PRIOR AUTHORIZATION POLICY

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

REVIEW DATE: 04/09/2025

INSTRUCTIONS FOR USE

THE FOLLOWING COVERAGE POLICY APPLIES TO HEALTH BENEFIT PLANS ADMINISTERED BY CIGNA COMPANIES. CERTAIN CIGNA COMPANIES AND/OR LINES OF BUSINESS ONLY PROVIDE UTILIZATION REVIEW SERVICES TO CLIENTS AND DO NOT MAKE COVERAGE DETERMINATIONS. REFERENCES TO STANDARD BENEFIT PLAN LANGUAGE AND COVERAGE DETERMINATIONS DO NOT APPLY TO THOSE CLIENTS. COVERAGE POLICIES ARE INTENDED TO PROVIDE GUIDANCE IN INTERPRETING CERTAIN STANDARD BENEFIT PLANS ADMINISTERED BY CIGNA COMPANIES. PLEASE NOTE, THE TERMS OF A CUSTOMER'S PARTICULAR BENEFIT PLAN DOCUMENT [GROUP SERVICE AGREEMENT, EVIDENCE OF COVERAGE, CERTIFICATE OF COVERAGE, SUMMARY PLAN DESCRIPTION (SPD) OR SIMILAR PLAN DOCUMENT] MAY DIFFER SIGNIFICANTLY FROM THE STANDARD BENEFIT PLANS UPON WHICH THESE COVERAGE POLICIES ARE BASED. FOR EXAMPLE, A CUSTOMER'S BENEFIT PLAN DOCUMENT MAY CONTAIN A SPECIFIC EXCLUSION RELATED TO A TOPIC ADDRESSED IN A COVERAGE POLICY. IN THE EVENT OF A CONFLICT, A CUSTOMER'S BENEFIT PLAN DOCUMENT ALWAYS SUPERSEDES THE INFORMATION IN THE COVERAGE POLICIES. IN THE ABSENCE OF A CONTROLLING FEDERAL OR STATE COVERAGE MANDATE, BENEFITS ARE ULTIMATELY DETERMINED BY THE TERMS OF THE APPLICABLE BENEFIT PLAN DOCUMENT. COVERAGE DETERMINATIONS IN EACH SPECIFIC INSTANCE REQUIRE CONSIDERATION OF 1) THE TERMS OF THE APPLICABLE BENEFIT PLAN DOCUMENT IN EFFECT ON THE DATE OF SERVICE; 2) ANY APPLICABLE LAWS/REGULATIONS; 3) ANY RELEVANT COLLATERAL SOURCE MATERIALS INCLUDING COVERAGE POLICIES AND; 4) THE SPECIFIC FACTS OF THE PARTICULAR SITUATION. EACH COVERAGE REQUEST SHOULD BE REVIEWED ON ITS OWN MERITS. MEDICAL DIRECTORS ARE EXPECTED TO EXERCISE CLINICAL JUDGMENT WHERE APPROPRIATE AND HAVE DISCRETION IN MAKING INDIVIDUAL COVERAGE DETERMINATIONS. WHERE COVERAGE FOR CARE OR SERVICES DOES NOT DEPEND ON SPECIFIC CIRCUMSTANCES, REIMBURSEMENT WILL ONLY BE PROVIDED IF A REQUESTED SERVICE(S) IS SUBMITTED IN ACCORDANCE WITH THE RELEVANT CRITERIA OUTLINED IN THE APPLICABLE COVERAGE POLICY, INCLUDING COVERED DIAGNOSIS AND/OR PROCEDURE CODE(S). REIMBURSEMENT IS NOT ALLOWED FOR SERVICES WHEN BILLED FOR CONDITIONS OR DIAGNOSES THAT ARE NOT COVERED UNDER THIS COVERAGE POLICY (SEE "CODING INFORMATION" BELOW). WHEN BILLING, PROVIDERS MUST USE THE MOST APPROPRIATE CODES AS OF THE EFFECTIVE DATE OF THE SUBMISSION. CLAIMS SUBMITTED FOR SERVICES THAT ARE NOT ACCOMPANIED BY COVERED CODE(S) UNDER THE APPLICABLE COVERAGE POLICY WILL BE DENIED AS NOT COVERED. COVERAGE POLICIES RELATE EXCLUSIVELY TO THE ADMINISTRATION OF HEALTH BENEFIT PLANS. COVERAGE POLICIES ARE NOT RECOMMENDATIONS FOR TREATMENT AND SHOULD NEVER BE USED AS TREATMENT GUIDELINES. IN CERTAIN MARKETS, DELEGATED VENDOR GUIDELINES MAY BE USED TO SUPPORT MEDICAL NECESSITY AND OTHER COVERAGE DETERMINATIONS.

CIGNA NATIONAL FORMULARY COVERAGE:

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 history 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.

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is(are) covered as medically necessary when the following criteria is(are) met for FDA-approved indication(s) or other uses with supportive evidence (if applicable):

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 COVERED

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is(are) considered not medically necessary for ANY other use(s) including the following (this list may not be all inclusive; criteria will be updated as new published data are available):

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), Ebglyss® (lebrikizumab-lbkz subcutaneous injection), Fasenra® (benralizumab SC injection), Nemluvio® (nemolizumab-ilto subcutaneous injection), Nucala® (mepolizumab SC injection), Tezspire® (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.[9-11,14]
   Note: Examples of JAK inhibitors are Cibinqo® (abrocitinib tablets), Leqselvi™ (deuruxolitinib tablets), Rinvoq®/Rinvoq® LQ (upadacitinib extended-release tablets and oral solution), 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.

REFERENCES

1. Adbry® subcutaneous injection [prescribing information]. Madison, NJ: Leo; June 2024.
2. Wollenberg A, Blauvelt A, Guttman-Yassky E, et al. Tralokinumab for moderate-to-severe atopic dermatitis: results from two 52-week, randomized, double-blind, multicenter, placebo-controlled phase III trials (ECZTRA 1 and ECZTRA 2). *Br J Dermatol*. 2021;184(3):437-449.
3. Silverberg JI, Toth D, Bieber T, et al. Tralokinumab plus topical corticosteroids for the treatment of moderate-to-severe atopic dermatitis: results from the double-blind, randomized, multicenter, placebo-controlled phase III ECZTRA 3 trial. *Br J Dermatol*. 2021;184(3):450-463.
4. Paller AS, Flohr C, Cork M, et al. Efficacy and safety of tralokinumab in adolescents with moderate to severe atopic dermatitis: the phase 3 ECZTRA 6 randomized clinical trial. *JAMA Dermatol*. 2023;159(6):596-605.
5. Sidbury R, Alikhan A, Cohen DE, et al. Guidelines of care for the management of atopic dermatitis in adults with topical therapies. *J Am Acad Dermatol*. 2023;89(e1-e20).
6. Davis DMR, Drucker AM, Alikhan A, et al. Guidelines of care for the management of atopic dermatitis in adults with phototherapy and systemic therapies. *J Am Acad Dermatol*. 2024;90(2):e43-e56.
7. Panettieri Jr. RA, Sjobring U, Peterffy AM, et al. Tralokinumab for severe, uncontrolled asthma (STRATOS 1 and STRATOS 2): two randomised, double-blind, placebo-controlled, phase 3 clinical trial. *Lancet Respir Med*. 2018;6(7):511-525.
8. Busse WW, Brusselle GG, Korn S, et al. Tralokinumab did not demonstrate oral corticosteroid-sparing effects in severe asthma. *Eur Respir J*. 2019;53(2):1800948.
9. Cibinqo® tablets [prescribing information]. New York, NY: Pfizer; December 2023.

10. Rinvoq® extended-release tablets/Rinvoq® LQ oral solution [prescribing information]. North Chicago, IL: AbbVie; April 2024.
11. Opzelura® cream [prescribing information]. Wilmington, DE: Incyte; March 2023.
12. Parker JM, Glaspole IN, Lancaster LH, et al. A phase 2 randomized controlled study of tralokinumab in subjects with idiopathic pulmonary fibrosis. *Am J Respir Crit Care Med*. 2018;197(1):94-103.
13. Danese S, Rudzinski J, Brandt W, et al. Tralokinumab for moderate-to-severe UC: a randomized, double-blind, placebo-controlled, phase IIa study. *Gut*. 2015;64(2):243-249.
14. Leqselvi™ tablets [prescribing information]. Whippany, NJ: Sun/Halo; July 2024.

HISTORY

Type of Revision	Summary of Changes	Review Date
Annual Revision	**Conditions Not Covered :** Criteria were updated to clarify that use of Adbry with another monoclonal antibody therapy is specific to Cinqair, Fasenra, Nucala, Dupixent, Tezspire, and Xolair.	03/22/2023
Selected Revision	**Conditions Not Covered :** Criteria were added for "Concurrent Use of Dupixent with Janus Kinase Inhibitors (JAKis) [oral or topical]".	05/10/2023
Selected Revision	**Atopic Dermatitis:** Age requirement was changed to "≥ 12 years of age"; previously, age requirement was "≥ 18 years of age".	12/20/2023
Annual Revision	No criteria changes.	04/19/2024
Annual Revision	**Conditions Not Covered, Concurrent Use of Adbry with another Monoclonal Antibody Therapy:** Ebglyss® (lebrikizumab-lbkz subcutaneous injection) and Nemluvio® (nemolizumab-ilto subcutaneous injection) were added as examples of monoclonal antibody therapies. **Conditions Not Covered, Concurrent Use of Adbry with Janus Kinase (JAK) Inhibitors (oral or topical):** Leqselvi™ (deuruxolitinib tablets) and Rinvoq® LQ (upadacitinib oral solution) were added as examples of JAK inhibitors.	04/09/2025