



RATIONALE FOR INCLUSION IN PA PROGRAM

Background

The U.S. Food and Drug Administration has approved Cialis (tadalafil) to treat the signs and symptoms of benign prostatic hyperplasia (BPH), a condition in which the prostate gland becomes enlarged. Common symptoms of BPH include difficulty in starting urination, weak urine stream; sudden urge to urinate; and more frequent urination at night (1).

Cialis for treatment of erectile dysfunction (ED) is **excluded** from coverage.

Regulatory Status

FDA-approved indications: Cialis is a phosphodiesterase 5 (PDE5) inhibitor indicated for the treatment of erectile dysfunction (ED), the signs and symptoms of benign prostatic hyperplasia (BPH) and ED and the signs and symptoms of BPH (ED/BPH) (1).

Cialis is not recommended in combination with alpha blockers for the treatment of BPH because of the efficacy of the combination has not been adequately studied and because of the risk of blood pressure lowering. When used in combination with finasteride, the recommended dose can be taken for up to 26 weeks. Patients should stop Cialis and seek medical care if a sudden loss of vision occurs in one or both eyes, which could be a sign of Non Arteritic Ischemic Optic Neuropathy (NAION). Patients should stop Cialis and seek prompt medical attention in the event of sudden decrease or loss of hearing (1).

Due to increased tadalafil exposure (AUC), limited clinical experience, and the lack of ability to influence clearance by dialysis, Cialis for once daily use is not recommended in patients with creatinine clearance less than 30 mL/min or on hemodialysis (1).

Administration of Cialis to patients who are using any form of organic nitrate, either regularly and/or intermittently, is contraindicated. In clinical pharmacology studies, Cialis was shown to potentiate the hypotensive effect of nitrates (1). Cialis is also contraindicated with guanylate cyclase (GC) stimulators, such as riociguat.



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CIALIS (tadalafil)

Cialis is not indicated for use in pediatric patients. Safety and efficacy in patients below the age of 18 years has not been established (1).

Summary

Cialis (tadalafil) is used to treat the signs and symptoms of benign prostatic hyperplasia (BPH), in patients 18 years of age or older that are actively symptomatic. Cialis is not recommended in combination with alpha blockers. Cialis for once daily use is not recommended in patients with creatinine clearance less than 30 mL/min or on hemodialysis. Administration of Cialis to patients who are using any form of organic nitrate, either regularly and/or intermittently, is contraindicated (1).

Prior authorization is required to ensure the safe, clinically appropriate, and cost-effective use of Cialis while maintaining optimal therapeutic outcomes.

Cialis for treatment of erectile dysfunction (ED) remains a plan exclusion.

References

1. Cialis [package Insert]. Indianapolis, IN: Eli Lilly and Company; April 2022.