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| **Section:** | Prescription Drugs | **Effective Date:** | April 1, 2024 |
| **Subsection:** | Cardiovascular Agents | **Original Policy Date:** | February 3, 2012 |
| **Subject:** | Cialis | **Page:** | 1 of 5 |

***Last Review Date:*** March 8, 2024

# Cialis

## Description

### Cialis (tadalafil)

**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.

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).

**Related policies**

## Policy

*This policy statement applies to clinical review performed for pre-service (Prior Approval, Precertification, Advanced Benefit Determination, etc.) and/or post-service claims.*

Cialis may be considered **medically necessary** if the conditions indicated below are met.

Cialis may be considered **investigational** for all other indications.

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

## Prior-Approval Requirements

**Age** 18 years of age or older

**Diagnosis**

Patient must have the following:

1. Benign Prostatic Hyperplasia / Hypertrophy (BPH)

**AND ALL** of the following:

1. Actively symptomatic, including **one or more** of the following:
    a. Dribbling at the end of urinating

b. Inability to urinate (urinary retention)
c. Incomplete emptying of bladder
d. Incontinence
e. Nocturia - needing to urinate two or more times per night
f. Pain with urination or bloody urine
g. Slowed or delayed start of the urinary stream
h. Straining to urinate
i. Strong and sudden urge to urinate
j. Weak urine stream

2. Treatment failure or clinically significant adverse reaction to **ONE** of the following:
   a. Alpha blocker
   b. 5-alpha reductase inhibitor

**AND NONE** of the following:

1. Concurrent therapy with any nitrates (in any form)
2. Concurrent therapy with another phosphodiesterase 5 (PDE5) inhibitor
3. Concurrent therapy with a guanylate cyclase (GC) stimulator

## Prior – Approval *Renewal* Requirements

**Age** 18 years of age or older

**Diagnosis**

Patient must have the following:

1. Benign Prostatic Hyperplasia / Hypertrophy (BPH)
   a. Improvement in urinary symptoms

**AND NONE** of the following

1. Concurrent therapy with any nitrates (in any form)
2. Concurrent therapy with another phosphodiesterase 5 (PDE5) inhibitor
3. Concurrent therapy with a guanylate cyclase (GC) stimulator

## Policy Guidelines

### Pre - PA Allowance

None

## Prior - Approval Limits

**Quantity** 2.5mg – 90 tablets per 90 days **OR**
5mg – 90 tablets per 90 days

**Duration** 12 months

## Prior – Approval *Renewal* Limits

Same as above

## Rationale

**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.

## Policy History

| Date | Action |
|---|---|
| March 2013 | Annual editorial review |
| June 2014 | Annual editorial review. Addition of renewal requirements |
| June 2015 | Annual editorial review and reference update. Addition of treatment failure with either an alpha blocker or 5-alpha reductase inhibitor |
| September 2015 | Annual Review |
| June 2016 | Annual editorial review and reference update<br>Addition of contraindication to concurrent therapy with guanylate cyclase (GC) stimulators<br>Policy number change from 5.06.02 to 5.40.22 |

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| September 2017 | Annual editorial review and reference update<br>Addition of age to renewal criteria |
| September 2018 | Annual review and reference update |
| September 2019 | Annual review |
| September 2020 | Annual review and reference update |
| March 2021 | Annual review |
| March 2022 | Annual review |
| December 2022 | Annual review and reference update. Changed policy number to 5.40.022 |
| January 2023 | Per SME, added limitation of 26 weeks when Cialis is initiated with finasteride to regulatory section. Removed male gender requirement from criteria. |
| March 2023 | Annual editorial review. Added requirement of no dual therapy with another PDE5 inhibitor |
| March 2024 | Annual review |

## Keywords

**This policy was approved by the FEP® Pharmacy and Medical Policy Committee on March 8, 2024 and is effective on April 1, 2024.**