MEDICAL MUTUAL®

Drug Policy

Policy:	**220301**	**Annual Review Date: 07/16/2024**
Code(s):	**HCPCS J3590 or C9399**	**Last Revised Date: 07/16/2024**
SUBJECT:	**Adbry ® (tralokinumab)**	

☒Subject to Site of Care

Prior approval is required for some or all procedure codes listed in this Corporate Drug Policy.

Initial and renewal requests for the medication(s) listed in this policy are subject to site of care management. When billed under the medical benefit, administration of the medication will be restricted to a non-hospital facility-based location (i.e., home infusion provider, provider's office, free-standing ambulatory infusion center) unless the member meets the site of care exception criteria. To view the exception criteria and a list of medications subject to site of care management please click here.

OVERVIEW

Adbry is an interleukin-13 antagonist indicated for treatment moderate-to-severe atopic dermatitis in patients 12 years of age or older whose disease is not adequately controlled with topical prescription therapies or when those therapies are not advisable. Adbry can be used with or without topical steroids.

POLICY STATEMENT

This policy involves the use of Adbry. Prior authorization is recommended for pharmacy benefit coverage of Adbry. Approval is recommended for those who meet the conditions of coverage in the **Criteria and Initial/Extended Approval** for the diagnosis provided. **Conditions Not Recommended for Approval** are listed following the recommended authorization criteria. Requests for uses not listed in this policy will be reviewed for evidence of efficacy and for medical necessity on a case-by-case basis.

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 be prescribed by or in consultation with a physician who specializes in the condition being treated. All approvals for initial therapy are provided for the initial approval duration noted below; if reauthorization is allowed, a response to therapy is required for continuation of therapy unless otherwise noted below.

RECOMMENDED AUTHORIZATION CRITERIA

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

1. **Atopic Dermatitis.** Approve for the duration noted if the patient meets one of the following (A or B):
   - **A)** Initial Therapy. Approve if the patient meets the following criteria (i, ii, iii and iv):
     - **i.** Patient is ≥ 12 years of age; AND

ii. Patient has moderate-to-severe atopic dermatitis with at least one of the following (a, b, c, d, or e):
- **a)** Involvement of at least 10% of body surface area (BSA); OR
- **b)** Eczema Area and Severity Index (EASI) score of 16 or greater; OR
- **c)** Investigator's Global Assessment (IGA) score of 3 or more; OR
- **d)** Scoring Atopic Dermatitis (SCORAD) score of 25 or more; OR
- **e)** Incapacitation due to AD lesion location; AND

iii. The medication is prescribed by or in consultation with an allergist, immunologist, or dermatologist.

iv. Two of the following three (2 of 3) conditions must be met:
1. Patient did not respond adequately (or is not a candidate) to a 3-month minimum trial of topical agents [e.g., corticosteroids, calcineurin inhibitors (e.g., tacrolimus or pimecrolimus), crisaborole, etc.]; OR
2. Patient did not respond adequately (or is not a candidate) to a 3-month minimum trial of at least one (1) systemic agent (e.g., cyclosporine, azathioprine, methotrexate, mycophenolate mofetil, oral corticosteroid, etc.); OR
3. Patient did not respond adequately (or is not a candidate) to a 3-month minimum trial of phototherapy (e.g. Psoralens with UVA light (PUVA), UVB, etc.)

B) Patient is Currently Receiving Adbry. Approve if the patient meets the following (i, ii, and iii):

i. Patient has already received at least 180 days of therapy with Adbry; AND
Note: A patient who has received < 180 days of therapy or who is restarting therapy with Adbry should be considered under Initial Therapy.

ii. Patient experienced a beneficial clinical response, defined as improvement from baseline (prior to initiating Adbry) in at least one of the following: estimated body surface area affected, erythema, induration/papulation/edema, excoriations, lichenification, and/or a decreased requirement for other topical or systemic therapies for atopic dermatitis; AND

iii. Compared with baseline (prior to receiving Adbry), patient experienced an improvement in at least one symptom, such as decreased itching.

Initial Approval/ Extended Approval.
A) *Initial Approval: 6 months*
B) *Extended Approval:1 year*

Dosing in Atopic Dermatitis. *Dosing must meet the following (medical benefit only):*
Administer, subcutaneously, an initial dose of 600 mg (four 150 mg injections or two 300 mg injections), followed by 300 mg (two 150 mg injections or one 300 mg injection) administered every other week. A dosage of 300 mg every 4 weeks may be considered for patients below 100 kg who achieve clear or almost clear skin after 16 weeks of treatment.

The adolescent dose is an initial loading dose of 300 mg (two 150 mg injections), followed by 150 mg (one 150 mg injection) administered every other week.

CONDITIONS NOT RECOMMENDED FOR APPROVAL

Adbry has not been shown to be effective, or there are limited or preliminary data or potential safety concerns that are not supportive of general approval for the following conditions. (Note: This is not an exhaustive list of Conditions Not Recommended for Approval).

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 of Adbry with another Anti-Interleukin Monoclonal Antibody.** The efficacy and safety of Adbry in combination with other anti-interleukin monoclonal antibodies (e.g., Dupixent® [dupilumab subcutaneous injection]) 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.

Documentation Requirements:

The Company reserves the right to request additional documentation as part of its coverage determination process. The Company may deny reimbursement when it has determined that the drug provided or services performed were not medically necessary, investigational, or experimental, not within the scope of benefits afforded to the member and/or a pattern of billing or other practice has been found to be either inappropriate or excessive. Additional documentation supporting medical necessity for the services provided must be made available upon request to the Company. Documentation requested may include patient records, test results and/or credentials of the provider ordering or performing a service. The Company also reserves the right to modify, revise, change, apply and interpret this policy at its sole discretion, and the exercise of this discretion shall be final and binding.

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Drug Policy

REFERENCES

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6. Sidbury R, et al. Guidelines of care for the management of atopic dermatitis Section 3. Management and treatment with phototherapy and systemic agents. *J Am Acad Dermatol*. 2014;71(2): 327-349.
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14. 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.

Prior approval is required for HCPCS Codes J3590 or C9399

†When *unclassified biologics* (J3590) or *unclassified drugs or biologicals [Hospital Outpatient Use ONLY]* (C9399) is determined to be Adbry

Edits and Denials:

Prior approval: Prior approval is required for Adbry **(HCPCS Codes J3590, C9399)**. Requests for prior approval will be authorized by a nurse reviewer if submitted documentation meets criteria outlined within the Corporate Medical Policy.

Requests for prior approval will be forwarded to a qualified physician reviewer if submitted documentation does not meet criteria outlined within Corporate Medical Policy.

TOPPS: Claims received with **HCPCS Codes J3590, C9399** will pend with **Remark Code M3M or M4M** and will be adjudicated in accordance with the Corporate Medical Policy.

Liability: A participating provider will be required to write off charges denied as not medically necessary.

HCPCS Code(s):	
J3590	Unclassified biologics
C9399	Unclassified drugs or biologicals (Hospital Outpatient Use ONLY)