PRIOR AUTHORIZATION CRITERIA

BRAND NAME (generic)

CIALIS 2.5 mg, 5 mg (tadalafil)

Status: CVS Caremark[®] Criteria Type: Initial Prior Authorization with Quantity Limit

POLICY

FDA-APPROVED INDICATIONS

<u>Erectile Dysfunction</u> Cialis is indicated for the treatment of erectile dysfunction (ED). <u>Benign Prostatic Hyperplasia</u> Cialis is indicated for the treatment of the signs and symptoms of benign prostatic hyperplasia (BPH). <u>Erectile Dysfunction and Benign Prostatic Hyperplasia</u> Cialis is indicated for the treatment of ED and the signs and symptoms of BPH (ED/BPH).

Limitation of Use

If Cialis is used with finasteride to initiate BPH treatment, such use is recommended for up to 26 weeks because the incremental benefit of Cialis decreases from 4 weeks until 26 weeks, and the incremental benefit of Cialis beyond 26 weeks is unknown.

COVERAGE CRITERIA

The requested drug will be covered with prior authorization when the following criteria are met:

• The requested drug is being prescribed for daily use for symptomatic benign prostatic hyperplasia (BPH) [Note: Examples of signs and symptoms of BPH are incomplete emptying, weak stream, straining, urinary frequency, intermittency, or urgency.]

AND

• The request is NOT for continuation of therapy

OR

• The request is for continuation of therapy

AND

The patient has achieved or maintained a positive clinical response to the requested drug

Quantity Limits apply.

30 tablets per 25 days* or 90 tablets per 75 days*

*The duration of 25 days is used for a 30-day fill period and 75 days is used for a 90-day fill period to allow time for refill processing

Duration of Approval (DOA):

• 865-C: Initial therapy DOA: 36 months; Continuation of therapy DOA: 36 months

REFERENCES

- 1. Cialis [package insert]. Indianapolis, IN: Eli Lilly and Company; April 2022.
- 2. Lexicomp Online, AHFS DI (Adult and Pediatric) Online. Waltham, MA: UpToDate, Inc.; 2023. https://online.lexi.com. Accessed March 29, 2023.

BPH Cialis 2.5mg, 5mg PA with Limit Policy 865-C UDR 05-2023

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- 3. Micromedex (electronic version). Merative, Ann Arbor, Michigan, USA. Available at: https://www.micromedexsolutions.com/ (cited: 03/29/2023).
- 4. 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;206:806-817.

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