

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.

Adbry (tralokinumab)	1
Summary	1
Definitions	3
Clinical Indications	3
Medical Necessity Criteria for Initial Clinical Review	3
Initial Indication-Specific Criteria	3
Atopic Dermatitis	3
Medical Necessity Criteria for Subsequent Clinical Review	4
Subsequent Indication-Specific Criteria	4
Atopic Dermatitis	4
Experimental or Investigational / Not Medically Necessary	5
References	5
Appendix A	8
Clinical Guideline Revision / History Information	10

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 clinical course of AD is characterized by chronic, relapsing episodes over months to years. In mild cases, one may experience intermittent flares that may or may not clear without the use of pharmacological intervention. In more

moderate and severe cases, flares rarely clear without pharmacological intervention/therapy. 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, Janus kinase inhibitors (JAK), antimicrobials/antiseptics, antihistamines, 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, oral janus kinase inhibitors 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 those 12 years and older 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):

- For adults 18 years and older - 300 mg (two 150 mg injections) every 2 weeks after an initial loading dose of 600 mg at the start of treatment. After 16 weeks of treatment, those with a body weight <100 kg who achieve clear or almost clear skin may be eligible for dosing every 4 weeks.
- For pediatrics 12 to 17 years old - 150 mg (one 150 mg injection) every other week after an initial loading dose of 300 mg (two 150 mg injections) at the start of treatment. In pediatrics, Adbry (tralokinumab) is to be administered by or under supervision of an adult.
- Adbry (tralokinumab) is available as both a prefilled syringe and an autoinjector. The autoinjector is only indicated for adults, available for both the initial loading dose and the subsequent dosages.
- It is recommended that all age appropriate vaccinations are completed prior to initiation of Adbry (tralokinumab).

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.

“Biologics” or “Biologicals” or “Biological therapeutics” as defined by the World Health Organization (WHO) are a class of medicines which are grown and then purified from large-scale cell cultures such as bacteria, yeast, animal or plant cells. Biologics can include but are not limited to vaccines, growth factors, immune modulators, and monoclonal antibodies. Unlike other medicines, biologics are generally proteins purified from living culture systems and/or blood, and are often referred to as “large modules.”

“Body surface area (BSA)” is a measure of the total area involved by plaques in relation to the total body surface area. There are a number of different methods, however most clinical trials on plaque psoriasis use the “handprint method”, where the patient’s actual palm/hand size is estimated as 1% of BSA. The head and neck, upper extremities, trunk, and lower extremities (including buttocks) typically correspond to approximately 10%, 20%, 30% and 40% of the BSA, respectively.

“Documentation” refers to written information, including but not limited to:

- Up-to-date chart notes, relevant test results, and/or relevant imaging reports to support diagnoses; or
- Prescription claims records, and/or prescription receipts to support prior trials of formulary alternatives.

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

“[s]” indicates state mandates may apply.

Clinical Indications

Medical Necessity Criteria for Initial Clinical Review

Initial Indication-Specific Criteria

Atopic Dermatitis

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

1. Prescribed by or in consultation with a specialist in dermatology, allergy or immunology; *AND*
2. The member is 12 years of age or older; *AND*
3. The member has a documented diagnosis of moderate-to-severe atopic dermatitis *AND ONE* (1) of the following:
 - a. Involvement of $\geq 10\%$ 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 tried and failed ONE (1) of the following topical therapies for at least 8 weeks each in the past 365 days:^[5]
 - 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. Adbry (tralokinumab) is being prescribed at a dose and frequency that is within FDA approved labeling OR is supported by compendia or evidence-based published dosing guidelines for the requested indication; *AND*
 - a. *The recommended FDA-labeled dosing is as follows:*
 - i. *Adult 18 years and older - an initial (one-time) dose of 600 mg (four 150 mg injections), followed by 300 mg (two 150 mg injections) administered every other week; or*
 - ii. *Pediatric 12 to 17 years old - an initial (one-time) dose of 300 mg (two 150 mg injections), followed by 150 mg (one 150 mg injection) every other week;*
- 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 up to 4 months.^[5]

Continued Care

Medical Necessity Criteria for Subsequent Clinical Review

Subsequent Indication-Specific Criteria

Atopic Dermatitis

The Plan considers Adbry (tralokinumab) medically necessary when recent chart documentation (within the past 4 months) is provided showing ALL of the following: :

- 1. The member is responding positively to Adbry (tralokinumab) treatment based upon the prescriber's assessment as demonstrated by ONE (1) 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. Adult 18 years and older:
 - i. 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*
 - ii. 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; *or*
 - b. Pediatric 12 to 17 years old - 150 mg (one 150 mg injection) every other week.

If the above reauthorization criteria are met, Adbry (tralokinumab) will be approved for up to 12 months.^[5]

Experimental or Investigational / Not Medically Necessary^[5]

Adbry (tralokinumab) for any other indication or use is considered not medically necessary by the Plan, as it is deemed to be experimental, investigational, unproven, or not medically necessary. Non-covered indications include, but are not limited to, the following:

- Asthma. Clinical studies have not consistently shown a benefit with Adbry (tralokinumab) for the management of asthma.
- Idiopathic Pulmonary Fibrosis. Only one phase 2 study evaluated Adbry (tralokinumab) for the management of idiopathic pulmonary fibrosis. The study ended early due to lack of efficacy at the interim analysis.

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Appendix A

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, Shampoo, Spray, and Solution
		Diflorasone diacetate	0.05%	Ointment
		Fluocinonide	0.1%	Cream
		Flurandrenolide	0.05%	Tape
		Halobetasol propionate	0.05%	Cream, Foam, Lotion and Ointment
II	High	Amcinonide	0.1%	Ointment
		Betamethasone dipropionate (augmented)	0.05%	Cream
		Betamethasone dipropionate	0.05%	Ointment
		Clobetasol propionate	0.025%	Cream
		Desoximetasone	0.25%	Cream, Ointment and Spray
		Desoximetasone	0.05%	Gel
		Diflorasone diacetate	0.05%	Cream, and Emollient Cream and Ointment
		Fluocinonide	0.05%	Cream, Gel, Ointment, and Solution
		Halcinonide	0.1%	Cream, Ointment, and Solution

		Halobetasol propionate	0.01%	Lotion
III	Upper Medium	Amcinonide	0.1%	Cream and Lotion
		Betamethasone dipropionate	0.05%	Cream
		Betamethasone valerate	0.12%	Foam
		Betamethasone valerate	0.1%	Ointment
		Desoximetasone	0.05%	Cream and Ointment
		Fluocinonide	0.05%	Emollient Cream
		Fluticasone propionate	0.005%	Ointment
		Mometasone furoate	0.1%	Ointment
		Triamcinolone acetonide	0.5%	Cream and Ointment
IV	Medium	Betamethasone dipropionate	0.05%	Spray
		Clocortolone pivalate	0.1%	Cream
		Desoximetasone	0.05%	Cream and Ointment
		Fluocinolone acetonide	0.025%	Cream and Ointment
		Flurandrenolide	0.05%	Ointment
		Fluticasone propionate	0.05%	Cream
		Hydrocortisone valerate	0.2%	Ointment
		Mometasone furoate	0.1%	Cream, Lotion, and Solution
		Triamcinolone acetonide	0.1%	Cream, Dental Paste, Ointment, and Spray
V	Lower Medium	Betamethasone dipropionate	0.05%	Lotion
		Betamethasone valerate	0.1%	Cream
		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%	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
		Betamethasone valerate	0.1%	Lotion
		Desonide	0.05%	Cream, Lotion, and Foam
		Fluocinolone acetonide	0.01%	Cream, Oil, Shampoo and Solution
		Triamcinolone acetonide	0.025%	Cream and Lotion
VII	Lowest	Hydrocortisone acetate	1% to 2.5%	Cream, Lotion, and Ointment
		Hydrocortisone base	0.5% to 2.5%	Cream, Gel, Liquid, Lotion, Ointment, Solution, and Spray

Clinical Guideline Revision / History Information

Original Date: 03/17/2022
Reviewed/Revised: 12/08/2022, 3/23/2023, 9/21/2023, 10/27/2023, 1/26/2024, 7/1/2025, 08/03/2026