

## Pharmacy Medical Necessity Guidelines: Cialis® (tadalafil) 5 mg for BPH

Effective: November 10, 2020

Prior Authorization Required	√	Type of Review – Care Management	
Not Covered		Type of Review – Clinical Review	√
Pharmacy (RX) or Medical (MED) Benefit	RX	Department to Review	RXUM
<p>These pharmacy medical necessity guidelines apply to the following:</p> <p><b>Commercial Products</b></p> <ul style="list-style-type: none"> <li><input checked="" type="checkbox"/> Tufts Health Plan Commercial products – large group plans</li> <li><input checked="" type="checkbox"/> Tufts Health Plan Commercial products – small group and individual plans</li> <li><input checked="" type="checkbox"/> Tufts Health Freedom Plan products – large group plans</li> <li><input checked="" type="checkbox"/> Tufts Health Freedom Plan products – small group plans</li> <li>• CareLink<sup>SM</sup> – Refer to CareLink Procedures, Services and Items Requiring Prior Authorization</li> </ul> <p><b>Tufts Health Public Plans Products</b></p> <ul style="list-style-type: none"> <li><input checked="" type="checkbox"/> Tufts Health Direct – A Massachusetts Qualified Health Plan (QHP) (a commercial product)</li> <li><input type="checkbox"/> Tufts Health Together – MassHealth MCO Plan and Accountable Care Partnership Plans</li> <li><input type="checkbox"/> Tufts Health RITogether – A Rhode Island Medicaid Plan</li> </ul>		<p><b>Fax Numbers:</b></p> <p>RXUM: 617.673.0988</p>	

**Note:** This guideline does not apply to Medicare Members (includes dual eligible Members).

### OVERVIEW

#### FOOD AND DRUG ADMINISTRATION-APPROVED INDICATIONS

Cialis (tadalafil) 5 mg is indicated for the treatment of erectile dysfunction (ED) and the signs and symptoms of benign prostatic hyperplasia (BPH) and ED and the signs and symptoms of BPH.

### COVERAGE GUIDELINES

The plan may authorize coverage of Cialis (tadalafil) for members when **all** the following criteria are met:

#### For Benign Prostatic Hyperplasia (BPH)

1. The member has a documented diagnosis of benign prostatic hyperplasia  
**AND**
2. Documented failure, adverse reaction, or contraindication to a 30-day trial of at least two medications from either of the following drug classes:
  - a) Alpha-1 Adrenergic Blockers (e.g., alfuzosin, doxazosin, tamsulosin, terazosin)
  - b) 5-Alpha Reductase Inhibitors (e.g., finasteride, Avodart)

### LIMITATIONS

1. For Benign Prostatic Hyperplasia, coverage is limited to 30 tablets per 30 days of the 5mg tablet.
2. Members should not concurrently be using an alpha-blocker (e.g. doxazosin, tamsulosin, alfuzosin, silodosin, or terazosin) when Cialis (tadalafil) is taken as a once-daily maintenance regimen.
3. The plan does not authorize any requests over the QL of 4 tablets per day, not meeting the BPH criteria. For Erectile Dysfunction, the plan quantity limitation for Cialis (tadalafil) is 4 tablets/30 days total of any combination of Cialis (tadalafil) of any strength, Levitra (vardenafil), Staxyn (vardenafil), Stendra (avanfil) and Viagra (sildenafil). Not covered for Members 17 years of age or younger (No exceptions). Refer to the Pharmacy Medical Necessity Guidelines for Drugs with Quantity Limitations.
4. Cialis is not covered for all Commercial formularies. If requesting brand name Cialis please refer to the Pharmacy Medical Necessity Guidelines for Non-Covered Drugs with Suggested Alternatives.

### CODES

None

### REFERENCES

1. American Urological Association. Management of benign prostatic hyperplasia (BPH). 2010 URL: [auanet.org/common/pdf/education/clinical-guidance/Benign-Prostatic-Hyperplasia.pdf](http://auanet.org/common/pdf/education/clinical-guidance/Benign-Prostatic-Hyperplasia.pdf). Available from Internet. Accessed 2016 July 21.
2. Barry MJ, Fowler FJ, O'Leary MP, et al. The American Urological Association symptom index for benign prostatic hyperplasia. *J Urol*. 1992;148:1549-57.

3. Brown GA, Sussman DO. A current review of medical therapy for benign prostatic hyperplasia. *J Am Osteopath Assoc*. 2004;104(2 Suppl 2):S11-6.
4. Chapple CR. Pharmacological therapy of benign prostatic hyperplasia/lower urinary tract symptoms: an overview for the practicing clinician. *BJU Int*. 2004;94:738-44.
5. Cialis (tadalafil) [package insert] Indianapolis, IN: Lilly USA LLC.; 2020 October.
6. Clifford GM, Farmer RDT. Medical therapy for benign prostatic hyperplasia: a review of the literature. *Eur Urol*. 2000;38:2-19.
7. Cooper KL, McKiernan JM, Kaplan SA. Alpha-adrenoreceptor antagonists in the treatment of benign prostatic hyperplasia. *Drugs*. 1999;57(1):9-17.
8. Croom KF, Wagstaff AJ. Management of benign prostatic hyperplasia: defining the role of tamsulosin. *Dis Manage Health Outcomes*. 2004;12(5):338-47.
9. De La Rosette J, Van Der Schoot D, Debruyne F. Recent developments in guidelines on benign prostatic hyperplasia. *Curr Opin Urol*. 2002;12:3-6.
10. Debruyne F, Barkin J, van Erps P, et al. Efficacy and safety of long-term treatment with the dual 5 $\alpha$ -reductase inhibitor dutasteride in men with symptomatic benign prostatic hyperplasia. *Eur Urol*. 2004;46:488-95.
11. Djavan B, Marberger M. A meta-analysis on the efficacy and tolerability of alpha1-adrenoreceptor antagonists in patients with lower urinary tract symptoms suggestive of benign prostatic obstruction. *Eur Urol*. 1999;36:1-13.
12. Djavan B, Chapple C, Milani S, et al. State of the art on the efficacy and tolerability of alpha1-adrenoreceptor antagonists in patients with lower urinary tract symptoms suggestive of benign prostatic hyperplasia. *Urology*. 2004;64:1081-8.
13. Dull P, Reagan RW, Bahnson RR. Managing benign prostatic hyperplasia. *Am Fam Physician*. 2002;66(1):77-84.
14. Kaplan SA, McConnell JD, Roehrborn CG et al. Combination therapy with doxazosin and finasteride for benign prostatic hyperplasia in patients with lower urinary tract symptoms and a baseline total prostate volume of 25 mL or greater. *J Urol*. 2006;175:217-21.
15. Kirby RS, Roehrborn C, Boyle P, et al. Efficacy and tolerability of doxazosin and finasteride, alone or in combination, in treatment of symptomatic benign prostatic hyperplasia: the prospective European doxazosin and combination therapy (PREDICT) trial. *Urology*. 2003b;61(1):119-26.
16. Kirby RS. A randomized, double-blind crossover study of tamsulosin and controlled-release doxazosin in patients with benign prostatic hyperplasia. *BJU Int*. 2003a;91:41-4.
17. Lepor H, Williford WO, Barry MJ, et al. The efficacy of terazosin, finasteride, or both in benign prostatic hyperplasia. *N Engl J Med*. 1996;335(8):533-9.
18. McConnell JD, Roehrborn CG, Bautista OM et al. The long-term effect of doxazosin, finasteride, and combination therapy on the clinical progression of benign prostatic hyperplasia. *N Engl J Med*. 2003;349:2387-98.
19. McVary KT. A review of combination therapy in patients with benign prostatic hyperplasia. *Clin Ther*. 2007;29:387-98.
20. McVary KT. BPH: Epidemiology and comorbidities. *Am J Manag Care*. 2006;12:S122-8.
21. McVary KT. Clinical evaluation of benign prostatic hyperplasia. *Rev Urol*. 2003;5:S3-11.
22. Narayan P, O'Leary MP, Davidai G. Early efficacy of tamsulosin versus terazosin in the treatment of men with benign prostatic hyperplasia: a randomized, open-label trial. *J Appl Res*. 2005;5(2):237-45.
23. Oelke M, Giuliano F, Mirone V, et al. Monotherapy with tadalafil or tamsulosin similarly improved lower urinary tract symptoms suggestive of benign prostatic hyperplasia in an international, randomised, parallel, placebo-controlled clinical trial. *Eur Urol*. 2012 May;61(5):917-25.
24. Oesterling JE. Benign prostatic hyperplasia: medical and minimally invasive treatment options. *N Engl J Med*. 1995;332(2):99-109.
25. Porst H, Kim ED, Casabé AR et al. Efficacy and safety of tadalafil once daily in the treatment of men with lower urinary tract symptoms suggestive of benign prostatic hyperplasia: results of an international randomized, double-blind, placebo-controlled trial. *Eur Urol*. 2011 Nov;60(5):1105-13.
26. Roehrborn CG, Siami P, Barkin J et al. The effects of dutasteride, tamsulosin, and combination therapy on lower urinary tract symptoms in men with benign prostatic hyperplasia and prostatic enlargement: 2-year results from CombAT study. *J Urol*. 2008;179:616-21.

#### APPROVAL HISTORY

November 15, 2011: Reviewed by Pharmacy & Therapeutics Committee.

Subsequent endorsement date(s) and changes made:

- October 9, 2012: Added 5-Alpha Reductase Inhibitors to list of prerequisite medications

- August 6, 2013: No changes.
- August 12, 2014: Added limitation: Members should not concurrently be using an alpha-blocker (e.g. doxazosin, tamsulosin, alfuzosin, silodosin, or terazosin) when Cialis (tadalafil) is taken as a once-daily maintenance regimen.
- August 11, 2015: No changes.
- January 1, 2016: Administrative change to rebranded template applicable to Tufts Health Direct.
- August 9, 2016: No changes.
- November 15, 2016: Changed the name of the Medical Necessity Guideline from "Cialis® (tadalafil) for BPH" to "Cialis® (tadalafil) 5 mg for BPH." Administrative update to specify that the Medical Necessity Guideline applies to Cialis (tadalafil) 5 mg only.
- April 11, 2017: Administrative update, Adding Tufts Health RITogether to the template.
- November 14, 2017: Administrative update. Removed unnecessary background information from the overview section.
- December 11, 2018: Effective April 1, 2019, added all Cialis indications to the overview section and added the following limitations: defined the QL for Cialis (tadalafil) 5 mg for BPH as 30 tablets per 30 days, the plan QL for the treatment of ED with Cialis (tadalafil) of any strength is 4 tablets/30 days total of any combination of ED medications, and moved brand Cialis to not covered for all Commercial lines of business.
- November 12, 2019: No changes
- November 10, 2020: No changes

#### **BACKGROUND, PRODUCT AND DISCLAIMER INFORMATION**

Pharmacy Medical Necessity Guidelines have been developed for determining coverage for plan benefits and are published to provide a better understanding of the basis upon which coverage decisions are made. The plan makes coverage decisions on a case-by-case basis considering the individual member's health care needs. Pharmacy Medical Necessity Guidelines are developed for selected therapeutic classes or drugs found to be safe, but proven to be effective in a limited, defined population of patients or clinical circumstances. They include concise clinical coverage criteria based on current literature review, consultation with practicing physicians in the service area who are medical experts in the particular field, FDA and other government agency policies, and standards adopted by national accreditation organizations. The plan revises and updates Pharmacy Medical Necessity Guidelines annually, or more frequently if new evidence becomes available that suggests needed revisions.

For self-insured plans, coverage may vary depending on the terms of the benefit document. If a discrepancy exists between a Pharmacy Medical Necessity Guideline and a self-insured Member's benefit document, the provisions of the benefit document will govern.

Treating providers are solely responsible for the medical advice and treatment of members. The use of this policy is not a guarantee of payment or a final prediction of how specific claim(s) will be adjudicated. Claims payment is subject to member eligibility and benefits on the date of service, coordination of benefits, referral/authorization and utilization management guidelines when applicable, and adherence to plan policies and procedures and claims editing logic.