Oscar Clinical Guideline: Adbry (tralokinumab) (PG110, Ver. 5)

Adbry (tralokinumab)

Disclaimer

Clinical guidelines are developed and adopted to establish evidence-based clinical criteria for utilization management decisions. Clinical guidelines are applicable according to policy and plan type. The Plan may delegate utilization management decisions of certain services to third parties who may develop and adopt their own clinical criteria.

Coverage of services is subject to the terms, conditions, and limitations of a member's policy, as well as applicable state and federal law. Clinical guidelines are also subject to in-force criteria such as the Centers for Medicare & Medicaid Services (CMS) national coverage determination (NCD) or local coverage determination (LCD) for Medicare Advantage plans. Please refer to the member's policy documents (e.g., Certificate/Evidence of Coverage, Schedule of Benefits, Plan Formulary) or contact the Plan to confirm coverage.

Summary

Atopic dermatitis (AD) is a chronic inflammatory skin disorder that affects approximately 10% of adults and 20% of children worldwide. It is characterized by intense itching, redness, and eczematous lesions, which can be accompanied by skin dryness, scaling, and thickening. The severity of AD can be classified as mild, moderate, or severe, depending on the extent and intensity of skin inflammation, as well as the impact on the patient's quality of life. Moderate-to-severe AD is defined by the presence of extensive or widespread lesions, intense pruritus, and a significant impairment of daily activities, sleep, and mood.

Treatment options for moderate-to-severe AD involve a combination of topical and systemic therapies, tailored to the individual patient's needs and preferences. The goal of treatment is to control inflammation, relieve itching, restore the skin barrier, prevent flares, and improve quality of life.

- Topical treatments for moderate-to-severe AD include corticosteroids, calcineurin inhibitors, and phosphodiesterase-4 (PDE4) inhibitors. These drugs act by reducing inflammation and pruritus and promoting skin healing. However, their long-term use may be limited by adverse effects, such as skin atrophy, telangiectasias, or the potential risk of skin infections or malignancies.

- Systemic treatments for moderate-to-severe AD are reserved for patients with inadequate response or contraindications to topical therapies, or those with severe or rapidly worsening disease. The most commonly used systemic agents include oral immunosuppressants, such as cyclosporine, methotrexate, or mycophenolate mofetil, and biologic agents, such as dupilumab, which targets the interleukin-4 (IL-4)/interleukin-13 (IL-13) pathway.

Adbry (tralokinumab) is FDA-approved 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 (tralokinumab) can be used with or without topical corticosteroids. Adbry (tralokinumab) works by directly inhibiting interleukin (IL)-13 cytokine, which is a major driver of atopic dermatitis signs and symptoms. Adbry (tralokinumab) is administered subcutaneously (SC) every 2 weeks after an initial loading dose of 600 mg at the start of treatment. After 16 weeks of treatment, patients with a body weight <100 kg who achieve clear or almost clear skin may be eligible for dosing every 4 weeks.

Definitions

"Atopic Dermatitis" also known as **eczema** is a chronic skin condition that makes a person's skin red, itchy and scaly. Atopic dermatitis (AD) often begins during childhood and persists into adulthood. Some people experience occasional flares followed by periods of improvement or a "waxing and waning" course of the disease.

"**Interleukin (IL)-13 cytokine**" is a protein secreted by certain cells of the immune system that affects many aspects of chronic airway inflammation.

Medical Necessity Criteria for Initial Authorization

The Plan considers **Adbry (tralokinumab)** medically necessary when **ALL** of the following criteria are met:

1. Prescribed by or in consultation with a dermatologist, allergist, or immunologist***; AND***
2. The member is 18 years of age or older***; AND***
3. The member has a documented diagnosis of moderate to severe atopic dermatitis **AND ONE** of the following:
    a. Involvement of (≥) 10% or more of body surface area***; or***
    b. Involvement of sensitive body areas (e.g., hands, feet, face, neck, scalp, genitals/groin, intertriginous areas)***; AND***

4. The member is unable to use, or has adequately tried and failed ONE of the following topical therapies for at least 8 weeks each in the past 365 days:
    a. A topical corticosteroid (TCS) from medium potency (group III to IV) classes to higher potencies (groups I to II) classes (see Table 1)***; and/or***
    b. Tacrolimus ointment***; and/or***
    c. Eucrisa (crisaborole) [PA may be required, please check the member's Plan-specific Formulary]***; AND***
5. Adbry (tralokinumab) will not be used concomitantly with other biologics (e.g., Dupixent, Cibinqo, or Rinvoq) in the treatment of atopic dermatitis***; AND***
6. Dosage does **NOT** exceed an initial (one-time) dose of 600 mg (four 150 mg injections), followed by 300 mg (two 150 mg injections) administered every other week***; AND***
7. Clinical chart documentation is provided for review to substantiate the above listed requirements.

If the above prior authorization criteria are met, Adbry (tralokinumab) will be approved for 4 months.

Medical Necessity Criteria for Reauthorization

Authorization of 12 months may be provided for members 18 years of age or older when recent chart documentation (within the past 4 months) is provided showing **ALL** of the following criteria are met:

1. The member is responding positively to Adbry (tralokinumab) treatment based upon the prescriber's assessment as demonstrated by **ONE** of the following:
    a. decreased disease activity (e.g., a reduction in BSA%)***; or***
    b. symptomatic improvement (e.g., redness, itching, oozing/crusting)***; AND***
2. Adbry (tralokinumab) will not be used concomitantly with other biologics (e.g., Dupixent, Cibinqo, or Rinvoq) in the treatment of atopic dermatitis***; AND***
3. The requested dosage does **NOT** exceed the following:
    a. 300 mg every 4 weeks for a member with body weight below 100 kg who achieve clear or almost clear skin after 16 weeks of treatment***; or***
    b. 300 mg every 2 weeks for a member weighing at least 100 kg **OR** documentation supports member has not achieved clear or almost clear skin after 16 weeks of treatment.

Table 1: Topical Corticosteroid Potency

NOTE: The following chart is only for approximate comparative purposes. Please check product-specific information to best assess product potency, which can also be affected by a multitude of factors (e.g., formulation, site of application, member and disease-specific factors)

Group	Potency	Steroid	Strength	Dosage Form
I	Very High	Betamethasone dipropionate (augmented)	0.05%	Gel, Lotion, and Ointment
		Clobetasol propionate	0.05%	Cream, Emollient Cream, Foam, Gel, Lotion, Ointment, Spray, and Solution
		Desoximetasone	0.25%	Spray
		Diflorasone diacetate	0.05%	Ointment
		Fluocinonide	0.1%	Cream
		Flurandrenolide	0.05%	Tape
		Halobetasol propionate	0.05% and 0.01%	Cream, Foam, Lotion and Ointment
II	High	Amcinonide	0.1%	Ointment
		Betamethasone dipropionate (augmented)	0.05%	Cream
		Betamethasone dipropionate	0.05%	Ointment
		Desoximetasone	0.25%	Cream and Ointment
		Desoximetasone	0.05%	Gel
		Diflorasone diacetate	0.05%	Cream, and Emollient Cream
		Fluocinonide	0.05%	Cream, Gel, Ointment, and Solution
		Halcinonide	0.1%	Cream, Ointment, and Solution
		Triamcinolone acetonide	0.5%	Ointment
III	Upper Medium	Amcinonide	0.1%	Cream and Lotion
		Betamethasone dipropionate	0.05%	Cream
		Betamethasone valerate	0.12%	Foam

		Betamethasone valerate	0.1%	Ointment
		Fluocinonide	0.05%	Emollient Cream
		Fluticasone propionate	0.005%	Ointment
		Mometasone furoate	0.1%	Ointment
		Triamcinolone acetonide	0.5%	Cream
		Triamcinolone acetonide	0.1%	Ointment
IV	Medium	Betamethasone dipropionate	0.05%	Spray
		Clocortolone pivalate	0.1%	Cream
		Desoximetasone	0.05%	Cream and Ointment
		Fluocinolone acetonide	0.025%	Ointment
		Flurandrenolide	0.05%	Ointment
		Hydrocortisone valerate	0.2%	Ointment
		Mometasone furoate	0.1%	Cream, Lotion, and Solution
		Triamcinolone acetonide	0.1%	Cream and Spray
V	Lower Medium	Betamethasone dipropionate	0.05%	Lotion
		Betamethasone valerate	0.1%	Cream and Lotion
		Desonide	0.05%	Gel and Ointment
		Fluocinolone acetonide	0.025%	Cream
		Fluocinolone acetonide	0.01%	Shampoo
		Flurandrenolide	0.05%	Cream and Lotion
		Fluticasone propionate	0.05%	Cream and Lotion
		Hydrocortisone butyrate	0.1%	Cream, Lotion, Ointment, and Solution
		Hydrocortisone probutate	0.1%	Cream
		Hydrocortisone valerate	0.2%	Cream

		Prenicarbate	0.1%	Emollient Cream and Ointment
		Triamcinolone acetonide	0.1%	Lotion
		Triamcinolone acetonide	0.025%	Ointment
VI	Low	Alclometasone dipropionate	0.05%	Cream and Ointment
		Desonide	0.05%	Cream, Lotion, and Foam
		Fluocinolone acetonide	0.01%	Cream, Oil, and Solution
		Triamcinolone acetonide	0.025%	Cream and Lotion
VII	Lowest	Hydrocortisone acetate	0.5% and 1%	Cream and Ointment
		Hydrocortisone base	0.5% to 2.5%	Cream, Lotion, Ointment, Solution, and Spray

Experimental or Investigational / Not Medically Necessary

Adbry (tralokinumab) for any other indication is considered not medically necessary by the Plan, as it is deemed to be experimental, investigational, or unproven.

References

1. Adbry (tralokinumab) [prescribing information]. Madison, NJ: LEO Pharma Inc; July 2022.
2. Blauvelt A, Gooderham M, Bhatia N, Langley RG, Schneider S, Zoidis J, Kurbasic A, Armstrong A, Silverberg JI. Tralokinumab Efficacy and Safety, with or without Topical Corticosteroids, in North American Adults with Moderate-to-Severe Atopic Dermatitis: A Subanalysis of Phase 3 Trials ECZTRA 1, 2, and 3. Dermatol Ther (Heidelb). 2022 Nov;12(11):2499-2516. doi: 10.1007/s13555-022-00805-y.
3. Boguniewicz M, Fonacier L, Guttman-Yassky E, Ong PY, Silverberg J, Farrar JR. Atopic dermatitis yardstick: Practical recommendations for an evolving therapeutic landscape. Ann Allergy Asthma Immunol. 2018 Jan;120(1):10-22.e2. doi: 10.1016/j.anai.2017.10.039. PMID: 29273118.
4. Draelos, Z. D., Feldman, S. R., Berman, B., Olivadoti, M., Sierka, D., Tallman, A. M., ... & Baldwin, S. (2019). Tolerability of topical treatments for atopic dermatitis. Dermatology and Therapy, 9(1), 71-102.
5. 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.
6. Eichenfield LF et al: Current guidelines for the evaluation and management of atopic dermatitis: a comparison of the Joint Task Force Practice Parameter and American Academy of Dermatology guidelines. J Allergy Clin Immunol. 139(4S):S49-S57, 2017

7. Eichenfield LF et al: Guidelines of care for the management of atopic dermatitis: section 1. Diagnosis and assessment of atopic dermatitis. J Am Acad Dermatol. 70(2):338-51, 2014
8. Eichenfield LF et al: Translating atopic dermatitis management guidelines into practice for primary care providers. Pediatrics. 136(3):554-65, 2015
9. 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;71:116-32. (Including potencies of topical corticosteroids).
10. Mayo Clinic.org - Atopic Dermatitis. Available at: https://www.mayoclinic.org/diseases-conditions/atopic-dermatitis-eczema. Last Update June 2020. Accessed Feb 28, 2022.
11. 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
12. Simpson EL, Merola JF, Silverberg JI, Reich K, Warren RB, Staumont-Sallé D, Girolomoni G, Papp K, de Bruin-Weller M, Thyssen JP, Zachariae R, Olsen CK, Wollenberg A. Safety of tralokinumab in adult patients with moderate-to-severe atopic dermatitis: pooled analysis of five randomized, double-blind, placebo-controlled phase II and phase III trials. Br J Dermatol. 2022 Sep 9. doi: 10.1111/bjd.21867.
13. Wollenberg A, Blauvelt A, Guttman-Yassky E, Worm M, Lynde C, Lacour JP, Spelman L, Katoh N, Saeki H, Poulin Y, Lesiak A, Kircik L, Cho SH, Herranz P, Cork MJ, Peris K, Steffensen LA, Bang B, Kuznetsova A, Jensen TN, Østerdal ML, Simpson EL; 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 Mar;184(3):437-449. doi: 10.1111/bjd.19574.
14. 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.
15. Wollenberg A, Oranje A, Deleuran M, et al. ETFAD/EADV Eczema task force 2015 position paper on diagnosis and treatment of atopic dermatitis in adult and paediatric patients. J Eur Acad Dermatol Venereol 2016; 30:729.
16. Wong, I. T., Tsuyuki, R. T., Cresswell-Melville, A., Doiron, P., & Drucker, A. M. (2017). Guidelines for the management of atopic dermatitis (eczema) for pharmacists. Canadian Pharmacists Journal/Revue des Pharmaciens du Canada, 150(5), 285-297.
17. Yew, Y. W., Thyssen, J. P., & Silverberg, J. I. (2019). A systematic review and meta-analysis of the regional and age-related differences in atopic dermatitis clinical characteristics. Journal of the American Academy of Dermatology, 80(2), 390-401.

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