DRUG QUANTITY MANAGEMENT POLICY - PER RX

POLICY: Alpha-Adrenergic Blockers – Doxazosin Drug Quantity Management Policy – Per Rx

- Cardura® (doxazosin tablets Pfizer, generic)
- Cardura® XL (doxazosin extended-release tablets Pfizer)

REVIEW DATE: 07/13/2022

OVERVIEW

Doxazosin (Cardura, generic) and Cardura XL are alpha₁ adrenergic antagonists. ^{1,2}

Doxazosin is indicated for:1

- Benign prostatic hyperplasia (BPH) signs and symptoms.
- **Hypertension** treatment.

Cardura XL is indicated for:²

• **BPH** signs and symptoms.

Dosing

Doxazosin (Cardura, generic)

For the management of signs and symptoms of BPH, the recommended initial dose of doxazosin is 1 mg once daily (QD).¹ Depending on the individual patient, the dose may be titrated at 1 to 2 week intervals to 2 mg QD, and thereafter to 4 mg and 8 mg QD. The maximum recommended for BPH is 8 mg QD.

For the treatment of hypertension, the recommended initial dose of doxazosin is 1 mg QD. The dose may be doubled up to 16 mg QD, as needed, to achieve the desired reduction in blood pressure.

Cardura XL

The recommended initial dose of Cardura XL is 4 mg QD. Based on the patient's response and tolerability, the dose may be titrated at an interval of 3 to 4 weeks to 8 mg QD, which is the maximum recommended dose. Cardura XL is not approved for hypertension. Cardura XL tablets must be swallowed whole and must not be chewed, divided, cut, or crushed.

Availability

Doxazosin (Cardura, generic) is available as 1 mg, 2 mg, 4 mg, 8 mg tablets.¹ Doxazosin tablets are scored. According to the dosing above, 30 of the 1 mg, 2 mg, or 4 mg tablets would supply enough drug for a 30-day supply of initial or maintenance therapy for patients taking 1 mg, 2 mg or 4 mg QD. If higher once daily doses are needed, the patient should be referred to the next higher tablet strength. Overrides to the quantity limit are provided below. Additionally, 60 of the 8 mg tablets is a quantity sufficient for a 30-day supply at the maximum dose for hypertension, 16 mg QD.

Cardura XL is available as 4 mg and 8 mg extended-release tablets.² According to the dosing above, 30 of the 4 mg or 8 mg tablets would supply enough drug for a 30-day supply of initial or maintenance therapy for patients taking 4 mg or 8 mg QD.

POLICY STATEMENT

This Drug Quantity Management program has been developed to promote the safe, effective, and economic use of doxazosin. 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 1 year in duration.

<u>Automation</u>: None.

Drug Quantity Limits

Product	Strength and Form	Maximum Quantity per Rx
Cardura [®]	1 mg tablets	30 tablets
(doxazosin tablets, generic)	2 mg tablets	30 tablets
	4 mg tablets	30 tablets
	8 mg tablets	60 tablets
Cardura® XL	4 mg tablets	30 tablets
(doxazosin extended-release tablets)	8 mg tablets	30 tablets

CRITERIA

Doxazosin 1 mg tablets (Cardura, generic)

- 1. If the patient is taking doxazosin (Cardura, generic) twice daily, approve 60 tablets per dispensing.
- 2. If the patient is taking a dose that does not correspond to a commercially-available dosage form (that is, the dose requires multiple same strength tablets be used AND would otherwise require two or more strengths to be used), approve the requested quantity, not to exceed 450 tablets per dispensing.
 Note: Doxazosin (Cardura, generic) is available as 1 mg, 2 mg, 4 mg, and 8 mg tablets. This override provides a quantity sufficient for a dose of up to 15 mg per day. The maximum recommended dose of doxazosin is 8 mg per day for BPH and 16 mg per day for hypertension. A patient who requires a dose of 16 mg per day should use the 8 mg tablets.

Doxazosin 2 mg tablets (Cardura, generic)

- 1. If the patient is taking doxazosin (Cardura, generic) twice daily, approve 60 tablets per dispensing.
- 2. If the patient is taking a dose that does not correspond to a commercially-available dosage form (that is, the dose requires multiple same strength tablets be used AND would otherwise require two or more strengths to be used), approve the requested quantity, not to exceed 210 tablets per dispensing.
 Note: Doxazosin (Cardura, generic) is available as 1 mg, 2 mg, 4 mg, and 8 mg tablets. This override provides a quantity sufficient for a dose of up to 14 mg per day. The maximum recommended dose of doxazosin is 8 mg per day for BPH and 16 mg per day for hypertension. A patient who requires a dose of 16 mg per day should be referred to the 8 mg tablets.

Doxazosin 4 mg tablets (Cardura, generic)

- 1. If the patient is taking doxazosin (Cardura, generic) twice daily, approve 60 tablets per dispensing.
- 2. If the patient is taking a dose that does not correspond to a commercially-available dosage form (that is, the dose requires multiple same strength tablets be used AND would otherwise require two or more strengths to be used), approve the requested quantity, not to exceed 90 tablets per dispensing.

 Note: Doxazosin (Cardura, generic) is available as 1 mg, 2 mg, 4 mg, and 8 mg tablets. This override provides a quantity sufficient for a dose of up to 12 mg per day. The maximum recommended dose of doxazosin is 8 mg per day for BPH and 16 mg per day for hypertension. A patient who requires a dose of 16 mg per day should be referred to the 8 mg tablets.

Alpha-Adrenergic Blockers – Doxazosin DQM Policy – Per Rx Page 3

Doxazosin 8 mg tablets (Cardura, generic)

No overrides recommended.

Cardura XL 4 mg tablets

No overrides recommended.

Cardura XL 8 mg tablets

No overrides recommended.

REFERENCES

- 1. Cardura® tablets [prescribing information]. New York, NY: Pfizer; June 2021.
- 2. Cardura® XL extended-release tablets [prescribing information]. New York, NY: Pfizer; June 2021.