

STEP THERAPY POLICY

- POLICY:** Benign Prostatic Hyperplasia – Alpha Blockers Step Therapy Policy
- Cardura® (doxazosin mesylate tablets – Pfizer, generic)
 - Cardura® XL (doxazosin mesylate extended-release tablets – Pfizer)
 - Flomax® (tamsulosin capsules – Sanofi-Aventis, generic)
 - Terazosin capsules – Avet Pharmaceuticals, generic
 - Rapaflo® (silodosin capsules – Allergan, generic)
 - Uroxatral® (alfuzosin extended-release tablets – Concardia, generic)

REVIEW DATE: 12/11/2024

OVERVIEW

Alpha blockers in the treatment of benign prostatic hyperplasia (BPH) are selective for alpha_{1A} receptors. Alpha_{1A} blocker receptors are more predominant in the prostate and alpha_{1B} receptors are more predominant in the vascular smooth muscle.¹ Doxazosin (immediate-release) and terazosin are indicated for the symptomatic treatment of BPH and for hypertension.^{2,3} Cardura XL is only indicated for the treatment of signs and symptoms of BPH.⁴ Tamsulosin has 10 times greater selectivity for the alpha_{1A} receptor versus the alpha_{1B} receptor¹ and is only indicated for BPH⁵. Silodosin has 162 times greater selectivity for the alpha_{1A} receptor versus the alpha_{1B} receptor¹ and is only indicated for BPH⁶. Alfuzosin is not selective for a specific alpha₁ receptor subtype, but instead exhibits selectivity for alpha₁-adrenergic receptors in the lower urinary tract; it is only indicated for BPH.⁷ Theoretically, agents with high selectivity for the alpha_{1A}-receptor should have less effect on blood pressure compared with other non-selective alpha₁-blockers.

Guidelines

The American Urological Association (AUA) guidelines on the management of lower urinary tract symptoms attributed to benign prostatic hyperplasia (2023) recommends that clinicians should offer one of the following alpha blockers as a treatment for patients with moderate to severe lower urinary tract symptoms/BPH: alfuzosin, doxazosin, silodosin, tamsulosin, or terazosin.⁸ AUA also recommends the choice of alpha blocker should be based on patient age and comorbidities.

POLICY STATEMENT

This program has been developed to encourage use of Step 1 Product prior to the use of a Step 2 Product. If the Step Therapy rule is not met for a Step 2 Product at the point of service, coverage will be determined by the Step Therapy criteria below. All approvals are provided for 1 year in duration.

Automation: A patient with a of one Step 1 Product within the 130-day look-back period is excluded from Step Therapy.

- Step 1:** generic alfuzosin extended-release tablets, generic doxazosin tablets, generic silodosin capsules, generic tamsulosin capsules, generic terazosin capsules
- Step 2:** Cardura tablets, Cardura XL extended-release tablets, Flomax capsules, Rapaflo capsules, Uroxatral extended-release tablets

CRITERIA

1. If the patient has tried one Step 1 Product, approve a Step 2 Product.
2. No other exceptions are recommended.

REFERENCES

1. Alpha Blockers. Clinical Pharmacology [database online]. Philadelphia, PA. Elsevier 2024. Available at: <https://www.clinicalkey.com/pharmacology/>. Accessed on December 5, 2024. Search terms: Alpha Blockers.
2. Cardura® tablets [prescribing information]. New York, NY: Pfizer; January 2022.
3. Terazosin capsules [prescribing information]. Congers, NY: Chartwell RX; February 2023.
4. Cardura® XL extended-release tablets [prescribing information]. New York, NY: Pfizer; May 2023.
5. Flomax® capsules [prescribing information]. Bridgewater, NJ: Sanofi-Aventis; November 2023.
6. Rapaflo® capsules [prescribing information]. Madison, NJ: Allergan; December 2020.
7. Uroxatral® extended-release tablets [prescribing information]. St. Michael, Barbados: Concordia; May 2020.
8. Sandhu JS, Bixler BR, Dahm P, et al. Management of lower urinary tract symptoms attributed to benign prostatic hyperplasia (BPH): AUA Guideline amendment 2023. *J Urol.* 2023;211:1-8.