PRIOR AUTHORIZATION CRITERIA

BRAND NAME*
(generic)

CIALIS 5 mg
(tadalafil)

Status: CVS Caremark Criteria
Type: Post Limit Prior Authorization ***Ref # 709-J***

** Drugs that are listed in the target drug box include both brand and generic and all dosage forms and strengths unless otherwise stated*

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) 5 mg is being prescribed for daily use for symptomatic benign prostatic hyperplasia (BPH) with or without erectile dysfunction (ED) in a patient that is 18 years of age or older.
  [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). Cialis is intended for use in adult males only.[1-3]

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. The age and gender must still be specified for a diagnosis of ED.[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 and ED/BPH is 5mg, taken at approximately the same time every day, without regard to timing of sexual activity.[1-3] The post limit quantity for approval for Cialis (tadalafil) 5 mg will be 30 tablets per month for BPH and ED/BPH for once daily use.

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 Solutions [database online]. Greenwood Village, CO: Truven Health Analytics Inc. Updated periodically. www.micromedexsolutions.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 (TM)
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Revised:	(TM) 11/2011, 05/2012, (NB/PL) 10/2012 (extended duration), (TM) 04/2013; (CF) 04/2014, 09/2014 (changed Cialis 5 mg qty), 04/2015; (JH) 04/2016, 09/2016 (updated for TGC); (KM) 04/2017 (removed contraindication question, added partial approval question)
Reviewed:	Medical Affairs (KP) 10/2011, (KP) 11/2011, (DR) 05/2012, (KP) 10/2012, (DC) 04/2013, (SES) 04/2014, 09/2014; (ADA) 04/2015; (TP) 04/2016; (ME) 09/2016; (JG) 04/2017 External Review: 12/2011, 06/2012, 08/2013, 08/2014, 09/2014, 10/2014, 08/2015, 08/2016, 08/2017

CRITERIA FOR APPROVAL

1	Is Cialis (tadalafil) 5 mg being prescribed for daily use for symptomatic benign prostatic hyperplasia (BPH) with or without erectile dysfunction (ED) in a patient that is 18 years of age or older? [Note: Examples of signs and symptoms of BPH 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.] [Tech Note: If yes, then deny and enter a partial approval for 30 tablets per month of Cialis 5 mg.]	Yes	No

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 meet all of these conditions: - You are 18 years of age or older - You have benign prostatic hyperplasia (BPH) that is causing symptoms Your use of this drug does not meet the requirements. This is based on the information we have.

2.	Deny	Approve for 36 months 30 tablets per 25 days* 90 tablets per 75 days*	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.

* **The patient should receive only one drug from this drug class at a time.**
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 patient should receive only one drug from this drug class at a time.**
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.