

Drug Policy

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| Policy: | Cialis (tadalafil) 2.5 and 5 mg tablets Prior Approval Criteria | Annual Review Date: 09/19/2024 Last Revised Date: 09/19/2024 |
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OVERVIEW

Cialis is a phosphodiesterase 5 (PDE-5) inhibitor, indicated for the treatment of erectile dysfunction, the signs and symptoms of benign prostatic hyperplasia (BPH), and the combination of erectile dysfunction and the signs and symptoms of BPH.

POLICY STATEMENT

This policy involves the use of Cialis. Prior authorization is recommended for pharmacy benefit coverage of Cialis. This prior authorization is for plans who do not cover Cialis for erectile dysfunction. Approval is recommended for those who meet the conditions of coverage in the **Criteria and Initial/Extended Approval** for the diagnosis provided. **Conditions Not Recommended for Approval** are listed following the recommended authorization criteria. Requests for uses not listed in this policy will be reviewed for evidence of efficacy and for medical necessity on a case-by-case basis.

All approvals for initial therapy are provided for the initial approval duration noted below; if reauthorization is allowed, a response to therapy is required for continuation of therapy unless otherwise noted below.

Automation:

- When available, the ICD-10 codes for Benign Prostatic Hyperplasia (ICD-10: N40*) will be used for automation to allow approval of tadalafil (generic to Cialis): OR
- When available, claim history for amlodipine, felodipine, nicardipine, or nifedipine AND the ICD-10 codes for Raynaud’s Phenomenon (ICD-10: I73.0*) will be used for automation to allow approval of tadalafil (generic to Cialis).

RECOMMENDED AUTHORIZATION CRITERIA

Coverage of Cialis is recommended in those who meet the following criteria:

1. **Benign Prostatic Hyperplasia (BPH)** Approve for 1 year

Initial Approval/ Extended Approval.

- A) *Initial Approval:* 1 year
- B) *Extended Approval:* 1 year

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Drug Policy

OTHER USES WITH SUPPORTIVE EVIDENCE

1. **High-Altitude Pulmonary Edema (HAPE), Treatment or Prevention.** Approve for 1 year in patients with HAPE or a history of HAPE
2. **Prophylaxis After Radical Prostatectomy (Early Penile Rehabilitation).** Approve for 1 year in patients who meet the following criteria (A and B):
 - a. Patient had radical prostatectomy within the previous 12 months; AND
 - b. The medication is prescribed by or in consultation with an urologist.
3. **Raynaud's Phenomenon Criteria.** *Patient must meet the following criteria*
 - a. Patient has tried one calcium channel blocker; OR
 - b. Note: Examples of calcium channel blockers include amlodipine, felodipine, nifedipine.
 - c. According to the prescriber, use of a calcium channel blocker is contraindicated.
 - d. Note: Examples of reasons a patient cannot take calcium channel blocker therapy include right heart failure or decreased cardiac output.
4. **Patient has been started on Cialis Criteria.** *Approve for an indication or condition addressed as an approval in this document if the patient has had a beneficial response to therapy.*

Initial Approval/ Extended Approval.

A) *Initial Approval:* 1 year

B) *Extended Approval:* 1 year

CONDITIONS NOT RECOMMENDED FOR APPROVAL

Cialis has not been shown to be effective, or there are limited or preliminary data or potential safety concerns that are not supportive of general approval for the following conditions. (Note: This is not an exhaustive list of Conditions Not Recommended for Approval).

1. Erectile Dysfunction.

Documentation Requirements:

The Company reserves the right to request additional documentation as part of its coverage determination process. The Company may deny reimbursement when it has determined that the drug provided or services performed were not medically necessary, investigational or experimental, not within the scope of benefits afforded to the member and/or a pattern of billing or other practice has been found to be either inappropriate or excessive. Additional documentation supporting medical necessity for the services provided must be made available upon request to the Company. Documentation requested may include patient records, test results and/or credentials of the provider ordering or

Drug Policy

performing a service. The Company also reserves the right to modify, revise, change, apply and interpret this policy at its sole discretion, and the exercise of this discretion shall be final and binding.

REFERENCES

1. Cialis® [prescribing information]. Indianapolis, IN: Eli Lilly and Company; May 2017.
2. McVary KT., Claus RG, Avins, AL. American Urological Association Guideline: management of benign prostatic hyperplasia (BPH). Revised 2010. *J Urol.* 2011 May;185(5):1793-803.
3. Tadalafil. In: DRUGDEX [online database]. Truven Health Analytics; Greenwood Village, CO. Last updated 3 September 2019. Accessed on 15 September 2019.
4. Schioppa E, Hsu VM, Impens AJ, et al. Randomized placebo-controlled crossover trial of tadalafil in Raynaud's phenomenon secondary to systemic sclerosis. *J Rheumatol.* 2009; 36(10): 2264-2268.
5. Goundry G, Bell L, Langtree M, et al. Diagnosis and management of Raynaud's phenomenon. *BMJ.* 2012; 344:e289.
6. Levien TL. Phosphodiesterase inhibitors in Raynaud's phenomenon. *Ann Pharmacother.* 2006; 40:1388-1393.