

**Pharmacy Policy**

**Benign Prostatic Hyperplasia (BPH) Medications**

**Policy Number:** 9.805

**Revision Number:** R1

**Version Effective Date:** 1/1/2021

|                                                                                                        |                                                                                                                                                                                                                                                                                                      |
|--------------------------------------------------------------------------------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>Product Applicability</b> <input type="checkbox"/> <b>All Plan+ Products</b>                        |                                                                                                                                                                                                                                                                                                      |
| <p><b>Well Sense Health Plan</b></p> <p><input checked="" type="checkbox"/> New Hampshire Medicaid</p> | <p><b>Boston Medical Center HealthNet Plan</b></p> <p><input type="checkbox"/> MassHealth - MCO</p> <p><input type="checkbox"/> MassHealth - ACO</p> <p><input type="checkbox"/> Qualified Health Plans/ConnectorCare/Employer Choice Direct</p> <p><input type="checkbox"/> Senior Care Options</p> |

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

**Prior Authorization Policy**

**Products Affected:**

- Cardura XL (doxazosin)
- Tadalafil

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

|                                     |                                                                                                                                                                                                                                                                                                                            |
|-------------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>Covered Use</b>                  | All FDA approved indications not otherwise excluded                                                                                                                                                                                                                                                                        |
| <b>Exclusion Criteria</b>           | None                                                                                                                                                                                                                                                                                                                       |
| <b>Required Medical Information</b> | <p><b>Cardura XL<sup>®</sup></b></p> <ol style="list-style-type: none"> <li>1. A diagnosis of benign prostatic hyperplasia; AND</li> <li>2. An inadequate response to a trial of immediate-release doxazosin and one other generic alpha-adrenergic antagonist</li> </ol> <p><b>Cialis<sup>®</sup> 5mg<sup>#</sup></b></p> |

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|                               |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                |
|-------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
|                               | <ol style="list-style-type: none"> <li>1. A diagnosis of benign prostatic hyperplasia; AND</li> <li>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</li> <li>3. A contraindication or an intolerance to 5-alpha reductase inhibitors and an inadequate response, or intolerance to three generic alpha-adrenergic antagonists</li> </ol> <p><i>#The Plan will not approve coverage of Cialis® for the indication of erectile dysfunction</i></p> |
| <b>Age Restriction</b>        | 18 years of age or older                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                       |
| <b>Prescriber Restriction</b> | None                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           |
| <b>Coverage Duration</b>      | 12 months                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                      |
| <b>Other criteria</b>         | Reauthorization: <ol style="list-style-type: none"> <li>1. A decrease in symptom severity and frequency associated with benign prostatic hyperplasia; OR</li> <li>2. A decrease in prostate-specific antigen levels; OR</li> <li>3. A decrease in prostate volume from baseline for chemoprevention of prostate cancer (if requesting a 5-alpha reductase inhibitor)</li> </ol>                                                                                                                                                                                                |

### Clinical Background Information and References

1. American Society of Clinical Oncology. Use of 5- $\alpha$ -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. American Urological Association, Inc. Chapter 1: Guideline on the Management of Benign Prostatic Hyperplasia (BPH). 2010 (Revised). Available at: <https://www.auanet.org/common/pdf/education/clinical-guidance/Benign-Prostatic-Hyperplasia.pdf>. Accessed Dec 9, 2015
3. Auffenberg GB, Helfand BT, McVary KT. Established Medical Therapy for Benign Prostatic Hyperplasia. Urol Clin N Am 36.2009.443-459.
4. Cialis® [prescribing information]. Indianapolis (IN): Eli Lilly and Co.; 2011 Oct.
5. Crawford ED. Chemoprevention Strategies in Prostate Cancer. UptoDate® Last updated Jan15, 2015. Accessed Dec 9, 2015. [www.uptodate.com](http://www.uptodate.com).
6. Cunningham GR., Kadmon D. Clinical Manifestations and Diagnosis of Benign Prostatic Hyperplasia. UptoDate®. Last updated Aug 20, 2015. Accessed Dec 9, 2015. [www.uptodate.com](http://www.uptodate.com).
7. Cunningham GR., Kadmon D. Medical Treatment of Benign Prostatic Hyperplasia. UptoDate®. Last updated Oct 8, 2015. Accessed Dec 1, 2015. [www.uptodate.com](http://www.uptodate.com).
8. Djavan B, Eckersberger E, Finkelstein J, et al. Benign Prostatic Hyperplasia: Current Clinical Practice. Prim Care Clin Office Pract.37.2010. 583-597.
9. Stephenson AJ, Abouassaly R, Klein EA. Chemoprevention of Prostate Cancer. Urol Clin N Am.37.2010.11-21.

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

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## 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. Tadalafil preferred PA product; Cialis NP for indication. Removed Rapaflo from policy as generic is preferred and brand requires same step through per PDL. | 1/1/2021                | P&T Committee, NH DHHS |

### Next Review Date

2021

### 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.

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