BOSTON MEDICAL CENTER HEALTHNet PLAN

bmchp.org | 888-566-0008

Pharmacy Policy

Benign Prostatic Hyperplasia (BPH) Medications

Policy Number: 9.805
Version Number: 2
Version Effective Date: 3/1/2022

Product Applicability	☐ **All Plan+ Products**
Well Sense Health Plan ☐ New Hampshire Medicaid	**Boston Medical Center HealthNet Plan** ☒ MassHealth - MCO ☒ MassHealth - ACO ☐ Qualified Health Plans/ConnectorCare/Employer Choice Direct ☐ Senior Care Options

Note: Disclaimer and audit information is located at the end of this document.

Prior Authorization Policy

Products Affected:

- silodosin
- Cardura XL (doxazosin)
- dutasteride
- dutasteride/tamsulosin
- tadalafil

The Plan may authorize coverage of the above products for members meeting the following criteria:

Covered Use	All FDA approved indications not otherwise excluded
Exclusion Criteria	None

+ *Plan* refers to Boston Medical Center Health Plan, Inc. and its affiliates and subsidiaries offering health coverage plans to enrolled members. The Plan operates in Massachusetts under the trade name Boston Medical Center HealthNet Plan and in other states under the trade name Well Sense Health Plan.

Required Medical Information	***Cardura XL®*** 1. A diagnosis of benign prostatic hyperplasia; AND **2.** An inadequate response, intolerance, or contraindication to a trial of immediate-release doxazosin and one other generic alpha-adrenergic antagonist **silodosin** 1. A diagnosis of benign prostatic hyperplasia; AND 2. An inadequate response, intolerance, or contraindication to a trial of two generic alpha-adrenergic antagonists ***dutasteride*** 1. A diagnosis of benign prostatic hyperplasia; AND 2. An inadequate response, intolerance, or contraindication to at least a 6-month trial of generic finasteride ***dutasteride/tamsulosin*** 1. A diagnosis of benign prostatic hyperplasia; AND 2. An inadequate response, intolerance, or contraindication to at least a 6-month trial of generic finasteride; AND 3. Clinical evidence supporting that the patient is unable to take dutasteride and tamsulosin separately ***tadalafil 5mg*** 1. A diagnosis of benign prostatic hyperplasia; AND 2. An inadequate response to at least a 6-month trial of two regimens each consisting of a 5-alpha reductase inhibitor in combination with an alpha-adrenergic antagonist; OR 3. A contraindication or an intolerance to 5-alpha reductase inhibitors and an inadequate response, intolerance or contraindication to three generic alpha-adrenergic antagonists *#The Plan will not approve coverage of Cialis® (tadalafil) for the indication of erectile dysfunction*
Age Restriction	18 years of age or older
Prescriber Restriction	None
Coverage Duration	12 months
Other criteria	Reauthorization: 1. A decrease in symptom severity and frequency associated with benign prostatic hyperplasia; OR 2. A decrease in prostate-specific antigen levels; OR 3. A decrease in prostate volume from baseline (if requesting a 5-alpha reductase inhibitor)

Clinical Background Information and References

1. American Society of Clinical Oncology. Use of 5-α-Reductase Inhibitors for Prostate Cancer Chemoprevention: American Society of Clinical Oncology/American Urological Association 2008 Clinical Practice Guideline. J Clin Oncol.27(9):1502-1516. Available at: http://jco.ascopubs.org/content/27/9/1502.full.pdf Accessed Dec 9, 2015
2. Auffenberg GB, Helfand BT, McVary KT. Established Medical Therapy for Benign Prostatic Hyperplasia. Urol Clin N Am 36.2009.443-459.
3. Cialis® (tadalafil) [prescribing information]. Indianapolis (IN): Eli Lilly and Co.; 2017 May.
4. Sartor A. Chemoprevention Strategies in Prostate Cancer. UptoDate® Last updated Jan 12, 2021.
5. McVery K. Clinical Manifestations and Diagnosis of Benign Prostatic Hyperplasia. UptoDate®. Last updated October 20, 2021.
6. McVery K. Medical Treatment of Benign Prostatic Hyperplasia. UptoDate®. Last updated Oct 4, 2021
7. Djavan B, Eckersberger E, Finkelstein J, et al. Benign Prostatic Hyperplasia: Current Clinical Practice. Prim Care Clin Office Pract.37.2010. 583-597.
8. Stephenson AJ, Abouassaly R, Klein EA. Chemoprevention of Prostate Cancer. Urol Clin N Am.37.2010.11-21.
9. Lerner LB, McVary, KT, Barry MJ et al: Management of lower urinary tract symptoms attributed to benign prostatic hyperplasia: AUA Guideline part I, initial work-up and medical management. J Urol 2021; 206: 806. Lerner LB, McVary, KT, Barry MJ et al: Management of lower urinary tract symptoms attributed to benign prostatic hyperplasia: AUA Guideline part II, surgical evaluation and treatment . J Urol 2021; 206: 818.

Original Approval Date	Original Effective Date	Policy Owner	Approved by
12/1/2020	1/1/2021	Pharmacy Services	Pharmacy & Therapeutics (P&T) Committee

Policy Revisions History			
Review Date	**Summary of Revisions**	**Revision Effective Date**	**Approved by**
12/1/2020	9.135 BPH Medications Policy retired, new policy created. Removed Rapaflo and Cialis form coverage, moved them to NP and added sildosin and tadalafil to preferred product requiring PA.	1/1/2021	P&T Committee
11/11/2021	P&T annual review 9.805 Updated language on policy, require clinical reason to take combination dutasteride/finasteride instead of separately.	3/1/2022	P&T Committee

Next Review Date

11/2022

Other Applicable Policies

Reference to Applicable Laws and Regulations, If Any

Disclaimer Information

Medical Policies are the Plan's guidelines for determining the medical necessity of certain services or supplies for purposes of determining coverage. These Policies may also describe when a service or supply is considered experimental or investigational, or cosmetic. In making coverage decisions, the Plan uses these guidelines and other Plan Policies, as well as the Member's benefit document, and when appropriate, coordinates with the Member's health care Providers to consider the individual Member's health care needs.

Plan Policies are developed in accordance with applicable state and federal laws and regulations, and accrediting organization standards (including NCQA). Medical Policies are also developed, as appropriate, with consideration of the medical necessity definitions in various Plan products, review of current literature, consultation with practicing Providers in the Plan's service area who are medical experts in the particular field, and adherence to FDA and other government agency policies. Applicable state or federal mandates, as well as the Member's benefit document, take precedence over these guidelines. Policies are reviewed and updated on an annual basis, or more frequently as needed. Treating providers are solely responsible for the medical advice and treatment of Members.

The use of this Policy is neither a guarantee of payment nor a final prediction of how a specific claim(s) will be adjudicated. Reimbursement is based on many factors, including member eligibility and benefits on the date of service; medical necessity; utilization management guidelines (when applicable); coordination of benefits; adherence with applicable Plan policies and procedures; clinical coding criteria; claim editing logic; and the applicable Plan – Provider agreement.