

STEP THERAPY POLICY

- POLICY:** Alpha Blockers for Benign Prostatic Hyperplasia Step Therapy Policy
- Cardura® (doxazosin mesylate tablets – Pfizer, generics)
 - Cardura® XL (doxazosin mesylate extended-release tablets – Pfizer)
 - Flomax® (tamsulosin capsules – Boehringer Ingelheim, generics)
 - Terazosin capsules – Mylan; generics
 - Rapaflo™ (silodosin capsules – Allergan, Inc., generics)
 - Uroxatral® (alfuzosin extended-release tablets – Concardia, generics)

REVIEW DATE: 09/30/2020

OVERVIEW

Alpha₁-blockers are classified as first-, second-, or third-generation agents based on their specificity for the prostate.¹ The first-generation alpha₁-blockers are not indicated for benign prostatic hyperplasia (BPH). Terazosin, doxazosin, and prazosin are second-generation alpha₁-blockers.¹ They are considered non-uroselective and have affinity for all three alpha₁ receptor subtypes. 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, alfuzosin, and Rapaflo are third-generation alpha₁-blockers because they exhibit selectivity for alpha_{1A}-receptors in the prostate.^{5,6} Alfuzosin is considered functionally and clinically uroselective.¹ Alfuzosin is not selective for a specific alpha₁ receptor subtype, but instead exhibits selectivity for alpha₁-adrenergic receptors in the lower urinary tract.⁷ The clinical significance of selectivity for the alpha_{1A}-receptor continues to be debated. Theoretically, agents with high selectivity for the alpha_{1A}-receptor should have less effect on blood pressure compared to other non-selective alpha₁-blockers.

POLICY STATEMENT

This program has been developed to encourage use of Step 1 drug prior to the use of a Step 2 drug. If the Step Therapy rule is not met for a Step 2 drug 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 history of one Step 1 drug within the 130-day look-back period is excluded from Step Therapy.

Step 1: alfuzosin extended-release tablets, doxazosin tablets, silodosin capsules, tamsulosin capsules, 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 drug, authorization for a Step 2 drug may be given.
2. No other exceptions are recommended.

REFERENCES

1. Lepor H, Lowe FC. Evaluation and nonsurgical management of benign prostatic hyperplasia. In: Campbell's Urology. 8th Ed. WB Saunders Company. Philadelphia, PA. 2002:1337-1378.
2. Cardura[®] tablets [prescribing information]. New York, NY: Pfizer, Inc; March 2019.
3. Terazosin capsules [prescribing information]. Morgantown, WV: Mylan Pharmaceuticals Inc.; July 2017.
4. Cardura[®] XL extended-release tablets [prescribing information]. New York, NY: Pfizer, Inc; February 2017.
5. Flomax[®] capsules [prescribing information]. Ridgefield, CT: Boehringer Ingelheim; March 2017.
6. Rapaflo[™] capsules [prescribing information]. Irvine, CA: Allergan USA, Inc; June 2017.
7. UroXatral[®] extended-release tablets [prescribing information]. St. Michael, Barbados: Concordia Pharmaceuticals Inc.; May 2020.