PRIOR AUTHORIZATION POLICY

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

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OVERVIEW

Adbry, an interleukin (IL)-13 antagonist, is indicated for the treatment of moderate to severe **atopic dermatitis** in adults 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.[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 activitiy 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.

Guidelines

Adbry is not addressed in any current atopic dermatitis guidelines. However, US and European guidelines note that most patients with atopic dermatitis can achieve disease control with non-pharmacologic interventions (e.g., emollients), standard topical anti-inflammatory therapies (e.g., topical corticosteroids, topical calcineurin inhibitors), and elimination of exacerbating factors.[4-10] Systemic therapies are recommended after these standard topical therapies have failed and should generally be used in conjunction with daily emollients and topical anti-inflammatory medications as needed.

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 Adbry for the duration noted if the patient meets one of the following conditions (A or B):
   - **A)** Initial Therapy. Approve for 4 months if the patient meets the following criteria (i, ii, iii, and iv):
     - **i.** Patient is ≥ 18 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 criteria (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 criteria (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 responses observed.

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.[11,12] In STRATOS 1 and STRATOS 2 (published) [n = 1,202], Adbry 300 mg subcutaneously once every 2 weeks did not significantly reduce the annualized asthma exacerbation rate compared with placebo.[11] 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.[12] Following 40 weeks of therapy, the percent reduction from baseline in the final daily average oral corticosteroid dose was not significantly different between tralokinumab and placebo.

2. **Concurrent use with another Monoclonal Antibody Therapy.** The efficacy and safety of Adbry in combination with other monoclonal antibodies (e.g., Dupixent, Cinqair, Fasenra, Nucala, Tezspire, Xolair) have not been established.

3. **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].[13] However, this study was

terminated early after an interim analysis showed lack of efficacy. Neither tralokinumab dose studied significantly improved the least-squares mean difference percent predicted forced vital capacity from baseline to Week 52:

4. **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.[14] Following 8 weeks of therapy, tralokinumab did not significantly improve clinical response rates compared with placebo.

5. 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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