10/2026 Medical Policy Implementation Committee approval. Coverage eligibility unchanged.

Next Scheduled Review Date: 06/2027

\*Investigational – A medical treatment, procedure, drug, device, or biological product is Investigational if the effectiveness has not been clearly tested and it has not been incorporated into standard medical practice. Any determination we make that a medical treatment, procedure, drug, device, or biological product is Investigational will be based on a consideration of the following:

- A. Whether the medical treatment, procedure, drug, device, or biological product can be lawfully marketed without approval of the U.S. Food and Drug Administration (FDA) and whether such approval has been granted at the time the medical treatment, procedure, drug, device, or biological product is sought to be furnished; or
- B. Whether the medical treatment, procedure, drug, device, or biological product requires further studies or clinical trials to determine its maximum tolerated dose, toxicity, safety, effectiveness, or effectiveness as compared with the standard means of treatment or diagnosis, must improve health outcomes, according to the consensus of opinion among experts as shown by reliable evidence, including:
  1. Consultation with technology evaluation center(s);
  2. Credible scientific evidence published in peer-reviewed medical literature generally recognized by the relevant medical community; or
  3. Reference to federal regulations.

\*\*Medically Necessary (or “Medical Necessity”) - Health care services, treatment, procedures, equipment, drugs, devices, items or supplies that a Provider, exercising prudent clinical judgment, would provide to a patient for the purpose of preventing, evaluating, diagnosing or treating an illness, injury, disease or its symptoms, and that are:

- A. In accordance with nationally accepted standards of medical practice;
- B. Clinically appropriate, in terms of type, frequency, extent, level of care, site and duration, and considered effective for the patient's illness, injury or disease; and
- C. Not primarily for the personal comfort or convenience of the patient, physician or other health care provider, and not more costly than an alternative service or sequence of services at least as likely to produce equivalent therapeutic or diagnostic results as to the diagnosis or treatment of that patient's illness, injury or disease.

For these purposes, “nationally accepted standards of medical practice” means standards that are based on credible scientific evidence published in peer-reviewed medical literature generally recognized by the relevant medical community, Physician Specialty Society recommendations and the views of Physicians practicing in relevant clinical areas and any other relevant factors.

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‡ Indicated trademarks are the registered trademarks of their respective owners.

**NOTICE:** If the Patient's health insurance contract contains language that differs from the BCBSLA Medical Policy definition noted above, the definition in the health insurance contract will be relied upon for specific coverage determinations.

**NOTICE:** Medical Policies are scientific based opinions, provided solely for coverage and informational purposes. Medical Policies should not be construed to suggest that the Company recommends, advocates, requires, encourages, or discourages any particular treatment, procedure, or service, or any particular course of treatment, procedure, or service.

**NOTICE:** Federal and State law, as well as contract language, including definitions and specific contract provisions/exclusions, take precedence over Medical Policy and must be considered first in determining eligibility for coverage.

**NOTICE:** If an authorization for an ongoing course of treatment has been provided to a member and the member changes from one health plan to another health plan (e.g., a member moves from carrier A to Louisiana Blue), Louisiana Blue may honor the previous health plan's authorization for the same service under the same type of in-network benefit for a 90-day transition period. Documentation of the authorization for the ongoing course of treatment from the previous health plan must be provided to us by the member or their provider and the services provided for the course of treatment must otherwise be a covered service under the Louisiana Blue health plan. This provision does not apply to medications covered under the plan's pharmacy benefit.