Prior Authorization Review Panel

CHC-MCO Policy Submission

A separate copy of this form must accompany each policy submitted for review.
Policies submitted without this form will not be considered for review.

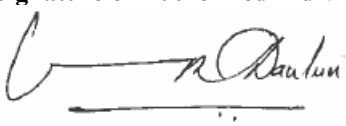
Plan: PA Health & Wellness	**Submission Date: 05/01/2022**
Policy Number: PA.CP.PHAR.577	**Effective Date: 01/2022** **Revision Date: 04/2022**
Policy Name: Tralokinumab-ldrm (Adbry)	

Type of Submission – Check all that apply:

- ✓ **New Policy**
- ☐ **Revised Policy***
- ☐ **Annual Review - No Revisions**
- ☐ **Statewide PDL -** *Select this box when submitting policies for Statewide PDL implementation and when submitting policies for drug classes included on the Statewide PDL.*

***All revisions to the policy must be highlighted using track changes throughout the document.**

Please provide any changes or clarifying information for the policy below:

Name of Authorized Individual (Please type or print): **Venkateswara R. Davuluri, MD**	**Signature of Authorized Individual:** 

Clinical Policy: Tralokinumab-ldrm (Adbry)

Reference Number: CP.PHAR.577
Effective Date: 05/2022
Last Review Date: 04/2022

Coding Implications
Revision Log

Description
Tralokinumab-ldrm (Adbry®) is an interleukin-13 antagonist.

FDA Approved Indication(s)
Adbry is 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. Adbry can be used with or without topical corticosteroids.

Policy/Criteria
Provider must submit documentation (such as office chart notes, lab results or other clinical information) supporting that member has met all approval criteria.

It is the policy of health plans affiliated with PA Health & Wellness ® that Adbry is **medically necessary** when the following criteria are met:

I. Initial Approval Criteria

A. Atopic Dermatitis (must meet all)**:**

1. Diagnosis of moderate to severe atopic dermatitis;
2. Prescribed by or in consultation with a dermatologist or allergist;
3. Age ≥ 18 years;
4. Failure of two of the following (a, b, or c), unless contraindicated or clinically significant adverse effects are experienced:
   a. A formulary topical corticosteroids, used for ≥ 2 weeks (i or ii):
      i. For treatment of the face, skin folds, or other critical areas, a low-potency topical corticosteroid;
      ii. For treatment of areas other than face, skin folds, or other critical areas, a medium to very high potency topical corticosteroid;
   b. One non-steroidal topical therapy* used for ≥ 4 weeks: topical calcineurin inhibitor (e.g., tacrolimus 0.03% ointment, pimecrolimus 1% cream) or Eucrisa®;
   **These agents may require prior authorization*
   c. One systemic agent used for ≥ 3 months: azathioprine, methotrexate, mycophenolate mofetil, or cyclosporine;
5. Adbry is not prescribed concurrently with another biologic medication (e.g., Dupixent®) or a JAK inhibitor (e.g., Olumiant®, Rinvoq®, Cibinqo®, Opzelura™);
6. Dose does not exceed the following:
   a. Initial (one-time) dose of 600 mg (four injections);
   b. Maintenance dose of 300 mg (two injections) every 2 weeks;

Approval duration: 4 months (18 injections)

B. Other diagnoses/indications: Refer to PA.CP.PMN.53

II. Continued Therapy

A. Atopic Dermatitis (must meet all)**:**

1. Currently receiving medication via PA Health & Wellness benefit and documentation supports positive response to therapy or the Continuity of Care policy (PA.LTSS.PHAR.01) applies;
2. Member is responding positively to therapy as evidenced by, including but not limited to, reduction in itching and scratching;
3. Adbry is not prescribed concurrently with another biologic medication (e.g., Dupixent) or a JAK inhibitor (e.g., Olumiant, Rinvoq, Cibinqo, Opzelura);
4. For members with weight < 100 kg: Request is for 300 mg every 4 weeks, unless documentation supports member has not achieved clear or almost clear skin;
5. If request is for a dose increase, new dose does not exceed 300 mg every 2 weeks.

Approval duration: 12 months

B. Other diagnoses/indications (must meet 1 or 2)**:**

1. Currently receiving medication via PA Health & Wellness benefit and documentation supports positive response to therapy or the Continuity of Care policy (PA.LTSS.PHAR.01) applies; or
2. Refer to PA.CP.PMN.53.

III. Appendices/General Information

Appendix A: Abbreviation/Acronym Key

BSA: body surface area
FDA: Food and Drug Administration
JAK: Janus kinase

This table provides a listing of preferred alternative therapy recommended in the approval criteria. The drugs listed here may not be a formulary agent for all relevant lines of business and may require prior authorization.

Drug Name	Dosing Regimen	Dose Limit/ Maximum Dose
Very High Potency Topical Corticosteroids		
augmented betamethasone 0.05% (Diprolene® AF) cream, ointment, gel, lotion	Apply topically to the affected area(s) BID	Varies
clobetasol propionate 0.05% (Temovate®) cream, ointment, gel, solution		
diflorasone diacetate 0.05% (Maxiflor®, Psorcon E®) cream, ointment		
halobetasol propionate 0.05% (Ultravate®) cream, ointment		
High Potency Topical Corticosteroids		
augmented betamethasone 0.05% (Diprolene® AF) cream, ointment, gel, lotion	Apply topically to the affected area(s) BID	Varies

Drug Name	Dosing Regimen	Dose Limit/ Maximum Dose
diflorasone 0.05% (Florone®, Florone E®, Maxiflor®,Psorcon E®) cream		
fluocinonide acetonide 0.05% (Lidex®, Lidex E®) cream, ointment, gel, solution		
triamcinolone acetonide 0.5% (Aristocort®, Kenalog®) cream, ointment		
Medium Potency Topical Corticosteroids		
desoximetasone 0.05% (Topicort ®) cream, ointment, gel	Apply topically to the affected area(s) BID	Varies
fluocinolone acetonide 0.025% (Synalar®) cream, ointment		
mometasone 0.1% (Elocon®) cream, ointment, lotion		
triamcinolone acetonide 0.025%, 0.1% (Aristocort®, Kenalog®) cream, ointment		
Low Potency Topical Corticosteroids		
alclometasone 0.05% (Aclovate®) cream, ointment	Apply topically to the affected area(s) BID	Varies
desonide 0.05% (Desowen®) cream, ointment, lotion		
fluocinolone acetonide 0.01% (Synalar®) solution		
hydrocortisone 2.5% (Hytone®) cream, ointment		
Other Classes of Agents		
Protopic® (tacrolimus), Elidel® (pimecrolimus)	Children ≥ 2 years and adults: Apply a thin layer topically to affected skin BID. Treatment should be discontinued if resolution of disease occurs.	Varies
Eucrisa® (crisaborole)	Apply to the affected areas BID	Varies
cyclosporine	3-6 mg/kg/day PO BID	300 mg/day
azathioprine	1-3 mg/kg/day PO QD	Weight-based
methotrexate	7.5-25 mg/wk PO once weekly	25 mg/week
mycophenolate mofetil	1-1.5 g PO BID	3 g/day

Therapeutic alternatives are listed as Brand name® (generic) when the drug is available by brand name only and generic (Brand name®) when the drug is available by both brand and generic.

Appendix C: Contraindications/Boxed Warnings

- Contraindication(s): known hypersensitivity to tralokinumab-ldrm or any excipients in Adbry
- Boxed warning(s): none

IV. Dosage and Administration

Indication	Dosing Regimen	Maximum Dose
Moderate-to-severe atopic dermatitis	Initial dose of 600 mg SC followed by 300 mg SC every other week After 16 weeks of treatment, for patients with body weight < 100 kg who achieve clear or almost clear skin, a dosage of 300 mg every 4 weeks may be considered	See regimen

V. Product Availability

Pre-filled syringe: 150 mg/mL

VI. References

1. Adbry Prescribing Information. Madison, NJ: LEO Pharma, Inc.; December 2021. Available at: https://www.adbry.com/. Accessed January 20, 2022.
2. DRUGDEX® System [Internet database]. Greenwood Village, Colo: Thomson Healthcare. Updated periodically. Accessed January 20, 2022.
3. 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 Dec;34(12):2717-2744.
4. Eichenfield F, Tom WL, Chamlin SL, et al. Guidelines of Care for the Management of Atopic Dematitis. *J Am Acad Dermatol*. 2014 February; 70(2): 338–351.
5. 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 Mar;184(3):437-449.
6. 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. 2021 Mar;184(3):450-463.
7. Drucker AM, Ellis AG, Bohdanowicz M, et al. Systemic Immunomodulatory Treatments for Patients with Atopic Dermatitis: A Systematic Review and Network Meta-analysis. JAMA Dermatol. 2020;156(6):659-667.

Coding Implications

Codes referenced in this clinical policy are for informational purposes only. Inclusion or exclusion of any codes does not guarantee coverage. Providers should reference the most up-to-date sources of professional coding guidance prior to the submission of claims for reimbursement of covered services.

HCPCS Codes	Description
J3590	Unclassified biologics
C9399	Unclassified drugs or biologicals (hospital outpatient use)

Reviews, Revisions, and Approvals	Date	P&T Approval Date
Policy created	04/2022	