DRUG QUANTITY MANAGEMENT POLICY – PER DAYS

POLICY: Immunologicals – Adbry Drug Quantity Management Policy – Per Days
- Adbry® (tralokinumab-ldrm subcutaneous injection – Leo)

REVIEW DATE: 06/25/2025

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.

Dosing

Adbry should be used under the guidance of a healthcare provider; however, it may be self-administered following SC injection training.[1]

In adults, the recommended initial dose of Adbry is 600 mg by subcutaneous (SC) injection once, followed by 300 mg SC 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.

In 12 to 17 years of age, the recommended initial dose of Adbry is 300 mg SC injection once, followed by 150 mg once every 2 weeks.[1]

Availability

Adbry is available as 150 mg/mL prefilled syringes supplied in packs of two or four syringes and 300 mg/mL auto-injectors supplied in packs of one or two auto-injectors.[1]

POLICY STATEMENT

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. "One-time" approvals are provided for 30 days in duration.

Drug Quantity Limits

Product	Strength and Form	Retail Maximum Quantity per 28 Days	Home Delivery Maximum Quantity per 84 Days
Adbry® (tralokinumab-ldrm subcutaneous injection)	150 mg/mL prefilled syringes	4 syringes	12 syringes
	300 mg/2 mL auto-injectors	2 auto-injectors	6 auto-injectors

EXCEPTIONS TO THE QUANTITY LIMITS LISTED ABOVE ARE COVERED AS MEDICALLY NECESSARY WHEN THE FOLLOWING CRITERIA ARE MET. ANY OTHER EXCEPTION IS CONSIDERED NOT MEDICALLY NECESSARY.

CRITERIA

Adbry 150 mg/mL prefilled syringes

1. If the patient is initiating therapy, as verified by the absence of claims for Adbry in the past 130 days, approve a one-time override for 6 syringes at retail or 14 syringes at home delivery.
Note: The retail quantity of 6 syringes provides a quantity sufficient for an initial loading dose of up to 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 syringes provides for an initial loading dose of up to 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.

Adbry 300 mg/2 mL auto-injectors

1. If the patient is initiating therapy, as verified by the absence of claims for Adbry in the past 130 days, approve a one-time override for 3 auto-injectors at retail or 7 auto-injectors at home delivery.
Note: The retail quantity of 3 auto-injectors provides a quantity sufficient for an initial loading dose of 600 mg (two 300 mg injections) followed by 300 mg (one 300 mg injection) once every 2 weeks thereafter for 28 days. The home delivery quantity of 7 auto-injectors provides for an initial loading dose of 600 mg (two 300 mg injections) followed by 300 mg (one 300 mg injection) once every 2 weeks thereafter for a total of 84 days.

REFERENCES

1. Adbry® subcutaneous injection [prescribing information]. Madison, NJ: Leo; June 2024.

HISTORY

Type of Revision	Summary of Changes	Review Date
Annual Revision	"Days supply" information was removed from override criteria as this is a one-time override.	12/05/2023
Early Annual Revision	**Adbry 300 mg/2 mL auto-injectors:** New quantity limits of 2 auto-injectors per 28 days at retail and 6 auto-injectors per 84 days at home delivery were added to the policy. Clinical override criteria apply. **Adbry 150 mg/mL prefilled syringes:** Quantity limits were changed from 4 syringes per 28 days at retail and 12 syringes per 84 days at home delivery to 2 syringes per 28 days at retail and 6 syringes per 84 days at home delivery. Override criteria were updated to approve a one-time override for 3 syringes at retail or 7 syringes at home delivery if the patient is initiating therapy. Previously, these criteria approved 6 syringes at retail or 14 syringes at home delivery.	07/17/2024
Selected Revision	**Adbry 150 mg/mL prefilled syringes:** A new note was added to clarify that for 600 mg initial doses and 300 mg maintenance doses, 300 mg auto-injectors are available.	11/22/2024
Annual Revision	Policy Statement was updated to clarify that "one-time" overrides are provided for 30 days in duration. **Adbry 150 mg/mL prefilled syringes:** Quantity limits were changed from 2 syringes per 28 days at retail and 6 syringes per 84 days at home delivery to 4 syringes per 28 days at retail and 12 syringes per 84 days at home delivery. Override criteria were updated to approve a one-time override for 6 syringes at retail or 14 syringes at home delivery if the patient is initiating therapy. Previously, these criteria approved up to 3 syringes at retail or 7 syringes at home delivery. **Adbry 300 mg/2 mL auto-injectors:** Override criteria were updated to approve a one-time override for 3 auto-injectors at retail or 7 auto-injectors at home delivery. Previously, these criteria approved a one-time override for "up to" 3 auto-injectors at retail or 7 auto-injectors at home delivery.	06/25/2025