

PRIOR AUTHORIZATION CRITERIA

BRAND NAME
(generic)

CIALIS 2.5 mg, 5 mg
(tadalafil)

Status: CVS Caremark Criteria

Type: Initial Prior Authorization with Quantity Limit

Ref # 865-C

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).

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:

- Cialis (tadalafil) 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 Limits apply.

RATIONALE

The intent of the criteria is to provide coverage consistent with product labeling, FDA guidance, standards of medical practice, evidence-based drug information, and/or published guidelines. Cialis is indicated for the treatment of erectile dysfunction (ED), for the treatment of the signs and symptoms of benign prostatic hyperplasia (BPH), and for the treatment of ED and the signs and symptoms of BPH (ED/BPH).¹⁻³ However, the diagnosis of ED will not be included in these criteria for approval.

Cialis is intended for use in adult males only. Cialis is not indicated for use in newborns, children or women. Since BPH is typically a condition that occurs in older males, the Criteria for Approval does not specify this information related to the BPH diagnosis.¹⁻³

According to the American Urological Association (AUA) BPH guidelines, lower urinary tract symptoms (LUTS) secondary to BPH may include incomplete emptying, weak stream, straining, urinary frequency, intermittency, or urgency. The presence of moderate-to-severe LUTS is also associated with the development of acute urinary retention (AUR) as a symptom of BPH progression. Therapy decisions should be influenced by symptoms and prostate size. Also, the overall benefit and risks of therapy must be considered. Per AUA BPH guidelines, the primary goal of treatment is to alleviate bothersome LUTS that result from prostatic enlargement and on the alteration of disease progression and prevention of complications that can be associated with BPH/LUTS. If treatment is successful, a yearly follow-up should include a

repeat of the initial evaluation to detect any changes that have occurred, if symptoms have progressed, or if a complication has developed.⁴

The recommended dose of Cialis for once daily use for BPH is 5mg, taken at approximately the same time every day. For BPH, a starting dose of 2.5 mg is recommended for creatinine clearance 30 to 50 mL/min.¹⁻³

The quantity for approval for Cialis (tadalafil) 2.5mg and 5mg will be 30 tablets per month.

REFERENCES

1. Cialis [package insert]. Indianapolis, IN: Eli Lilly and Company; April 2016.
2. 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 2017.
3. Micromedex Healthcare Series [database online]. Greenwood Village, CO: Thomson Reuters (Healthcare) Inc. Updated periodically. <http://www.thomsonhc.com> [available with subscription]. Accessed April 2017.
4. American Urological Association Guideline Management of Benign Prostatic Hyperplasia (BPH). 2010. <https://www.auanet.org/Documents/education/clinical-guidance/Benign-Prostatic-Hyperplasia.pdf>. Accessed April 2017.

Written by: UM Development (SE)
 Date Written: 10/2011
 Revised: (TM) 05/2012; (PL) 10/2012 (extended duration), (TM) 04/2013; (CT) 04/2014; (CF) 04/2015; (JH) 04/2016; (KM) 04/2017 (removed contraindication question, added limit question)
 Reviewed: Medical Affairs (KP) 10/2011, (DR) 05/2012, (DC) 04/2013; (KP) 04/2014; (ADA) 04/2015; (TP) 04/2016; (JG) 04/2017
 External Review: 11/2011, 06/2012, 08/2013, 08/2014, 08/2015, 08/2016, 08/2017

CRITERIA FOR APPROVAL

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|---|---|-----|----|
| 1 | Is Cialis (tadalafil) 2.5 mg or 5 mg 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.] | Yes | No |
| 2 | Does the patient require more than 1 tablet per day?
[Note: Coverage is provided for up to 1 tablet per day.] | Yes | No |
- [Tech Note: If yes, then deny and enter a partial approval for 30 tablets per month of Cialis 2.5 mg or Cialis 5 mg.]

Mapping Instructions			
	Yes	No	DENIAL REASONS – DO NOT USE FOR MEDICARE PART D
1.	Go to 2	Deny	Your plan covers this drug when you have benign prostatic hyperplasia (BPH) that is causing symptoms. Your use of this drug does not meet this requirement. This is based on the information we have.
2.	Deny	Approve, 36 months 30 tablets per 25 days* 90 tablets per	You have requested more than the maximum quantity allowed by your plan. Current plan approved criteria cover up to 30 tablets per month of the requested drug and strength. You have been approved for the maximum quantity that your plan covers. Your request for additional quantities of the requested drug and strength has been denied.

		75 days*	
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* 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.

Guidelines for Approval	
Duration of Approval	36 months
Quantity for Approval	30 tablets per 25 days* 90 tablets per 75 days*
Set 1	
Yes to question(s)	No to question(s)
1	2

* 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.