Adbry® (tralokinumab-ldrm) (Subcutaneous)

Document Number: IC-0297

Last Review Date: 07/02/2024
Date of Origin: 02/01/2022
Dates Reviewed: 02/2022, 10/2022, 10/2023, 01/2024, 07/2024

I. Length of Authorization

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

II. Dosing Limits

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

- Adbry 150 mg single-dose prefilled syringe: 4 syringes for initial loading dose, then 2 syringes every 14 days
- Adbry 300 mg/2 mL single-dose autoinjector: 2 autoinjectors for initial loading dose, then 1 autoinjector 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 12 years of age; **AND**
- Patient is up to date with all age-appropriate vaccinations, in accordance with current vaccination guidelines, prior to initiating therapy; **AND**
- Patient has been evaluated to identify or rule out other causes of atopic dermatitis (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.) or other non-biologic agents (e.g., apremilast, abrocitinib, baricitinib, ruxolitinib, tofacitinib, upadacitinib, deucravacitinib, etc.); **AND**
- Will not be administered concurrently with live vaccines; **AND**

- Patient does not have an active or untreated helminth infection; **AND**

Atopic Dermatitis (AD) † [1-11]

- 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**
  - Pruritus Numerical Rating Scale (NRS) score of 4 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, ruxolitinib, 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: [5,6]
– Xeroderma pigmentosum – Other rare photosensitive genodermatoses (e.g., trichothiodystrophy, Cockayne syndrome, Bloom syndrome, Rothmund-Thomson syndrome) *(UVB only)* – Genetic disorders associated with increased risk of skin cancer (e.g., Gorlin syndrome, oculocutaneous albinism) *(UVB only)* – 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)* – Young age < 12 years old *(PUVA only)*

† FDA Approved Indication(s); ‡ Compendium Recommended 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: 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, SCORAD and/or NRS; **AND**

  Adult Patients ONLY:

  - 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]

<table>
<tr><th>Indication</th><th>Dose</th></tr>
<tr><td>Atopic Dermatitis</td><td>
<u>Adult patients ≥18 years of age</u> §:

Administer the contents of the prefilled syringe or autoinjector via subcutaneous injection as noted in the dosing table below.
After 16 weeks of treatment, for adult 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.

<table>
<tr><th></th><th>Initial Loading Dose</th><th>Subsequent Dosage</th></tr>
<tr><td>Prefilled Syringe</td><td>600 mg (four 150 mg injections)</td><td>300 mg (two 150 mg injections) every other week</td></tr>
<tr><td>Autoinjector</td><td>600 mg (two 300 mg injections)</td><td>300 mg (one 300 mg injection) every other week</td></tr>
</table>
<u>Pediatric patients 12 to 17 years of age</u> §:

Administer the contents of the prefilled syringe via subcutaneous injection as noted in the dosing table below.

<table>
<tr><th></th><th>Initial Loading Dose</th><th>Subsequent Dosage</th></tr>
<tr><td>Prefilled Syringe</td><td>300 mg (two 150 mg injections)</td><td>150 mg (one 150 mg injection) every other week</td></tr>
</table>
</td></tr>
<tr><td colspan="2"><u>NOTE:</u>

Adbry is administered by subcutaneous injection and intended for use under the guidance of a healthcare provider. Provide proper training to patients and/or caregivers on the preparation and administration according to the "Instructions for Use".
§ The Adbry autoinjector is for use in adults only. A caregiver or adult patient may inject using the autoinjector.

</td></tr>
</table>

Indication	Dose
• *§ The Adbry prefilled syringe is for use in adults and pediatric patients 12 years of age and older. A caregiver or patient 12 years of age and older may inject using the prefilled syringe. In pediatric patients 12 years of age and older, administer under the supervision of an adult.* • *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(s):

- J3590 – Unclassified biologic
- C9399 – Unclassified drugs or biologicals

NDC(s):

- Adbry 150 mg/mL single-dose pre-filled syringe with needle guard (2-pack or 4-pack): 50222-0346-xx
- Adbry 300 mg/2 mL single-dose autoinjector (1-pack or 2-pack): 50222-0350-xx

VII. References

1. Adbry [package insert]. Madison, NJ; Leo Pharma, Inc.; June 2024. Accessed June 2024.
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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 Jul;71(1):116-32.
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5. Richard EG. (2022). Psoralen plus ultraviolet A (PUVA) photochemotherapy. In Elmets CA, Corona R (Eds.), *UptoDate*. Last updated: Dec 01, 2022. Accessed on: August 30, 2023. Available from https://www.uptodate.com/contents/psoralen-plus-ultraviolet-a-puva-photochemotherapy?search=Psoralen%20plus%20ultraviolet%20A%20(PUVA)%20photochemotherapy&source=search_result&selectedTitle=1~150&usage_type=default&display_rank=1.
6. Hönigsmann H. (2023). UVB therapy (broadband and narrowband). In Elmets CA, Corona R (Eds.), *UptoDate*. Last updated: Jan 18, 2023; Accessed on August 30, 2023. Available from https://www.uptodate.com/contents/uvb-therapy-broadband-and-narrowband?search=UVB%20therapy%20(broadband%20and%20narrowband&source=search_result&selectedTitle=1~80&usage_type=default&display_rank=1#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.

8. Wollenberg A, Christen-Zach S, Taieb A, et al. European Task Force on Atopic Dermatitis/EADV Eczema Task Force. ETFAD/EADV Eczema task force 2020 position paper on diagnosis and treatment of atopic dermatitis in adults and children. *JEADV* 2020, 34, 2717–2744. DOI: 10.1111/jdv.16892.
9. Wollenberg A, Blauvelt A, Guttman-Yassky E, et al; ECZTRA 1 and ECZTRA 2 study investigators. 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.
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.
11. Sidbury R, Alikhan A, Bercovitch L, Cohen DE, et al. Guidelines of care for the management of atopic dermatitis in adults with topical therapies. J Am Acad Dermatol. 2023 Jul;89(1):e1-e20. doi: 10.1016/j.jaad.2022.12.029.
12. Paller A, Blauvelt A, Soong W, et al; 308 Tralokinumab provides other clinically meaningful improvements in adolescents with moderate-to-severe atopic dermatitis who did not achieve IGA 0/1 at week 16, British Journal of Dermatology, Volume 188, Issue Supplement_2, February 2023, ljac140.008, https://doi.org/10.1093/bjd/ljac140.008.

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)

The preceding information is intended for non-Medicare coverage determinations. 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 Determinations (NCDs) and/or Local Coverage Determinations (LCDs) may exist and compliance with these policies is required where applicable. Local Coverage Articles (LCAs) may also exist for claims payment purposes or to clarify benefit eligibility under Part B for drugs which may be self-administered. The following link may be used to search for NCD, LCD, or LCA documents: https://www.cms.gov/medicare-coverage-database/search.aspx. Additional indications, including any preceding information, may be applied 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
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
M (11)	NC, SC, WV, VA (excluding below)	Palmetto GBA
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