



PRIOR AUTHORIZATION POLICY

POLICY: Erectile Dysfunction – Tadalafil (Cialis) Prior Authorization Policy

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

REVIEW DATE: 10/13/2021

OVERVIEW

Tadalafil (Cialis, generics) are indicated for the following uses:

- **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.¹¹ 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.⁵⁻⁷
- **Pulmonary arterial hypertension.** Adcirca® (tadalafil tablets, generic) contain the same active ingredient as tadalafil (Cialis, generic) and are indicated for the treatment of pulmonary arterial hypertension. Tadalafil (Cialis, generic) are available in 2.5 mg, 5 mg, 10 mg, and 20 mg tablets. Adcirca is available as a 20 mg tablet. Tadalafil (Cialis, generic) have been used in multiple studies for pulmonary arterial hypertension.⁸⁻¹⁰
- **Raynaud phenomenon.** Multiple studies have evaluated the efficacy of tadalafil for Raynaud disease.²⁻⁴

POLICY STATEMENT

Prior Authorization is recommended for prescription benefit coverage of tadalafil (Cialis, generic). All approvals are provided for the duration noted below. Because of the specialized skills required for evaluation and diagnosis of patients treated with tadalafil (Cialis, generic) as well as the monitoring required for adverse events and long-term efficacy, some approvals require tadalafil (Cialis, generic) 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.

Note: Phosphodiesterase type 5 inhibitors should not be administered, either regularly or intermittently, with concomitant nitrate therapy. Patients will be informed of the consequences should they initiate nitrate therapy while taking a phosphodiesterase type 5 inhibitor.

RECOMMENDED AUTHORIZATION CRITERIA

Coverage of tadalafil (Cialis, generic) are recommended in those who meet one of the following criteria:

FDA-Approved Indications

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

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

- A) Patient has tried an α_1 -blocker; OR

Note: Examples of α_1 -blockers include doxazosin, terazosin, tamsulosin, alfuzosin.

- B) Patient has tried a 5α -reductase inhibitor.

Note: Examples of 5α -reductase inhibitor includes finasteride, dutasteride.

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

Other Uses with Supportive Evidence

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

- A) Patient has HAPE or a history 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, Viagra (sildenafil).

4. **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.

6. **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).

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

- A) Patient has tried at least two of the following therapies for Raynaud disease: calcium channel blockers, α -adrenergic blockers, nitroglycerin, losartan, fluoxetine, or angiotensin converting enzyme (ACE) inhibitors; OR

Note: Examples of calcium channel blockers include amlodipine, felodipine, nifedipine. Examples of α -adrenergic blockers include prazosin, doxazosin. Examples of ACE inhibitors include lisinopril, benazepril, captopril, enalapril.

- B) Patient has tried one vasodilator.

Note: Examples of vasodilators include Flolan (epoprostenol for injection), Edex (alprostadil for injection), Tracleer (bosentan tablets).

CONDITIONS NOT RECOMMENDED FOR APPROVAL

Coverage of tadalafil (Cialis, generic) 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; June 2020.
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 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. 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 [package insert]. 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.
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