

### Clinical Pharmacy Program Guidelines for Cialis for BPH

Program	Prior Authorization
Medication	Cialis (tadalafil) for BPH
Markets in Scope	Arizona, California, Florida-CHIP, Hawaii, Maryland, Nevada, New Mexico, New York, New York EPP, Ohio, Rhode Island, Washington, New Jersey, Louisiana
Issue Date	12/2011
Pharmacy and Therapeutics Approval Date	2/2018
Effective Date	4/2018

**1. Background:**

The intent of the criteria is to ensure appropriate utilization of Cialis 5mg once daily within its labeled indication for BPH, consistent with current BPH literature, and for patients with a diagnosis of BPH when preferred alternative therapies are not appropriate.

**2. Coverage Criteria:**

<p><b>A. <u>Benign Prostatic Hyperplasia</u></b></p> <p>1. <b>Cialis 5mg once daily</b> will be approved based on all of the following:</p> <p style="padding-left: 40px;">a. The patient has a diagnosis of benign prostatic hyperplasia (BPH)</p> <p style="text-align: center;">–AND–</p> <p style="padding-left: 40px;">b. The patient is not currently utilizing nitrates</p> <p style="text-align: center;">–AND–</p> <p style="padding-left: 40px;">c. History of failure, intolerance, or contraindication to <b><u>both</u></b> of the following:</p> <p style="padding-left: 80px;">(1) Alpha Blockers: tamsulosin, afluzosin, doxazosin, or terazosin</p> <p style="padding-left: 80px;">(2) 5-alpha reductase inhibitors: finasteride</p> <p><b>Authorization will be issued for 12 months.</b></p>
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### 3. References:

1. Cialis [package insert]. Indianapolis, IN. Eli Lilly and Co; May 2017.
2. American Urological Association Education and Research, Inc. Guideline on the management of benign prostatic hyperplasia (BPH). Linthicum (MD): American Urological Association Education and Research, Inc.;2014. 34 p.
3. Broderick GA, Brock GB, Roehrn CG, et al. Effects of Tadalafil on Lower Urinary Tract Symptoms Secondary to Benign Prostatic Hyperplasia in Men with or without Erectile Dysfunction. *Urology*. 2010; 75: 1452-1459.
4. Roehrn CG, Kaminetsky JC, Auerbach SM, et al. Changes in peak urinary flow and voiding efficiency in men with signs and symptoms of benign prostatic hyperplasia during once daily tadalafil treatment. *BJUI*. 2009;105: 502-507.
5. Porst H, McVary KT, Montorsi F, et al. Effects of Once daily Tadalafil on Erectile Function in Men with Erectile Dysfunction and Signs and Symptoms of Benign Prostatic Hyperplasia. *European Urology*. 2009; 56: 727-736.
6. Clinical Pharmacology Gold Standard 2017.
7. [Hatzimouratidis K](#), A review of the use of tadalafil in the treatment of benign prostatic hyperplasia in men with and without erectile dysfunction. *Ther Adv Urol*. 2014 Aug; 6(4): 135–147.

Program	Prior Authorization - Cialis (tadalafil) for BPH
<b>Change Control</b>	
Date	Change
12/2011	New Guideline
12/2012	Annual Review, no changes
12/2015	Combined requirements c(1), c(2), and c(3) into a single requirement of “History of failure, intolerance, or contraindication to both of the following”. Simplified 3 lines of the criteria into a single line while maintaining the same level of requirements.
10/2016	Annual review, updated policy template
7/2017	Annual review, updated references.
2/2018	Annual review. No changes.