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***

** Drugs that are listed in the target drug box include both brand and generic and all dosage forms and strengths unless otherwise stated. OTC products are not included 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:

- 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.]

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 not indicated for use in newborns or children. Since BPH is typically a condition that occurs in older patients, 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. If drug therapy is considered, decisions will be influenced by coexisting overactive bladder symptoms and prostate size or serum PSA levels.[4] While tadalafil is effective in treating obstructive BPH/LUTs symptoms, studies have indicated that it does not affect peak urinary flow, indicating it is not helpful in the treatment of acute urinary retention (AUR).[1,5] 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 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 5 mg, 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 2.5 mg and 5 mg will be 30 tablets per month.

REFERENCES

1. Cialis [package insert]. Indianapolis, IN: Eli Lilly and Company; February 2018.
2. Lexicomp Online, AHFS DI (Adult and Pediatric) Online. Hudson, OH: Wolters Kluwer Clinical Drug Information, Inc. http://online.lexi.com/. Accessed April 2020.
3. Micromedex (electronic version). Truven Health Analytics, Greenwood Village, Colorado, USA. http://www.micromedexsolutions.com/. Accessed April 2020.
4. American Urological Association Guideline Management of Benign Prostatic Hyperplasia (BPH). 2010. Available at https://www.auanet.org/guidelines/benign-prostatic-hyperplasia-(bph)-guideline/benign-prostatic-hyperplasia-(2010-reviewed-and-validity-confirmed-2014). Accessed April 2020.
5. Roehrborn CG, Kaminetsky JC, Auerbach SM et al. Changes in peak urinary flow and voiding efficiency in men with signs and symptoms of benign prostatic hyperplasia during once daily tadalafil treatment. *BJU Int* 2010; 105: 502-507.

Written by:	UM Development (SE)
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Reviewed:	Medical Affairs: (KP) 10/2011; (DR) 05/2012; (DC) 04/2013; (KP) 04/2014; (ADA) 04/2015; (TP) 04/2016; (JG) 04/2017; (CHART) 04/30/20, 09/03/20 External Review: 11/2011, 06/2012, 08/2013, 08/2014, 08/2015, 08/2016, 08/2017, 08/2018, 08/2019

CRITERIA FOR APPROVAL

1	Is the requested drug 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.]	Yes	No
2	Does the patient require MORE than the plan allowance of 1 tablet per day? [Rph Note: If yes, then deny and enter a partial approval for 30 tablets / 25 days or 90 tablets / 75 days of the requested drug.]	Yes	No

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.*

Mapping Instructions			
	Yes	**No**	**DENIAL REASONS – DO NOT USE FOR MEDICARE PART D**
1.	Go to 2	Deny	Coverage for this medication is denied for the following reason(s). We reviewed the information we received about your condition and circumstances. We used the policy (INSERT CRITERIA NAME) when making this decision. The policy states that this medication may be approved when the member is requesting the medication for daily use for symptomatic benign prostatic hyperplasia (BPH). Based on the policy and the information we have, the request is denied. The request was denied because the information provided to us indicates that you are not requesting the medication for the treatment of symptomatic benign prostatic hyperplasia (BPH). [Short Description: No approvable diagnosis]
2.	Deny	Approve, 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 for a duration of 36 months. Your request for additional quantities of the requested drug and strength has been denied. [Short Description: Over max quantity]

** 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.*