PRIOR AUTHORIZATION CRITERIA

BRAND NAME CIALIS 2.5 mg, 5 mg

(generic) (tadalafil)

Status: CVS Caremark Criteria

Type: Initial Prior Authorization with Quantity Limit

POLICY

FDA-APPROVED INDICATIONS

Erectile Dysfunction

Cialis is indicated for the treatment of erectile dysfunction (ED).

Benign Prostatic Hyperplasia

Cialis is indicated for the treatment of the signs and symptoms of benign prostatic hyperplasia (BPH).

Erectile Dysfunction and Benign Prostatic Hyperplasia

Cialis is indicated for the treatment of ED and the signs and symptoms of BPH (ED/BPH).

COVERAGE CRITERIA

- Cialis 2.5 mg and 5 mg (tadalafil) will be covered with prior authorization when the following criteria are met:
 - o The patient does not require nitrate therapy on a regular OR on an intermittent basis

AND

Cialis 2.5 mg or 5 mg is being prescribed for daily use for symptomatic benign prostatic hyperplasia (BPH) [Note: examples of signs and symptoms are incomplete emptying, weak stream, straining, urinary frequency, intermittency, urgency, or acute urinary retention.]

Quantity Limit may apply.

REFERENCES

- 1. Cialis [package insert]. Indianapolis, IN: Eli Lilly and Company; October 2013.
- AHFS DI (Adult and Pediatric) [database online]. Hudson, OH: Lexi-Comp, Inc.; http://online.lexi.com/lco/action/index/dataset/complete_ashp [available with subscription]. Accessed April 2014.
- 3. Micromedex Healthcare Series [database online]. Greenwood Village, CO: Thomson Reuters (Healthcare) Inc. Updated periodically. http://www.thomsonhc.com [available with subscription]. Accessed April 2014.
- 4. American Urological Association Guideline Management of Benign Prostatic Hyperplasia (BPH). 2010. http://www.auanet.org/education/quidelines/benign-prostatic-hyperplasia.cfm. Accessed April 2014.
- 5. Porst H, Kim E, Casabe A, 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. *European Urology* 2011; 60:1105-1113.
- 6. Roehrborn C, McVary K, Elion-Mboussa A, Viktrup L. Tadalafil Administered Once Daily for Lower Urinary Tract Symptoms Secondary to Benign Prostatic Hyperplasia: A Dose Finding Study. *The Journal of Urology* 2008; 180:1228-1234.