JOHNS HOPKINS HEALTH PLANS	Johns Hopkins Health Plans **Pharmacy Public** **Pharmacy Management Drug Policies**	*Policy Number*	MEDS155
		Effective Date	10/19/2022
		Approval Date	10/19/2022
	Subject **Adbry**	*Supersedes Date*	N/A
		Page	1 of 3

This document applies to the following Participating Organizations:

Priority Partners

Keywords: Adbry

Table of Contents		Page Number
I.	**POLICY**	**1**
II.	**POLICY CRITERIA**	**1**
	A. Adbry	**1**
III.	**AUTHORIZATION PERIOD/LIMITATIONS**	**2**
IV.	**EXCLUSIONS**	**2**
V.	**RECOMMENDED DOSE**	**2**
VI.	**REFERENCES**	**3**
VII.	**APPROVALS**	**3**

I. POLICY

Adbry (tralokinumab-ldrm) will require prior authorization to ensure it is used only when clinically appropriate. The process for initiating a prior authorization request can be found in policy PHARM 20.

1. PPMCO members are subject to the Priority Partners formulary, available at www.ppmco.org.
2. USFHP members are subject to prior authorization criteria, step-edits and days-supply limits outlined in the Tricare Policy Manual. Tricare Policy supersedes JHHC Medical/Pharmacy Policies. Tricare limits may be accessed at: http://pec.ha.osd.mil/formulary_search.php?submenuheader=1

II. POLICY CRITERIA

A. **Adbry** may be approved for the following:

1. **Moderate-to-Severe Atopic Dermatitis**
   a. Patient is 18 years of age or older
   b. Patient has a confirmed diagnosis of moderate to severe chronic atopic dermatitis with documented BSA coverage of 10% or greater.
   c. Patient has documented functional impairment as a result of chronic atopic dermatitis, which can include limitation of activities of daily living (ex. consistent sleep disturbances, problems wearing clothing, skin infections, etc.)
   d. Documentation has been provided showing a baseline assessment using one of the following tools:
      I. Investigator's Static Global Assessment (ISGA) score
      II. Eczema Area and Severity Index (EASI)
      III. Patient-Oriented Eczema Measure (POEM)
      IV. Scoring Atopic Dermatitis (SCORAD) index
   e. Patient has a documented history of treatment failure, contraindication, or intolerance to both of the following formulary alternatives:
      I. Two medium to very-high potency topical corticosteroids
      II. One topical calcineurin inhibitor [ex. Elidel (pimecrolimus) or Protopic (tacrolimus)]
      III. Caveat for patients with moderate disease:

i. In addition to trials of topical corticosteroids and a calcinuerin inhibitor, documentation of trial and inadequate response to Eucrisa (crisaborole) is required.

f. Patient has had trial and inadequate response to phototherapy, unless such use is not advised (i.e. patient has a history of skin cancer history, currently taking medication that may be photosensitizing, etc.)

g. Patient has had trial and inadequate response to at least one of the following systemic agents traditionally used for refractory disease, or has a contraindication to systemic therapy:
   I. cyclosporine
   II. methotrexate
   III. mycophenolate mofetil
   IV. azathioprine

h. Patient is not being concomitantly treated with other biologics (Dupixent, Enbrel, Xolair, Rituxan, etc.), or JAK inhibitors (Cibinqo, Rinvoq, etc.) that are indicated for treatment of atopic dermatitis

i. Prescriber is one of the following specialists: allergist, dermatologist, or immunologist

III. AUTHORIZATION PERIOD/LIMITATIONS

A. Initial approval will be limited to 4 months of therapy

B. Approval for continuation of therapy may be extended in 6-month intervals with documentation of positive clinical response to therapy. Documentation should also consist of a assessment score reduction using ONE of the following clinical evaluation tools:
   1. ISGA: decrease from baseline by at least 2 points
   2. EASI: decrease from baseline by at least 75%
   3. POEM: decrease from baseline by at least 3 points
   4. SCORAD: decrease from baseline by at least 50%

IV. EXCLUSIONS

A. Adbry will not be approved for the following:
   1. Pediatric patients
   2. Experimental or investigative uses including, but not limited to, the following indications that are not FDA-approved:
      a. Contact dermatitis
      b. Seborrheic dermatitis
      c. Lichen planus
      d. Lichen sclerosis
      e. Psoriasis
      f. Rosacea
      g. Acne Vulgaris
   3. Concurrent use with another biologic or JAK inhibitor product

B. The use of physician samples, or manufacturer product discounts, does not guarantee coverage under the provisions of the medical and/or pharmacy benefit. All pertinent criteria must be met in order to be eligible for benefit coverage.

V. RECOMMENDED DOSE

Please refer to the FDA-approved prescribing information for indication-specific dosing details.

VI. REFERENCES

1. Adbry [prescribing information]. Madison, NJ: LEO Pharma Inc; July 2022
2. Eichenfield LF, Tom WL, Berger TG, 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
3. 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.
4. 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 Aug;71(2):327-49.
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.

VII. APPROVALS

Signature on file at JHHC

DATE OF REVISION	SUMMARY OF CHANGE
10/19/2022	Policy Creation

Review Date: 10/19/2022

Revision Date: