



## Drug Quantity Management – Per Rx Alpha-Adrenergic Blockers – Doxazosin

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### Product Identifier(s)

**Effective 1/1/23 to 2/6/23:** 108180

**Effective 2/7/23:** 34632

#### 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

#### Drugs Affected

- Cardura® (doxazosin tablets – generic)
- Cardura® XL (doxazosin extended-release tablets)

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.

#### Drug Quantity Limits

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

## Criteria

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

### Doxazosin 1 mg tablets (Cardura, generic)

1. If the individual is taking doxazosin (Cardura, generic) twice daily, approve 60 tablets per dispensing.
2. If the individual 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. An individual who requires a dose of 16 mg per day should use the 8 mg tablets.

### Doxazosin 2 mg tablets (Cardura, generic)

1. If the individual is taking doxazosin (Cardura, generic) twice daily, approve 60 tablets per dispensing.
2. If the individual 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. An individual 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 individual is taking doxazosin (Cardura, generic) twice daily, approve 60 tablets per dispensing.
2. If the individual 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. An individual who requires a dose of 16 mg per day should be referred to the 8 mg tablets.

### 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.

## Conditions Not Covered

Any other exception is considered not medically necessary.

## Background

### **Overview**

Doxazosin (Cardura, generic) and Cardura XL are alpha<sub>1</sub> adrenergic antagonists.<sup>1,2</sup>

Doxazosin is indicated for:<sup>1</sup>

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

Cardura XL is indicated for:<sup>2</sup>

- **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).<sup>1</sup> 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.<sup>1</sup> 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.<sup>1</sup> 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.<sup>2</sup> 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.

## References

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

## Revision History

Type of Revision	Summary of Changes	Approval Date
Annual Revision	<p>Approval duration was changed from 3 years to 1 year.</p> <p><b>Doxazosin 1 mg tablets (Cardura, generic):</b> Language was updated to clarify override criteria to approve 60 tablets per dispensing if the patient is taking doxazosin (Cardura, generic) twice daily. Previously, this criteria approved a quantity sufficient to allow for 2 tablets per day for a 30-day supply. The override criteria for patients who are taking a dose that does not correspond to a commercially-available dosage form was updated to approve the requested quantity not to exceed 450 tablets per dispensing. Previously, there was not a maximum limit. The override criteria for patients taking doxazosin 6 mg daily was removed as this is not a commercially-available dose and those patients would be granted a sufficient override quantity in criterion #2.</p> <p><b>Doxazosin 2 mg tablets (Cardura, generic):</b> Language was updated to clarify override criteria to approve 60 tablets per dispensing if the patient is taking doxazosin (Cardura, generic) twice daily. Previously, this criteria approved a quantity sufficient to allow for 2 tablets per day for a 30-day supply. The override</p>	07/13/2022

	<p>criteria for patients who are taking a dose that does not correspond to a commercially-available dosage form was updated to approve the requested quantity not to exceed 210 tablets per dispensing. Previously, there was not a maximum limit. The override criteria for patients taking doxazosin 6 mg daily was removed as this is not a commercially-available dose and those patients would be granted a sufficient override quantity in criterion #2.</p> <p><b>Doxazosin 4 mg tablets (Cardura, generic):</b> Language was updated to clarify override criteria to approve 60 tablets per dispensing if the patient is taking doxazosin (Cardura, generic) twice daily. Previously, this criteria approved a quantity sufficient to allow for 2 tablets per day for a 30-day supply. The override criteria for patients who are taking a dose that does not correspond to a commercially-available dosage form was updated to approve the requested quantity not to exceed 90 tablets per dispensing. Previously, there was not a maximum limit. The override criteria for patients taking doxazosin 6 mg daily was removed as this is not a commercially-available dose and those patients would be granted a sufficient override quantity in criterion #2.</p>	
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