

Clinical Policy: Benign Prostatic Hyperplasia Agents

Reference Number: OH.PHAR.PPA.61

Effective Date: 01.01.21

Last Review Date: 11.20

Line of Business: Medicaid

See [Important Reminder](#) at the end of this policy for important regulatory and legal information.

Description

BENIGN PROSTATIC HYPERPLASIA AGENTS – ALPHA-1 ADRENERGIC BLOCKERS

NO PA REQUIRED "PREFERRED"	PA REQUIRED "NON-PREFERRED"
ALFUZOSIN (GENERIC OF UROXATRAL®) DOXAZOSIN (generic of Cardura®) PRAZOSIN (generic of Minipress®) TAMSULOSIN (generic of Flomax®) TERAZOSIN (generic of Hytrin®)	CARDURA® XL (doxazosin) SILODOSIN (generic of Rapaflo®)

BENIGN PROSTATIC HYPERPLASIA AGENTS – 5-ALPHA REDUCTASE INHIBITORS

NO PA REQUIRED "PREFERRED"	PA REQUIRED "NON-PREFERRED"
DUTASTERIDE (generic of Avodart®) FINASTERIDE (generic of Proscar®)	

BENIGN PROSTATIC HYPERPLASIA AGENTS – COMBINATION 5-ALPHA REDUCTASE INHIBITOR/ALPHA-1 ADRENERGIC BLOCKER

NO PA REQUIRED "PREFERRED"	PA REQUIRED "NON-PREFERRED"
	DUTASTERIDE/TAMSULOSIN (generic of Jalyn®)

BENIGN PROSTATIC HYPERPLASIA AGENTS – PHOSPHODIESTERASE TYPE 5 INHIBITORS

NO PA REQUIRED "PREFERRED"	PA REQUIRED "NON-PREFERRED"
TADALAFIL (generic for Cialis®) 2.5mg, 5mg only *	

* Note: Clinical PA required for tadalafil. Patient must have diagnosis of benign prostatic hyperplasia and demonstrate trials of preferred products.

FDA Approved Indication(s)

- Refer to Clinical Pharmacology or other appropriate clinical resource for FDA approved indications

Policy/Criteria

Provider must submit documentation (such as office chart notes, lab results or other clinical information) supporting that member has met all approval criteria.

It is the policy of health plans affiliated with Centene Corporation[®] that the medications listed in the above tables are **medically necessary** when the following criteria are met:

I. Initial Approval Criteria

A. Benign Prostatic Hyperplasia (must meet all):

1. Diagnosis of BPH;
2. Age \geq 18 years;
3. Member has had therapeutic failure to no less than a 30 day trial on at least two medications that are preferred unless one of the following:
 - a. Allergy to medications not requiring prior approval
 - b. Contraindications to or drug interaction with medications not requiring prior approval
 - c. History of unacceptable/toxic side effects to medications not requiring prior approval
4. If the requested medication is Cialis (2.5mg, 5mg only):
 - a. Member has had therapeutic failure to no less than a 30 day trial on at least one alpha-1 adrenergic blocker and a 90 day trial of finasteride.

Approval duration: 12 months

II. Diagnoses/Indications for which coverage is NOT authorized:

- A.** Non-FDA approved indications, which are not addressed in this policy, unless there is sufficient documentation of efficacy and safety according to the off label use policies –CP.CPA.09 for commercial and CP.PMN.53 for Medicaid or evidence of coverage documents.

III. Appendices/General Information

Appendix A: Abbreviation/Acronym Key

BPH: benign prostatic hyperplasia

FDA: Food and Drug Administration

Appendix B: Therapeutic Alternatives

This table provides a listing of preferred alternative therapy recommended in the approval criteria. The drugs listed here may not be a formulary agent for all relevant lines of business and may require prior authorization.

Drug Name	Dosing Regimen	Dose Limit/ Maximum Dose
doxazosin (Cardura [®])	1 mg PO once daily	8 mg/day

Drug Name	Dosing Regimen	Dose Limit/ Maximum Dose
prazosin (Minipress [®])	2 mg PO twice daily	9 mg/day
tamsulosin (Flomax [®])	0.4 mg PO once daily	0.8 mg/day
terazosin (Hytrin [®])	5 – 10 mg PO once daily	20 mg/day
finasteride (Proscar [®])	5 mg PO once daily	5 mg/day

Therapeutic alternatives are listed as Brand name[®] (generic) when the drug is available by brand name only and generic (Brand name[®]) when the drug is available by both brand and generic

Appendix C: Contraindications/Boxed Warnings

- Refer to Clinical Pharmacology or other appropriate clinical resource for contraindications or black box warnings

IV. Dosage and Administration

- A. Varies by drug product. See FDA approved dosing and administration.

V. Product Availability

- A. Varies by drug product. Refer to Clinical Pharmacology or other appropriate clinical resource for product availability

VI. References

Refer to package insert

Reviews, Revisions, and Approvals	Date	P&T Approval Date
Policy created	11.19	
Policy updated. Added patient must have a therapeutic failure to no less than a 30-day trial on at least two medications that are preferred.	11.20	

Important Reminder

This clinical policy has been developed by appropriately experienced and licensed health care professionals based on a review and consideration of currently available generally accepted standards of medical practice; peer-reviewed medical literature; government agency/program approval status; evidence-based guidelines and positions of leading national health professional organizations; views of physicians practicing in relevant clinical areas affected by this clinical policy; and other available clinical information. The Health Plan makes no representations and

accepts no liability with respect to the content of any external information used or relied upon in developing this clinical policy. This clinical policy is consistent with standards of medical practice current at the time that this clinical policy was approved. “Health Plan” means a health plan that has adopted this clinical policy and that is operated or administered, in whole or in part, by Centene Management Company, LLC, or any of such health plan’s affiliates, as applicable.

The purpose of this clinical policy is to provide a guide to medical necessity, which is a component of the guidelines used to assist in making coverage decisions and administering benefits. It does not constitute a contract or guarantee regarding payment or results. Coverage decisions and the administration of benefits are subject to all terms, conditions, exclusions and limitations of the coverage documents (e.g., evidence of coverage, certificate of coverage, policy, contract of insurance, etc.), as well as to state and federal requirements and applicable Health Plan-level administrative policies and procedures.

This clinical policy is effective as of the date determined by the Health Plan. The date of posting may not be the effective date of this clinical policy. This clinical policy may be subject to applicable legal and regulatory requirements relating to provider notification. If there is a discrepancy between the effective date of this clinical policy and any applicable legal or regulatory requirement, the requirements of law and regulation shall govern. The Health Plan retains the right to change, amend or withdraw this clinical policy, and additional clinical policies may be developed and adopted as needed, at any time.

This clinical policy does not constitute medical advice, medical treatment or medical care. It is not intended to dictate to providers how to practice medicine. Providers are expected to exercise professional medical judgment in providing the most appropriate care, and are solely responsible for the medical advice and treatment of members. This clinical policy is not intended to recommend treatment for members. Members should consult with their treating physician in connection with diagnosis and treatment decisions.

Providers referred to in this clinical policy are independent contractors who exercise independent judgment and over whom the Health Plan has no control or right of control. Providers are not agents or employees of the Health Plan.

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Note:

For Medicaid members, when state Medicaid coverage provisions conflict with the coverage provisions in this clinical policy, state Medicaid coverage provisions take precedence. Please refer to the state Medicaid manual for any coverage provisions pertaining to this clinical policy.

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