PRIOR AUTHORIZATION POLICY

POLICY: Immunologicals – Adbry Prior Authorization Policy
- Adbry® (tralokinumab-ldrm subcutaneous injection – Leo)

REVIEW DATE: 04/19/2024

OVERVIEW

Adbry, an interleukin (IL)-13 antagonist, is indicated for the treatment of moderate to severe **atopic dermatitis** in patients ≥ 12 years of age whose disease is not adequately controlled with topical prescription therapies or when those therapies are not advisable.[1] Adbry may be used with or without topical corticosteroids.

Clinical Efficacy

Three pivotal Adbry studies enrolled adults (≥ 18 years of age) with moderate to severe chronic atopic dermatitis affecting ≥ 10% of their body surface area (BSA).[1-3] Patients also had a recent of an inadequate response to a sufficient course of topical therapy (e.g., topical corticosteroids and/or topical calcineurin inhibitors). Inadequate response was defined as a failure to either achieve or maintain remission or low disease activity following at least 28 days of topical corticosteroid treatment (medium potency or higher) or for the maximum duration recommended by the topical corticosteroid prescribing information, with or without a topical calcineurin inhibitor. Patients who had received systemic treatment for atopic dermatitis in the previous year were also considered to be non-responders to topical therapies and were eligible for study inclusion. At Week 16, Adbry was found to be more effective in achieving a clinical response compared with placebo. In the monotherapy trials, the majority of patients who achieved a clinical response to Adbry at Week 16 experienced sustained efficacy at Week 52. Similarly, the patients enrolled in the Adbry pivotal trial in adolescents (12 to 17 years of age) had moderate to severe atopic dermatitis affecting 10% BSA or more and a previous inadequate response to topical medication (e.g., topical corticosteroids and/or topical calcineurin inhibitors).[4] As was observed in trials in adults, significantly more patients achieved a clinical response at Week 16 and again, efficacy was sustained through Week 52.

Guidelines

Guidelines for the care and management of atopic dermatitis (with topical therapies in adults [2022], with phototherapy and systemic agents [2023]) have been updated to address Adbry.[5,6] The guidelines note that despite the availability of newer, systemic therapies (e.g., Adbry), topical agents remain the mainstay of treatment due to their proven track record and favorable safety profiles. Several topical agents are recommended, with topical corticosteroids commonly used first-line for mild to severe atopic dermatitis in all skin regions. If topical therapy and basic management (e.g., moisturizers, bathing modifications) have been optimized and the patient has not achieved adequate control, consider an alternative diagnosis or systemic therapy. In this setting, use of Adbry is recommended in patients with moderate to severe disease (strong recommendation).

POLICY STATEMENT

Prior Authorization is recommended for prescription benefit coverage of Adbry. All approvals are provided for the duration noted below. In cases where the approval is authorized in months, 1 month is equal to 30 days. Because of the specialized skills required for evaluation and diagnosis of patients treated with Adbry as well as the monitoring required for adverse events and long-term efficacy, initial approval requires Adbry to be prescribed by or in consultation with a physician who specializes in the condition being treated.

Automation: None.

RECOMMENDED AUTHORIZATION CRITERIA

Coverage of Adbry is recommended in those who meet the following criteria:

FDA-Approved Indication

1. **Atopic Dermatitis.** Approve for the duration noted if the patient meets one of the following (A or B):
   - **A)** Initial Therapy. Approve for 4 months if the patient meets the following (i, ii, iii, and iv):
     - **i.** Patient is ≥ 12 years of age; AND
     - **ii.** Patient has atopic dermatitis involvement estimated to be ≥ 10% of the body surface area according to the prescriber; AND
     - **iii.** Patient meets ALL of the following (a, b, and c):
       - **a)** Patient has tried at least one medium-, medium-high, high-, and/or super-high-potency prescription topical corticosteroid; AND
       - **b)** This topical corticosteroid was applied daily for at least 28 consecutive days; AND
       - **c)** Inadequate efficacy was demonstrated with this topical corticosteroid therapy, according to the prescriber; AND
     - **iv.** The medication is prescribed by or in consultation with an allergist, immunologist, or dermatologist.
   - **B)** Patient is Currently Receiving Adbry. Approve for 1 year if the patient meets the following (i and ii):
     - **i.** Patient has already received at least 4 months of therapy with Adbry; AND
       Note: A patient who has received < 4 months of therapy or who is restarting therapy with Adbry should be considered under criterion 1A (Atopic Dermatitis, Initial Therapy).
     - **ii.** Patient has responded to therapy as determined by the prescriber.
       Note: Examples of a response to Adbry therapy are marked improvements in erythema, induration/papulation/edema, excoriations, and lichenification; reduced pruritus; decreased requirement for other topical or systemic therapies; reduced body surface area affected with atopic dermatitis; or other observed responses.

CONDITIONS NOT RECOMMENDED FOR APPROVAL

Coverage of Adbry is not recommended in the following situations:

1. **Asthma.** Adbry is not indicated for the treatment of asthma.[1] Three Phase III studies evaluated tralokinumab for the treatment of adults and adolescent patients with severe, uncontrolled asthma.[7,8] In STRATOS 1 and STRATOS 2 (published) [n = 1,202], Adbry 300 mg administered subcutaneously once every 2 weeks did not significantly reduce the annualized asthma exacerbation rate compared with placebo.[7] TROPOS (published) [n = 140] included patients with severe, uncontrolled asthma that required maintenance oral corticosteroid treatment plus inhaled corticosteroids and inhaled long-acting beta$_2$-agonists.[8] Following 40 weeks of therapy, the percent reduction from baseline in the final daily average oral corticosteroid dose was not significantly different between Adbry and placebo.

2. **Concurrent use of Adbry with another Monoclonal Antibody Therapy.** The efficacy and safety of Adbry in combination with other monoclonal antibodies have not been established.
   Note: Monoclonal antibody therapies are Dupixent® (dupilumab subcutaneous [SC] injection), Cinqair® (reslizumab intravenous injection), Fasenra® (benralizumab SC injection), Nucala® (mepolizumab SC injection), Teszpire® (tezepelumab-ekko SC injection), or Xolair® (omalizumab SC injection).

3. **Concurrent Use of Adbry with Janus Kinase (JAK) Inhibitors (oral or topical).** Use of JAK inhibitors is not recommended in combination with other JAK inhibitors, biologic immunomodulators (e.g., Adbry), or with other immunosuppressants.[9-11]
   Note: Examples of JAK inhibitors are Cibinqo® (abrocitinib tablets), Rinvoq® (upadacitinib tablets), and Opzelura™ (ruxolitinib cream).

4. **Idiopathic Pulmonary Fibrosis**. Adbry is not indicated for the treatment of idiopathic pulmonary fibrosis.[1] Intravenous tralokinumab has been studied for the treatment of idiopathic pulmonary fibrosis in a Phase II, randomized, placebo-controlled study (published) [n = 176].[12] However, this study was terminated early after an interim analysis showed lack of efficacy. Two doses of tralokinumab were studied and neither dose significantly improved the least-squares mean difference percent predicted forced vital capacity from baseline to Week 52.

5. **Ulcerative Colitis.** Adbry is not indicated for the treatment of ulcerative colitis.[1] One Phase IIa, randomized, double-blind, placebo-controlled study (published) [n = 111] evaluated tralokinumab for the treatment of patients with moderate to severe ulcerative colitis despite standard treatments.[13] Following 8 weeks of therapy, tralokinumab did not significantly improve clinical response rates compared with placebo.

6. Coverage is not recommended for circumstances not listed in the Recommended Authorization Criteria. Criteria will be updated as new published data are available.

REFERENCES

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