

DRUG QUANTITY MANAGEMENT POLICY – PER DAYS

POLICY: Migraine – Non-Steroidal Anti-Inflammatory Drugs Drug Quantity Management Policy – Per Days

- Cambia® (diclofenac potassium powder for oral solution – Assertio)
- Elyxyb® (celecoxib oral solution – Dr. Reddy's)

REVIEW DATE: 10/26/2022

OVERVIEW

Cambia and Elyxyb are indicated for the **acute treatment of migraine with or without aura** in adults.^{1,2} Cambia is labeled to be used at the lowest effective dose for the shortest duration that is consistent with the patient's treatment goals, while Elyxyb should be used for the fewest number of days per months as possible.

Use of acute treatments for migraine headache can potentially lead to medication-overuse headache (generally defined as use for 10 or more days per month for 3 months or more), therefore, they are not intended for regular use.³ Guidelines for the management of migraine headache recommend limiting acute (abortive) therapy to less than 2 days per week on a regular basis or 8 treatment days per month. If patients require abortive therapies more frequently, then re-evaluation of the diagnosis and assessment for the use of preventive therapy may be needed.

In general, the quantity limits provided are adequate for two headaches per week at the maximum FDA-approved dose for 4 weeks at retail and 12 weeks at home delivery. Quantities are rounded up to the nearest whole package if needed. The quantity limit is specific to a chemical entity within the same dosage form. Of note, conventional tablets and orally-disintegrating tablets are considered the same dosage form for these purposes.

Dosing and Availability

Refer to the Drug Quantity Limits table below for dosing and availability information.

POLICY STATEMENT

This Drug Quantity Management program has been developed to prevent the stockpiling misuse and/or overuse of the non-steroidal anti-inflammatory migraine medications. 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. Approvals are provided for the duration noted below.

Automation: None.

Drug Quantity Limits

Drug Name	Maximum Dose per 24 Hours	Availability	Retail Maximum Quantity per 28 Days	Home Delivery Maximum Quantity per 84 days
Cambia® (diclofenac potassium powder for oral solution)	Single 50 mg (one packet) dose. Safety and effectiveness of a second dose have not been established.	Single-dose packets: 50 mg Each box contains 9 packets.	9 packets (1 box)	27 packets (3 boxes)
Elyxyb® (celecoxib oral solution)	Single 120 mg dose. Safety and effectiveness of a second dose in a 24-hour period have not been established.	Glass bottles: 120 mg/4.8 mL Each carton contains 6 glass bottles.	12 bottles (2 cartons)	36 bottles (6 cartons)

CRITERIA**Cambia 50 mg powder packets**

1. If the patient is using the medication to treat intermittent acute migraine headaches (i.e., the request is NOT for continuous/daily use for prevention or prophylaxis), approve a one-time override for 9 packets (1 box) at retail or home delivery.

Note: This provides an extra 9 packets (1 box) for a total of 18 packets (2 boxes) at retail or a total of 36 packets (4 boxes) at home delivery. The override quantity corresponds with the number of units required to treat four additional headaches at the maximum FDA-approved dose, rounded to the nearest whole package size.

Elyxyb 120 mg/4.8 mL bottles

1. If the patient is using the medication to treat intermittent acute migraine headaches (i.e., the request is NOT for continuous/daily use for prevention or prophylaxis), approve a one-time override for 6 bottles (1 carton) at retail or home delivery.

Note: This provides an extra 6 bottles (1 carton) for a total of 18 bottles (3 cartons) at retail or a total of 42 (7 cartons) at home delivery. The override quantity corresponds with the number of units required to treat four additional headaches at the maximum FDA-approved dose, rounded to the nearest whole package size.

REFERENCES

1. Cambia® for oral solution [prescribing information]. Lake Forest, IL: Assertio; April 2021.
2. Elyxyb® oral solution [prescribing information]. Hyderabad, India: Dr. Reddy's; April 2021.
3. American Headache Society. The American Headache Society position statement on integrating new migraine treatments into clinical practice. *Headache*. 2019;59:1-18.

