Adbry™ (tralokinumab-ldrm)
(Subcutaneous)

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I. Length of Authorization

Coverage will be provided for 16 weeks initially. Coverage may be renewed every 6 months thereafter.

II. Dosing Limits

A. Quantity Limit (max daily dose) [NDC Unit]:

- Adbry 150 mg prefilled syringe (2-pack): 2 kits for initial loading dose, then 1 kit every 14 days

B. Max Units (per dose and over time) [HCPCS Unit]:

- 600 mg initial loading dose, followed by 300 mg every other week

III. Initial Approval Criteria [1,8]

Coverage is provided in the following conditions:

- Patient is at least 18 years of age; **AND**
- Patient is up to date with all vaccinations, in accordance with current vaccination guidelines, prior to initiating therapy; **AND**
- Patient has been evaluated to identify or rule out other causes of AD (e.g., hypersensitivity-allergen identification, cutaneous lymphomas, etc.); **AND**

Universal Criteria [1,8]

- Will not be used in combination with other monoclonal antibody biologics (e.g., tezepelumab, omalizumab, mepolizumab, reslizumab, benralizumab, dupilumab, etc.); **AND**
- Must not be administered concurrently with live vaccines; **AND**
- Patient does not have an active or untreated helminth infection; **AND**

Atopic Dermatitis † [1-10]

- Patient has moderate-to-severe atopic dermatitis (AD) with at least 1 of the following:
  - Involvement of at least 10% of body surface area (BSA); **OR**

- Eczema Area and Severity Index (EASI) score of 16 or greater; **OR**
- Investigator's Global Assessment (IGA) score of 3 or more; **OR**
- Scoring Atopic Dermatitis (SCORAD) score of 25 or more; **OR**
- Incapacitation due to AD lesion location (i.e., head and neck, palms, soles, or genitalia); **AND**

- Patient did not respond adequately (or is not a candidate) to a 3-month minimum trial of topical agents [e.g., corticosteroids, calcineurin inhibitors (e.g., tacrolimus or pimecrolimus), crisaborole, etc.]; **AND**
- Patient did not respond adequately (or is not a candidate) to a 3-month minimum trial of at least one (1) systemic agent (e.g., cyclosporine, azathioprine, methotrexate, mycophenolate mofetil, etc.); **AND**
- Patient did not respond adequately (or is not a candidate**) to a 3-month minimum trial of phototherapy (e.g., Psoralens with UVA light (PUVA), UVB, etc.)

**Examples of contraindications to phototherapy (PUVA or UVB) include the following: [11,12]
– Xeroderma pigmentosum – Pregnancy or lactation *(PUVA only)* – Lupus Erythematosus – History of one of the following: photosensitivity diseases (e.g., chronic actinic dermatitis, solar urticaria), melanoma, non-melanoma skin cancer, extensive solar damage *(PUVA only)*, or treatment with arsenic or ionizing radiation – Immunosuppression in an organ transplant patient *(UVB only)* – Photosensitizing medications *(PUVA only)* – Severe liver, renal, or cardiac disease *(PUVA only)*

† FDA Approved Indication(s); Φ Orphan Drug

IV. Renewal Criteria [1,9,10]

Coverage can be renewed based upon the following criteria:

- Patient continues to meet universal and other indication-specific relevant criteria as identified in section III; **AND**
- Absence of unacceptable toxicity from the drug. Examples of unacceptable toxicity include the following: hypersensitivity, conjunctivitis, keratitis, severe infections, etc.; **AND**
- Disease response as indicated by improvement in signs and symptoms compared to baseline in one or more of the following: pruritus, the amount of surface area involvement, EASI, IGA, and/or SCORAD; **AND**
    - Patient has not achieved remission/control (*defined as a period of at least 8 weeks without a flare*) OR patient experienced a disease flare and will require more frequent dosing; **OR**
    - Patient has achieved clear or almost clear skin defined as achievement of an IGA 0/1 or EASI-75 at Week 16: **AND**
        - Patient actual body weight is less than 100 kg; **AND**

- Maintenance treatment of 300 mg every 4 weeks will be attempted

V. Dosage/Administration [1]

Indication	Dose
Atopic Dermatitis	Administer, subcutaneously, an initial dose of 600 mg (four 150 mg injections), followed by 300 mg (two 150 mg injections) administered every other week. • A dosage of 300 mg every 4 weeks may be considered for patients below 100 kg who achieve clear or almost clear skin after 16 weeks of treatment. *Note: Adbry can be used with or without topical corticosteroids. Topical calcineurin inhibitors may be used, but should be reserved for problem areas only, such as the face, neck, intertriginous and genital areas*

VI. Billing Code/Availability Information

HCPCS Code:

- J3590 – Unclassified biologic
- C9399 – Unclassified drugs or biologicals (*Hospital Outpatient Use ONLY*)

NDC(s):

- Adbry 150 mg/ mL pre-filled syringe with needle guard (2-pack or 4-pack): 50222-0346-xx

VII. References

1. Adbry [package insert]. Madison, NJ; Leo Pharma, Inc.; January 2022. Accessed January 2022.
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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. Richard EG. (2019). Psoralen plus ultraviolet A (PUVA) photochemotherapy. In Elmets CA, Corona R (Eds.), *UptoDate*. Available from https://www.uptodate.com/contents/psoralen-plus-ultraviolet-a-puva-photochemotherapy?sectionName=Skin%20cancer&search=psoriasis%20phototherapy&topicRef=5666&anchor=H31513976&source=see_link#H2099103.
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TERM%20ADVERSE%20EFFECTS&search=psoriasis%20phototherapy&topicRef=5666&anchor=H10844620&source=see_link#H10844627.
7. Gandhi NA, Bennett BL, Graham NMH, et al. Targeting key proximal drivers of type 2 inflammation in disease. Nat Rev Drug Discov. 2016;15(1):35-50.
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10. Silverberg JI, Toth D, Bieber T, et al; ECZTRA 3 study investigators. 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;184(3):450-463. doi:10.1111/bjd.19573.

Appendix 1 – Covered Diagnosis Codes

ICD-10	ICD-10 Description
L20.0	Besnier's prurigo
L20.81	Atopic neurodermatitis
L20.82	Flexural eczema
L20.84	Intrinsic (allergic) eczema
L20.89	Other atopic dermatitis
L20.9	Atopic dermatitis, unspecified

Appendix 2 – Centers for Medicare and Medicaid Services (CMS)

Medicare coverage for outpatient (Part B) drugs is outlined in the Medicare Benefit Policy Manual (Pub. 100-2), Chapter 15, §50 Drugs and Biologicals. In addition, National Coverage Determination (NCD), Local Coverage Articles (LCAs) and Local Coverage Determinations (LCDs) may exist and compliance with these policies is required where applicable. They can be found at: http://www.cms.gov/medicare-coverage-database/search/advanced-search.aspx. Additional indications may be covered at the discretion of the health plan.

Medicare Part B Covered Diagnosis Codes (applicable to existing NCD/LCD/LCA): N/A

Medicare Part B Administrative Contractor (MAC) Jurisdictions		
Jurisdiction	**Applicable State/US Territory**	**Contractor**
E (1)	CA, HI, NV, AS, GU, CNMI	Noridian Healthcare Solutions, LLC
F (2 & 3)	AK, WA, OR, ID, ND, SD, MT, WY, UT, AZ	Noridian Healthcare Solutions, LLC

Medicare Part B Administrative Contractor (MAC) Jurisdictions		
Jurisdiction	**Applicable State/US Territory**	**Contractor**
5	KS, NE, IA, MO	Wisconsin Physicians Service Insurance Corp (WPS)
6	MN, WI, IL	National Government Services, Inc. (NGS)
H (4 & 7)	LA, AR, MS, TX, OK, CO, NM	Novitas Solutions, Inc.
8	MI, IN	Wisconsin Physicians Service Insurance Corp (WPS)
N (9)	FL, PR, VI	First Coast Service Options, Inc.
J (10)	TN, GA, AL	Palmetto GBA, LLC
M (11)	NC, SC, WV, VA (excluding below)	Palmetto GBA, LLC
L (12)	DE, MD, PA, NJ, DC (includes Arlington & Fairfax counties and the city of Alexandria in VA)	Novitas Solutions, Inc.
K (13 & 14)	NY, CT, MA, RI, VT, ME, NH	National Government Services, Inc. (NGS)
15	KY, OH	CGS Administrators, LLC