



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: 11/29/2023

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.

CIGNA NATIONAL FORMULARY COVERAGE:

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.

Benign Prostatic Hyperplasia – Alpha Blockers product(s) is(are) covered as medically necessary when the following step therapy criteria is(are) met. Any other exception is considered not medically necessary.

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.

REFERENCES

1. Alpha Blockers. Clinical Pharmacology [database online]. Philadelphia, PA: Elsevier 2023. Available at: <https://www.clinicalkey.com/pharmacology/resources/overviews?id=1216665>. Accessed on November 21, 2023. 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; April 2022.
5. Flomax® capsules [prescribing information]. Bridgewater, NJ: Sanofi-Aventis; January 2019.
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.

HISTORY

Type of Revision	Summary of Changes	Review Date
Annual Revision	No criteria changes.	11/16/2022
Annual Revision	No criteria changes.	11/29/2023

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