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5.40.022

Section:	Prescription Drugs	**Effective Date:**	April 1, 2023
Subsection:	Cardiovascular Agents	**Original Policy Date:**	February 3, 2012
Subject:	Cialis	**Page:**	1 of 5

Last Review Date: March 10, 2023

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** for patients 18 years and older for the treatment of benign prostatic hyperplasia (BPH) and if the conditions indicated below are met.

Cialis may be considered **investigational** in patients under the age of 18 and 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)
2. 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

3. 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)
2. 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 Addition of contraindication to concurrent therapy with guanylate cyclase (GC) stimulators Policy number change from 5.06.02 to 5.40.22
September 2017	Annual editorial review and reference update 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

Keywords

This policy was approved by the FEP® Pharmacy and Medical Policy Committee on March 10, 2023 and is effective on April 1, 2023.