Cigna National Formulary Coverage Policy

Effective Date **2/1/2023**
Next Review Date **2/1/2024**

Drug Quantity Management – Per Days
Immunologicals – Adbry™ (tralokinumab-ldrm subcutaneous injection)

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Product Identifier(s)

101657

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. 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.

National Formulary Medical Necessity

This Drug Quantity Management program has been developed to manage potential dose escalation of Adbry. If the Drug Quantity Management rule is not met for the requested medication at the point of service, coverage will be determined by the Criteria below. All approvals are provided for the duration noted below.

Drug Quantity Limits

Product	Strength and Form	Retail Maximum Quantity per 28 Days	Home Delivery Maximum Quantity per 84 Days
Adbry™ (tralokinumab-ldrm SC injection)	150 mg/mL prefilled syringes	4 prefilled syringes†	12 prefilled syringes†

SC – Subcutaneous; † This provides a quantity sufficient for dosing at 300 mg given once every 2 weeks.

Cigna covers quantities as medically necessary when the following criteria are met:

1. If the individual is initiating therapy, as verified by the absence of claims for Adbry in the past 130 days, approve a one-time override for up to 6 prefilled syringes for 28-day supply at retail or 14 prefilled syringes for an 84-day supply at home delivery.

Note: The retail quantity of 6 prefilled pens or prefilled syringes provides a quantity sufficient for the initial loading dose of 600 mg (four 150 mg injections) followed by 300 mg (two 150 mg injections) once every 2 weeks thereafter for 28 days. The home delivery quantity of 14 prefilled pens or prefilled syringes provides for the initial loading dose of 600 mg (four 150 mg injections) followed by 300 mg (two 150 mg injections) once every 2 weeks thereafter for a total of 84 days.

Conditions Not Covered

Any other exception is considered not medically necessary.

Background

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.

Dosing
The recommended initial dose of Adbry is 600 mg by subcutaneous (SC) injection (four 150 mg injections) once, followed by 300 mg SC (two 150 mg injections) once every 2 weeks.[1] Following 16 weeks of treatment, a dose of 300 mg SC once every 4 weeks may be considered in patients weighing < 100 kg who achieve clear or almost clear skin. Adbry should be used under the guidance of a healthcare provider; however, it may be self-administered following SC injection training.

Availability
Adbry is available as 150 mg/mL prefilled syringes supplied in packs of two or four syringes.[1]

References

1. Adbry® subcutaneous injection [prescribing information]. Madison, NJ: Leo; December 2021.

Revision History

Type of Revision	Summary of Changes	Approval Date
Annual Revision	No change to criteria. Policy was updated to include the existing quantity limits when the product is obtained via home delivery.	12/01/2022

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