

## PRIOR AUTHORIZATION POLICY

**POLICY:** Erectile Dysfunction – Tadalafil Prior Authorization Policy

- Cialis® (tadalafil tablets – Eli Lilly, generic)

**REVIEW DATE:** 11/06/2024

---

### OVERVIEW

Tadalafil (Cialis, generic), a phosphodiesterase type 5 (PDE5) inhibitor, is indicated for the following uses<sup>1</sup>:

- **Benign prostatic hyperplasia.**
- **Erectile dysfunction.**
- **Erectile dysfunction and the signs and symptoms of benign prostatic hyperplasia.**

Tadalafil has been studied for other indications:

- **High-Altitude pulmonary edema.** Published guidelines for the prevention of high-altitude pulmonary edema recommend nifedipine as the preferred pharmacologic treatment option.<sup>11</sup> Other pharmacologic therapies include salmeterol, sildenafil, dexamethasone, or acetazolamide.
- **Prophylaxis after radical prostatectomy.** Multiple studies have evaluated the efficacy of tadalafil for prophylaxis after radical prostatectomy.<sup>5-7</sup>
- **Pulmonary arterial hypertension.** Adcirca® (tadalafil tablets, generic) contain the same active ingredient as tadalafil (Cialis, generic) and is indicated for the treatment of pulmonary arterial hypertension. Tadalafil (Cialis, generic) is available in 2.5 mg, 5 mg, 10 mg, and 20 mg tablets. Adcirca is available as a 20 mg tablet. Tadalafil (Cialis, generic) has been used in multiple studies for pulmonary arterial hypertension.<sup>8-10</sup>
- **Raynaud's phenomenon.** There are studies which show tadalafil has been beneficial in patients with Raynaud's phenomenon.<sup>2,3</sup> Guidelines from the European League against Rheumatism (EULAR) on the treatment of systemic sclerosis (2023) recommend considering dihydropyridine calcium channel blockers (CCBs), usually oral nifedipine, for first-line therapy of Raynaud's phenomenon in patients with systemic sclerosis.<sup>4</sup> Phosphodiesterase type 5 inhibitors should also be considered in such clinical scenarios.

### POLICY STATEMENT

Prior Authorization is recommended for prescription benefit coverage of tadalafil. All approvals are provided for the duration noted below. Because of the specialized skills required for evaluation and diagnosis of patients treated with tadalafil as well as the monitoring required for adverse events and long-term efficacy, some approvals require tadalafil to be prescribed by or in consultation with a physician who specializes in the condition being treated.

**Automation:** When available, the ICD-10 codes for male erectile dysfunction (ICD-10: N52.\*) will be used for automation to allow approval of the requested medication. This automation is gender-selective and is not applicable for women; approval for use in women is always determined by prior authorization criteria.

### RECOMMENDED AUTHORIZATION CRITERIA

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

11/06/2024

© 2024. All Rights Reserved.

This document is confidential and proprietary. Unauthorized use and distribution are prohibited.

### FDA-Approved Indications

1. **Benign Prostatic Hyperplasia.** Approve for 1 year if the patient meets ONE of the following (A or B):

Note: For men with erectile dysfunction and benign prostatic hyperplasia, use criterion 2 below.

- A) Patient has tried an alpha-1 ( $\alpha$ 1) blocker; OR

Note: Examples of alpha-1 ( $\alpha$ 1) blockers include doxazosin, terazosin, tamsulosin, alfuzosin.

- B) Patient has tried a 5 $\alpha$ -reductase inhibitor.

Note: Examples of 5 $\alpha$ -reductase inhibitor includes finasteride, dutasteride.

2. **Erectile Dysfunction.** Approve for 1 year.

### Other Uses with Supportive Evidence

3. **High-Altitude Pulmonary Edema (HAPE), Treatment or Prevention.** Approve for 1 year in patients who meet BOTH of the following (A and B):

- A) Patient has HAPE or a of HAPE; AND

- B) Patient has tried one other pharmacologic therapy for treatment or prevention of HAPE.

Note: Examples of other pharmacologic therapy for the treatment of HAPE are nifedipine, Serevent (salmeterol inhalation powder), dexamethasone, acetazolamide, sildenafil.

4. **Prophylaxis After Radical Prostatectomy (Early Penile Rehabilitation).** Approve for 1 year in patients who meet BOTH of the following (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.

5. **Pulmonary Arterial Hypertension (PAH).** Approve for 1 year in patients who cannot use Adcirca (tadalafil tablets, generic) because the dose is not available using Adcirca (tadalafil tablets, generic), that is, patients who are using 10 mg doses of tadalafil (Cialis, generic).

Note: Patients using 20 mg or 40 mg of tadalafil (Cialis, generic) for PAH should use Adcirca (tadalafil tablets, generic).

6. **Raynaud's Phenomenon.** Approve for 1 year if the patient meets ONE of the following (A or B):

- A) Patient has tried one calcium channel blocker; OR

Note: Examples of calcium channel blockers include amlodipine, felodipine, nifedipine.

- B) According to the prescriber, use of a calcium channel blocker is contraindicated.

Note: Examples of reasons a patient cannot take calcium channel blocker therapy include right heart failure or decreased cardiac output.

### CONDITIONS NOT RECOMMENDED FOR APPROVAL

Coverage of tadalafil is not recommended in the following situations:

1. Coverage is not recommended for circumstances not listed in the Recommended Authorization Criteria. Criteria will be updated as new published data are available.

### REFERENCES

1. Cialis® tablets [prescribing information]. Indianapolis, IN: Eli Lilly; April 2023.
2. Fernandez-Codina A, Canas-Ruano E, Pope JE. Management of Raynaud's phenomenon in systemic sclerosis-a practical approach. *J Scleroderm Relat Disord.* 2019;4(2):102-110.

3. Hinze AM, Wigley FM. Pharmacotherapy options in the management of Raynaud's phenomenon. *Curr Treat Opt Rheumatol*. 2018;4(3):235-254.
4. Del Galdo F, Lescoat A, Conaghan PG, et al. 2023 Update of EULAR recommendations for the treatment of systemic sclerosis. *Ann Rheum Dis*. 2023;82:154-155.
5. Aydogdu O, Gokce MI, Burgu B, et al. Tadalafil rehabilitation therapy preserves penile size after bilateral nerve sparing radical retropubic prostatectomy. *Int Braz J Urol*. 2011;37:336-346.
6. Montorsi F, Brock G, Stolzenburg JU, Mulhall J, et al. Effects of tadalafil treatment on erectile function recovery following bilateral nerve-sparing radical prostatectomy: a randomized placebo-controlled study (REACTT). *Eur Urol*. 2014;65:587-596.
7. Mulhall JP, Brock G, Oelke M, et al. Effects of tadalafil once-daily or on-demand vs. placebo on return to baseline erectile function after bilateral nerve-sparing radical prostatectomy – results from a randomized controlled trial (REACTT). *J Sex Med*. 2016;13:679-683.
8. Adcirca tablets [prescribing information]. Indianapolis, IN: Eli Lilly (marketed by United Therapeutics; September 2020.
9. Tay EL, Geok-Mui MK, Poh-Hoon MC, et al. Sustained benefit of tadalafil in patients with pulmonary arterial hypertension with prior response to sildenafil: A case series of 12 patients. *Int J Cardiol*. 2008;125:416-417.
10. Palmieri EA, Affuso F, Fazio S, et al. Tadalafil in primary pulmonary arterial hypertension. *Ann Intern Med*. 2004;141:743-744.
11. Luks AM, Auerbach PS, Freer L, et al. Wilderness Medical Society Consensus Guidelines for the Prevention and Treatment of Acute Altitude Illness: 2019 Update. Available at: [https://www.wemjournal.org/article/S1080-6032\(19\)30090-0/fulltext](https://www.wemjournal.org/article/S1080-6032(19)30090-0/fulltext). Accessed on November 4, 2024.