



Wellmark Blue Cross and Blue Shield is an Independent Licensee of the Blue Cross and Blue Shield Association.

## DRUG POLICY

# Adbry (tralokinumab-ldrm)

### NOTICE

This policy contains information which is clinical in nature. The policy is not medical advice. The information in this policy is used by Wellmark to make determinations whether medical treatment is covered under the terms of a Wellmark member's health benefit plan. Physicians and other health care providers are responsible for medical advice and treatment. If you have specific health care needs, you should consult an appropriate health care professional. If you would like to request an accessible version of this document, please contact customer service at 800-524-9242.

### 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. For this program, Dupixent, Ebglyss and Rinvoq are the preferred products and will apply to members requesting treatment for an indication that is FDA-approved for the preferred product. The criteria will require the use of two of the health plan's preferred products before the use of non-preferred products unless there are clinical circumstances that exclude the use of all the preferred products, the patient is currently receiving treatment with the non-preferred drug and experience a positive therapeutic outcome, or there is only one preferred product for an indication

#### FDA-Approved Indication

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. Adbry 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. Initial requests:
  1. Patient's chart notes or medical records showing affected area(s) and affected body surface area

2. Patient's chart notes, medical record documentation and claims history of prerequisite therapies (including topical calcineurin inhibitors and topical corticosteroids) including dosage, duration, and response to therapy. If therapy is not advisable, documentation of why topical calcineurin inhibitors and/or topical corticosteroids are not advisable for the patient.
- B. Continuation requests: Documentation (e.g., chart notes) that the patient has experienced a positive clinical response to therapy as evidenced by low disease activity or improvement in signs or symptoms of atopic dermatitis.

Must meet BOTH the Preferred Drug Plan Design and Criteria for Initial Approval when applicable.

#### Preferred Drug Plan Design

- A. Criteria for initial approval for Adbry (tralokinumab-ldrm) will only apply when ONE of the following criteria are met:
1. The patient has had an inadequate response to treatment, intolerable adverse event, or has a contraindication to therapy with at least two of the preferred products, Dupixent, Ebglyss, and Rinvoq.
  2. The patient is currently receiving therapy with Adbry, excluding when Adbry is obtained as samples or via manufacturer's patient assistance programs, and experiencing a positive therapeutic outcome

#### Prescriber Specialties

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

#### Criteria for Initial Approval

##### **A. Moderate-to-severe atopic dermatitis**

Authorization of **4 months** may be granted for treatment of moderate-to-severe atopic dermatitis when all of the following criteria are met:

1. 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.
  - a. Patient has had an inadequate treatment response to both of the following in the past 180 days:
    - i. A medium potency to super-high potency topical corticosteroid (TCS) (see Appendix), or the use of topical corticosteroids is not advisable for the patient (e.g., due to contraindications, prior intolerances).
    - ii. A topical calcineurin inhibitor (TCI) [e.g., tacrolimus], or the use of a topical calcineurin inhibitor is not advisable for the patient (e.g., due to contraindications, prior intolerances).
2. Patient is 12 years of age or older
3. Patient will not use Adbry concomitantly with other biologics or targeted synthetic drug indicated for atopic dermatitis

#### Continuation of Therapy

##### **A. Moderate-to-severe atopic dermatitis**

Authorization of **12 months** may be granted for patients 12 years of age or older who are using the requested medication for moderate-to-severe atopic dermatitis when all of the following criteria is met:

1. Patient has achieved or maintained a positive clinical response 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. Patient will not use Adbry concomitantly with other biologics or targeted synthetic drugs indicated for atopic dermatitis.

### Other

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

Member cannot use Adbry 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.*

### Non-Formulary Exception Criteria

Non-Formulary Exception criteria applies to formularies which do not include the requested product(s) on the formulary drug list. Meeting the criteria above may satisfy some, or all, portions of the Non-Formulary Exception Criteria. A medication that is non-formulary may be covered when the Criteria for Approval AND the following criteria are met:

1. The requested drug must be used for an FDA-approved indication, or an indication supported in the compendia of current literature (examples: AHFS, Micromedex, current accepted guidelines). Diagnostic testing/lab results required when applicable.
2. The prescribed dose/quantity must fall within the FDA-approved labeling or dosing guidelines found in the compendia of current literature.
3. All covered formulary alternative drugs on any tier will be ineffective, have been ineffective, would not be as effective as the non-formulary drug, or would have adverse effects. Documentation is required and must include chart note(s) or other documentation indicating prior treatment failure, severity of the adverse event (if any), and dosage and duration of the prior treatment, or contraindication to formulary alternatives.

### 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	Quantity Limit	FDA-recommended dosing
Adbry 300 mg/2 mL auto-injector	Initiation of therapy: Three 300 mg injections per first 28 days  Maintenance: Two 300 mg per 28 days	Atopic Dermatitis <ul style="list-style-type: none"><li>• Initial dose of 600 mg (four 150 mg injections OR two 300 mg injections), followed by 300 mg (two 150 mg injections OR one 300 mg injection) administered every other week</li><li>• After 16 weeks of treatment, for patients with body weight below 100 kg who achieve clear or almost clear skin, a dosage of 300 mg every 4 weeks may be considered</li></ul>
Adbry 150 mg/mL prefilled syringe	Initiation of therapy: Six 150 mg injections per first 28 days  Maintenance: Four 150 mg injections per 28 days	

Appendix

<b>Relative potency of select topical corticosteroid products</b>			
<b>Potency</b>	<b>Drug</b>	<b>Dosage form</b>	<b>Strength</b>
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 <sup>2</sup>
	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%
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%

Relative potency of select topical corticosteroid products			
Potency	Drug	Dosage form	Strength
	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

- Adbry [package insert]. Madison, NJ: LEO Pharma Inc.; December 2023.
- Eichenfield LF, Tom WL, Chamlin SL, et. al. Guidelines of care for the management of atopic dermatitis: Section 1. Diagnosis and Assessment of Atopic Dermatitis. J Am Acad Dermatol. 2014;70:338-51.
- Utilization Management (UM) Criteria Review CVS Caremark P&T Subgroup. Dermatology – Biologic Agents – UM Criteria. April 2019.
- Topical Corticosteroids. Drug Facts and Comparisons. Facts & Comparisons [database online]. St. Louis, MO: Wolters Kluwer Health Inc; December 1, 2021. Accessed November 7, 2022.
- Atlas SJ, Brouwer E, Fox G, et al. JAK inhibitors and monoclonal antibodies for the treatment of atopic dermatitis: effectiveness and value. Final evidence report. Institute for Clinical and Economic Review (ICER). August 17, 2021. Accessed January 24, 2022. [https://icer.org/wp-content/uploads/2021/08/Atopic-Dermatitis\\_Final-Evidence-Report\\_081721.pdf](https://icer.org/wp-content/uploads/2021/08/Atopic-Dermatitis_Final-Evidence-Report_081721.pdf)
- Bieber T, Simpson EL, Silverberg JI, et al. Abrocitinib versus placebo or dupilumab for atopic dermatitis. N Engl J Med. 2021;384(12):1101-1112. doi:10.1056/NEJMoa2019380

- Chiricozzi A, Belloni Fortina A, Galli E, et al. Current therapeutic paradigm in pediatric atopic dermatitis: Practical guidance from a national expert panel. *Allergol Immunopathol (Madr)*. 2019;47(2):194-206. doi:10.1016/j.aller.2018.06.008
- Cibinco. Prescribing information. Pfizer Labs; January 2022. Accessed January 24, 2022.
- Dupixent. Prescribing information. Regeneron Pharmaceuticals, Inc.; December 2021.
- Eichenfield LF, Tom WL, Berger TG, et al. Guidelines of care for the management of atopic dermatitis: section 2. Management and treatment of atopic dermatitis with topical therapies. *J Am Acad Dermatol*. 2014;71(1):116-132. doi:10.1016/j.jaad.2014.03.023
- Elidel. Prescribing information. Bausch Health US, LLC; September 2020.
- Eucrisa. Prescribing information. Pfizer Labs; March 2020.
- Fleming P, Yang YB, Lynde C, O'Neill B, Lee KO. Diagnosis and management of atopic dermatitis for primary care providers. *J Am Board Fam Med*. 2020;33(4):626-635. doi:10.3122/jabfm.2020.04.190449
- Food and Drug Administration (FDA). *Drugs@FDA*. Accessed January 31, 2022. <http://www.accessdata.fda.gov/scripts/cder/drugsatfda>
- National Eczema Association (NEA). *Eczema stats*. Accessed January 24, 2022. <https://nationaleczema.org/research/eczema-facts/>
- National Institute of Health and Care Excellence (NICE). Upadacitinib, abrocitinib and tralokinumab for dermatitis. October 17, 2022. Accessed January 24, 2022. <https://www.nice.org.uk/guidance/indevelopment/gid-ta10856>
- National Institute of Health and Care Excellence (NICE). Baricitinib for treating moderate to severe atopic dermatitis. March 3, 2021. Accessed January 24, 2022. <https://www.nice.org.uk/guidance/indevelopment/gid-ta10562>.
- National Institute of Health and Care Excellence (NICE). Dupilumab for treating moderate to severe atopic dermatitis. August 1, 2018. Accessed January 24, 2022. <https://www.nice.org.uk/guidance/ta534>.
- Protopic. Prescribing information. Leo Pharma Inc.; February 2019. Accessed January 24, 2022.
- Rinvoq. Prescribing information. AbbVie Inc.; January 2022. Accessed January 24, 2022.
- Schneider L, Tilles S, Lio P, et al. Atopic dermatitis: a practice parameter update 2012. *J Allergy Clin Immunol*. 2013;131(2):295-9.e27. doi:10.1016/j.jaci.2012.12.672
- Sidbury R, Davis DM, Cohen DE, et al. Guidelines of care for the management of atopic dermatitis: section 3. Management and treatment with phototherapy and systemic agents. *J Am Acad Dermatol*. 2014;71(2):327-349. doi:10.1016/j.jaad.2014.03.030
- Silverberg JI, Thyssen JP, Fahrback K, et al. Comparative efficacy and safety of systemic therapies used in moderate-to-severe atopic dermatitis: a systematic literature review and network meta-analysis. *J Eur Acad Dermatol Venereol*. 2021b;35(9):1797-1810. doi:10.1111/jdv.17351
- Silverberg JI, Toth D, Bieber T, et al. Tralokinumab plus topical corticosteroids for the treatment of moderate-to-severe atopic dermatitis: results from the double-blind, randomized, multicentre, placebo-controlled phase III ECZTRA 3 trial. *Br J Dermatol*. 2021a;184(3):450-463. doi:10.1111/bjd.19573
- Simpson EL, Lacour J-P, Spelman L et al. Baricitinib in patients with moderate-to-severe atopic dermatitis and inadequate response to topical corticosteroids: results from two randomized monotherapy phase III trials. *Br J Dermatol*. 2020; 183(2):242–55.
- Ständer S. Atopic dermatitis. *N Engl J Med*. 2021;384(12):1136-1143. doi:10.1056/NEJMra2023911
- Wollenberg A, Barbarot S, Bieber T, et al. Consensus-based European guidelines for treatment of atopic eczema (atopic dermatitis) in adults and children: part I [published correction appears in *J Eur Acad Dermatol Venereol*. 2019 Jul;33(7):1436]. *J Eur Acad Dermatol Venereol*. 2018a;32(5):657-682. doi:10.1111/jdv.14891
- Wollenberg A, Barbarot S, Bieber T, et al. Consensus-based European guidelines for treatment of atopic eczema (atopic dermatitis) in adults and children: part II. *J Eur Acad Dermatol Venereol*. 2018b;32(6):850-878. doi:10.1111/jdv.14888

- Wollenberg A, Blauvelt A, Guttman-Yassky E, et al. Tralokinumab for moderate-to-severe atopic dermatitis: results from two 52-week, randomized, double-blind, multicentre, placebo-controlled phase III trials (ECZTRA 1 and ECZTRA 2). *Br J Dermatol*. 2021;184(3):437-449. doi:10.1111/bjd.19574
- Yang YB, Gohari A, Lam J. Brief Academic Review and Clinical Practice Guidelines for Pediatric Atopic Dermatitis. *Curr Pediatr Rev*. 2021;17(3):229-237. doi:10.2174/1573396316999200820163434
- Zonalon. Prescribing information. Mylan Pharmaceuticals Inc.; June 2017. Accessed January 24, 2022.
- Eichenfield LF, Tom WL, et al. Guidelines of care for the management of atopic dermatitis: Section 2. Management and treatment of atopic dermatitis with topical therapies. *J Am Acad Dermatol*. 2014;71:116-32.
- Fishbein AB, Silverberg, JI, Wilson EJ, et al. Update on atopic dermatitis: Diagnosis, severity assessment, and treatment selection. *J Allergy Clin Immunol Pract*. 2020;8(1): 91-101.
- Wollenberg A, Christen-Zäch S, Taieb A, et al. ETFAD/EADV Eczema task force 2020 position paper on diagnosis and treatment of atopic dermatitis in adults and children. *J Eur Acad Dermatol Venereol*. 2020;34(12):2717-2744.

\*Some content reprinted from CVSHealth

## POLICY HISTORY

**Policy #:** 05.04.55

**Original Effective Date:** July 1, 2022

**Reviewed:** August 2025

**Revised:** August 2024

**Current Effective Date:** September 28, 2025